

**International Patent Regime for Pharmaceuticals**  
**From the Paris Convention to the TRIPS Agreement**

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## **Contents**

|   |           |
|---|-----------|
| <b>Abstract</b>   | <b>4</b>  |
| <b>List of Acronyms</b>   | <b>6</b>  |
| <br>  |           |
| <b>Introduction</b>   | <b>8</b>  |
| <br>  |           |
| <b>Chapter I The Pre-Uruguay Round International Regime of Patent Protection for Pharmaceuticals Under the Paris Convention</b> |           |
| <br>  |           |
| <b>1.1 Introduction</b>   | <b>17</b> |
| <b>1.2 Patent defined</b>   | <b>22</b> |
| <b>1.3 Research-based pharmaceutical industry and patent</b>  | <b>28</b> |
| <b>1.4 Developing countries and economic issues relating to patent protection</b>   | <b>35</b> |
| <b>1.4.1 Monopolistic effects</b>   | <b>38</b> |
| <b>1.4.2 Foreign technology transfer</b>  | <b>40</b> |
| <b>1.4.3 R&amp;D activities</b>   | <b>47</b> |
| <b>1.5 The legal framework of patent protection under the Paris Convention</b>  | <b>51</b> |
| <b>1.5.1 DCs' criticism of the Convention</b>   | <b>61</b> |
| <b>1.5.2 ICs' concerns over the Convention</b>  | <b>64</b> |
| <br>  |           |
| <b>Chapter II How Did TRIPS Come to be Brought Under the Uruguay Round Multilateral Trade Negotiations</b>                      |           |
| <br>  |           |
| <b>2.1 Introduction</b>   | <b>69</b> |
| <b>2.2 DCs' participation in multilateral trade negotiations</b>  | <b>72</b> |
| <b>2.3 Political pressure from the US domestic trade legislation</b>  | <b>81</b> |
| <b>2.3.1 Section 301 provisions</b>   | <b>86</b> |
| <b>2.4 DCs' position on TRIPS in MTNs</b>   | <b>96</b> |

### **Chapter III GATT Principles and TRIPS**

|            |   |            |
|------------|---|------------|
| <b>3.1</b> | <b>Introduction</b>   | <b>102</b> |
| <b>3.2</b> | <b>The Creation of GATT</b>   | <b>104</b> |
| <b>3.3</b> | <b>GATT principles discussed</b>                                    | <b>108</b> |
|            | <b>3.3.1 The principle of Most-Favoured-Nation Treatment</b>        | <b>108</b> |
|            | <b>3.3.2 The principle of National Treatment</b>                    | <b>118</b> |
|            | <b>3.3.3 Reciprocity</b>  | <b>122</b> |
| <b>3.4</b> | <b>GATT provisions relating to intellectual property protection</b> | <b>128</b> |

### **Chapter IV Patent Protection for Pharmaceuticals under the TRIPS Agreement**

|            |  |            |
|------------|--|------------|
| <b>4.1</b> | <b>Introduction</b>  | <b>137</b> |
| <b>4.2</b> | <b>The negotiation history of the TRIPS Agreement</b>                                      | <b>143</b> |
| <b>4.3</b> | <b>Salient features of the TRIPS Agreement</b>   | <b>149</b> |
| <b>4.4</b> | <b>The legal provisions of patent system for pharmaceuticals under the TRIPS Agreement</b> | <b>167</b> |
| <b>4.5</b> | <b>Post-TRIPS Agreement uncertainties</b>  | <b>176</b> |

### **Chapter V Unresolved Issues**

|            |   |            |
|------------|---|------------|
| <b>5.1</b> | <b>Introduction</b>   | <b>181</b> |
| <b>5.2</b> | <b>Global trade in IPP and competition policy</b>                       | <b>187</b> |
| <b>5.3</b> | <b>The Doctrine of Exhaustion and the issue of parallel importation</b> | <b>196</b> |

|                   |            |
|-------------------|------------|
| <b>Conclusion</b> | <b>208</b> |
|-------------------|------------|

|                     |            |
|---------------------|------------|
| <b>Bibliography</b> | <b>215</b> |
|---------------------|------------|

## **Abstract**

Intellectual property protection (IPP) attained its importance in recent years because of the steady increase of intellectual property-endowed goods and technology in global trade. Technology producers, among them multilateral pharmaceutical companies (MPCs) felt that the Paris Convention (the Convention) was not adequate in dealing with trade related issues, and that an agreement was needed to integrate the subject of IPP; especially patent protection for pharmaceuticals, into the broader context of global trade law.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) concluded in the Uruguay Round in 1994 brought IPP into the global trading system. The patent system contained in the Agreement reflects to a large extent MPCs' proposal for a strengthened patent system which paves the way to ensure market access and equal competition opportunity in their endeavour to expand global operation.

The objective of the global trading system is to liberalise trade, achieved by securing commitments of market access and equal competition opportunity through the application of the principles of most-favoured-nation treatment, national treatment and reciprocity, reinforced by domestic competition policy to ensure efficient functioning of markets.

However, in regard to patent protection for pharmaceuticals, the exercise of the exclusive marketing rights conferred by patent protection has trade restricting effect because competition is excluded during the patent term. This trade restricting effect does not compliment the objective of the global trading system nor promote competition. But the TRIPS Agreement does not cover a negotiated result on securing the recognition in domestic competition policy of the exclusive marketing rights conferred by patent protection, especially when domestic competition policy is designed to compliment microeconomic policy such as health care cost control. The implementation of international exhaustion to allow parallel importation of patented products during the term of patent is an example in point. It is an issue the TRIPS Agreement does not address and is excluded from the World Trade Organisation (WTO) dispute settlement mechanism. It is a legal issue because the disparity among national competition policy will cause trade distortions. It is political because the issue touches upon nations' regulatory autonomy in designing their competition policy to compliment other government policies. It also has economic implications in that countries might wish to rely on parallel importation as a mechanism to bring down prices of patent products. A complex issue as such requires a multilateral solution enshrined in a legally binding agreement. In the absence of such an agreement, patent system under the TRIPS Agreement will be inadequate and ineffective because it will become inoperable and nations will incline to retrieve to unilateral actions for the resolution of grievances.

## Acronyms

|             |   |
|-------------|---|
| AIDS        | Acquired Immune Deficiency Syndrome                                     |
| BIRPI       | United International Bureau for the protection of Intellectual Property |
| BISD        | Basic Instruments and Selected Documents                                |
| CMLR        | Common Market Law Review  |
| CPC         | The Community Patent Convention   |
| CPs         | Contracting parties   |
| CPs         | Contracting Parties   |
| DCs         | Developing Countries  |
| DMFT        | Differential and More Favourable Treatments                             |
| DSB         | Dispute Settlement Body   |
| DSM         | Dispute Settlement Mechanism  |
| DSU         | Dispute Settlement Understanding  |
| EC          | The European Communities  |
| ECJ         | The European Court of Justice   |
| EEC         | The European Economic Community   |
| EIPR        | European Intellectual Property Review                                   |
| EU          | The European Union  |
| FDI         | Foreign Direct Investment   |
| FOGS        | Functioning of the GATT System  |
| FT          | Financial Times   |
| GA Res      | General Assembly Resolution   |
| GATT        | The General Agreement on Tariffs and Trade                              |
| GDP         | Gross Domestic Product  |
| GNS         | Group of Negotiations on Services                                       |
| GSP         | Generalised System of Preferences                                       |
| ICJ         | The International Court of Justice                                      |
| ICs         | Industrial Countries  |
| IFPMA       | International Federation of Pharmaceutical Manufacturers Association    |
| IIC         | International Review of Industrial Property and Copyright Law           |
| IMF         | International Monetary Fund   |
| IPIC Treaty | Treaty on Intellectual Property in respect of Integrated Circuits       |
| IPP         | Intellectual Property Protection  |
| IPRs        | Intellectual Property Rights  |
| ITC         | International Trade Commission  |

|          |  |
|----------|--|
| ITO      | International Trade Organisation                           |
| JIBL     | Journal of International Business Studies                  |
| JWT      | Journal of World Trade                                     |
| JWTL     | Journal of World Trade Law                                 |
| JWTL     | Journal of World Trade Law                                 |
| LDCs     | Least Developed Countries                                  |
| MFN      | Most-Favoured Nation Principle                             |
| MJIL     | Michigan Journal of International Law                      |
| MNCs     | Multinational Corporations                                 |
| MPCs     | Multinational Pharmaceutical Corporations                  |
| MTNs     | Multilateral Trade Negotiations                            |
| NAFTA    | North America Free Trade Agreement                         |
| NCEs     | New Chemical Entities                                      |
| NIEs     | Newly Industrialised Economies                             |
| NT       | National Treatment Principle                               |
| NTBs     | Non-Tariff Barriers  |
| OECD     | The Organisation for Economic Co-operation and Development |
| OTCs     | Over-the Counter Medicines                                 |
| PCT      | Patent Co-operation Treaty 1970                            |
| PMA      | Pharmaceutical Manufacturers' Association                  |
| R&D      | Research and Development                                   |
| RBPs     | Restrictive Business Practices                             |
| TBR      | Trade Barriers Regulation                                  |
| TNCs     | Transnational corporations                                 |
| TRIPS    | Trade-Related Aspects of Intellectual Property Rights      |
| UN       | United Nations   |
| UNCTAD   | United Nations Conference on Trade and Development         |
| US       | The United States  |
| USITC    | The United States International Trade Commission           |
| USTR     | The United States Trade Representative                     |
| Vand JTL | Vanderbilt Journal of Transnational Law                    |
| WIPO     | World Intellectual Property Organisation                   |
| WTO      | The World Trade Organisation                               |

## Introduction

The TRIPS Agreement<sup>1</sup> was concluded in 1994 after seven tortuous years of multilateral trade negotiations (MTNs) under the auspices of the General Agreement on Tariffs and Trade (GATT). It provides the most comprehensive multilateral agreement on IPP to date. And for the first time in a multilateral treaty, it contains provisions specifically relating to patent protection for pharmaceuticals. Among the supporters of such an agreement, MPCs had played an influential role in bringing IPP into the global trading system and securing a multilateral patent regime of industrialised countries' (ICs') standard. They believed such an agreement was essential in laying the groundwork for their expansion of global trade in pharmaceuticals.

In seeking such an agreement within the framework of the global trading system, the liberalisation and expansion of global trade could be achieved by securing market access and equal competition opportunity commitments through MTNs under the auspices of the GATT, with the reinforcement of domestic competition policy to ensure the efficient functioning of markets as the basis for the implementation of treaty obligations. These two inter-linked factors will serve as the benchmarks to evaluate whether the patent system for pharmaceuticals<sup>2</sup> conferred by the TRIPS Agreement provides an adequate

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<sup>1</sup> GATT, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Annex IC, 15 April 1994 (hereinafter the Final Act).

<sup>2</sup> Whether to include patent protection for pharmaceuticals within the framework of TRIPS MTNs had attracted more debates than other issues in the Uruguay Round across the North-South axis. See discussion in Zutshi, B. K., 'Bringing TRIPS into the Multilateral Trading System', in Bhagwati and Hirsch (eds.), *The Uruguay Round and Beyond*, Heidelberg: Springer, 1998, pp. 37-50, Subramanian, Arvind, 'Putting Some Numbers on the TRIPS Pharmaceutical Debate', *International Journal of Technology Management*,



and effective patent regime for MPCs<sup>3</sup> which ensures the legal recognition of the exclusive marketing rights among nations.

The substantive analysis of this thesis begins with the examination of economic and legal dimensions of patent protection for pharmaceuticals. It gives insight to ICs and developing countries' (DCs') different perspectives<sup>4</sup> as to their desired legal standard of a multilateral patent system, its function in the domestic and global economies,<sup>5</sup> why the

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10(2/3), 1990a, p. 253, and Hoekman, Bernard M. and Michel M. Kostecki, *The Political Economy of the World Trading System – From GATT To WTO*, Oxford: Oxford University Press, 1995, p. 151.

<sup>3</sup> MTNs on TRIPS under the auspices of the global trading system came about as a market-driven initiative by multinational corporations (MNCs) from industrialised countries, who are the major producers of intellectual property-endowed products and technology. Among them, MPCs were at the forefront of advocating the inclusion of patent protection for pharmaceuticals as a part of TRIPS MTNs in the Uruguay Round. In their survey of British industries, Taylor and Silberston comment that the pharmaceutical industry stands alone in the extent of its involvement with the patent system. See Taylor, C. T. and Z. H. Silberston, *The Economic Impact of the Patent System: A Study of British Experience*, Cambridge: Cambridge University Press, 1973, p. 231. Mansfield and Levin et al also confirm the importance of patent in protecting the process and product innovations of the pharmaceutical industry. See Mansfield, Edwin, 'Patent and Innovation: An Empirical Study', *Management Science*, 32, 1986, pp. 173-181 and Levin, Richard C., Alvin K. Klevorick, Richard R. Nelson, and Sidney G. Winter, *Appropriating the Return from Industrial Research and Development*, Cowles Foundation Paper no. 714, Cowles Foundation for Research in Economics at Yale University, 1989, p. 797. In this thesis, multinational pharmaceutical corporations refer to those research based pharmaceutical companies that produce original brand name products and operate in the global market. These companies are described as "multinational" because however large the companies may be and however many subsidiaries they may have scattered across the globe, most of them have a centralised management structure (see Mead, Richard, *International Management – Cross-Cultural Dimensions*, 2<sup>nd</sup> ed., Oxford: Blackwell Publishers, 1998, pp. 356-357 and Lessem, Ronnie, *Global Management Principles*, Hertfordshire: Prentice Hall, 1989, pp. 12-13.) Although some manufacturers from this industry also engage in the production of generic products, it is only as a strategic move to counter generic erosion of market shares of their patent-expired products. The original brand name products are ethical products, which require physicians' prescription to dispense, i.e., physicians make the decision as to what medicine to prescribe for their patients. The original brand name pharmaceuticals are not proprietary medicines commonly known as Over-the-Counter medicines (OTCs) which are considered to be safe for self-medication which are available without prescription.

<sup>4</sup> It is important to give a balanced view on patent protection for pharmaceuticals from the perspectives of both ICs and DCs even though the assessment of the adequacy and effectiveness of the patent system for pharmaceuticals under the TRIPS Agreement in this thesis is made from the stand point of MPCs.

<sup>5</sup> Going beyond economic debates, ICs viewed a strengthened IP system as necessary to provide a fair rule-based global trading environment that safeguards patent holders' exercise of exclusive marketing rights conferred by patent protection. DCs, the majority of them technology purchasers, remained defensive in protecting their economies from the invasion of monopolistic power derived from exclusive marketing rights patent holders enjoy. DCs argued that there is a divorce between patent protection in DCs and incentive on the R&D investment in that that granting of patent protection to MPCs had not had influence on their decision on where to conduct their R&D, and it was unlikely to affect MPCs' foreign investment decisions. Instead, it had been used as a tool to erect barriers of entry to DCs' markets. Furthermore, the

Convention was inadequate, how the patent system should be revised<sup>6</sup> and under which forum.<sup>7</sup> The inclusion of TRIPS in general, and the patent system for pharmaceuticals in specific, on the agenda of the Uruguay Round MTNs was only made possible by two major events which took place in the global political and economic scenes prior to the Uruguay Round. Firstly, the global economy was faced with severe recession during that

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patent regime under the Convention failed to address DCs' development needs, nor did it curtail monopolistic power exercised by foreign patent owners. See Vaitos, Constantine V., 'The Revision of the International Patent System: Legal Considerations for a Third World Position', *World Development*, 4(2), 1976, pp. 85-102 and from the same author 'Patent Revisited: Their Function in Developing Countries', *Journal of Development Studies*, 4(2), 1972, pp. 85-102, Lall, Sanjaya, 'The Patent System and the Transfer of Technology to LDCs', *JWTL*, 10(1), 1976, pp. 1-16, and Oddi, Samuel A., 'The International Patent System and Third World Development: Reality or Myth?' *Duke Law Journal*, 1987, pp. 831-878. See discussion in Chapter 1.5.1.

<sup>6</sup> A strengthened IP system was seen by ICs as essential to conduct the global trade of IP-endowed products and technology. But DCs sought more freedom to adopt a patent system which could reflect their domestic public concerns, especially when pharmaceuticals are regarded as an important component of public health policy.

<sup>7</sup> ICs proposed GATT as the negotiation forum because the elimination and reduction of trade distortions caused by non-tariff barriers was within the jurisdiction of GATT. (See David, Paul A., 'Intellectual property Institutions and the Panda's Thumb: Patent, Copyrights, and Trade Secrets in Economic Theory and History', in Wallerstein, Moguee, and Schoen (eds.), *Global Dimensions of Intellectual Property Rights in Science and Technology*, Office of International Affairs National Research Council, Washington, D.C.: National Academy Press, 1993, pp. 119-61, p. 20 and Primo Braga, Carlos Alberto, 'The Economics of Intellectual Property Rights and the GATT: A View from the South', *Vand. JTL*, 22(2), 1989, pp. 243-264, p. 245, Meessen, Karl M., 'Intellectual Property Rights in International Trade', *JWTL*, 21(1), 1987, p. 68, Stern, Richard H., 'Intellectual Property', in Finger and Olechowski (eds.), *A Handbook for the Multilateral Trade Negotiations*, Washington, D.C.: The World Bank, 1987, p. 205, and statements in the Basic Framework of GATT Provisions on Intellectual Property, Statement of Views of the European, Japanese and United States Business Communities, The Intellectual Property Committee (USA), UNICE (Europe), and Keidanren (Japan), June, 1988 (hereinafter the Basic Framework.) Furthermore, ICs identified the difficulty of revising and strengthening the patent regime under the Convention because the voting system of the Convention and the political dynamic among the member states within the Convention were as such that ICs did not think they were in a strong bargaining position to push their revision proposal through. (See Remarks of Professor John H. Jackson, *Vand JTL*, 22(2), 1989, p. 346 (hereinafter Jackson Remarks) and Remarks of Professor Robert Hudec, *Vand JTL*, 22(2), 1989, p. 321 (hereinafter Hudec Remark), Blakeney, Michael, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement*, London: Sweet & Maxwell, 1996, p. 27, and Emmert, Frank, 'Intellectual Property in the Uruguay Round – Negotiating Strategies of the Western Industrialized Countries', *Michigan Journal of International Law*, 11(4), 1990, p. 1343. Furthermore, the World Intellectual Property Organisation (WIPO) was seen by the business community in ICs as being sympathetic to some anti-IP activities. See Kastenmeier, R. W. and David Beier, 'International Trade and Intellectual Property: Promise, Risk, and Reality', *Vand JTL*, 22(2), 1989, p. 293.) But DCs chose to continue their revision endeavour under the Convention insisting that it had been in existence for more than one hundred years, and that the WIPO was the competent and appropriate forum for handling intellectual property matters. It was in June 1974, during the sixth session of the co-ordination Commission of WIPO, that the idea of possible revision of the Convention was put forward based on the proposal made by the delegates of India and the UK representing DCs and ICs respectively. See WIPO, PR/DC/3, June 25, 1979, p. 6. See also Kunz-Hallstein, Hans Peter,

period of time. Protectionism flourished partly due to ICs' resentment of DCs free-riding on the benefits of MTNs<sup>8</sup> without making reciprocal trade concessions. DCs soon came to the realisation that their more active participation in MTNs was necessary to rid ICs of the resentment. And with the legitimate expectation to achieve trade-offs between topics important to parties in the MTNs under the GATT system, DCs consented to ICs' demand for the inclusion of IPP issues on the agenda for MTNs in exchange for ICs' agreeing to bring agriculture and other commodities important to DCs' economies into the fold of the global trading system.<sup>9</sup> Secondly, the political and economic pressure from ICs, in particular the US, linking IPP with their domestic trade legislation and imposing unilateral trade sanctions against countries with lower standard of IP system than theirs<sup>10</sup> served as a reminder to trading nations that a multilateral agreement would

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'The Revision of the International System of Patent Protection in the Interest of Developing Countries', *IIC*, 10, 1979, pp. 649-670.

<sup>8</sup> Despite the benefit of differential and more favourable treatments conferred by GATT, many DCs' economies remained in tatters. Some of them initiated unilateral trade liberalisation and export expansion policies in the wake of the early 1980s debt crisis. Their efforts were hindered by the proliferation of protectionism among many ICs which could partly be attributed by the resentment toward differential and more favourable treatments (DMFT) DCs had enjoyed in GATT, the strongest of which came from the US political establishment. See Bhagwati, Jagdish, 'Fair Trade, Reciprocity and harmonisation; The New Challenge to the Theory and Policy of Free Trade', in Deardorff and Stern (eds.), *Analytical and Negotiating Issues – In the Global Trading System*, Ann Arbor: The University of Michigan Press, 1994, pp. 547-598, Whalley, John (cord.), *The Uruguay Round and Beyond, The Final Report from the Ford Foundation Project on Developing Countries and the Global Trading System*, London: The MacMillan Press Ltd., 1989 (hereinafter Ford Foundation Report), p. 5, and Greenway, David and Robert C. Hine, 'Introduction: Trends in World Trade and Protection', in Greenaway, Hine, O'Brien, and Thornton (eds.), *Global Protectionism*, Hampshire: MacMillan Academic and Professional Ltd., 1991, p. 7.

<sup>9</sup> Hoekman and Kosteki, note 2 above., p. 78, Jackson, John, *The World Trading System – Law and Policy of International Economic Relations*, Massachusetts: The MIT Press, 1992, p. 125, and Cottier, Thomas, 'The Prospects for Intellectual Property in GATT', 28, *CMLR*, 1991, pp. 383-414.

<sup>10</sup> Since 1970s, the US administration enacted domestic trade legislation, the most well-known ones being Section 301 provisions, linking IPP with its trade policy as the result of domestic political pressure from the US Congress and lobbying efforts by high technology industries, compounded by the frustration of US administration in their effort to bring the IPP issue into the auspices of GATT. The perceived inadequate and ineffective IP system in some countries was regarded as unfair foreign trade practices with the effect of denying US firms market access and fair commercial opportunity. When a country was being identified as to have practised as such, they were targeted for unilateral trade sanctions by being denied the access to the US market. See Hudec, Robert E., 'Thinking About the New Section 301: Beyond Good and Evil', in Bhagwati and Patrick (eds.), *Aggressive Unilateralism – American's 301 Trade Policy and the World Trading System*, Hertfordshire: Harvester Wheatsheaf, 1991, p. 130, Remarks by David Beier in *Vand. JTL*,

be more desirable to defend one's trade interests than unilateral or bilateral sanctions based on arbitrary rules set by individual countries.<sup>11</sup>

Since the provisional application of GATT in 1947, it had not only provided a legal framework for the conduct of global trade relations, shaped by national and global politics,<sup>12</sup> it had also been used by contracting parties (CPs)<sup>13</sup> as a forum for settling disputes. But ICs' endeavour to introduce TRIPS into GATT raised the question of the competence of GATT, in particular, the application of the Most-Favoured-Nation principle (MFN),<sup>14</sup> the principle of National Treatment (NT),<sup>15</sup> and Reciprocity,<sup>16</sup> in dealing with the protection of intellectual property rights (IPRs). How the three

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22(2), 1989, p. 334 (hereinafter Beier Remark), Gadbow, Michael R., and Timothy J. Richards, 'Introduction', in Gadbow and Richards (eds.), *Intellectual Property Rights – Global Consensus, Global Conflict?* Boulder, Colorado: Westview Press, 1988a, GATT, BISD 28<sup>th</sup> Supp., 1982, p. 15 and GATT, L/4817, 31 July, 1979.

<sup>11</sup> See Getlan, Myles, 'TRIPS and the Future of Section 301: A Comparative Study of Trade Dispute Resolution', *Columbia Journal of Transnational Law*, 34(1), 1995, pp. 173-218 and Primo Braga, Carlos Alberto, 'Intellectual Property Rights in NAFTA: Implications for International Trade', in Riggs and Velk (eds.), *Beyond NAFTA: An Economic, Political and Sociological Perspective*, Vancouver: The Fraser Institute, 1993, p. 107, Cottier, op. Cit., p. 389.

<sup>12</sup> The Economist, Forty Years on for GATT, October 24, 1987.

<sup>13</sup> As GATT was applied provisionally in 1947, its members were referred to as the "contracting parties" (hereinafter CPs). Under Article XXV:I of GATT: "... whenever reference is made.. to the contracting parties acting jointly, they are designated as the CONTRACTING PARTIES ...". "Contracting parties" in the lower case represents individual contracting parties. GATT 1994 is one of the agreements reached in the Uruguay Round (1986-1994) which has subjected many articles of GATT to amendments. As distinguished from GATT 1994, GATT 1947 will be referred to as GATT, and GATT 1994 specified as GATT 1994.

<sup>14</sup> The unconditional MFN as stated in Article I of GATT requires each contracting party to grant to every other contracting party unconditionally the most favourable treatment which it grants to any country. It confers on contracting parties of GATT equal right of market access irrespective of their size and bargaining power. But its application was limited to trade in goods prior to the TRIPS Agreement. See discussion in Chapter 3.3.1.

<sup>15</sup> NT as stated in Article III of GATT obliges contracting parties to apply domestic law in a non-discriminatory manner and accord no less favourable treatment to imported products than what has been conferred on like products of domestic origin. It is to prevent domestic taxes and government regulations from being used to afford protection to domestic productions. It touches upon domestic regulatory autonomy and restricts what government could do to deny foreign products equal opportunities for competition. See discussion in Chapter 3.3.2.

<sup>16</sup> "Reciprocity" was not defined in the General Agreement, but it has been applied in GATT MTNs through mutually accepted tariff and non-tariff concessions on the basis of an overall balance of rights and

principles have evolved over the years and worked in tandem to secure market access and equal competition opportunity commitments from trading nations demonstrates their responsiveness to the changing needs of trading nations and global business communities,<sup>17</sup> which is essential for the handling of the legal, economic, and political dynamics which underline MTNs.<sup>18</sup>

Following the conclusion of the TRIPS Agreement, the legal analysis of which illustrates the success of the Agreement in securing market access and equal competition opportunity commitments by incorporating MFN and NT applicable to natural or legal IP owners, with the application of reciprocity reflected in the mandatory requirement of the WTO members to implement the minimum standards set out in TRIPS. And the concern of the ineffectiveness of the patent system under the Convention has been rectified by the introduction of detailed provisions for a domestic enforcement mechanism<sup>19</sup> and the incorporation into the TRIPS Agreement of the WTO dispute settlement procedures.<sup>20</sup>

But two areas of concern have been identified which might undermine the adequacy and effectiveness of the patent system for pharmaceuticals conferred by the TRIPS Agreement which ensures the recognition of the exclusive marketing rights among nations. The first area concerns the uncertainty in relation to how governments might

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obligations. It also has been relied on to limit the scope of free riding that may arise from the application of unconditional MFN. See discussion in Chapter 3.3.3.

<sup>17</sup> Jackson, John, 'The Crumbling Institutions of the Liberal Trade System', *JWTL*, 12(2), 1978, p. 98.

<sup>18</sup> Especially in accommodating different domestic economic and political agendas among negotiating parties. Long, Olivier, *Law and its Limitations in the GATT Multilateral Trade System*, Dordrecht: Martinus Nijhoff Publishers, 1987, p. 22 and Low, Patrick, *Trading Free – The GATT and US Trade Policy*, NY: The Twentieth Century Fund Press, 1993.

<sup>19</sup> Articles 41- 61 of the TRIPS Agreement

<sup>20</sup> Article 64 of the TRIPS Agreement.

exercise their discretion in implementing the exception clause and the contractual licensing provision contained in the TRIPS Agreement.<sup>21</sup> The TRIPS Agreement does not prohibit governments' practices which restrict the exercise of the exclusive marketing rights conferred by patent protection. But at least the WTO Dispute Settlement Body could adjudicate the legality of government measures if disputes do arise in this area. What concerns MPCs most is the absence of an agreement on prohibiting the adoption of international exhaustion<sup>22</sup> and parallel importation,<sup>23</sup> where patented products are faced with competition from unauthorised import of cheaper original products during patent terms. And the TRIPS Agreement specifically excludes disputes arising from the issue of the exhaustion of IP from its jurisdiction.<sup>24</sup> Recognising that the exclusive marketing rights conferred by patent protection have a restrictive effect on competition, and that competition policy remains with domestic jurisdiction, a multilateral solution is needed to address the question of to what extent domestic government policy promoting competition should give consideration to those exclusive rights. Or it will put into question the adequacy and effectiveness of the patent system for pharmaceuticals under the TRIPS Agreement.

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<sup>21</sup> Although WTO member states are under obligations to incorporate the minimum standards stipulated in the TRIPS Agreement into their domestic legislation, they are free to determine the appropriate methods of implementation so long as they are consistent with the Agreement (Article 1.1 of the TRIPS Agreement). See discussion in Chapter 4.4.

<sup>22</sup> Under the doctrine of international exhaustion, a patent holder is not entitled to any legal control over the subsequent commercialisation of the patented product within the territory of the state granting the protection following the first authorised domestic sale of the patented product. Parallel importation is thus allowed. See discussion in Chapter 5.3.

<sup>23</sup> Parallel importation of pharmaceuticals involves the importation of patented drugs, lawfully put on the market in the place of export, by third parties without patent holders' consent, to countries where identical products have been legitimately put onto markets but are selling at a higher price. See discussion in Chapter 5.3.

<sup>24</sup> Article 6 of the TRIPS Agreement.

Structurally, this thesis is divided into five chapters. Chapter I explores why ICs and developing countries (DCs) both found the patent regime under the Convention inadequate,<sup>25</sup> and discusses their diverse perceptions with regard to patent protection for pharmaceuticals. Chapter II identifies two major factors which have contributed to the eventual agreement between ICs and DCs to include TRIPS on the agenda of the Uruguay Round MTNs which includes the issue of patent protection for pharmaceuticals. Chapter III is to take up the question of the competence of the legal framework of GATT, in particular, the three pivotal principles of MFN, NT, and Reciprocity, in dealing with the non-traditional subject matter of IPP for the benefit of natural and legal persons.<sup>26</sup>

For the purpose of assessing whether the patent system for pharmaceuticals conferred by the TRIPS Agreement provides an adequate and effective legal regime that ensures the recognition of the exclusive marketing rights among nations, Chapter IV contains the analysis of the legal framework of the TRIPS Agreement which underlines the achievement of the Agreement as far as securing market access and equal competition opportunity commitments from members of the WTO for the implementation of a strengthened IP system, in particular, a patent system for pharmaceuticals of ICs' standard.<sup>27</sup> But two areas of concerns deriving from the TRIPS Agreement are discussed

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<sup>25</sup> The Convention was the major multilateral agreement governing patent protection prior to the conclusion of the TRIPS Agreement. See Bodenhausen, G.H.C., *Guide to the Application of the Paris Convention for the Protection of Industrial Property*, Paris: United International Bureau for the Protection of Intellectual Property (BIRPI), 1968, p. 175 and Bogsch, Arpad, 'The First Hundred Years of the Paris Convention for the Protection of Industrial Property, Special Issue for the Commemoration of the Centenary of the Paris Convention', *Industrial Property*, Geneva: WIPO, 1983.

<sup>26</sup> The 1947 General Agreement on Tariffs and Trade is to secure the liberalisation and expansion of global trade in tangible goods only.

<sup>27</sup> For example, the inclusion of pharmaceutical process and product as patentable subject matters (Article 28.1 of the TRIPS Agreement), twenty years of patent protection from the date of filing (Article 33 of the TRIPS Agreement), and the reversal of burden of proof now on the defendant in case of breach (Article 34.1(a) of the TRIPS Agreement).

in Chapter V which raise doubts as to the adequacy and effectiveness of the patent system in the implementation of the TRIPS Agreement so to secure the exercise of the exclusive marketing rights it confers.



## Chapter I

### The Pre-Uruguay Round International Patent Regime for Pharmaceuticals Under the Paris Convention

This chapter looks into the economic as well as the legal dimensions of IPP and explores the very different underlying perceptions of ICs and DCs in regard to IPP to explain why and what ICs and DCs sought in the legal regime of patent protection under the Convention. A detailed analysis of the legal regime of the Convention provides a full picture, linking the perceived inadequacies of the Convention from both sides with the changes they sought.

#### 1.1 Introduction

TRIPS was introduced, for the first time, as a subject in MTNs in the Uruguay Round.<sup>1</sup> Among the subject areas negotiated, patent protection for pharmaceuticals had attracted more debate than any other issue across the North-South axis.<sup>2</sup> Prior to the Uruguay Round, the Convention administered by the World Intellectual Property Organisation (WIPO) had been the major multilateral agreement governing the international regime of patent protection.<sup>3</sup> Patent protection had not been treated as an issue related to trade but

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<sup>1</sup> The Uruguay Round MTNs (1986-1994) started with the participation of 108 nations represented more than 90% of world trade at the time.

<sup>2</sup> Zutshi, B. K., 'Bringing TRIPS into the Multilateral Trading System', in Bhagwati and Hirsch (eds.), *The Uruguay Round and Beyond*, Heidelberg: Springer, 1998, pp. 37-50, Subramanian, Arvind, 'Putting Some Numbers on the TRIPS Pharmaceutical Debate', *International Journal of Technology Management*, 10(2/3), 1990a, p. 253, and Hoekman, Bernard M. and Michel M. Kostecki, *The Political Economy of the World Trading System – From GATT To WTO*, Oxford: Oxford University Press, 1995, p. 151.

<sup>3</sup> Other major international agreements relating to patents are the Patent Co-operation Treaty (1970), the Budapest Treaty (1977), and the Strasbourg Agreement (1971). Primo Braga, Carlos A., 'Trade-Related Intellectual Property Issues: The Uruguay Round Agreements and its Economic Implications', in Martin and Winters (eds.), *The Uruguay Round and the Developing Countries*, Cambridge: Cambridge University

more of an economic one with direct relevance to industrial development policy.<sup>4</sup> Furthermore, as pharmaceuticals were seen to be of direct relevance to public health, the patent regime for pharmaceuticals was also within the sphere of public health policy.

It was the alleged inadequacies of the Convention expressed both by DCs and ICs which prompted both sides to seek changes in the international legal framework. MPCs from ICs were in the forefront of lobbying their respective governments to bring intellectual property protection as a trade issue to the negotiation table in the Uruguay Round.<sup>5</sup> It was a market-necessity driven initiative. Patent protection is important to MPCs. The exclusive marketing rights conferred by patent protection prevent generic versions from entering into markets during the patent life of the new chemical entity (NCE). It allows MPCs to recoup R&D costs<sup>6</sup> and to compensate for the high risks involved in research and development (R&D) and post product launch. But with generic competition appearing on the scene upon the expiration of patent protection, accompanied by government measures such as price capping of patented products and generic substitution

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Press, 1996, p. 343, Table 12.1. These three treaties are administered by WIPO. The Patent Co-operation Treaty (PCT) implements the concept of a single international patent application. Once such an application is filed, it has the effect in the members to the PCT. An applicant then has time to decide in which of the countries to continue with the application. PCT opens to the member states of the Paris Convention by virtue of Article 19 of the Paris Convention. It was concluded in 1970, and was amended in 1979 and 1984. As to February 1997, 89 of 140 states party to the Convention were party to the PCT. The Budapest Treaty is on the international recognition of the Deposit of micro-organisms for the purposes of patent procedure. And the Strasbourg Agreement concerns the international patent classification to assist anyone considering to apply for a patent whether the invention is new or is owned or claimed by someone else.

<sup>4</sup> United Nations, World Investment Report 1998: Trends and Determinants, NY: UN, 1998 (hereinafter World Investment Report 1998), p. 350.

<sup>5</sup> The success of bringing patent protection into the MTNs in the Uruguay Round was described as a private-sector driven initiative. Remarks by David Beier in *Vand-JTL*, 22(2), 1989, p. 334 (hereinafter Beier Remark).

<sup>6</sup> Redwood, Heinz, *New Horizons in India*, Suffolk: Oldwicks Press, 1994, p.89.

to keep health care budgets in check,<sup>7</sup> the erosion of MPCs' profit is considerable. Gaining access to unexplored markets, most of them in DCs, becomes a necessary option. This is why patent protection for pharmaceuticals has become an important component of MPCs' global competition strategy.<sup>8</sup>

MPCs from the United States (US), the European Union (EU), and Japan were very active in lobbying their respective governments to take up the issue of IPP in MTNs under the auspices of GATT. In these free market economies, policy consideration has largely shifted from welfare impacts of patent regime to the mechanics of the legal system. In an interdependent global economy, business practices of MNCs play an increasingly influential role in shaping both the domestic and global regulatory frameworks to ensure fair competition on both domestic and global fronts. This policy emphasis has been reflected in MPCs' expressed concerns over the inadequacy of the Convention. They felt that the Convention allowed its member states too much discretion in establishing their domestic patent system, resulting in disparity among national systems which in turn caused distortions to international trade. They were also dissatisfied with the lack of domestic enforcement procedures and a workable dispute settlement mechanism under the Convention to ensure compliance of treaty obligations.

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<sup>7</sup> See Nogues, Julio, *Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries*, International Economic Department, Washington, D.C.: The World Bank, 1990, Grabowski, H., *Health Reform and Pharmaceutical Innovation*, Washington, D.C.: American Enterprise Institute of Public Research, 1994b, and Grabowski, H., and J. Vernon, 'Brand Loyalty, Entry and Price Competition', *Journal of Law and Economics*, 35, 1992, pp. 305-331. It could also be caused by generic substitution. Mansfield, E., 'How Rapidly Industrial Technology Leak out', *The Journal of Industrial Economics*, 34(2), 1985, pp. 217-223.

<sup>8</sup> Trade marks, copyrights, and trade secret legislation all form the armouries for the research-based pharmaceutical industry to protect the proprietary rights of their inventions.

With the steady increase of their innovative products crossing national borders,<sup>9</sup> MPCs viewed lower or no patent protection in foreign countries as non-tariff barriers (NTBs)<sup>10</sup> inhibiting their market access and causing economic losses. As the elimination and reduction of trade distortions caused by NTBs was within the jurisdiction of GATT, MPCs called for a negotiated rule-based multilateral legal framework under the auspices of GATT.<sup>11</sup>

From DCs' viewpoint, the Convention failed to address their development needs and curtail monopolistic power exercised by the multinational corporations (MNCs). They sought revisions of the Convention and requested more freedom to adopt patent systems so as to reflect domestic public concerns and meet their developmental needs. They insisted that as the Convention has been in existence for more than one hundred years providing a workable patent regime administered by WIPO, that it was WIPO, and not GATT, which was the competent and appropriate forum for handling IP matters.

At the time of debate for the inclusion of patent protection for pharmaceuticals on the agenda for the Uruguay Round MTNs, many DCs provided very little or no protection for pharmaceuticals.<sup>12</sup> While considering whether to introduce a patent regime for

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<sup>9</sup> Formerly dominated by primary products, international trade is now concentrated in technology-intensive goods. High technology goods alone doubled their share of world merchandise export from 11 percent in 1976 to 22 percent in 1996. But the share of primary products dropped to less than 25 percent from about 45 percent in 1976. See The World Bank, *World Development Report, 1998/99*, NY: Oxford University Press for the World Bank (hereinafter *World Development Report 1998/99*), p. 27.

<sup>10</sup> Stern, Richard H., 'Intellectual Property', in Finger and Olechowski (eds.), *A Handbook for the Multilateral Trade Negotiations*, Washington, D.C.: The World Bank, 1987, p. 205.

<sup>11</sup> See discussion in Chapter 1.5.2.

<sup>12</sup> Examples include Argentina, Brazil, Colombia, India, and Mexico. For full list, see GATT, MTN.GNG/NG11/W/24/Rev.1, 1988 prepared by the International Bureau of WIPO for the GATT Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods (Negotiating Group 11) (hereinafter *WIPO Report for GATT*).

pharmaceuticals, policy makers in DCs focused almost exclusively on economic analysis. This approach took place from the perspective of maximising economic efficiency and welfare at the level of the world or national economy as a whole.<sup>13</sup> It focused almost exclusively on the balance of costs (such as monopoly rent and social welfare losses) and benefits (increases in foreign technology transfer and domestic and foreign investment in research and development).<sup>14</sup> Based on the premise that patent protection does confer monopoly to patent holders, it believed that the monopolistic power could cause domestic welfare losses to consumers and societies as a whole. In the international context, the static effect of patent protection could be to diminish global welfare in the short term and redistribute world income in foreign producers' favour, with the dynamic effects of inducing foreign technology transfer and R&D activities.

The validity of the claim that the introduction of patent system would encourage foreign technology transfer and foreign R&D activities has been investigated extensively, but with no conclusive results. Nevertheless, it is a commonly held view that patent protection serves as an important groundwork in encouraging local innovative activities when a country wishes to establish the scientific and technological infrastructure required for developing the capability to select, absorb and adapt technologies available, with a long term view of attracting foreign investment in technology and R&D activities. The introduction of patent protection is necessary, although not sufficient, to ensure any

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<sup>13</sup> Abbott, Kenneth W., 'Defensive Unfairness: The Normative Structure of Section 301', in Bhagwati and Hudec (eds.), *Fair Trade and Harmonisation – Prerequisites for Free Trade?* Vol. 2, Legal Analysis, Cambridge: The MIT Press, 1996, p. 419.

<sup>14</sup> Primo Braga, Carlos Alberto, 'Intellectual Property Rights in NAFTA: Implications for International Trade', in Riggs and Velk (eds.), *Beyond NAFTA: An Economic, Political and Sociological Perspective*, Vancouver: The Fraser Institute, 1993, pp. 107-108.

possibility of attracting desirable foreign technology transfer and R&D investment in the short-term.

## 1.2 Patent defined

Prior to the completion of TRIPS MTNs, the Paris Convention (the Convention) for the protection of Industrial Property as revised in 1967 was the major multilateral patent regime, administered by WIPO. Under the Convention, industrial property was divided into two areas: one covered patents, industrial designs and trade secrets, and the other for the protection of distinctive signs, in particular trademarks and geographical indications.<sup>15</sup> Intellectual property (IP) has been used collectively to cover both industrial property and copyright and rights related to copyright.<sup>16</sup> Following the conclusion of the Uruguay Round, all categories of intellectual property are covered by the TRIPS Agreement,<sup>17</sup> which is administered by the World Trade Organisation (WTO).

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<sup>15</sup> WTO Website, <http://www.wto.org>, February 2, 1998.

<sup>16</sup> Copyright and rights related to copyright was traditionally under the separate jurisdiction of the Berne Convention. The Berne Convention came into force in 1886. The aim of this Convention was to help nationals of its member states obtain international protection of their right to control, and receive payment for, the use of their creative works such as novels, poems, musicals, paintings, and architectural works, etc. See WIPO, General Information, Geneva: WIPO, July 1998, p. 4. After several revisions, the most recent one is the Paris Act of the Berne Convention for the Protection of Literary and Artistic Works of July 1971. The Convention is administered by WIPO.

<sup>17</sup> Article 1.2 of the TRIPS Agreement:

“For the Purposes of this Agreement, the term “intellectual property” refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.”

These subjects are: copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-design (topographies) of integrated circuits, and protection of undisclosed information.

“Patent” was not defined in the Convention. But a description of “patent” has been given in an United Nations (UN) report on “The Role of Patents in the Transfer of Technology to Developing Countries” as

“a statutory privilege granted by the government to inventors, and to other persons deriving their rights from the inventor, for a fixed period of years, to exclude other persons from manufacturing, using or selling a patented product or from utilising a patented method or process. At the expiration of the time for which the privilege is granted, the patented invention is available to the general public or, as it is sometimes put, falls into the ‘public domain’.”<sup>18</sup>

In a separate study by the UN, United Nations Conference on Trade and Development (UNCTAD), and WIPO in 1974 on “The Role of the Patent System in the Transfer of Technology to Developing Countries”, a patent was described as

“a legally enforceable right granted by virtue of a law to a person to exclude, for a limited time, others from certain acts in relation to a described invention; the privilege is granted by a government authority as a matter of right to the person who is entitled to apply for it and who fulfils the prescribed conditions.”<sup>19</sup>

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<sup>18</sup> UN, The Role of Patents in the Transfer of Technology to Developing Countries, UN Doc. E/3861/Rev. 1. 1964, (hereinafter UN 1964 Report).

<sup>19</sup> UN, UNCTAD, and WIPO, The Role of the patent system in the Transfer of Technology to Developing Countries, UN Doc. TD/B/AC.11/19, 1974, (hereinafter UN 1974 Report),

In more concise terms, a patent could be defined as an exclusive property right conferred on an invention<sup>20</sup> by law<sup>21</sup> for a limited duration, to prevent others from making, using, offering for sale, selling or importing without the patent holder's consent,<sup>22</sup> in exchange for the disclosure of the invention to the public.

The disclosure provision is set out in Article 29 of the TRIPS Agreement. It requires an applicant for patent to disclose the invention "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art ..."<sup>23</sup> By providing financial incentives in the form of market exclusivity to recover R&D cost in exchange for the disclosure of the innovative information to the society, it not only facilitates the generation and diffusion of new knowledge,<sup>24</sup> but also facilitates further R&D, and prevents duplicate effort of conducting identical research.<sup>25</sup>

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<sup>20</sup> Invention can take forms of a new product, a new process for making the product, or a new molecule. See Jackson, John H., Davey, William J., and Alan O. Sykes, Jr., *Legal Problems of International Economic Relations – Cases, Materials and Text*, Third Edition, St. Paul: West Publishing Co., 1995 (hereinafter Jackson et al.), p. 845.

<sup>21</sup> Sherwood, Robert, *Intellectual Property and Economic Development*, Boulder, Colorado: Westview Press, 1990, ch. 2.

<sup>22</sup> Article 28.1(a) of the TRIPS Agreement.

<sup>23</sup> An almost identical requirement is stipulated in Article 83 of the European Patent Convention specified that an application "must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art".

<sup>24</sup> Schumann, Gunda, 'Economic Development and Intellectual Property Protection in Southeast Asia: Korea, Taiwan, Singapore, and Thailand', in Rushing and Brown (eds.), *Intellectual Property Rights in Science and Technology and Economic Performance*, Boulder, Colorado: Westview Press, 1990, ch. 9.

<sup>25</sup> See discussion in Beier, Friedrich-Karl and J. Straus, 'The Patent system and Its Information Function – Yesterday and Today', 8, *IIC*, 1977.



In order for an invention to be patentable, most of the states require an invention to be novel, non-obvious, and industrially applicable.<sup>26</sup> An invention has to be a novel idea, which provides in practice the solution of a specific problem in the field of technology. The idea, in order to be protected by law, must be new in the sense that it has not been published or publicly used before the date on which the application for the grant of a patent was filed. The invention is non-obvious if it would not have occurred to any specialist in the particular industrial field had such a specialist been asked to find a solution to the particular problem. And the invention is industrially applicable if it can be industrially manufactured or used.<sup>27</sup>

Why?  
What?

In the context of international law, the protection conferred is upheld by both Article 27(2) of the Universal Declaration of Human Rights<sup>28</sup> and Article 15(c) of the International Covenant on Economic, Social and Cultural Rights of 1966 which recognise:

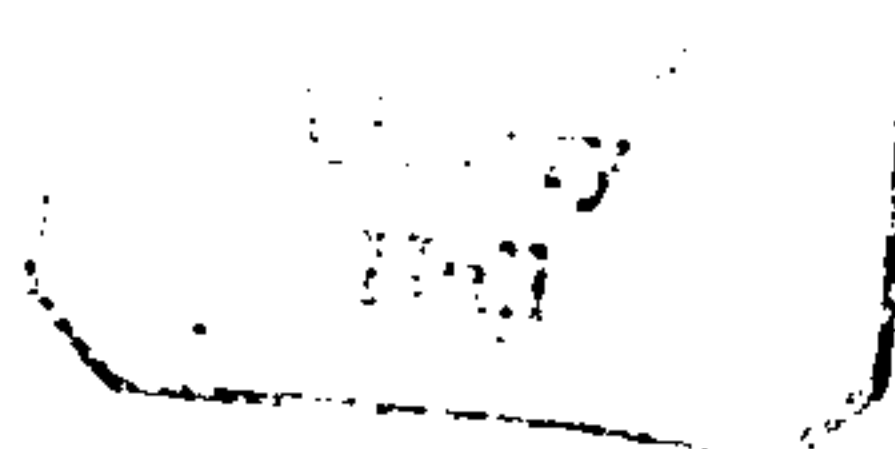
“the right of everyone...to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author”.<sup>29</sup>

<sup>26</sup>The Patent Co-operation Treaty 1970 contains definition of novelty, non-obviousness and industrial applicability.

<sup>27</sup> WIPO Web site, <http://www.wipo.org>, pp. 1 & 29, April 1997.

<sup>28</sup> GA Res 217, UN Doc A/810, 1948. For a detailed discussion of the legal status of the General Assembly resolutions, see Subedi, Surya P., *Land and Maritime Zones of Peace in International Law*, Oxford: Clarendon Press, 1996, pp. 96-101.

<sup>29</sup> GA Res 2200, 21 UN GAOR Supp (No.16), UN Doc A/6316 (1966).



There is a debate of whether receiving protection is one's natural right as against the knowledge itself being a "common heritage of mankind". Natural right theory, which has its origin in French patent law emerged during the French Revolution, is predominately a western belief.<sup>30</sup> It has been suggested that the examination of the patentability precedes the granting of the patent which makes it difficult to reconcile the protection with the notion of inherent right.<sup>31</sup> By placing a balance on private and public interests, some continental countries have evolved away from a natural law basis.

The DCs' view is that an innovation is the equivalence of information, which has a zero marginal cost of use, i.e. a given piece of information can be used by an infinite number of people simultaneously without exhausting the information itself.<sup>32</sup> It might be expensive to create but, due to its inexhaustible nature,<sup>33</sup> it may be used at no additional economic costs once created.<sup>34</sup> Hence, the innovative information is a public good, not private property. It should be made freely available to the greater general public.

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<sup>30</sup> Meessen, Karl m., 'Intellectual Property Rights in International Trade', *JWTL*, 21(1), 1987, p. 68 and Emmert, Frank, 'Intellectual Property in the Uruguay Round – Negotiating Strategies of the Western Industrialised Countries', *MJIL*, , 11(4), 1990, pp. 1317-1399.

<sup>31</sup> Primo Braga, Carlos, 'Guidance from Economic Theory', in Siebeck, Evenson, Lesser, and Primo Braga (eds.), *Strengthening Protection of Intellectual Property in Developing Countries – A Survey of the Literature*, Part III, World Bank Discussion Papers #112, Washington, D.C.: The World Bank, 1990a, p. 18.

<sup>32</sup> OECD, *Competition Policy and Intellectual Property Rights*, Paris: OECD, 1989, p.11.

<sup>33</sup> Vaitsos, Constantine V., 'Patent Revisited: Their Function in Developing Countries', *Journal of Development Studies*, 4(2), 1972, p. 72.

<sup>34</sup> Benko, Robert, 'Intellectual Property Rights and New Technologies', in Walker and Bloomfield (eds.), *Intellectual Property Rights and Capital Formation in the Next Decade*, Lanham, MD: University Press of America, 1988.

The US Constitution provides for the exclusive right for limited times to inventors for their discoveries as a means to promote the progress of science and useful arts.<sup>35</sup> The official position of the US is to regard IP as a right the legislators create for the promotion of public policy goals, i.e., it is an artificial right.<sup>36</sup> Primo Braga argues that the debate on the justification for granting the protection has been replaced by more utilitarian perspectives which addresses the patent protection as a social contract between inventors and society in terms of inventors disclosing technology secrets in exchange for a privilege.<sup>37</sup> It is often seen as a trade-off between the objective of stimulating invention and the loss of social welfare associated with the life of the patent.<sup>38</sup>

This exclusive property right is often regarded as the equivalent of granting a statutory monopoly to the patent owner by governments thereby interfering with free market competition. Some believe that monopolies created by patent are temporary because new technologies are continuously invented to replace old ones.<sup>39</sup> Others argue that the creation of exclusive legal rights does not necessarily establish right holders' ability to exercise market power because market power stems from the nature of demand for the product, and this demand depends on the availability of substitutes and the cross-elasticity of demand between these substitutes.<sup>40</sup> Sherwood further argues that although IP creates the right to exclude others from a discrete product or process, the classic monopoly is the ability to exclude others from a specific market. But rarely is a single

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<sup>35</sup> Article 1.8.8 of the US Constitution: "To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries".

<sup>36</sup> Reichman, J.H., 'Intellectual Property in International Trade: Opportunities and Risks of a GATT Connection', *Vand JTL*, 22(2), 1989, p. 776.

<sup>37</sup> Primo Braga, 1990a, note 31 above.

<sup>38</sup> UNCTAD, *Uruguay Round: Paper on Selected Issues, Trade and Development*, NY: UN, 1989, p.150.

<sup>39</sup> Tirole, Jean, *The Theory of Industrial Organisation*, Cambridge, The MIT Press, 1988, p. 400

product the equivalent of a market. Therefore, it is necessary to distinguish the effect of monopoly from the operation of IPP.<sup>41</sup> Especially in the research-based pharmaceutical industry where competition takes the form of rivalry in innovation<sup>42</sup> and the profit margin is often being competed away by rival firms introducing substitutable versions of the NCE.

### 1.3 The research-based pharmaceutical industry and patent

The research-based pharmaceutical industry (the industry) is a knowledge-based technology-intensive industry<sup>43</sup> in constant search for therapeutically innovative products in order to stay ahead of the competition.<sup>44</sup> Therefore, patent protection for pharmaceutical product and process has direct relevance to the competitiveness and profitability of the industry. As Taylor and Silberston point out in their surveys of British industries, the industry “stands alone in the extent of its involvement with the patent system”.<sup>45</sup> Various US industry surveys also confirm the importance of patent in protecting the process and product innovations of the drug industry and its function of appropriating return from investment on innovation.<sup>46</sup>

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<sup>40</sup> OECD, 1989, note 38 above, pp. 16, 20, and 25.

<sup>41</sup> Sherwood, 1990, note 21 above, p. 51.

<sup>42</sup> Parker, John E.S., ‘Pharmaceuticals and Third World Concerns: The Lall Report and the Otago Study’, in Helms (ed.), *The International Supply of medicines*, Washington D.C.: American Enterprise Institute for Public Policy Research, 1980, p. 136.

<sup>43</sup> Pharmaceutical industry is regarded as a high technology industry because it draws on most recent scientific advances in their R&D activities and it high ratio of R&D expenditures to sales. See Krugman, Paul, ‘Technology-Intensive Goods’, in Finger and Olechowski (eds.), *The Uruguay Round – A Handbook for the Multilateral Trade Negotiations*, Washington, D.C., The World Bank, 1987, p. 191.

<sup>44</sup> Parker, note 42 above, p. 138.

<sup>45</sup> Taylor, C. T. and Z. H. Silberston, *The Economic Impact of the Patent System: A Study of British Experience*, Cambridge: Cambridge University Press, 1973, p. 231.

<sup>46</sup> For example, Mansfield, Edwin, ‘Patent and Innovation: An Empirical Study’, *Management Science*, 32, 1986, pp. 173-181 and Levin, Richard C., Alvin K. Klevorick, Richard R. Nelson, and Sidney G. Winter,

The market exclusivity conferred by patent protection is taken as allowing the industry pricing freedom for NCEs to compensate for R&D costs and high risks associated with the investment. And the exclusive property right makes illegal generic versions of patented products during the term of patent protection. But the effective patent life has been shortened as the result of more stringent domestic regulatory requirements for gaining marketing approval. And the effectiveness of patent protection has been eroded in recent years as the consequence of government policies such as price capping or health budget control. These four inter-related strands explain why patent protection is important for the research-based industry. They are elaborated further as follows:

**Pricing freedom** – The industry is an investment intensive industry.<sup>47</sup> Patents offer the industry an opportunity to recoup their investments in R&D<sup>48</sup> and receive reasonable profit to reinvest for future R&D. The pharmaceutical industry is the most R&D intensive in the industrial sector as illustrated by the International R&D Scoreboard of 1997 whereby the pharmaceutical industry spent on average 12.8% of their sales on R&D, the highest among the industries.<sup>49</sup> According to DiMasi et.al.:<sup>50</sup> the actual average R&D costs per NCE was US\$54 million in 1976. Hansen using the same model

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*Appropriating the Return from Industrial Research and Development*, Cowles Foundation Paper no. 714, Cowles Foundation for Research in Economics at Yale University, 1989 (hereinafter Levin et al), p. 797.

<sup>47</sup> OECD, *Sector Case Study of Globalisation in the Pharmaceutical Industry*, Paris: OECD, 1994.

<sup>48</sup> R&D costs are divisible. According to Redwood, research costs represent about one-third of the total R&D costs and development costs two-third of the total R&D costs. Redwood, 1994, note 6 above, p.89.

<sup>49</sup> Published by the Department of Trade and Industry. FT, "The R&D Scoreboard", Tuesday, June 25, 1998.

<sup>50</sup> DiMasi, J, R. Hansen, H. Grabowski and L. Lasagna, 'The Cost of Innovation in the Pharmaceutical Industry', *Journal of Health Economics*, 10, 1991, pp. 107-142.

predicted that the average R&D costs for 1987 would be US\$100.7 million.<sup>51</sup> But the actual figure for the average R&D costs per NCE discovered and developed by the US firms for 93 drugs in 1987 was estimated at \$231 million. One of the factors contributing to the continuous increase of the cost, according to Grabowski, is the shift in research focus toward therapeutics to treat chronic clinical conditions, such as cancer. The result is higher development costs caused by drugs for chronic disease requiring more long-term testing and greater overall investment prior to commercial introduction.<sup>52</sup>

The risks associated with pharmaceutical R&D are high and unique -- Statistically, only one in five thousand of patented new chemical entities succeed in passing stringent safety and efficacy tests during development and regulatory approval stages.<sup>53</sup> According to a Financial Times Survey, for a NCE whose development started in 1995, the average total cost of bringing a NCE to market is estimated at US\$600million, of which US\$170 million is the cost of the NCE. The remainder is spent on other compounds that failed during the R&D process.<sup>54</sup> The industry has to pin their hope on the one successful NCE to finance the R&D costs of the other five thousand NCEs. In addition, there is a unique life time risk associated with the product after its eventual launch in the market. As explained by Blee, the chemical agents obtained from research are in almost all cases, also by definition, potentially dangerous to the human body. Because each person is

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<sup>51</sup> Hansen, R, 'The Pharmaceutical Development process: Estimates of Current Development Costs and Times and the Effects of Regulatory Changes', in Chien (ed.), *Issues in Pharmaceutical Economics*, Lexington, Mass: Lexington Books, 1979, pp. 151-187.

<sup>52</sup> Grabowski, Henry, 'Price and Profit Control, New Competitive Dynamics and the Economics of Innovation in the Pharmaceutical Industry', in Towse (ed.), *Industrial Policy and the Pharmaceutical Industry*, London: Office of Health Economics, 1994a, p. 81. Enough reserves are necessary to deal with negative cash flows over the pre-clinical and clinical R&D period. Negative cash flows continue on in the market launch stage due to costs involved from initial heavy promotional activities.

<sup>53</sup> Redwood, 1994, note 6 above., p. 13.

unique, the danger of side effects can arise in any stage of the research and development processes and post-marketing phase. When ingested by humans, the development of a serious side effect can virtually destroy the commercial value of the product and the economic value of the research conducted over many years.<sup>55</sup> Furthermore, compensations payable as the result of litigation could lead to a significant financial burden. An adequate level of profitability is necessary in order to undertake these risks.<sup>56</sup>

**Imitation of patented product made illegal** -- The exclusion of others from interfering with the right of the patent holder is of great importance to pharmaceutical companies because pharmaceutical products are easy to imitate by reverse engineering.<sup>57</sup> The pharmaceutical research in recent years has focused more on discovering drugs that treat diseases for which no drugs as yet exist and have large potential market instead of investing in "me-too" drug discovery which replicate the therapeutic properties of drugs already on the market.<sup>58</sup> Drugs with a large potential market often attract imitators in countries with no product or process patent protection. To demonstrate the ease of imitation, Mansfield reported from a survey of 100 US firms in 1985 that information

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<sup>54</sup> FT, FT Survey – Pharmaceuticals, March 15, 1999.

<sup>55</sup> Blee, Francis J., 'Commentary', in Helms (ed.), *The International Supply of medicines*, Washington, D.C.: American Enterprise Institute for Public Policy Research, 1980, pp. 126-132, p. 126.

<sup>56</sup> Gereffi, Gary, *The Pharmaceutical Industry and Dependency in the Third World*, Princeton: Princeton University Press, 1983, p. 190. The fact that most of the R&D activities in the industry are self-financed could be seen as another reason to justify the high profitability of the industry. Apart from putting in place the patent system, government involvement in supporting the industry's R&D effort is minimal. For example, the industry receives less than two percent of direct R&D supports from governments in most of the OECD Countries. See Holmes, Jeremy and John Dunning, 'Factors Influencing the Location of Multinational Investment in the pharmaceutical Industry', in Towse (ed.), *Industrial Policy and the Pharmaceutical Industry*, London: Office of Health Economics, 1994, pp. 92-105, p. 103.

<sup>57</sup> Reverse engineering is a process of studying and analysing technological information endowed in a particular product. And the process itself does not violate patent protection but what ensues might Sherwood, 1990, note 21 above, p.59.

concerning the detailed nature and operation of a new product generally leaked out within about a year. With regard to processes, it generally becomes available in less than fifteen months.<sup>59</sup> For pharmaceuticals, it means that generic versions of a new product could be available in the market less than twelve months from the market launch of a patented product with direct impacts on sales and profit margins for the patent owner.<sup>60</sup>

**Effective patent life** – In the early 1990s, the average time spent on R&D for a NCE has remained at ten to twelve years.<sup>61</sup> With a twenty-year patent protection period, a NCE could enjoy an effective patent life of approximately eight years during which it enjoys the market exclusivity. Statman explains this as follows:<sup>62</sup>

“a drug is invented when a chemical compound is found to have some therapeutic utility. As a practical matter, a drug firm must apply for a patent at this point, since a delay may result in a loss of the rights for a patent if a competitor is the first to file... The invention of a drug, however, is only one step in the process that may eventually lead to

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<sup>58</sup> Brada, Josef C., ‘Government Policy and the Transfer of Pharmaceutical Technology Among Developed Countries’, in Helms (ed.), *The International Supply of Medicines*, Washington, D.C., American Enterprise Institute for Public Policy Research, 1980, pp. 37-70, p.48.

<sup>59</sup> Mansfield, 1985, note 7 above, pp.217-223.

<sup>60</sup> It might also have implications on the original manufacturer’s liability if, for example, a patient is injured as a result of taking the medicine manufactured by the original company but was smuggled in without authorisation. It only makes sense for the patient to bring a suit against the original manufacturer who has resources to pay for damages. In all probabilities, the smuggler would have disappeared from the scene. This is a common occurrence in many DCs when drugs are mainly supplied by importation.

<sup>61</sup> FT, March 15, 1999, op. cit. It was calculated that a mean total R&D time is almost twelve years for US new drugs. To obtain a mean total R&D time of almost twelve years, the clinical investigation phase averages over five years, regulatory review phase about two and a-half years, and the pre-clinical phase two to four years. Grabowski, 1994a, note 52 above, p. 78.

<sup>62</sup> Statman, M., ‘The Effect of Patent Expiration on the Market Position of Drugs’, in Helms (ed.), *Drugs and Health: Economic Issues and Policy Objectives*, Washington, D.C.: American Enterprise for Public Policy Research, 1981, p.141.



commercial marketing of a drug. A chemical entity must undergo a lengthy development process and be approved by the relevant regulatory agency before it can appear on the market and enjoy the protection provided by the patent for the duration of effective patent life.”

In recent years, effective patent life has been shortened as a result of lengthier clinical trial and domestic regulatory approval delay, which postpones the market launch of new products. For example, it takes on average two years to conduct country-specific local clinical trials to satisfy local product registration requirements. Countries such as Japan have requested MPCs to do so, insisting that genetic and metabolic differences mean that evidence of a drug's safety and efficacy data gathered in the west has only limited validity in Japan.<sup>63</sup>

**Effectiveness of patent protection** -- Price capping of new drugs by governments to control public health budgets is common.<sup>64</sup> It affects the effectiveness of patent protection by taking away the pricing freedom patent protection confers. Patent as a major factor in sustaining drug prices<sup>65</sup> no longer holds true.

The industry's profit margin is further eroded by competition from two quarters: one being existing substitutable alternatives of a NCE, and the other generic versions of a

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<sup>63</sup> FT, March 4, 1999, p. 4.

<sup>64</sup> Governments from countries such as Australia, Canada, Germany, Japan and the UK exercise pharmaceutical price control. The extent of the impact can be demonstrated by the example of Japan where a clampdown on drug prices by the Japanese government in 1998 resulted in reducing the cost of 1,588 prescription drugs by an average of 9.7 per cent. See FT, September 24, 1998 and November 24, 1998, p. 10.

<sup>65</sup> Nogues, note 7 above.

NCE following the expiration of patent. Both forms of competition pose an imminent threat to the market share of the product involved during its patent life. Grabowski gave an illustration for the first form of competition from the cholesterol-reducing therapeutic group. The blockbuster drug <sup>66</sup> was introduced in 1987. The second and third entrants were introduced in the following year and priced below the first entrant. A 1994 competitive entrant in the same class was priced at a discount of 50% below the first entrant. This competitive experience also applies to other therapeutic groups. <sup>67</sup> To explain the second form of competition, Grabowski and Vernon examined 18 economically significant band name products whose generic competition occurred during 1984 and 1987. They discovered that, on average, a product was subject to twenty generic competitors and lost approximately half its market share within two years. <sup>68</sup> In 1994, with patent expiration, fifty percent of the overall revenue from a particular product was lost in the first month of facing generic competition. <sup>69</sup> The sense of crisis deepens with governments' encouragement of generic substitution in their reimbursement policy.

In February 1999, a WTO dispute settlement panel was established to investigate the ECs' claim that Canada is in breach of its obligation under the TRIPS Agreement by allowing third parties (generic manufacturers), without the consent of the patent holder, to carry out clinical trials for the purpose of applying for marketing approval, and the manufacturing and stockpiling of patented products before the expiry of the patents

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<sup>66</sup> To be a blockbuster drug, the qualifying level of annual sales is reckoned to be in the region of US\$ 750 million in 1990. Nine drugs achieved sales in excess of US\$ 1 billion. A further five reached a level between US\$ 750 to US\$ 1 billion. See Barclays de Zoete Wedd Research, *Pharmaceutical Industry Perspectives – The World's 50 Best Selling Drugs*, London: Barclays de Zoete Wedd Research, 1991.

<sup>67</sup> Grabowski, 1994b, note 7 above.

<sup>68</sup> Grabowski and Vernon, note 7 above, pp. 331-305.

<sup>69</sup> Scrip, Effect of US generic Price Cuts, April 12, 1994, p. 19.

concerned.<sup>70</sup> This case highlights both the intensity of competition in the pharmaceutical market and increased government involvement in public health care policy.

It is deeply felt within the industry that, regardless of the stage of development, government policy has considerable influence on the future level and sources of drug innovation.<sup>71</sup> The decision to adopt an innovative strategy, instead of an imitative one, rests firmly in the hand of public policy makers. From the investors and technology sellers' perspective, the introduction of patent protection in DCs is an important prerequisite to ensure success in attracting desirable foreign technology transfer and foreign R&D investment in the future.

#### **1.4 Developing countries and economic issues relating to patent protection**

In DCs' effort to seek institutional changes for global management of world resources and to assert the right of access of every nation to "the universal heritage" of technology, they paid considerable attention to the revision of the patent system under the Convention.<sup>72</sup> DCs were concerned that the majority of patents granted by them are to the foreign nationals, most of them MNCs.<sup>73</sup> This phenomenon is perceived as a threat to

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<sup>70</sup> WTO, Focus, January-February 1999, p. 5 and FT, November 13, 1998. See further discussion in Chapter 5.2.

<sup>71</sup> Especially in areas such as the regulatory regime for marketing approval and reimbursement scheme for new drugs. See Grabowski, 1994a, note 52 above, p. 87.

<sup>72</sup> It was in June 1974, during the sixth Session of the Co-ordination Committee of WIPO, that the idea of possible revision of the Convention was put forward based on the proposals made by the delegates of India and the UK representing DCs and ICs respectively. See WIPO, PR/DC/3, June 25, 1979, p. 6.

<sup>73</sup> 84% of the patents issued are owned by nationals of the US, Germany, France, Switzerland, and the United Kingdom. UNCTAD, The Role of the Patent System in the Transfer of Technology to Developing Countries, UN Doc. no. TD/B/AC.11/19, 1974 (hereinafter UNCTAD 1974 Report), p.92.

national economic independence and development.<sup>74</sup> Granting patent protection to foreigners is based on the assumption that it will encourage them to introduce new technologies or products into the patent granting country so that DCs will benefit from the actual use of the invention within their countries.<sup>75</sup> But many patents granted in DCs are never worked in those countries.<sup>76</sup> And the lowest exploitation rates are found among the most technology-intensive industries such as pharmaceuticals.<sup>77</sup>

DCs have also expressed concerns that the patent protection granted by DCs has hardly had any influence over the locations where MPCs conduct their R & D,<sup>78</sup> nor did not affect foreign direct investment decisions of MPCs. Instead, the requirement of the working of the patent was often met by importation of the patented innovation and the foreign patents became an import monopoly.<sup>79</sup> It was unacceptable to DCs that patent protection granted to MNCs was used as a tool to erect barriers of entry to their markets in order to protect patent owners' competitive advantages. And monopolistic effects of

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<sup>74</sup> Bifani, Paolo, *Intellectual Property Rights and International Trade, Uruguay Round - Papers on Selected Issues*, UNCTAD, NY: UN, 1989. Different opinions have been expressed on this point. For example, Kunz-Hallstein cited studies that have shown that the dominance of foreign patent in the Third World does not produce harmful effect and that there is a positive correlation between the GNPs of these countries and both the number of foreign patent applications and the level of patented products they import, see Kunz-Hallstein, Hans Peter, 'The Revision of the International System of Patent Protection in the Interest of Developing Countries', *IIC*, 10, 1979, p. 665.

<sup>75</sup> Bifani, note 74 above.

<sup>76</sup> It is a phenomenon also occurs in some ICs whereby more than 90% of the patent granted were accorded to foreigners and a large part of them not worked. See GATT, MTN.GNG/NG11/14, 12 September 1989, p. 31.

<sup>77</sup> Adikibi uses Nigeria as an example: in a sample of 590 patents, only 40 are being worked effectively in the country. It represents 6.8% of the sample total with a national estimate of 5% exploitation rate. See Adikibi, Owen T., 'The Multinational Corporation and Monopoly of Patents in Nigeria', *World Development*, 16(4), 1988, pp. 511-526, p. 517.

<sup>78</sup> Vaitos, Constantine V., 'The Revision of the International Patent System: Legal Considerations for a Third World Position', *World Development*, 4(2), 1976, pp. 85-102. He claimed that there is a divorce between patent protection in DCs and incentive on the R&D investment.

<sup>79</sup> Oddi, Samuel A., 'The International Patent System and Third World Development: Reality or Myth?' *Duke Law Journal*, 1987. He also commented that technological know-how could be strategically withheld

patent protection could lead to price increases and welfare loss to the DCs with welfare gain accruing to innovative MNCs.<sup>80</sup> But the proponents of IP system advocate that the South should introduce patent protection so as to encourage potential long-term dynamic benefits of inducing domestic and foreign innovations.<sup>81</sup> DCs were assured that by introducing patent protection, it will encourage foreign direct investment (FDI) by MNCs. And along with FDI, there will be transferred technology that supports DCs' economic development, and investments in R&D activities that are essential in building up their scientific and technological infrastructure.<sup>82</sup>

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depriving DCs of control over the technology at the end of royalty period whether supported by patent or not.

<sup>80</sup> Vaitsos, 1976, note 78 above.

<sup>81</sup> Maskus and Konan believe that IPP alone cannot guarantee success in economic development, other factors such as technical capability and market size are relevant. They are not alone in stating as such, more discussion will ensue in Chapters 1.4.1 and 1.4.2. Maskus Keith. E. and Denise Eby Konan, 'Trade Related Intellectual Property Rights: Issues and Exploratory Results', in Deardorff and Stern (eds.), *Analytical and Negotiating Issues in the Global Trading System*, Ann Arbor: The Michigan University Press, 1994, ch. 10, p. 411.

<sup>82</sup> See, for example, Basic Framework of GATT Provisions on Intellectual Property, Statement of Views of the European, Japanese and United States Business Communities. The Intellectual Property Committee (USA), UNICE(Europe), and Keidanren (Japan) (hereinafter Basic Framework). Also Suggestion by the United States for Achieving the Negotiating Objective – Revision, GATT, MTN.GNG/NG11/W/14 Rev.1, 17 October 1988. Although these economic incentives were the subject of many surveys and empirical research, Cottier comments that they are still largely one of political debate rather than in-depth analysis and field studies. The absence of comparable data on the impacts of patent protection in DCs leads to inconclusive and fragmented results. See Cottier, Thomas, 'The Prospects for Intellectual Property in GATT', *CMLE*, 28, 1991. and Maskus and Konan, note 81 above, p. 438. Evenson also commented that the costs and benefits of protection for DCs are difficult to establish due to fragmented empirical data available, see Evenson, Robert E., 'Survey of Empirical Study', in Siebeck, Evenson, Lesser, and Primo Braga (eds.), *Strengthening Protection of Intellectual Property in Developing Countries – A Survey of the Literature*, Part IV, World Bank Discussion Papers #112, Washington, D.C.: The World Bank, 1990a. Also Mansfield, 1986, note 46 above: the "before and after" analysis of how economic activities and

### 1.4.1 Monopolistic effects

With the premise that patent protection does grant monopoly to patent holders,<sup>83</sup> the economic impact of introducing patent protection is often expressed as social welfare loss to patent granting countries.<sup>84</sup> Welfare is defined as the sum of benefits to consumers, often addressed as consumer surplus.<sup>85</sup> Economic theory has it that under perfect competition, monopoly rent (monopoly profit) created by a patent is non-existent. With the introduction of patent protection, the best-known monopoly distortion is its pricing behaviour. As the result of monopoly rent, there will be welfare losses accruing to consumers and the society as a whole partly because of the relatively weak bargaining power of developing countries in negotiating prices with monopoly suppliers.<sup>86</sup> The magnitude of welfare losses may affect government's policy in patent protection especially when the country is poor. Furthermore, if patented products are supplied through importation, monopoly rent would mostly be repatriated to the country of manufacturing, depleting the host country's foreign exchange reserves and possibly

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technology development may have changed in response to IP regime change is a suggested area for future research.

<sup>83</sup> Sherwood does not think patent protection grants monopoly to the patent holder. Maskus and Konan point out that even though patent grants a monopoly, the monopoly is rarely introduced into a market that previously had been perfectly competitive. The patent-seeking foreign firm is likely to enjoy limited market power while it faces competition from substitute products or imports from other countries of the identical product. Sherwood, 1990, note 21 above, p. 51 and Maskus and Konan, note 81 above, p. 411.

<sup>84</sup> Other economic costs include loss in employment and tax receipts because of a reduction of domestic output and employment from firms that have been producing counterfeit and pirated goods. Whether these short term costs will generate long term economic benefits or costs depends on the specific circumstances of a country. Potential economic benefits might come from gains in other sectors of employment and tax revenue from reallocated labour out of counterfeited or pirated activities. See UNCTAD, *The TRIPS Agreement and Developing Countries*, NT: UN, 1996, pp. 16-18.

<sup>85</sup> Subramarian, 1990a, note 2 above, p.254.

<sup>86</sup> World Development Report 1998/99, note 9 above, p. 35.

adding to its debt burden.<sup>87</sup> These are the reasons based upon which DCs argued against the introduction of patent protection in their countries and why the critics of patent monopoly have been severe toward the industry.<sup>88</sup>

In an international context, many hold the view that strengthening of patent protection will have a distributive effect on world welfare and cause an international welfare transfer.<sup>89</sup> Subramanian estimates that the full economic impact of welfare losses and gains would not be felt until 10 or 20 years after the adoption of the TRIPS Agreement to grant patent protection to pharmaceuticals.<sup>90</sup> In his comparative study of the impact of higher level of patent protection for pharmaceuticals on DCs of different market structure,<sup>91</sup> he found that, for those small DCs with perfect competitive markets but which became monopolies after the introduction of patent protection, foreign producers always gained less than losses accruing to those DCs. Patent protection diminishes global welfare<sup>92</sup> in the short term at least, and serves to redistribute world income in foreign producers' favour, and the greater the gains to foreign producers the greater the welfare losses to individual DCs. But apart from looking into the static effect of monopoly rent for foreign producers thus causing international rent transfer, many

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<sup>87</sup> Hurlbut, David, 'Fixing the Biodiversity Convention: Toward a Special Protocol for Related Intellectual Property', *National Resources Journal*, 34, 1994, p. 379.

<sup>88</sup> Taylor and Silberston, note 45 above, p. 231.

<sup>89</sup> Sherwood, 1990, note 21 above, and Subramanian, 1990a, note 2 above. See Dani Rodrik's comment in Deardroff and Stern (eds.), *Analytical and Negotiating Issues in the Global Trading System*, Ann Arbor: The Michigan University Press, 1994, for a detailed analysis on the distributive effects of enhanced IP system.

<sup>90</sup> Subramanian, 1990a, note 2 above, p. 263. According to UNCTAD, price increases from stronger pharmaceutical patents are relatively modest in large DCs such as India, Brazil, Argentina and Mexico. Much depends on the competitive reaction of foreign rights holders and the technology capacity of local firms. See UNCTAD, 1996, note 84 above, Annex 1.

<sup>91</sup> Ibid.

<sup>92</sup> Feinberg R. M. and D. J. Rousslang, 'The Economic Effects of Intellectual Property Rights Infringements', *Journal of Business*, 63, 1990, pp. 79-90.

caution the need to look into the dynamic benefits of patent system to induce R&D activities and technology transfer<sup>93</sup> that DCs will gain if these dynamic effects outweigh consumer losses from monopoly pricing.

#### 1.4.2 Foreign technology transfer<sup>94</sup>

The introduction of patent protection into domestic legislation has been seen as strongly correlated with the economic development of a country since the Middle Ages, and was affirmed in the Inventors Act of Venice of 1474, the first European patent statute.<sup>95</sup>

Although ICs and DCs both recognise the contribution of IP to a nation's economic development, DCs believe that the absence or low level of patent protection could reduce the costs of production and secure lower prices for consumers as the result of free market competition.<sup>96</sup> In the area of pharmaceuticals, DCs' public health policy often places priority on affordability and self-sufficiency. And they view a low level of patent protection as a means to reduce the costs of acquiring technology and to decrease foreign

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<sup>93</sup> See, for example, Subramanian, Arvind, 'TRIPS and the Paradigm of the GATT: A Tropical Temperature View', *The World Economy*, 4, December 1990b, p. 514 and Yarrow, George, 'CEC and EC Member State Industrial Policy and the Pharmaceutical Industry', in Towse (ed.), *Industrial Policy and the Pharmaceutical Industry*, London: Office of Health Economics, 1994, pp. 1-12, p. 3.

<sup>94</sup> Transfer of technology" is defined by UNCTAD as "the transfer of systematic knowledge for the manufacturer of a product, for the application of a process or for the rendering of a service and does not extend to the transactions involving the mere sale or mere lease of goods". It also includes the provision of know-how and technical expertise in the form of instruction. UNCTAD, Code of Conduct for the International Transfer of Technology, UN Doc. TD/CODE TOT/41, 1983, ch. 2.1, p. 2.

<sup>95</sup> Blakeney, Michael, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement*, London: Sweet & Maxwell, 1996 and Appendix I and Maskus and Konan, note 81 above, p. 429.

<sup>96</sup> One major reason why DCs take this stance is because DCs are technology purchasers. DCs as the major technology purchasers can be demonstrated by a 1974 UNCTAD report which concludes that: The nationals of developing countries hold in their own countries no more than 1 per cent of the world stock of patents, and in other countries, no more than about two thirds of 1 per cent of foreign-owned patents. These countries have plainly been on the periphery of the patented system. See UNCTAD 1974 Report, note 19 above, p. 92.



exchange outflows in the form of royalties, fees and profits.<sup>97</sup> Some DCs therefore adopted a policy of reducing or revoking the national patent protection as a means of achieving their development goals<sup>98</sup> despite some studies advise against such an approach.<sup>99</sup>

MNCs are the major players in the global technology market as both transferors and sellers.<sup>100</sup> Technology transfer is another aspect of their cross-border activities, as distinguished from direct cross-border trade in goods. The major modes of transfer<sup>101</sup> for patented technology include foreign direct investment<sup>102</sup> and arm's length technology purchasing arrangements<sup>103</sup> such as licensing agreements.

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<sup>97</sup> Costs of technology to DCs are estimated to be about 37% of their public debt service payments. Licence fees and royalties account for around 56% of the annual flow of direct private foreign investments. UNCTAD, *Major Issues Arising From the Transfer of Technology to Developing Countries*, UN Doc. TD/B/AC.11/10/Rev.2, 1975, para. 98. In the same report, it was estimated that the annual rate of growth of the direct cost of technology to DCs was about 20%, para. 101.

<sup>98</sup> Example of Turkey revoking patent protection conferred on pharmaceuticals in 1961. Kirim, Arman S., 'Reconsidering patents and Economic Development: A Case Study of the Turkish Pharmaceutical Industry', *World Development*, 13(2), 1985, pp. 219-236.

<sup>99</sup> For example, a study conducted in 1976 by the Kiel Institute for Economic Policy recommended against reducing patent protection as a development strategy device even in the critical sector of pharmaceuticals. Kunz-Hallstein, 1979, note 74 above, pp. 649-670, p 665. Even Lall, a staunch critic of introducing patent protection in DCs, warns against overestimating the shortcomings of the patent system in regard to the policies promoting technical development in and transferring technology to DCs. See Lall, Sanjaya, 'The Patent System and the Transfer of Technology to LDCs', *JWTL*, 10(1), pp. 1-16. In a more recent study conducted by Evenson, he comments that by weakening the scope of patent coverage to discourage foreign patenting, DCs have discouraged domestic invention as the unintended result. See Evenson, Robert, 'International invention: Implication for Technology Market Analysis', in Griliches (ed.), *R&D, Patents, and Productivity*, Chicago: University of Chicago Press, 1984.

<sup>100</sup> World Investment Report 1998, note 3 above, ch. 1.

<sup>101</sup> Buckley has identified ten forms of technology transfer: wholly-owned foreign affiliates, joint ventures, foreign minority holdings, "fading-out" agreements, licensing, franchising, management contracts, turnkey ventures, contractual joint ventures, and international subcontracting. See Buckley, P. J., 'New forms of International Industrial Co-operations', in Buckley and Casson (eds.), *The Economic Theory of the Multinational Enterprise*, London: Macmillan, 1985, pp. 38-59.

<sup>102</sup> The most widely used definition of FDI is that of the IMF for balance-of-payment statistics:

"foreign direct investment (FDI) refers to an investment that is made to acquire a lasting interest in an enterprise operating in an economy other than that of the investor; the investor's purpose being to have an effective voice in the management of enterprise."

See IMF, *Balance of Payment Manual*, 5<sup>th</sup> ed., Washington, D.C.: IMF, 1993. The OECD has also established a definition of FDI, and recommends that an enterprise in which a single foreign investor

A licensing agreement is the common mode of arm's length technology transfer for the pharmaceutical industry. It could protect IPRs while providing licensees access to the latest technology. This mode of transfer is particularly important as an alternative in countries with no IPP,<sup>104</sup> or when the foreign market is too small to warrant direct investment.<sup>105</sup> Nevertheless, it is a common knowledge that if IPRs are not adequately protected in a particular country, foreign firms tend to avoid selling a licence or investing there.<sup>106</sup> An OECD survey result shows that inadequate IPP is the greatest disincentive

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controls more than 10% of the ordinary share or voting power of the enterprise is to be considered a FDI. When the equity participation is less than 10%, it will be considered a FDI provided that the investor has an effective voice in the management of the enterprise. See OECD, *Detailed Benchmark Definition of Foreign Direct Investment*, 2<sup>nd</sup> ed., Paris: OECD, 1992. Technology could be transfer through intra-firm or inter-firm arrangements. Intra-firm technology transfer involves foreign direct investment, mostly by MNCs, it takes the forms of wholly-owned foreign affiliates, joint ventures, or foreign minority holdings. Wholly-owned foreign affiliate is the conventional form of foreign direct investment for intra-firm technology transfer. Wholly-owned foreign affiliate transfer takes place when product quality standard is a matter of concern or when the technology involved is sophisticated and the transferee lacks the know-how to assimilate it. See Mansfield, Edwin, 'Unauthorised use of Intellectual Property: Effects on Investment, Technology Transfer, and Innovation', in Wallerstein, Moge, and Schoen (eds.), *Global Dimensions of Intellectual property Rights in Science and Technology*, Office of International Affairs National Research Council, Washington, D.C.: National Academy Press, 1993, pp. 107-145, p. 116.

<sup>103</sup> Inter-firm transfer takes place mostly by means of arm's length purchase. The 1990s saw an upsurge of inter-firm technology agreements from a yearly average of less than 300 in the 1980s to over 600 in the mid-1990s. (World Investment Report 1998, note 3 above, pp. 23-25.) Receipts and payment of royalties and license fees are a measure of the value of technology flow by MNCs. This value is increasing at double-digit rates predominantly from inter-firm transaction. The increase in R&D expenditure and the speed and risk involved of new product development and introduction in the last two decades underlie the need for MNCs to seek to increase their flexibility and leverage their R&D investments through inter-firm transfer. UNCTAD had identified two types of inter-firm agreements with the two way agreement on a rising trend in 1990s: 1) one-way technology agreement in which the flow of technology is from licensor to licensee or from one joint-venture partner to the other; 2) two way agreement involving joint research and/or development agreements and the creation of joint R&D ventures with specific research programmes. See UN, *World Investment Report 1997 – Transnational Corporations, Market Structure and competition Policy*, Geneva and NY: UN, 1997, p. 14 and Holmes and Dunning, note 56 above, p. 92.

<sup>104</sup> Rozek, Richard P., 'Protection of Intellectual Property Through Licensing: Efficiency Considerations', *JWL*, 22(5), 1988, pp. 27-34.

<sup>105</sup> Mansfield, 1993, note 102 above, p. 119.

<sup>106</sup> OECD, 1989, note 32 above, p. 11. Also Primo Braga, Carlso, 'The Developing Country Case for and Against Intellectual Property Protection', in Siebeck, Evenson, Lesser, and Primo Braga (eds.), *Strengthening Protection of Intellectual Property in Developing Countries – A Survey of the Literature*, Part VII, World Bank Discussion Papers #112, Washington, D.C.: The World Bank, 1990b, p. 83.

when the pharmaceutical industry considers technology licensing,<sup>107</sup> which might explain why DCs only have minor involvement in the increasing number of inter-firm technology agreements despite the finding that highly knowledge-intensive industries such as pharmaceuticals have the largest number of such inter-firm agreements,<sup>108</sup> but mostly with both partnering firms from ICs.<sup>109</sup>

Another means of acquiring knowledge is to free-ride on the technological information available in the international market.<sup>110</sup> The impressive speed and magnitude of development among the Newly Industrialised Economies (NIEs) with no domestic patent protection installed but by free-riding on western technologies is an example in point. Sherwood comments that free riding is easy in pharmaceutical technology, but it only involves a taking of a product, not an appropriation of technology. He warns that those who copy would learn very little about developing medicine because skills gained from copying are typically not useful in the transfer to the process of innovation.<sup>111</sup>

Apart from considering the mode of technology transfer, DCs are faced with the choice of technology that will benefit them most. Even though the modern technology market is saturated with choices, many latest technologies might not be appropriate for the

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<sup>107</sup> OECD, *International Technology Licensing: Survey Result*, 1987, Table 40. Two other disincentives identified by the survey are imposition of foreign exchange control and burdensome government approval regulations.

<sup>108</sup> World Investment Report 1998, note 3 above, p. 25.

<sup>109</sup> *Ibid.*, p. 29. Less than 6% of inter-firm technology agreements involve a DC firm. It might partly due to a shift in MPCs' approach toward a more co-operative stance in their emphasis of investment founded on the upgrading of the competitiveness of indigenous assets such as know-how.

<sup>110</sup> Maskus and Konan, note 81 above, p. 415

<sup>111</sup> Sherwood, Robert M., 'Why a Uniform Intellectual Property system Makes Sense for the World', in Wallerstein, Moge, and Schoen (eds.), *Global Dimensions of Intellectual property Rights in Science and Technology*, Office of International Affairs National Research Council, Washington, D.C.: National Academy Press, 1993, p. 76.

production and consumption needs of DCs. Jennings comments that there is a tremendous attraction to high technology in less developed countries (LDCs) which sometimes distorts the pattern of their investment in pharmaceuticals and health care supply <sup>112</sup> ignoring their economic capability, difference in disease pattern, and the specific medicines most needed by their respective population. Some argue that it is not the most advanced technology that will benefit DCs most, but the appropriate one <sup>113</sup> which matches the capacity of the recipient country to absorb and successfully exploit the technology. <sup>114</sup> The inappropriateness could be substantially lessened <sup>115</sup> when DCs develop the competence and build up technological capacity to search, select, absorb and adapt so to take advantage of the vast stock of global knowledge. <sup>116</sup>

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A study conducted by Diwan and Rodrik shows that an increase in patent protection has indeed led to a greater fit between the available technologies and the preferences of patenting countries. <sup>117</sup> According to UNCTAD, closer co-operation on technology matters appear to have increased world wide due to the growing cost of developing new technology, the difficulty in its appropriation, and the increased complexity of its transfer. <sup>118</sup> From the perspective of the pharmaceutical industry, the readiness to invest and transfer technological know-how would increase if a country strengthened its patent

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<sup>112</sup> Jennings, John, 'Commentary'. In Helms (ed.), *The International Supply of Medicines*, Washington, D.C.: American Enterprise Institute for Public Policy Research, 1980, p. 152.

<sup>113</sup> Stewart, Frances, 'Technology Transfer for Development, in Science and Technology – Lessons for Development Policy', in Evenson and Ranis (eds.), *Economic Development: An International Comparative Study, in Science and Technology – Lessons from Development Policy*, Colorado: Westview Press, 1990, p. 308.

<sup>114</sup> UNCTAD, Further Consultations on a Draft International Code of Conduct on the Transfer of Technology – Report by the Secretary General of UNCTAD, TD/CODE TOT/56, 1990a, p.6.

<sup>115</sup> Stewart, note 113 above, p. 315.

<sup>116</sup> World Development Report, 1998/99, note 9 above, p. 36 and Stewart, note 113 above, p. 315.

<sup>117</sup> Diwan, Ishac and Dani Rodrik, *Patents, Appropriate Technology, and North-South Trade*, International Economic Department, WPS #251, Washington, D C: The World Bank, August 1989, p.29.

standard.<sup>119</sup> The strength and weakness of a country's IPP system seems to have a substantial effect not only on the mode of transfer<sup>120</sup> but also on the kind of technology transferred.<sup>121</sup>

As IP is strongly correlated with economic development,<sup>122</sup> DCs have been advised to assume a more liberal attitude with regard to patentees and to direct the national law toward offering real incentives for technology transfer.<sup>123</sup> As modern technology is mostly in the hands of private enterprises in ICs, their co-operation is essential, and it can only be obtained by incentives.<sup>124</sup> More importantly, conscious government efforts are

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<sup>118</sup> UNCTAD, 1990a, note 114, p.6.

<sup>119</sup> Stamm, Otto A., 'Intellectual Property Rights and Competitive Strategy: A Multinational Pharmaceutical Firm', in Wallerstein, Moguee, and Schoen (eds.), *Global Dimensions of Intellectual property Rights in Science and Technology*, Office of International Affairs National Research Council, Washington, D.C.: National Academy Press, 1993, pp. 221-228, p. 226.

<sup>120</sup> According to Chen, while transnational corporations as the major actors in international technology transfer, their choice of mode of transfer is often between foreign direct investment (intra-firm) and licensing (arm's length). Chen, Edward K.Y., *Transnational Corporations and Technology Transfer to Developing Countries, Transnational Corporations and World Development*, published by Routledge on behalf of the UNCTAD Division on Transnational Corporation and Investment, London: International Thomson Business Press, 1996. When making choices, foreign direct investment is preferred when technologies involved are more advanced and the transferor is more R&D intensive, see Davidson, W.H. and D.G. McFetridge, 'Key Characteristics in the Choice of International Technology Transfer Mode', *Journal of international Business Studies*, 1985, pp. 5-21.

<sup>121</sup> Primo Braga, 1990b, note 106 above, p.30.

<sup>122</sup> Maskus and Konan, note 81 above, p. 429.

<sup>123</sup> Penrose, E., 'International Patenting and the Less-developed Countries', *Economic Journal*, 83, 1973, p. 784.

<sup>124</sup> Kunz-Hallstein, 1979, note 74 above, p. 666. Incentives are defined as  
"any measurable economic advantage afforded to specific enterprises,  
or categories of enterprises by a government, in order to encourage  
them to behave in a certain manner. They include measures either to  
increase the rate of return of a particular FDI undertaking, or to  
reduce its costs or risk."

Incentives are a relatively minor factor in the locational decisions of MNCs relative to other locational advantages such as market size, adequate infrastructure, economic stability, and the quality of the general regulatory framework. See UNCTAD, *World Investment Report 1996 – Investment, Trade and International Policy Arrangements*, NY: UN, 1996.

also needed to establish the education system and basic R&D facilities so as to build up local technological capacity to ensure efficient transfer of technology.<sup>125</sup>

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<sup>125</sup> See Stewart, 1990, note 113 above, pp. 315-322 and UN 1964 Reports, note 18 above, pp. 48-49. The report states that:

“the question of patents must be seen and dealt with in the broader context of facilitating the transfer of patent and non-patented technology to the DCs, and enhancing the ability to adopt and use such foreign technology in the implementation of their development programmes.”

This report was conducted as the result of a General Assembly resolution (1713 (XVI), December 1961) calling for a survey of patent legislation and the effect of patents on developing countries. This report is the most extensive official study of the patent systems in developing countries and remains widely quoted. See discussion in, for example, Penrose, 1973, note 123 above, pp. 768-786 and Oddi, 1987, note 79 above, pp. 831-878.

### 1.4.3 R&D Activities

Dependency on foreign technology is viewed by some as perpetuating the inequitable distribution of income and only fulfilling the consumption demands of the elite.<sup>126</sup> It is expected that by fostering local R&D through strengthening IPP, it would lessen DCs' dependency on technology imports and tailor domestic R&D activities to meet the specific needs of a country so as to benefit the majority of the population. But Primo Braga cautions that in a world of growing inter-dependence, it is futile to equate technological independence with strict self-reliance.<sup>127</sup>

According to Redwood, the major reason why the medicines for tropical disease which LDCs demand are not available is because it is unlikely to prove profitable for TPCs,<sup>128</sup> partly because many governments in DCs have imposed price control over pharmaceuticals essential to their preventive or primary health care. Furthermore, TPCs'

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<sup>126</sup> Lall, note 99 above, pp. 1-16. Stewart further explains that:

“countries that adopt the more capital intensive of the technologies produced by developed countries, without modifications, face a dualistic pattern of development with a small high-income sector absorbing almost all the countries investable resources, its infrastructure and skills, generating demand among a small elite for the modern products produced in the sector, while the remainder of the economy, encompassing the majority of the population, remains deprived of investment resources, modern technology or appropriate products, in conditions of extreme poverty.”

See Stewart, 1990, note 113 above, p. 306.

<sup>127</sup> Primo Braga also cautions that inadequate IPP in DCs may dampen MPCs desire to invest in R&D in areas such as tropical diseases, which is of specific interest to DCs. Primo Braga, 1990a, note 31 above, p. 28, and Siebeck, Wolfgang E., ‘Conclusions and Recommendations’, in Siebeck, Evenson, Lesser, Primo Braga (eds.), *Strengthening Protection of Intellectual Property in Developing Countries – A Survey of the Literature*, Part VIII, World Bank Discussion Papers #112, Washington, D.C.: The World Bank, 1990, p. 91. Also Sherwood, 1990, note 21 above and Yusuf, Abdulqawi A., ‘Developing Countries and Trade Related Aspects of Intellectual property Rights’, in UNCTAD, *Uruguay Round – Paper on Selected Issues*, NY: UN, 1989.

failure to provide adequate production for essential drugs is because the research priorities of TPCs are oriented toward the major maladies of the industrialised societies, such as cancer, HIV, or life-quality enhancing products.<sup>129</sup>

FDI in R&D operations is attracted to locations that feature particular kinds of intellectual resources.<sup>130</sup> According to Mansfield's survey, the strength or weakness of a country's IPP seems to have a substantial effect on the pharmaceutical industry's investment decision in R&D facilities.<sup>131</sup> MPCs will not make any substantial investments in countries with weak IPP as their products and processes are relatively easy to imitate.<sup>132</sup> And when MPCs do consider R&D investment targeting a specific location, the existence of a patent system forms one of the considerations, but inadequate patent protection is a total turn-off.<sup>133</sup>

Other considerations?

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<sup>128</sup> Redwood, 1994, note 6 above.

<sup>129</sup> Gereffi, note 56 above, p. 201. A point of caution to this statement: patient population for many incurable diseases such as cancer and HIV are spreading all over the world, they are not the privilege of people living in western atmosphere. The difference is that the major markets for new cancer or HIV drugs will be where patients or health care system can afford to pay.

<sup>130</sup> World Investment Report 1998, note 3 above, p.116. The result of the research conducted by Economists Advisory Group in 1988 shows that three factors have been identified which influence MNCs' decision in choosing locations for R&D investment. Host country's R&D track record is the most important consideration. The availability of suitable personnel such as trained scientist and medical professions comes second, and government incentives rank the third. This research result was mentioned in Holmes and Dunning, note 56 above, p. 97. The EAG report is an unpublished report prepared for the American Pharmaceutical Group on American pharmaceutical companies in Britain and Europe.

<sup>131</sup> Mansfield, Edwin, *Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer*, International Financial Corporation, Discussion Paper #19, Washington, D.C.: The World Bank, 1994. Mansfield conducts a survey of 94 US firms operating in six countries, mostly NIEs or major DCs. He observes that IPP seems to influence the composition and extent of US direct investment, although the effect differs among industries. There are five kinds of direct investment decision involved in the survey: R&D facilities, facilities to manufacture complete products, facilities to manufacture components, rudimentary production and assembly facilities, and sales and distribution outlets. The chemical industry (includes pharmaceuticals) regards IPP as important for the first three types of investment.

<sup>132</sup> Mansfield, Edwin, *Intellectual Property Protection, Direct Investment, and Technology Transfer - Germany, Japan, and the United States*, International Finance Corporation, Discussion Paper #27, Washington, D.C.: The World Bank, 1995

<sup>133</sup> Redwood, 1994, note 6 above, p. 87.



MPCs have been cautious in moving research facilities abroad for the first stage of drug discovery. They feel that there are few countries which have sufficiently developed scientific support to provide the large scale facility needed. And it could not be expected to make any significant breakthrough in the first eight to ten years<sup>134</sup> because drug innovation is a step-by-step cumulative process which comes about through the accumulation of a large number of minor changes.<sup>135</sup> The second and third stages of drug discovery involve pre-clinical and clinical researches. Clinical trial is one area of development activities which have been conducted away from one single location.<sup>136</sup> One of the reasons being that there is a growing regulatory requirement among countries to include results from different ethnic groups. And it would need to draw scientists, medical and pharmaceutical professions of similar calibre from the countries participating in the trial. So far, most of R&D operations take place in ICs.<sup>137</sup> There is an intensive competition among them to attract these R&D activities with required infrastructure and technology policies to support the contention.<sup>138</sup>

If DCs wish to participate more fully in pharmaceutical innovative activities and compete with ICs for R&D investments, the immediate effort must focus on establishing the

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<sup>134</sup> Brada, note 58 above, p. 47.

<sup>135</sup> Parker, note 42 above, p. 138, Sherwood, 1990, note 21 above, p. 171, and Magee, Stephen P., 'Commentary', in Helms (ed.), *The International Supply of Medicines*, Washington, D.C.: American Enterprise Institute for Public Policy Research, 1980, p. 148.

<sup>136</sup> World Investment Report 1998, note 3 above, p. 116. Also Dunning, John H., 'Location and the Multinational Enterprise: A Neglected Factor?', *Journal of International Business Studies*, 29(1), 1998, pp. 45-66.

<sup>137</sup> Ibid. According to World Investment Report 1998, some 90% of research conducted by US MNCs' foreign affiliates took place in ICs in 1994.

<sup>138</sup> Inter-governmental relations, particularly among the Triad, have become more competitive because the structure of their economies have converged and assets and intermediate products have become internationally more mobile. See Dunning, John H., *Multinational Enterprise and the Global Economy*, Reading, Mass: Addison-Wesley Publishing Co, 1993, p. 588 and Holmes and Dunning, note 56 above, p. 100.

domestic scientific and technological infrastructure conducive to domestic R&D activities.<sup>139</sup> As evidenced by Redwood's cross-analysis of his database of products, the maintenance of a patent system constitutes an important motivating factor to encourage and support local R&D activities.<sup>140</sup>

In regard to ICs' proposal for an international agreement to harmonise domestic patent systems, many caution the approach of applying an identical set of standard to both ICs and DCs regardless of the stage of development a country is in.<sup>141</sup> As Maskus suggests,

“a reasonable approach would be based on gradual enhancement of international protective regimes as the circumstances in various countries change to warrant increasing protection.... A gradual and flexible approach that can accommodate both changing technical requirements for protection...and evolving national interests seems advisable.”<sup>142</sup>

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<sup>139</sup> The endorsement of government public policy is necessary to support the effort. See Redwood, 1994, note 6 above, p. 82 and Stewart, 1990, note 113 above, p. 320.

<sup>140</sup> According to Redwood's study, only eight of the 265 major global drugs originated in countries without patent protection. See Redwood, 1994, note 6 above, Lall, note 99 above, p. 11, and Evenson, 1990a, note 82 above.

<sup>141</sup> Evenson, 1990a, note 82 above, Maskus and Konan, note 81 above, and Subramanian, 1990a, note 2 above.

<sup>142</sup> See Maskus, K. E., 'Normative Concerns in the International Protection of Intellectual Property Rights', *The World Economy*, 13, p. 408 and Evenson, Robert E., 'Intellectual Property Rights, R&D, Inventions, Technology Purchase, and Piracy', in Evenson and Ranis (eds.), *Economic Development: An International Comparative Study, in Science and Technology – Lessons from Development Policy*, Boulder, Colorado: Westview Press, 1990b, p.354. According to the survey conducted by Evenson, he observed that, among NIEs, initial effort was put in to nurture the capacity to reverse engineer which leads to high piracy activities. What followed was an increase in technology purchase but low technology export and productive domestic R&D activities. It then led to a rapid rise in the ratio of patents per scientist and engineer. He suggests that NIEs have a comparative advantage in adaptive invention, i.e. assimilating and modifying the invention of ICs. They should strengthen IPP to facilitate access to foreign invention and stimulate domestic adaptive and imitative invention.

DCs argued that IP is a function of a country's domestic situation that reflects the national social, development and technological policy objectives.<sup>143</sup> They feel that the degree of liberty allowed under the Convention is important to allow them to adopt appropriate measures consistent with its needs and social, economic and development policy.<sup>144</sup> They consider the approach under the Convention desirable whereby a gradual elevation of minimum standards built on a process of consensus enables all participants to determine the desired balance between monopoly and competition for themselves.<sup>145</sup>

### **1.5 The legal framework of patent protection under the Paris Convention**

The Paris Convention for the Protection of Industrial Property as revised in 1967 (the Convention) is the major multilateral Industrial Property treaty designed for the protection of patents, utility models, industrial designs, trademarks, service marks, trade names, indication of source or appellations of origin, and the repression of unfair competition.<sup>146</sup> The Convention was established in 1883<sup>147</sup> and is now administered by

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<sup>143</sup> Abbott, Frederick M., 'Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework', *Vand JTL*, 22(4), 1989.

<sup>144</sup> WIPO, PR/DC/3, June 25, 1979, p. 8.

<sup>145</sup> Reichman, note 36 above, p. 867.

<sup>146</sup> Article 1, paragraph (2) of the Convention. Service marks was added on in the Revision Conference of 1958 while patents, utility models, industrial designs, trademarks, trade names, indication of source, and the repression of unfair competition were already mentioned in the 1911 Act. Neither "industrial property" nor the objects is defined in the Convention with the exception of unfair competition, Bogsch, Arpad, *The First Hundred Years of the Paris Convention for the Protection of Industrial Property*, Paris: United International Bureau for the Protection of Intellectual Property (BIRPI), 1968, p.191.

<sup>147</sup> The agreement to establish the Paris Convention was adopted in a diplomatic conference held in Paris in 1880 and 1883 and was signed in March 1883. Since then, there have been six conferences of revision held in Brussels (1887 and 1900), Washington (1911), The Hague (1925), London (1934), Lisbon (1958), and Stockholm (1967). The seventh (also the last) revision was held in Geneva, Nairobi, and Geneva again during 1980-1985 ended in no agreement.

WIPO.<sup>148</sup> WIPO was established in 1967<sup>149</sup> with the International Bureau of Intellectual Property as the Secretariat of the Union.<sup>150</sup> In 1974, WIPO became a specialised agency in the UN system of organisation.<sup>151</sup>

The Convention recognises the principle of state sovereignty,<sup>152</sup> a general principle of international law.<sup>153</sup> It permits its members to legislate and enforce measures of protection for industrial property within their own borders and to define the extent and the subject matters (or technical fields) of the protection. For example, according to

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<sup>148</sup> Other industrial property agreements administered by the WIPO include: the Madrid Agreement (1891) for indications of source, the Madrid Agreement (1891) for marks, the Hague Agreement (1925) for industrial designs, the Nice Agreement (1957) for trademarks, the Lisbon Agreement (1958) for appellations of origin, the International Convention for the Protection of New Variety of Plants (1961), the Locarno Agreement (1968) for industrial designs, the PCT for patent, the International Patent Classification Agreement (1971) for patent, the Budapest Treaty (1977) for micro-organisms, and the Treaty on the Protection of Layout-designs (Topographies) of Microchips (1989) for microchips. The major international industrial property agreement not administered by WIPO is the European Patent Convention (1973) which is regional in character.

<sup>149</sup> WIPO was established by the "Convention Establishing the World Intellectual Property Organisation" signed in Stockholm in 1967 and entered into force on April 1970.

<sup>150</sup> "Union" first appeared in Article 1 of original 1883 text of the Convention to mean that a permanent link among countries is being created. In 1967 Act, Article 1, paragraph (1) states that "the countries to which this Convention applies constitute a Union for the protection of industrial Property." The original Convention of 1883 had established an International Bureau of the Union for the Protection of Industrial property, which was entrusted with the administration of the Union. This Bureau was later merged with the Bureau of the Union for the Protection of Literary and Artistic Works and became the BIRPI. Later on in the Revision Conference of Stockholm in 1967, International Bureau of intellectual Property was created and became the Secretariat of WIPO by virtue of Article 15(1)(a) of the Convention as revised at Stockholm. See Bodenhausen, G. H. C., *Guide to the Application of the Paris Convention for the Protection of Industrial Property, Special Issue for the Commemoration of the Centenary of the Paris Convention*, *Industrial Property*, Geneva: WIPO, 1983, p. 175.

<sup>151</sup> WIPO became a specialised agency in the United Nations system of organisation under General Assembly Resolution (GA Res) 3346, 29(1) UN GAOR Supp. (no. 31), UN Doc A/9631 (1974).

<sup>152</sup> Fikentscher, Wolfgang, *GATT Principles and Intellectual Property Protection*, in Beier & Schriker (eds), *GATT or WIPO? New Ways in the International Protection of Intellectual Property*, Munich: Max Planck Institute, 1989, pp. 101-126.

<sup>153</sup> According to Brownlie, state sovereignty is a legal shorthand for legal personality of statehood. It entails the legal competence of a state with rights of government, administration, and disposition recognised and delineated by international law. Sovereignty is also used to describe the legal competence which states have in general jurisdiction, including legislative competence over national territory. Under general international law, matters within the competence of states are said to be within the domestic jurisdiction or reserved domain of states. See Brownlie, Ian, *Principles of Public International Law*, 4<sup>th</sup> ed., NY: Oxford University Press, 1990, pp. 108, 289, and 291. See also Qureshi, Asif H., *International Economic Law*, London: Sweet & Maxwell, ch. 2 for discussion in economic sovereignty.

Article 27(2) of the Convention, member states are bound only by the “Act” they ratified at the time of accession.<sup>154</sup> Member states also have the freedom of choice not to be bound by certain provisions contained in the Act they subscribe to in their instrument of ratification or accession,<sup>155</sup> such as the provisions relating to dispute settlement, the substantive provisions of Articles 1 to 12, and the administrative clauses contained in Articles 13 to 17.

The Convention is designed to protect legal and natural persons.<sup>156</sup> A set of substantive rules is articulated in the Convention with self-executing character designed to protect nationals of the member states of the Union.<sup>157</sup> The self-executing character of the rules is important in an international legal instrument when persons, legal or natural, are the parties the treaty is designed to protect. These provisions of self-executing character are worded in such a way to be capable of direct application. But whether private parties could rely on it in front of domestic administrative or judicial authorities is a matter for the national law.<sup>158</sup> In some countries, the constitutional system permits administrative and judicial authorities to apply directly to private parties the provisions of the

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<sup>154</sup> An “act” is the incorporation of the original text of the 1883 Convention with the modified text agreed upon by the member states in each of the conference of revision. As the result of different legal requirements among the seven acts, rights and obligations of member states vary.

<sup>155</sup> Article 20.1 (b) of the Convention

<sup>156</sup> This was unanimously agreed by the Revision Conference at Brussels in 1900, see Bodenhausen, *op. cit.*, p. 27.

<sup>157</sup> They include Article 4 (Right of priority), Article 4 bis (Independence of Patents), Article 5 quarter (Right of the patentee of a process of manufacturer), and Article 5, Section A(1) (Importation of patented articles), Article 5, Section A(3) (Forfeiture of a patent), and Article 5, Section A(4) (Compulsory license). These articles will be discussed in detail in the text. This list itself is not exhaustive. See Bodenhausen, note 150 above, pp. 14 and 68.

<sup>158</sup> *Ibid.*, p. 14 and Fikentscher, Wolfgang, ‘GATT Principles and Intellectual Property Protection’, in Beier and Schriker (eds.), *GATT or WIPO? New Ways in the International Protection of Intellectual property*, Munich: Max Planck Institute, 1989, pp.109-111.

Convention while in some others, the provisions could be applied only after being incorporated into domestic legislation.

The Convention embodies two fundamental principles applicable to all objects covered: the principle of National Treatment (NT),<sup>159</sup> and the right of priority for when patent application is filed in more than one member states of the Union.<sup>160</sup> NT is the cardinal principle of the Convention. It obliges the member states to apply domestic law in a non-discriminatory manner and accord the same treatment to nationals of any country of the Union<sup>161</sup> as stated in Article 2, paragraph (1):

“nationals of any country of the Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this convention. Consequently, they shall have the same protection as the latter, and the same legal remedy against any infringement of their rights, provided that the conditions and formalities imposed upon nationals are complied with”.

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<sup>159</sup> Article 2, paragraph (1) of the Convention.

<sup>160</sup> Article 4 of the Convention.

<sup>161</sup> For nationals from countries of the Union to enjoy IPP, there is no requirement for domicile or establishment in the country where protection is claimed. But for nationals from countries outside the Union to apply for protection, domicile or real and effective industrial or commercial establishment is required. See Articles 2, paragraph (2) and 3 of the Convention.

NT under the Convention is interpreted as providing protection up to the national standard without being allowed to require reciprocity<sup>162</sup> and causing offence to nations' sovereign rights.<sup>163</sup> Bogsch, the former Director General of WIPO, comments that although reciprocity is an alternative to NT in term of ensuring equal treatment among nationals of different states, reciprocity runs a greater risk of bringing downward the standard of protection. He believed that the provision of a minimum standard in the Convention is designed to combat the possible risk of substandard protection resulting from the application of equal treatment.<sup>164</sup> But Bodenhausen holds a different view stating that reciprocity is sufficiently assured in the Convention, not by requiring reciprocal treatment of nationals from different member states, but by the obligation of adhering to the Convention.<sup>165</sup>

Article 4, Section A(1) confers on an applicant the right of priority to prevent a world wide loss of novelty<sup>166</sup> when several applications for the same invention are to be filed in different countries within the Union. Provided that the first application is filed in one of the member states, the subsequent applications will be treated as if they had been filed on the same day as the first application within twelve months of the first application. These applications will have priority over other applications filed during the twelve months period by other persons for the same invention.

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<sup>162</sup> Bodenhausen, note 150 above, p. 12.

<sup>163</sup> Evans, Gail E, 'The Principle of National Treatment and the International Protection of Industrial Property', *EIPR*, 3, 1996, p.150.

<sup>164</sup> Bogsch, note 146 above, p.197.

<sup>165</sup> According to Bodenhausen, the original Article 17 of the Convention, later on became Article 25 after some amendments, qualifies the obligations under the Convention as the "reciprocal engagements contained in the Convention". Bodenhausen, note 150 above, pp.12 and 108. Bodenhausen was Mr. Bogsch's predecessor.

<sup>166</sup> Kunz-Hallstein, 1979, note 74 above, p. 655.

Under Article 4<sup>bis</sup>, the member states within the Union are obliged to consider a patent application independently irrespective of whether the patent application has been filed inside or outside the Union<sup>167</sup> during the period of priority or not.<sup>168</sup> Each member state is obliged to evaluate the patent application according to its own law independent of what might be the fate of other applications for the same invention in other countries.

In the area of patent protection, the Convention does not expressly require the member states to establish domestic a patent system.<sup>169</sup> Regardless of the stipulation of substantive patent protection rules in the Convention, it is up to the member states to legislate according to their policy orientation and objectives. As Bodenhausen pointed out:

“the Convention leaves the member states entirely free to establish the criteria for patentability, to decide whether patent applications should or should not be examined in order to determine, before a patent is granted, whether these criteria have been met, whether the patent should be

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<sup>167</sup> Article 4<sup>bis</sup>(1) of the Convention.

<sup>168</sup> Article 4<sup>bis</sup> (2) of the Convention.

<sup>169</sup> Bodenhausen stated that:

Protection of several subjects of industrial property has been expressly prescribed in the Convention, namely, industrial designs (Article 5<sup>quinquies</sup>), service marks (Article 6<sup>sexies</sup>), collective marks (Article 7<sup>bis</sup>), trade names (Articles 8, 9, and 10<sup>ter</sup>), indications of source (Articles 10 and 10<sup>ter</sup>); and protection against unfair competition (Articles 10<sup>bis</sup> and 10<sup>ter</sup>) is also mandatory, as well as the temporary protection of certain subjects exhibited at international exhibitions (Article 11).”

Bodenhausen, note 150 above, pp. 24-25. He was the first Director-General of WIPO (1970-1973).



granted to the first inventor or to the first applicant for a patent,<sup>170</sup> or whether patents should be granted for products only, for process only, or for both, and in which fields of industry and for what term.”<sup>171</sup>

Articles 5, Section A and 5<sup>quater</sup> are the substantive rules of the patent system under the Convention. Article 5, Section A concerns the importation of patented products, compulsory (non-voluntary) licences, and forfeiture of patent. Article 5<sup>quater</sup> relates to the importation of products manufactured by a process patented in the importing country.

Article 5, Section A(1) states that importation by the patent holder of patented products manufactured in any of the countries of the Union shall not entail forfeiture of the patent. But it does not answer the question of whether importation itself constitutes a “working” of the patent. The concept of working is not defined in the Convention. It is generally understood, in the case of product patents, as the manufacturing of products comprising the invention, and in case of process patents, that the process comprising the invention is used in manufacturing.<sup>172</sup> Failure to work a patent<sup>173</sup> might constitute an abuse by the

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<sup>170</sup> When the “first-to-file” rule applies, it requires novelty and non-obviousness to exist on the date the patent application is filed. This rule enables the first person to file the patent application the right to the patent after proving the patentability of the innovation. The “first-to-invent” rule is an alternative system the US, and the Philippines followed whereby a patent for an invention is awarded to the first person who actually makes the invention. See Wineberg, Arthur, ‘The Japanese Patent system: A Non-Tariff Barrier to Foreign Businesses?’, *JWT*, 22(1), 1988, p.14-16 and WIPO Report for GATT, p. 227. See also Roberts, Tim, ‘Paper, Scissors, Stone’, *EIPR*, 20(3), pp. 89-91. Roberts commented that first to file is cheaper, simpler, and is used everywhere in the world. Although popular belief is that first-to-invent is a fairer system, but it is debatable whether the extra expense is justified for the extra fairness.

<sup>171</sup> Bodenhausen, note 150 above, p. 15.

<sup>172</sup> WIPO, PR/DC/3. June 25, 1979, p. 41.

<sup>173</sup> What constitutes “failure to work” is for the member states to define. Common sense dictates that surrounding circumstances have to be taken into consideration to decide whether failure to work constitutes an abuse.

patent holder which could lead to the grant of compulsory license.<sup>174</sup> It is based on the belief that patented inventions should be worked in the country where patent is granted so to fully justify the exclusive rights the patent holder enjoys.<sup>175</sup>

The Convention allows the member states to take legislative measures for the granting of compulsory licences on the ground of failure to work or insufficient working when the patentee does not have legitimate reasons to justify the inaction.<sup>176</sup> “Compulsory licence” is not defined in the Convention. But it is understood as a license to work a patented invention without the authorisation or consent of the patent owner, or when the national law obliges the patent owner to give such a license.<sup>177</sup> The time constraint imposed for the application of a compulsory licence is after the expiration of a period of four years from the date of filing of the patent application, or three years from the date of the grant of the patent, whichever period expires last.<sup>178</sup> Such a licence has to be non-transferable and non-exclusive.<sup>179</sup> Non-exclusivity is not defined in the Convention but is construed by Bogsch to mean that exploitation of the patented invention will be legitimate by both the beneficiary of the compulsory license and the patent owner or any person authorised by the patent owner.<sup>180</sup>

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<sup>174</sup> Article 5, Section A(2) of the Convention.

<sup>175</sup> Bodenhausen, note 150 above, p. 70.

<sup>176</sup> Article 5, Section A(4) of the Convention. Most of the member states to the Convention has compulsory licensing provisions for non-working, with the exception of the US. Compulsory licences could also be granted on grounds of public health, national defence, economic development, or the violation of anti-trust law. See WIPO Report for GATT.

<sup>177</sup> WIPO, PR/PIC/II/13, July 22, 1977, Annex II.

<sup>178</sup> Ibid.

<sup>179</sup> Ibid.

<sup>180</sup> Bogsch, note 146 above, p. 202

The Convention further provides the forfeiture of patent as a remedy when the grant of compulsory licence is not sufficient to prevent the said abuse. In order to do so, two preconditions have to be met:<sup>181</sup> 1) when the grant of compulsory license would not have been sufficient to prevent the said abuse, and 2) the proceeding for forfeiture of a patent may be instigated two years after the grant of the first compulsory licence. In other words, the provision for compulsory license has to be provided for in a country's legislation before the forfeiture proceeding could become possible.

According to Article 5<sup>quater</sup>, if there exists a process patent in an importing country, the process patent holder's right extends to the imported product which has been manufactured with this particular process in another country. The process patent holder in the importing country has all the rights, with regard to the imported products, that are accorded to him by the legislation of the country of importation. In case of litigation, the burden of proof is often on the plaintiff but the reversal of the burden of proof is provided for in some countries.<sup>182</sup>

The Convention is silent on domestic enforcement procedures. It is a matter for domestic jurisdiction. Nevertheless, the member states are obliged to abide by NT and avail the same legal remedies for infringement to nationals of member states as those it grants to its own nationals.

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<sup>181</sup> Article 5, Section A(3) of the Convention.

<sup>182</sup> WIPO Report for GATT, note 12 above, Item 8iii.

The jurisdictional clause contained in Article 28(1) of the Convention <sup>183</sup> deals with the settlement of disputes concerning the interpretation or application of the Convention. It provides that:

“Any dispute between two or more countries of the Union concerning the interpretation or application of this [the Paris] Convention, not settled by negotiation, may, by any one of the countries concerned, be brought before the International Court of Justice by application in conformity with the Statute of the Court, <sup>184</sup> unless the countries concerned agree on some other method of settlement...”.

A country may declare not to be bound by the jurisdictional clause by making a reservation <sup>185</sup> by virtue of Article 28(2) of the Convention. <sup>186</sup> Under such a circumstance, the general rules and principles under international law will apply with regard to the enforcement of treaty obligations. <sup>187</sup>

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<sup>183</sup> This clause was added to the Convention at the Revision Conference of Stockholm in 1967.

<sup>184</sup> The International Court of Justice, established at the Hague (Netherlands) is competent to deal with all cases which the parties refer to it and all matters specially provided for in treaties and conventions in force (Article 36, paragraph 1 of the Statute of the Court). Only States may be parties in cases before the Court (Article 34, paragraph 1, of the Statute of the Court).

<sup>185</sup> Article 21.1(a) of the Vienna Convention on the Law of Treaties 1969 provides the legal effect of reservation “which is to modify for the reserving state in its relations with that other party the provisions of the treaty to which the reservation relates to the extent of the reservation”. It also modifies those provisions to the same extent for that other party in its relations with the reserving state (Article 21.1(b)).

<sup>186</sup> It can be done at the time when the member state signs the 1967 Stockholm Act or deposit its instrument on rectification or accession.

<sup>187</sup> According to Kunz-Hallstein: if a country is bound by the Convention but fails to carry out its treaty obligations, it commits an international wrongful act. The state affected by such delict may, as a matter of principle, take appropriate counter-measures. The affected state may resort to retorsion and limit its sanctions to merely unfriendly acts, or it may resort to reprisals and retort against the breach with acts which would otherwise be illegal. Retorsions are unfriendly acts, they do not affect the rights of the states against which they are directed. Reprisals respond to a violation of international law by an act which otherwise would be illegal. International law provides limits with respect to reprisals. For example, they have to be proportionate to the damage accrued as the result of the illegal acts and they have to be taken in

### 1.5.1 DCs' criticism of the Convention

From DCs' point of view, the Convention fails to address their development needs and the concern for public interest.<sup>188</sup> It also fails to curtail monopolistic power exercised by MNCs.<sup>189</sup> By the late 1970s, the view was widespread that the patent system of the Convention must be revised to address these concerns.<sup>190</sup> In the most recent revision conference under the auspices of the Convention held during 1980-1982, DCs<sup>191</sup> requested the revision of Article 5, Section A,<sup>192</sup> which concerns the importation of patented products, compulsory licences and forfeiture of patents; and the deletion of Article 5<sup>quater</sup> necessary to redress the problem of non-working of patent.<sup>193</sup>

In relation to Article 5, Section A, DCs proposed that patent granting countries should be permitted to require the invention to be worked locally; and when the patented invention

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due course; and the UN Charter prohibits reprisals by force or by non-peaceful means (Article 33, UN Charter). In practice, there was no example of a measure of reprisal having been applied during the hundred years the Convention has been in force. See discussion in Kunz-Hallstein, Hans Peter, 'The United States Proposal for a GATT Agreement on Intellectual Property and the Paris Convention for the Protection of Industrial Property', *Vand JTL*, 22(2), 1989, pp. 278-282.

<sup>188</sup> *Ibid.*

<sup>189</sup> IPR might serve as an instrument for market allocation treading the domain of antitrust law, as noted by Meessen, note 30 above, pp. 67-74.

<sup>190</sup> Lall, note 99 above, p. 1.

<sup>191</sup> In the context of WIPO member states' participation in the revision conference, "developing countries" are not defined, but

"they should be understood to mean the countries which, according to the practice of the United Nations, are regarded as being developing countries. At the present time (1979), these are the countries of Africa (except South Africa), Latin America and the Caribbean, Asia(except Japan), Oceania (except Australia and New Zealand) and, in Europe Romania and Yugoslavia."

WIPO, PR/DC/3, June 25, 1979, p. 83.

<sup>192</sup> Kunz-Hallstein, 1989, note 187 above, p. 267.

is not worked or is not sufficiently worked, DCs should have the right to grant non-voluntary licenses within two years from the grant of the patent.<sup>194</sup> And only DCs could forfeit or revoke the patent before the expiration of three years from the grant of the patent, provided that the national law of the country provided for a system of non-voluntary licenses.<sup>195</sup> DCs further proposed that governments should be permitted to grant exclusive non-voluntary licenses<sup>196</sup> to third parties for six years without competition for reasons of national security, nutrition, health, or the development of vital sectors of national economy.<sup>197</sup>

Article 5<sup>quater</sup> deals with the importation of products manufactured by a process patent in the importing country. It will constitute an infringement if it is done without the authorisation of the process patent holder. Vaitos explains that this situation leads to a complete monopoly for the patentee in countries where legislation grants not only production but also sale and use privileges to products manufactured by a patented process. Since most of the patents granted in DCs are not worked, Article 5<sup>quater</sup> entails the acceptance of the import monopoly if sale and use privileges are present in their national legislation. DCs proposed either to delete Article 5<sup>quater</sup> or be allowed not to

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<sup>193</sup> It was argued that it is an outmoded idea to impose compulsory licensing for non-working. Modern technology rendered the contemplation of working of a patent in every country a practice economically undesirable. See GATT, MTN.GNG/NG11/14, 12 September 1989, p. 39.

<sup>194</sup> WIPO, PR/DC/3, p. 40.

<sup>195</sup> Ibid., pp. 56-61.

<sup>196</sup> A non-voluntary license is considered exclusive when no one other than the non-voluntary licensee may work the patented invention on the territory of the country whose authorities have granted the patent and the non-voluntary license throughout the period of time during which the license is in force. WIPO, PR/DC/3, p. 53.

<sup>197</sup> WIPO, PR/DC/3, pp. 48-53 and Kunz-Hallstein, 1979, note 74 above..

apply it <sup>198</sup> so that they are free to import products covered by a local process patent if the patent is not worked locally.

In regard to Article 4<sup>bis</sup>, DCs proposed to include a provision enabling them to make use of the experience of patent offices in other countries by requiring an applicant for patent or patentee to furnish relevant information concerning the same invention published in other countries. <sup>199</sup> DCs also submitted a proposal requesting the incorporation of differential and more favourable treatments to nationals of DCs by deviating from the general rules of the Convention in respect of fees and the term of priority. <sup>200</sup>

From the DCs' standpoint, these efforts were aimed at correcting the economic and technical imbalance between DCs and ICs as reflected in their relatively insignificant participation in the international system of patent protection. <sup>201</sup> But no agreement was reached at the end of the Revision Conference to adopt the DCs' proposals. Oddi attributed the failure of DCs' efforts to the consensus voting rules and the power and intransigence of ICs on these matters. <sup>202</sup>

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<sup>198</sup> WIPO, PR/DC/3. June 25, 1979, pp. 64-65.

<sup>199</sup> WIPO, PR/PIC/II/13, pp. 12-15 and Annex V.

<sup>200</sup> WIPO, PR/DC/3, pp. 66-75. DCs proposed their nationals to pay one-half of the fees in respect of the application for the grant or registration of a patent, inventor's certificate, other title for the protection of an invention or innovation, etc.. And the priority period shall be extended by one-half of the applicable priority period; so that in case of patents, the priority period be extended to become 18 months.

<sup>201</sup> Kunz-Hallstein, 1979, note 74 above, p. 662.

## 1.5.2 ICs' concerns over the Convention

As discussed in Chapter 1.5, <sup>1.5</sup> the Convention left much discretion to its member states to establish their domestic patent systems. And the implementation of the minimum standard as set out in the Convention is not mandatory. ICs claim that it therefore results in trade distortions <sup>203</sup> and economic loss caused by infringement and other misappropriation of IP because of inadequate and ineffective IP standards in some countries. <sup>204</sup> In a joint paper prepared by business communities from the US, EU and Japan endorsed by their respective governments, comments were made that the IP regime under the Convention was never intended to address trade related issues such as distortions caused by inadequate and ineffective IPP. <sup>205</sup> As the result of the inability of the Convention to deal with trade distortions, countries resorted to bilateral and unilateral actions, <sup>206</sup> which damaged the trade relationship among nations and undermined the multilateral disciplines established under the world trading system.

One of the ICs' major concerns was the inadequacy of substantive norms on IPP seen in many member states of the Convention. Pharmaceuticals top the list of those products

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<sup>202</sup> Oddi, 1987, note 79 above, p.866.

<sup>203</sup> This point was contested by DCs. The representative from India pointed out that it was the restrictive and anti-competitive practices of IP owners that created trade distortions. See GATT, MTN.GNG/NG11/14, 12 September 1989, pp. 4 and 29.

<sup>204</sup> See, for example, GATT, MTN.GNG/NG11/W/14 Rev. 1, 17 October 1988, Suggestion by the US for Achieving the Negotiating Objective – Revision and GATT, MTN.GNG/NG11/W/26, 7 July 1988, Guidelines and Objectives Proposed by the EC for the Negotiations on Trade Related Aspects of Substantive Standards of IPRs (hereinafter EC Guidelines).

<sup>205</sup> Basic Framework, note 82 above, pp. 5-6. See also discussions among the delegates participating in the TRIPS MTNs on the competence of WIPO and GATT to deal with IPP and trade matters, GATT, PREP.COM(86)SR/3, 11 April 1986.

<sup>206</sup> Ibid.



most commonly excluded from patent.<sup>207</sup> The exclusion of both pharmaceutical process and product for patent protection was considered to be unacceptable. Furthermore, the duration of protection varies considerably among the member states ranging from five to twenty years depending on the way it is computed.<sup>208</sup> And that the right to grant compulsory licenses has been abused which resulted in patent inventions being used by or for the state without consultation or agreement of the patent holders.

Another concern related to the inadequacy or ineffectiveness of domestic enforcement provisions to resolve disputes as the Convention did not establish standards of national enforcement. Domestic enforcement mechanism is in place to ensure that the measures adopted in the domestic law will not be used as disguised restrictions on legitimate trade or as a means of discrimination. It is to ensure the compliance of international treaty obligations by invoking domestic legislation in a speedy manner in case of infringement. And it is utilised to settle disputes between private parties under national law. One area that draws particular criticism from the pharmaceutical industry is the prevailing system of the right holder bearing the burden of proof in process patent infringement proceedings. Because there are so many ways of producing a chemical compound with minor modification of the formula, it is difficult, if not impossible, to gather evidence to substantiate the claim. Reversal of burden of proof is seen as more equitable.

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<sup>207</sup> According to the study prepared by WIPO in 1988: among 98 members of WIPO at that time, 49 member states provided no pharmaceutical product patent protection and 10 member states did not provide patent protection for pharmaceutical processes. See WIPO Report for GATT, note 12 above, a study prepared by WIPO in 1988 for the GATT Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods

Dispute settlement mechanism is in place to resolve disputes between governments over their legal obligations under the international agreement. ICs are dissatisfied with the absence of consultation mechanisms and meaningful dispute settlement provisions under the Convention. Although the International Court of Justice (ICJ) is the competent authority to deal with disputes under the Convention, no case has been brought in front of it. One possible reason is the requirement<sup>209</sup> that a judgement by the ICJ can only be enforced by voluntary co-operation or by referral to the Security Council. But it is questionable whether the Security Council would act to enforce a judgement on patent protection. The other possibly is the perceived lacking of expertise of ICJ in intellectual property matters.<sup>210</sup> Among existing international agreements, GATT possesses a comparatively workable dispute settlement mechanism,<sup>211</sup> which in part explains the ICs choice of GATT as the forum to negotiate an agreement on IPP.

Suggestions?

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<sup>208</sup> Ibid. The duration of patent could be computed from the filing date of the application, the date from the filing date, the publication date of the examined application, the publication date of the unexamined application, or the date of the grant of the patent. And the duration could range from five to twenty years.

<sup>209</sup> Article 94 of the Charter of the UN.

<sup>210</sup> Emmert, note 30 above, p.1343.

<sup>211</sup> See De Lacharriere, Guy Ladreit, 'The Legal Framework for International Trade', in *Trade Policies for a Better Future – The "Leutwiler Report", The GATT and the Uruguay Round*, Dordrecht: Martinus Nijhoff publishers, 1987, p. 103. Also Remarks of Professor John H. Jackson, *Vand JTL*, 22(2), 1989, p. 346 (hereinafter Jackson Remark). In comparison with other international dispute settlement systems such as International Court of Justice (ICJ), GATT dispute settlement procedures work better. See Hudec, Robert, *Enforcing International Trade Law – The Evolution of the Modern GATT Legal System*, New Hampshire: Butterworth Legal Publishers, 1993, op. cit., p. 353, Jackson, John, *Restructuring the GATT system*, London: Royal Institute of International Affairs, 1990, p. 59, Cottier, note 82 above, p. 393, and Petersmann, Ernst-Ulrich, 'The Dispute Settlement System of the World Trade Organisation and the Evolution of the GATT Dispute Settlement System since 1948', *CMLR*, 31, 1994, pp. 1194 and 1195. The proof for such a claim can also be found in a 1985 US Review of the Effectiveness of Trade Dispute Settlement under the GATT and Tokyo Round Agreement. For example, tariffs and quotas have been the most frequent subject of complaints and these cases have generally been resolved satisfactorily under the existing dispute settlement procedures; panel report adoption rarely has been delayed for long periods averaging 10 months from when the Article XXIII: 2 complaints was filed to the date of report adoption; and implementation has been fairly prompt in the cases, averaging two years between the date of the Article XXIII:2 complaints and the date of implementation of panel recommendations. See USITC, Report to the Committee on Finance, US Senate, USITC Publication 1793, December 1985, pp. IX, XI, 58 and 64.

While setting out to rectify their concerns, ICs found it difficult, if not impossible, to revise and strengthen the standard of patent protection under the existing system of the Convention. One major stumbling block was the voting system under the Convention. The WIPO had adopted the United Nation style of voting by groups whereby four groups are represented: Group A consists of the DCs of the Afro-Asian region and Yugoslavia, and Group C represents countries from Latin America. These two groups meet together as the Group of 77.<sup>212</sup> The socialist countries form Group D. And Group B includes mostly western ICs.<sup>213</sup> The rule of procedure under the Convention to adopt a revision required consensus or, if consensus was unattainable, the voting of a majority of two-third of the member states, provided that the number of states voting against its approval did not exceed twelve.<sup>214</sup> It was unlikely that more stringent patent protection proposals could meet approval within the framework of the Convention.<sup>215</sup> ICs recognised that they did not have enough bargaining chips in WIPO,<sup>216</sup> and that an alternative forum had to be found where they could exert more influence to push forward their case.

With the intention of seeking a multilateral trade agreement to deal with IPP, the substantive norms and standards suggested by ICs contained a higher level of protection with wider coverage of subject matters than what was contained in the Convention. In order to persuade DCs to adopt a more advanced domestic IP system than is required for

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<sup>212</sup> Group of 77 was established at UNCTAD I in 1964. It represents the DCs as a group in the UN system and serves as the principal organ of the Third World for articulating and promoting its collective interest so to gain stronger bargaining power. The membership of the group has increased since its establishment but the numerical designation remains.

<sup>213</sup> Group B also includes countries such as Japan, Australia, and New Zealand. Blakeney, note 95 above, p. 27. See also Emmert, note 30 above, p. 1343.

<sup>214</sup> Bosgch, note 146 above, p. 237.

<sup>215</sup> See Jackson Remark, note 211 above.

<sup>216</sup> Remarks of Professor Robert Hudec, *Van JTL*, 22(2), 1989 (hereinafter Hudec Remark); p. 321.

their economic and technological development, assistance must be provided to deal with the costs of dislocation derived from, for example, not being able to acquire foreign technology or import products from alternative and cheaper sources, and the incursion of financial burdens in establishing and maintaining the judicial and administrative structures.<sup>217</sup> A mechanism to facilitate the transfer of technology with the aim to establish the scientific and technological infrastructure in DCs for long-term growth also needs to be addressed in the MTNs, or it would be unlikely for DCs to benefit from profit-oriented foreign investment decisions by MNCs.

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<sup>217</sup> Yusuf, note 127 above, pp. 191-194, Sherwood, 1990, note 21 above, ch. 8, and Blakeney, note 95 above, p. 155.

## Chapter II

### How Did Intellectual Property Protection come to be brought under the Auspices of GATT

Relevant events on the global political and economic scenes prior to the Uruguay Round are set out in a chronological order to elaborate why DCs' more active participation in the global trading system and the political pressure from ICs, especially the US, are the two major contributory factors to the eventual inclusion of the subject of TRIPS on the negotiation agenda of the Uruguay Round.

#### 2.1 Introduction

The inclusion of the subject of TRIPS on the agenda for the Uruguay Round MTNs<sup>1</sup> was held as a breakthrough, which was made possible by the conducive international economic and political climate of the early 1980s.

Following a period of strong economic growth in the 1960s,<sup>2</sup> and the significant reduction of tariffs after the end of the Kennedy Round, the value of international trade soared.<sup>3</sup> Protectionism concurrently flourished among trading nations as the result of

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<sup>1</sup> See GATT, MIN.DEC, 20 September 1986. The Punta del Este Declaration sets out the negotiation agenda for the Uruguay Round MTNs. It was adopted by the Ministers of contracting parties of GATT in September 1986. As GATT was applied provisionally in 1947, its members were referred to as the "contracting parties" (hereinafter CPs). Under Article XXV:I of GATT: "... whenever reference is made.. to the contracting parties acting jointly, they are designated as the CONTRACTING PARTIES..".

"Contracting parties" in the lower case represents individual contracting parties.

<sup>2</sup> The average annual GDP growth rate during the 1960s was 5.1% for all OECD countries. See OECD, *Economic Outlook Historical Statistics 1960-1989*, Paris: OECD, 1991, p. 48, Table 3.1.

<sup>3</sup> The average level of tariffs among ICs has been reduced from around 40% in the 1930s to under 10% after the end of the Kennedy Round in 1967. See GATT, *International Trade 1984/85*, Geneva: GATT,

intensified competition from an increasing interdependent global economy. The economic recession caused by the two oil shocks in the 1970s <sup>4</sup> further fuelled the protectionist sentiment. The Uruguay Round was launched against this background of a world trading system under great strain. Doubts existed among trading nations over the relevance and binding power of the GATT rules and disciplines. — Example

ICs were especially concerned with GATT's ability to respond to the development in the global trading environment, in particular the growing global trade brought about by technological advancements. As Low observed, there existed a conspiracy of non-compliance of rules and principles of GATT as political wrangling and manipulation led to compliance of the GATT rules giving way to the domestic political pressure, as demonstrated in the US. <sup>5</sup>

Since the 1970s, political support for GATT in the US Congress has started to deteriorate. The massive current account deficits seen in the mid-1980s were viewed not only as an indication of the US losing competitiveness in the global market, but also the failure of

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1985, p. 201, Table A-1. According to the statistics, the value of trade stood at US\$129 billion in 1960, US\$258 billion in 1968, US\$575 billion in 1973, and US\$1,635 billion in 1979.

<sup>4</sup> In 1973, the world suffered its first oil shock and caused a surge in inflation and a period of severe recession in 1974 and 1975. Although economic growth surged back to 4% after 1975, came the second oil shock in 1979 when prices of crude oil rose sharply and governments reacted to the increased inflation with tight money policy. In its wake, 1980-1982 was a period of economic stagnation, with high interest rates reaching historical levels. See Ahari, M.E., *OPEC, The Failing Giant*, Lexington: University Press of Kentucky, 1986, pp. 150-151, Table 29 and OECD, 1991, note 2 above.

<sup>5</sup> Low, Patrick, *Trading Free – The GATT and US Trade Policy*, NY: The Twentieth Century Fund Press, 1993. The 1982 Ministerial Declaration describes the multilateral trading system seriously endangered, that:

“In the current crisis of the world economy, to which the lack of convergence in national economic policies has contributed, protectionist pressures on governments have multiplied, disregard of GATT disciplines has increased and certain shortcomings in the functioning of the GATT system have been accentuated.”

See GATT, L/5424, 29 November 1982

GATT to provide substantive IP protection for high-technology products in which the US had comparative advantages. In response to congressional pressure, the US administration adopted a dual approach of continuing its multilateral approach within the GATT system,<sup>6</sup> while at the same time introduced domestic trade legislation to allow the administration to take unilateral measures against perceived unfair foreign practices such as inadequate or ineffective IPP. The latter approach was generally regarded as GATT-inconsistent. By accepting the inclusion of TRIPS on the Uruguay Round agenda, DCs saw it as a way of keeping such unilateral actions in check.

Following the debt crisis of early 1980s, many DCs started the process of unilateral trade liberalisation.<sup>7</sup> They found that differential and more favourable treatments (DMFT) conferred by the GATT system did not benefit them<sup>8</sup> and that they remained on the periphery of the world trading system.<sup>9</sup> With the adoption of export-oriented trade

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<sup>6</sup> The US's continued active participant within the GATT system reflected the US administration's purposeful drive toward modernising the system. Primo Braga, Carlos Alberto, 'The Economics of Intellectual Property Rights and the GATT: A View from the South', *Vand JTL*, 1989, p. 245.

<sup>7</sup> Bhagwati, Jagdish, 'Fair Trade, Reciprocity and Harmonisation: The New Challenge to the Theory and Policy of Free Trade', in Deardorff and Stern (eds.), *Analytical and Negotiating Issues – In the Global Trading System*, Ann Arbor: The University of Michigan Press, 1994, p. 575. It was the shift from preoccupation with protectionism, and the successful example provided by export-promoting newly industrialised economies (NIEs) which influenced DCs policy changes. Other reasons mentioned by Bhagwati as contributing to the trade liberalisation of DCs include economic writings and research into the negative impact and high costs of import substitution and the benefits of export promotion, and conditionality imposed on the lending by the World Bank and IMF based on these ideas and finding. Conditionality imposed by the World Bank and IMF is a substantive issue on its own, and will not be covered in this thesis.

<sup>8</sup> Despite DMFT, DCs' economies remained weak because they became dependent on tariff preferences, exporting at higher costs ignoring appropriate exchange rate adjustment and import liberalisation. See *Trade Policies for a Better Future, The 'Leutwiler Report', the GATT and the Uruguay Round*, Dordrecht: Martinus Nijhoff Publishers, 1987 (hereinafter the Leutwiler Report), p. 51. The Leutwiler Report was prepared by 7 members appointed in 1983 by then Director General of GATT Arthur Dunkel on the problems facing the international trading system.

<sup>9</sup> For example, despite being the beneficiaries of the Generalised System of Preference (GSP), DCs' preferential access to ICs' markets remained restricted. With changing economic environment and intensified competition in the global market, many donor countries of the GSP erected non-tariff barriers (NTBs) and imposed import restrictions in areas such as agriculture, textiles and clothing that DCs have comparative advantages for the protection of domestic industries vulnerable to import competition.

policies, DCs saw the benefits of participating more fully in the world trading system.<sup>10</sup> The political connotation of DCs' participation in GATT MTNs<sup>11</sup> is that it provides a political counterweight needed for governments to confront domestic opposition to newly adopted export-oriented trade policies. And as GATT allows concessions to be swapped across different sectors,<sup>12</sup> joining in MTNs offers the opportunity of trade-offs between the sectors important to parties to the negotiation. By agreeing to negotiate on the subjects important to ICs, such as TRIPS, it increases the possibility of bringing primary commodities important to DCs' economy into the GATT multilateral framework.

## 2.2 DCs' participation in multilateral trade negotiations

In the early 1980s, many DCs were faced with a severe debt crisis.<sup>13</sup> It triggered them to reconsider their economic policy direction in order to regain the capacity to service their debts and allow their economies to expand.<sup>14</sup> The debt crisis demonstrated to them that their earlier economic policies had failed completely, and different and more favourable treatments (DMFT) they enjoyed under the GATT system did not contribute positively to

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<sup>10</sup> DCs indeed became more active in the world trading system participated in the meetings and submitted proposals in preparation for the Uruguay Round. See Whalley, John (cord.), *The Uruguay Round and Beyond*, The Final Report from the Ford Foundation Project on Developing Countries and the Global Trading System, London: The MacMillan Press Ltd. (hereinafter Ford Foundation Report), p. 5.

<sup>11</sup> Hoekman, Bernard and Michael Kostecky, *The Political Economy of the World Trading System from GATT to WTO*, Oxford: Oxford University Press, 1994, p. 57.

<sup>12</sup> Jackson, John, *The World Trading System – Law and Policy of International Economic Relations*, Massachusetts: The MIT Press, 1992, p. 125.

<sup>13</sup> It was caused by a multitude of problems: The first oil shock of 1973 made private lending of recycled OPEC surplus easily available to DCs. Many of them borrowed excessively anticipating export earnings to service the debt. But the anticipated export earning did not materialise because of the decreased demand for their imports in the world market and the growing protectionism restricting DCs' exports in the wake of economic recessions. See Hudec, Robert, *Enforcing International Trade Law – The Evolution of the Modern GATT Legal System*, New Hampshire: Butterworth Legal Publishers, 1993, p. 22.

<sup>14</sup> *Ibid*, p. 115. With the exception of India, countries such as Mexico, Thailand, Kenya, Brazil, and Argentina had all adopted market-oriented policies.



their economic growth. As the Leutwiler Report published in 1983 found, the DMFT DCs enjoyed under the GATT system was of limited value to them.<sup>15</sup> Under the rules of DMFT, DCs were not required to give reciprocal concession when negotiating with ICs that “would be inconsistent with their industrial development, financial and trade needs.” In effect, it discouraged both sides from reducing trade barriers<sup>16</sup> and accelerated the trend toward protectionism<sup>17</sup> by alternative means, such as the utilisation of NTBs. With the implementation of Generalised System of Preferences (GSP), for example, the advantage DCs received is very limited because the seven rounds of MTNs have achieved significant reduction of tariffs. The benefits of GSP is further out-weighed by the adverse effects of discriminatory restrictions imposed by ICs on DCs’ exports of manufacturing goods, such as textiles and clothing, which DCs are the lowest-cost producers.<sup>18</sup> Over the years, DCs allowed themselves to be distracted by the idea of preferences and became dependent on them. This dependence not only led to mismanagement of economies, but also incurred high costs as the result of overlooking their fundamental interests in a non-discriminatory trading system.<sup>19</sup>

DCs’ endeavour in seeking DMFT can be traced back to 1946 when DCs tabled amendments to the draft Havana Charter requesting to be free from the application of the basic principles of MFN, NT, and Reciprocity,<sup>20</sup> but no agreement was reached at that

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<sup>15</sup> The Leutwiler Report, note 8 above, p. 51.

<sup>16</sup> Ibid., p. 27.

<sup>17</sup> Ibid., p. 28.

<sup>18</sup> Ibid., p. 27.

<sup>19</sup> Hoekman and Kostecki, note 11 above, p. 51.

<sup>20</sup> Article 1 of the Havana Charter for the establishment of the defunct International Trade Organisation did expressly call for preferential treatment for DCs. The Leutwiler Report described the proposed amendment as reflecting the inward-oriented development strategies of those newly independent ex-colonial countries in the 1940s, see the Leutwiler Report, note 8 above, p. 197.

time.<sup>21</sup> Khan attributes this result to the false assumption of economic equality of states which presumes equal bargaining powers among all parties entering into tariff negotiations.<sup>22</sup>

In 1964, Part IV of GATT entitled "Trade and Development" was incorporated into the General Agreement in 1964 as a result of the Kennedy Round. It amended the basic principle of reciprocity in MTNs for tariff concessions and introduced the concept of non-reciprocity into the GATT system.<sup>23</sup> It was a disappointing outcome for DCs because although Part IV contained agreed statements of principle giving DCs DMFT, the commitment set out was not legally binding.<sup>24</sup>

DCs continued to seek legal recognition of DMFT in the form of amendments to GATT during the Tokyo Round.<sup>25</sup> An "enabling clause" was adopted as a part of the outcome of the Round, which gave the GSP a legal base for the implementation in the GATT system. It is a scheme which authorised ICs to derogate from unconditional MFN by granting tariff preferences to DCs on a unilateral and temporary basis.<sup>26</sup> However, unconditional MFN was further eroded by the introduction of code-conditionality

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<sup>21</sup> An infant industry provision (Article XVIII of the General Agreement) was incorporated into the General Agreement instead to allow governmental assistance to economic development. It was not until 1954 that Article XVIII:b was included to allow quantitative restrictions to be used for balance-of-payment purposes necessary to assist economic development. See Hoekman and Kostecki, note 11 above, ch. 7.

<sup>22</sup> Ibid. Also Khan, K. R., 'International Law of Development and the Law of the GATT', in Snyder and Slinn (eds.), *International Law of Development; Comparative Perspective*, Abingdon: Professional Books, 1987, pp. 181-182. Khan further adds that the *raison d'être* of international law of development is the positive and co-operative actions by governments and organisations. But GATT is essentially non-interventionist in character.

<sup>23</sup> Part IV will be discussed in Chapter 3.3.3.

<sup>24</sup> Hudec, *Developing Countries in the GATT Legal System*, London: Trade Policy Research Centre, 1987, pp. 57-58.

<sup>25</sup> DCs insisted on a variety of DMFT concessions under the threat of a walk out. See Hudec, note 13 above, p. 26.

applicable to the agreements reached in the Tokyo Round which dealt with NTBs. It was introduced by ICs for the purpose of preventing countries that contributed very little or nothing but free rode on the concessions others made under conditional MFN.

Prior to the Tokyo Round, ICs accepted DCs' demands for DMFT, partly because DCs' import substitution policies and selective tariff preferences they enjoyed did not impose substantial economic or political costs on ICs.<sup>27</sup> But ICs' negotiation stance changed in the Tokyo Round because economic and political costs associated with tariff preferences for DCs became too high.<sup>28</sup> ICs also introduced the concept of graduation advocating that DCs should graduate from DMFT and participate more fully in the world trading system.<sup>29</sup> According to ICs, it was in the interest of DCs to reciprocate and have their trade policy re-evaluated through negotiations. It would then make it easier to ICs to convince domestic legislators to enact more favourable trade policies if DCs were seen to be bargaining in good faith.<sup>30</sup>

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<sup>26</sup> See discussion in Chapter 3.3.1.

<sup>27</sup> Greenaway, David and Robert C. Hine, 'Introduction: Trends in World Trade and Protection', in Greenaway, Hine, O'Brien and Thornton (eds.), *Global Protectionism*, Hampshire: MacMillan Academic and Professional Ltd., 1991, p. 7.

<sup>28</sup> Because economic and political costs associated with tariff preferences for DCs became too high, especially in the absence of market access to DCs. Milner, Chris, 'Graduation and Reciprocity', in Greenaway, Hine, O'Brien and Thornton (eds.), *Global Protectionism*, Hampshire: MacMillan Academic and Professional Ltd., 1991, p. 197.

<sup>29</sup> The graduation of NIEs from the GSP was particularly called for. According to a Ford Foundation Report, one major reasons why ICs called for NIEs to graduate from the GSP was that they saw the potential benefits from improved access to the growing markets in NIEs. Followed the economic prosperity in NIEs, brought with it not only disease patterns similar to those in the ICs, but also more affluent population who demands better health care with corresponding ability to pay. NIEs proved to be potentially lucrative markets for MPCs. Therefore, lobbying government to negotiate with these economies on the long-term trade rules assumed increased economic significance. Ford Foundation Report, note 10 above, pp. 3-5.

<sup>30</sup> *Ibid.*, p. 27.

Throughout the history of GATT, DCs' seeking DMFT has been a source of tension between DCs and ICs. ICs had repeatedly voiced their dissatisfaction with DCs' reluctance to accept the disciplines of GATT.<sup>31</sup> This dissatisfaction found its expression in the deployment of NTBs in the 1970s, a phenomenon described as "the new protectionism".<sup>32</sup> Since the early 1970s, the growing volume of international trade had intensified competition in the global market place.<sup>33</sup> NTBs were deployed for the protection of the domestic industries susceptible to import competition.<sup>34</sup> According to Ray and Marvel,<sup>35</sup> there is evidence to suggest that the initial increase of NTBs was linked to economic recession in ICs<sup>36</sup> in the wake of the two oil shocks in the 1970s. The characteristics of these NTBs are that they are non-transparent, and they are discriminatory directly against DCs, especially NIEs and it is the discriminatory nature of these instruments that had direct impact on the credibility of the GATT system.<sup>37</sup> Tariffs were used to protect labour-intensive low technology industries such as agriculture and textiles and clothing industries that the US was at a comparative disadvantage in world trade.<sup>38</sup> Because GATT prevents contracting parties from introducing new tariffs to protect declining industries, governments then turned to NTBs, such as voluntary export

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<sup>31</sup> Hoekman and Kostecki, note 11 above., p. 237.

<sup>32</sup> Greenaway and Hine, note 27 above.

<sup>33</sup> Hudec, 1993, note 13 above, p. 23.

<sup>34</sup> Hine, Robert C., 'Protection in the European Community Before and After 1992', in Greenaway, Hine, O'Brien, and Thornton (eds.), *Global Protectionism*, Hampshire: MacMillan Academic and Professional Ltd., 1991, p. 78.

<sup>35</sup> Ray E. J. and H. P. Marvel, 'The Pattern of Protection in the Industrialised World', *Review of Economics and Statistics*, 1984, pp. 456-458.

<sup>36</sup> Ibid. The US, Japan, Canada, and the EC were given as the examples.

<sup>37</sup> Greenaway and Hine, note 27 above, p. 7.

<sup>38</sup> See Ray, E. J., 'The Determinants of Tariff and Non-tariff Trade Restrictions in the United States', *Journal of Political Economy*, 89(1), 1981, pp. 105-121, and Deardorff, A. V. and R. M. Stern, *American Labour's Stake in International Trade, in Tariffs, Quotas and Trade: The Politics of Protectionism*, San Francisco: Institute for Contemporary Studies, 1979, pp. 125-148.

restraints (VERs),<sup>39</sup> to protect the industries vulnerable to foreign competition. which had lost their competitive edge relating to imports from DCs.<sup>40</sup>

Agricultural was an example of an industry which has been subjected to protective government measures because of the absence of clear and fair global trading rules.<sup>41</sup>

Primary commodities, in particular agriculture products have been virtually excluded from the framework of GATT.<sup>42</sup> The exclusion of agriculture produce from the multilateral trade discipline disadvantages DCs economically and financially because of their reliance on primary products as their major source of export earnings.<sup>43</sup> It discouraged DCs from participating in the global trading system as they felt that they

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<sup>39</sup> VERs are defined as quantitative restrictions imposed by an importing country but administered by the exporting country or countries. These restrictions have been referred to as 'grey-area measures'. Despite the general prohibition of quantitative restrictions in the GATT system, VERs were popular forms of quantitative restriction, which are often negotiated under the threat of anti-dumping actions. They are bilateral in nature which constitutes an erosion of MFN. According to Jackson, when countries have proved successful in their exports of a particular product, the product becomes the target of importing country governments' pressure to adopt export restraints of one form or the other.

See Deardorff, A. and R. Stern, *Methods of Measurement of Non-Tariff Barriers*, Geneva: UNCTAD, 1985, Hoekman and Kostecki, note 11 above, pp. 97-98, and Jackson, 1992, note 12 above, p. 140. One well-known example is the Multi-fibre Agreement introduced in 1974 during the Tokyo Round relating to textiles and clothing.

<sup>40</sup> Ray, Edward J., 'Protection of Manufacturers in the US Protectionism', in Greenaway, Hine, O'Brien and Thornton (eds.), *Global Protectionism*, Hampshire: MacMillan Academic and Professional Ltd., 1991, p. 14. There is a welfare dimension of the US protection in manufacturing sector. By protecting declining industries, it provide a welfare safety-net and reduce structural unemployment for industries that are not competitive and has no prospect of being able to compete in the future. See discussion in Baldwin, R. E., 'The Changing Nature of U.S. Trade Policy Since World War II', in Baldwin and Krueger (eds.), *The Structure and Evolution of Recent U.S. Trade Policy*, Baldwin, Chicago: National Bureau of Economic Research, 1984, pp. 5-27.

<sup>41</sup> Ibid., p. 43.

<sup>42</sup> It was largely brought about by Article XI:2(c) of GATT which allows "import restrictions on any agricultural or fisheries products... necessary to the enforcement of governmental measures". The waiver secured by the US in 1955 and the Common Agricultural Policy of the European Community are the two well-known examples.

<sup>43</sup> According to Barry Jones, the vulnerability of LDCs is a result of the continuation of over-concentration and over-dependence on a narrow range of commodity export and a limited number of major foreign market, many of them ex-colonial masters. Barry Jones, R. J., *Globalisation and Interdependence in the International Political Economy*, London: Pinter Publishers, 1995, pp. 135-142.

were left with little to bargain with in MTNs.<sup>44</sup> It was also seen as an evidence of ICs' unwillingness to liberalise trade so as to protect their commodity producers from adjustment difficulties when faced with competition from exports.<sup>45</sup>

The concept of graduation involves both DCs and ICs calling each other to adhere to the traditional GATT disciplines. The earlier discussion touched upon ICs' demand that DCs should graduate from DMFT and participate more fully in the world trading system. For DCs, they urged ICs also to graduate from protectionist measures and special treatments for industries such as agriculture and textiles and clothing.<sup>46</sup> As non-discrimination is the core of the multilateral trading system, DCs urged ICs to bring these trade policies into the open with clear and accepted multilateral rules.<sup>47</sup>

In the end, it was the DCs' who took unilateral liberalisation in the wake of the debt crisis, with a growing appreciation of the importance of maintaining an open trading system in favour of more outward-oriented development strategies focusing on import liberalisation and export promoting measures.<sup>48</sup> The success of the export-oriented

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<sup>44</sup> Khan, note 22 above, p. 192.

<sup>45</sup> Ford Foundation Report, note 10 above, p. 22.

<sup>46</sup> Milner C., note 28 above, p. 196. Textiles and clothing are subject to Multifibre Agreement introduced in 1974 during the Tokyo Round. It is a voluntary agreement that perpetuates a quota system for international trade in textiles and clothing. It is recognised as inconsistent with GATT. See Jackson, 1992, note 12 above, p. 181.

<sup>47</sup> The Leutwiler Report, note 8 above, p. 41.

<sup>48</sup> Whalley, John, 'Recent Trade Liberalisation in the Developing World: What is Behind It and Where is It Headed?' In Greenaway, Hine, O'Brien, and Thornton (eds.), *Global Protectionism*, Hampshire: MacMillan Academic and Professional Ltd., 1991, p. 226. According to the Ford Foundation Report: during the period of 1941 up to the time of debt crisis, many DCs considered it to be desirable to use high tariffs and quota to restrain imports, to maintain fixed exchange rates, and to use foreign exchange rationing as a trade restricting device. They accepted the theory advocated by Prebisch that reciprocity should not be expected from them in trading negotiation that the onus was on ICs unilaterally to implement trade policies to speed up the development process. They also believed that protection of domestic market allowed them to achieve more rapid industrialisation. Many countries followed import substitution

strategy implemented by NIEs<sup>49</sup> encouraged DCs to re-evaluate the merits of import-substitution strategies they had implemented since the 1960s. The newly adopted export-oriented development strategy brought the need for DCs to participate more fully in the world trading system. They recognised that participating in GATT would enable them to add the weight of international obligations into their open-door policies. It would also provide the political counterweight governments needed to confront the opposition from the interest groups representing those industries which would be disadvantaged from the change of policies. Participating in the new round of MTNs therefore provided an opportunity to cement domestic support for their new market oriented policies.<sup>50</sup>

In the Punta del Este Declaration, CPs of GATT<sup>51</sup> agreed to the principles of DMFT embodied in Part IV, and reiterated that ICs do not expect reciprocity for commitments made in the negotiation, and DCs were not expected to make contributions which were inconsistent with their individual development, financial and trade needs.<sup>52</sup> This declaration has to be seen as a compromise outcome to accommodate diverse interest

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strategies argued that they should be free from internationally negotiated disciplines limiting their freedom in adopting appropriate trade policy actions. The Ford Foundation Report, note 10 above, p. 17, and Prebisch, R., 'The Economic Development of Latin America and Its Principal Problems', *Economic Bulletin for Latin America*, 7, 1962, pp. 1-22.

<sup>49</sup> During the period of economic stagnation in the 1980s, many DCs' economic growth was brought to a virtual standstill. But NIEs' rapid and sustained growth continued unabated averaging 5.5 percent annual per capita real income growth since 1960. Their superior manufactured export performance demonstrated by their rising share of world export was largely credited to their economic growth. They used exports as a yardstick to evaluate their economic efficiency as export markets are likely to be more competitive. NIEs include Hong Kong, the Republic of Korea, Singapore, Taiwan, China, Indonesia, Malaysia and Thailand. Their share in world exports was 8 percent in 1965, 13 percent in 1980, and 18 percent in 1990. See World Bank, *The East Asian Miracle – Economic Growth and Public Policy*, A World Bank Policy Research Report, Oxford: Oxford University Press, 1993, (hereinafter World Bank Report 1993), pp. 28, 37 and 98.

<sup>50</sup> Hudec, 1993, note 13 above, p. 116.

<sup>51</sup> See note 1 above.

<sup>52</sup> Ibid.

between and within ICs and DCs.<sup>53</sup> Engaging in reciprocal exchange of concession remained a prominent feature in the Uruguay Round.<sup>54</sup> Reciprocity was seen by ICs, in particular the US, as an instrument to minimise free riding<sup>55</sup> and to ensure equal market access.<sup>56</sup> For DCs, it provided an opportunity to ensure progress on MTNs were made on sectors important to them if they were to be persuaded to concede anything on IPP.<sup>57</sup>

The Punta del Este Declaration included the subjects of trade-related IPRs, agriculture, textiles and clothing for MTNs. The advantage of dealing with such a broad range of subjects is that it tends to increase the scope for co-operative behaviour<sup>58</sup> and offer the possibility of trade-offs between sectors on the negotiation agenda, which if addressed in isolation could prove to be too difficult to reach any agreement.<sup>59</sup> Trade-off itself endorses the application of reciprocity,<sup>60</sup> and as Cottier pointed out, it is this legitimate expectation to achieve trade-offs that has made progress possible during the MTNs on TRIPs and the sectors such as agriculture and textiles and clothing.<sup>61</sup> And with the linkage of agriculture and IPP in the Uruguay Round, if ICs, especially the US and the

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<sup>53</sup> Hoekman and Kostecky, note 11 above, p. 241 and Milner C., note 28 above, p. 215.

<sup>54</sup> Winters, Alan L., 'Reciprocity', in Finger and Olechowski (eds.), *The Uruguay Round – A Handbook for the Multilateral Trade negotiations*, Washington, D.C.: The World Bank, 1987, p. 49.

<sup>55</sup> Hoekman & Kostecky, note 11 above, p. 27. NIEs recognised that there is little to expect from GATT MTNs on trade liberalisation while they enjoy DMFT, and graduation from GSP was a necessary step to avoid unilateral retaliation such as the US Section 301 actions linking sanction to the enforcement of IPP. For LDCs, they would not be asked to graduate, and the graduation of NIEs was welcomed by then because of the prospect of being able to enjoy increased market access to both ICs and NIEs under the principle of MFN. See the Leutwiler Report, note 8 above, p. 205.

<sup>56</sup> Committee for Economic Development, *Breaking New Ground in US Trade Policy*, Boulder, Colorado: Westview Press, 1991, p. 53.

<sup>57</sup> Winters, note 54 above.

<sup>58</sup> Hoekman and Kostecky, note 11 above, p. 78.

<sup>59</sup> Subramanian, Arvind, 'TRIPS and the Paradigm of the GATT: A Tropical, Temperate View', *The World Economy*, 13(4), 1990b, pp. 509-521.

<sup>60</sup> Winters, note 54 above.

<sup>61</sup> Cottier, Thomas, 'The Prospects for Intellectual Property in GATT', *CMLR*, 28, 1991, pp. 383-414.



EU could indeed be persuaded to do something on agriculture, the benefits to DCs would be significant. <sup>62</sup> *What?*

### 2.3 Political pressure from the US

The legitimacy of bringing the subject of trade-related IPP into GATT is based on the claim that non-tariff barriers in the form of inadequate and ineffective IPP caused trade distortions, <sup>63</sup> the elimination and reduction of which lies within the jurisdiction of GATT. By bringing the trade dimension into IP issues, the choice of a multilateral negotiation forum for a trade-related IPP agreement must be GATT, the only multilateral trade agreement to lay down a legal framework for the conduct of global trade. Politically, GATT provides a framework of self-imposed constraints that enables contracting parties to regulate conflicts of interests among states, and defend against protectionist lobbies from competing importers and interest groups within one's own country. <sup>64</sup>

The US MNCs were at the forefront of lobbying their government for the inclusion of trade-related IPP on the agenda of the Uruguay Round MTNs. <sup>65</sup> Some of them encouraged the US government to tackle the subject multilaterally for fear of being

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<sup>62</sup> Remarks of Professor John H. Jackson, *Vand JTL*, 22(2), 1989, p. 346 (hereinafter Jackson Remark).

<sup>63</sup> National IP laws act like NTBs where there is disharmony in the law of nations. See Stern, Richard H., 'Intellectual Property', in Finger and Olechowski (eds.), *A Handbook for the Multilateral Trade Negotiations*, Washington D.C.: The World Bank, 1987, p. 205.

<sup>64</sup> Roessler, Frieder, 'The Scope, Limits, and Function of the GATT Legal System', in *Trade Policies for a Better Future, The 'Leutwiler Report', the GATT and the Uruguay Round*, Dordrecht: Martinus Nijhoff Publishers, 1987.

<sup>65</sup> Remarks by David Beier in *Vand JTL*, 22(2), 1989, p. 334 (hereinafter Beier Remark), p. 334.

singled out for retaliation by host countries.<sup>66</sup> Others who regarded foreign markets as critical to their survival, such as high technology firms, seemed to prefer to rely on the US Section 301 legislation.<sup>67</sup> For US firms which hold the competitive edge in producing innovative products, such as the pharmaceutical industry, the susceptibility to free-riding led them to regard extensive IPP as indispensable in their pursuit of global expansion strategies. Their effort was supported by the belief that it was the responsibility of the state to act in the event of unauthorised appropriation by foreign nationals of private property protected by US legislation.<sup>68</sup> The act of pirating and counterfeiting technology or technology-related products protected by US IP legislation constitutes an unauthorised appropriation. They claimed that the inadequate and ineffective IPP in foreign countries hinders their market access, hence affecting their competitiveness in the global market. They suffered significant economic loss as their sale of IP protected goods was replaced by pirated and counterfeited products.<sup>69</sup>

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<sup>66</sup> Ibid.

<sup>67</sup> Ibid.

<sup>68</sup> Historically, FDI was made in the form of long term concession and was between a host state and a foreign national. Hence, the agreement was outside the international legal system as classical international law largely dealt with inter-state relations. However, the capital-exporting states developed the concept of state responsibility and evolved the assumption that an injury to a foreign national was an injury to the home state. Therefore, for example, taking of a foreign property independent of the concession agreement became a matter of international law. Despite the fact that these norms and rules were increasingly being challenged in recent years, ICs have persistently attempted to devise methods to internationalise the contractual regimes of FDI. (See, for example, Qureshi, Asif H., *International Economic Law*, London: Sweet & Maxwell, ch. 16). Section 301 of the US Trade and Tariff Act of 1974 as amended by the Omnibus Trade and Competitiveness Act of 1988 is a recent example of the adoption of specific rules and principles in relation to FDI by one of the major capital exporting countries. It was directed at foreign restrictions on US trade and was used to enforce trade rights as conferred by GATT and bilateral treaties, if necessary, through retaliation against those judged to have violated these right, with authority to undertake such actions conferred on the US Trade Representatives by the US Congress.

<sup>69</sup> According to US International Trade Commission (ITC), 193 US firms estimated their aggregate world-wide losses due to inadequate intellectual property protection in 1986 at \$23.8 billion or 2.7% of sales affected by intellectual property. The ITC further estimated that world-wide losses to all of US industry in 1986 from inadequate foreign protection of intellectual property ranged from \$43 billion to \$61 billion. See Basic Framework of GATT Provisions on Intellectual Property, Statement of Views of the European, Japanese and United States Business Communities, The Intellectual Property Committee (USA), UNICE (Europe), and Keidanren (Japan), 1988 and USITC, 'Economic Effects of Intellectual Property Right Infringement (Investigation No. 332-245)', *JWT*, 22(4), pp. 101-114.

The US government also recognised that technological development is where its new-found comparative advantage lies,<sup>70</sup> and exports in IP related products are increasingly important sources of national revenue.<sup>71</sup> The US government took up the MNCs' call for actions and concentrated on the legal reform within GATT to rectify the defects of the absence of a legal regime for the protection of IP in the global trading system.<sup>72</sup> It started its effort at the final stage of the Tokyo Round with the submission of a draft Anti-Counterfeiting Code,<sup>73</sup> but no agreement was reached to include it as part of the final result of the Tokyo Round. Its failure to attain an agreement for a new round of MTNs during the 1982 Ministerial Meeting was a further blow to its effort to negotiate multilaterally.<sup>74</sup>

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<sup>70</sup> The US's comparative advantage was reflected in its high percentage of export containing domestically generated technology more so than any other countries, see Davis, L, 'Technology Intensity of US, Canada, and Japanese Manufacturers' Output and Exports', in Niosi (ed.), *Technology and National Competitiveness*, Montreal: McGill-Queens, 1991.

<sup>71</sup> The relative percentage of the US exports with IP content more than double from 9.9 per cent in 1947 to 27.4 per cent in 1986 amounting to more than 25 per cent of all its export. See Gadbow, Michael and Timothy J. Richard, 'Introduction', in Gadbow and Richards (eds.), *Intellectual Property Rights – Global Consensus, Global Conflict?* Boulder, Colorado: Westview Press, 1988a, p. 4, chart 1.1.

<sup>72</sup> Hudec, Robert, 'Thinking About the New Section 301: Beyond Good and Evil', in Bhagwati and Patrick (eds.), *Aggressive Unilateralism – America's 301 Trade Policy and the World Trading System*, Hertfordshire: Harvester Wheatsheaf, 1991, p. 130. And there was no major effort made by the US to renegotiate the Convention within the auspices of WIPO in the 1980s. See David, Paul A., 'Intellectual Property Institutions and the Panda's Thumb: Patent, copyrights, and Trade Secrets in Economic Theory and History' in Wallerstein, Moge, and Schoen (eds.), *Global Dimensions of Intellectual property Rights in Science and Technology*, Office of International Affairs National Research Council, Washington, D.C.: National Academy Press, 1993, p. 20 and Raghavan, Chakravarthi, *Recolonisation – GATT, the Uruguay Round & the Third World*, London: Zed Books Ltd. and Third World Network in Malaysia, 1990, p. 120.

<sup>73</sup> The draft Code concerns border measures to combat counterfeited goods protected by trademarks. It was a joint submission by the US and the EU. GATT, L/4817, 31 July 1979, Agreement on measures to Discourage the Importation of Counterfeit Goods. See discussion in Bradley, Jane A., 'Intellectual Property Rights, Investment and Trade in Services in the Uruguay Round: Laying the Foundations', *Stanford Journal of International Law*, 23, 1987, pp. 57-98.

<sup>74</sup> 1982 Ministerial meeting was convened in November 1982 to assess the results of the Tokyo Round and to deal with outstanding issues, see Discussion to Convene the 38<sup>th</sup> Session at Ministerial level in GATT, BISD 28<sup>th</sup> Supp., 1982, p. 15. During the meeting, the ministers did not consider the working text of the Commercial Anti-Counterfeiting Code submitted by the US delegation, but they did agree to establish a work program for trade in counterfeiting goods to "clarify the legal and institutional aspects involved." See Ministerial Declaration, GATT, BISD 29<sup>th</sup> Supp., 1983, pp.9, 19, and 22. No specific deadline was set

Between 1980 and 1985, the Reagan Administration's priority was to fight domestic inflation. It neglected exchange rate and trade policies, and left the US Dollar perversely over-valued.<sup>75</sup> The US thus saw its exports decline by a third as its export products virtually priced out of world markets<sup>76</sup> and its imports rose even faster.<sup>77</sup> By the mid 1980s, the US deficit in merchandise trade grew significantly causing a decline in the US current account balance from a zero balance in 1982 to a \$147 billion deficit by 1987.<sup>78</sup> This massive current account deficit was seen as an indication of the US losing comparative advantage in global markets.<sup>79</sup> Congressional pressure grew for the executive branch to take action to reduce the trade deficit. It became more involved in the US trade policy and threatened to take drastic action to counter perceived unfair foreign trade practices which had contributed to the trade deficit. It started the debate on

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for the conclusion of the work in Counterfeiting goods although other work programs were all given one. Furthermore, India and Brazil had challenged the legal competence of the CPs to deal with commercial counterfeiting arguing that the WIPO has exclusive jurisdiction over IPP matters. See detailed discussion of the events leading up to the Uruguay Round in Chapter 4.2.

<sup>75</sup> As Hudec explained: normally, when trade deficit increases, the value of national currency declines because of the increase in the supply of the country's money on world markets. But in this case, the value of US dollar had risen by 1985 to almost 145% of its 1980 value. It was until the end of 1985 that the value of the dollar started to come down as leading governments agreed to intervene in world capital markets to lower the value of US dollar in the Plaza Agreement. See Hudec, 1993, note 13 above, p. 105.

<sup>76</sup> The US deficit in merchandise trade grew from \$36.4 billion in 1982 to \$160 billion in 1987. Lawrence, Robert Z., 'Commentary', in Bhagwati and Patrick (eds.), *Aggressive Unilateralism – America's 301 Trade Policy and the World Trading System*, Hertfordshire: Harvester Wheatsheaf, 1991, p. 108.

<sup>77</sup> Milner, Helen, *Resisting Protectionism*, Princeton: Princeton University Press, 1988, p. 300.

<sup>78</sup> Hufbauer, G., 'Background Paper', in *The Free Trade Debate: Report of the Twentieth Century Fund Task Force on the Future of American Trade Policy*, New York: Priority Press, 1989, pp. 164-67. Although the international trade performance was largely blamed for causing the current account deficits, Patterson and Patterson argued that the main reason was the combination of huge domestic budgetary deficits, high rate of domestic consumption, and consumer preferences for imported goods. See Patterson, Gardner and Eliza Patterson, 'Objectives of the Uruguay Round', in Finger and Olechowski (eds.), *The Uruguay Round: A Handbook for the Multilateral Trade Negotiations*, Washington D.C.: The World Bank, 1987, p. 12.

<sup>79</sup> Committee for Economic Development, note 56 above, p. 55 and Gadbow and Richards, 1988a, note 71 above, p. 6.

the revision of Section 301 to rectify the perceived unwillingness of the president to use the statute<sup>80</sup> to counter foreign trade barriers restricting US trade.<sup>81</sup>

The Reagan Administration in response announced its “New Trade Policy” in September 1985 by declaring that it would make active use of Section 301 procedures<sup>82</sup> and work with Congress in drafting a new trade policy that would deal specifically with unfair foreign trade practices.<sup>83</sup> The result is the revised and expanded Section 301 provisions contained in the Omnibus Trade and Competitiveness Act of 1988. The 1988 Act applies the principle of reciprocity in market access commitments and used the access to its vast domestic market as a bargaining tool to open markets abroad.<sup>84</sup> In the context of IPP, the thrust of the demand for market access on a reciprocal basis is that US firms should be given equivalent access to or commercial opportunities in a foreign market as firms

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<sup>80</sup> Cline, William, ‘Reciprocity: A New Approach to World Trade Policy’, in Cline (ed.), *Trade Policy in the 1980s*, Washington, D.C.: Institute for International Economics, 1983, p. 136.

<sup>81</sup> 18 petitions for Section 301 were filed during 1975 and 1979. The president did not take any retaliatory action. After minor revision of the 1974 Act in 1979, 35 petitions were filed between 1980-1985, but no removal of foreign trade barriers or retaliation took place. See Milner, Helen, ‘The Political Economy of U. S. Trade Policy: A Study of the Super 301 Provision’, in Bhagwati and Patrick (eds.), *Aggressive Unilateralism – America’s 301 Trade Policy and the World Trading System*, Hertfordshire: Harvester Wheatsheaf, 1991, p. 165.

<sup>82</sup> Kuroda, Makoto, ‘Super 301 and Japan’, in Bhagwati and Patrick (eds.), *Aggressive Unilateralism – America’s 301 Trade Policy and the World Trading System*, Hertfordshire: Harvester Wheatsheaf, 1991, p. 220.

<sup>83</sup> Palmeter, David, ‘Commentary’, in Bhagwati and Patrick (eds.), *Aggressive Unilateralism – America’s 301 Trade Policy and the World Trading System*, Hertfordshire: Harvester Wheatsheaf, 1991, p. 167. Most importantly, the administration announced an export expanding strategy to address the issue of trade deficit by aiming to remove unfair foreign trade practices and to ensure reciprocal market access to US industries. Under the assumption that countries with trade surplus practice trade unfairly, the administration also set out to persuade major trade surplus countries to remove import barriers and encourage domestic demand for US goods. See Feketekuty, Geza, ‘U.S. Policy on 301 and Super 301’, in Bhagwati and Patrick (eds.), *Aggressive Unilateralism – America’s 301 Trade Policy and the World Trading System*, Hertfordshire: Harvester Wheatsheaf, 1991, pp. 91 and 94.

<sup>84</sup> Gadbow, Michael R., and Rosemary E. Gwynn, ‘Intellectual Property Rights in the New GATT Round’, in Gadbow and Richards (eds.), *Intellectual Property Rights – Global Consensus, Global Conflict?* Boulder, Colorado: Westview Press, 1988, ch. 2, p. 50. See detailed discussion in Chapter 3.3.3.

from that particular foreign country has been offered in the US.<sup>85</sup> The US's earlier pursuit of multilateralism and free trade policy thus assumed lower priority. Fair trade and market opening were given prominence,<sup>86</sup> with the goal of ultimately harmonising other countries' IP law and practices to those of the US standard.<sup>87</sup>

### 2.3.1 Section 301 provisions

The enactment of the Omnibus Trade and Competitiveness Act of 1988 provides a mechanism to deal with trade issues that were not yet covered by GATT at the time of the enactment,<sup>88</sup> and is the exemplification of the US's determination to take up the IPP issue unilaterally. It provides a procedure under which US citizens may petition the US governments to investigate and act against potential violation of international trade agreement.<sup>89</sup> It also authorises the United States Trade Representative (USTR) to investigate at its own initiative<sup>90</sup> and to retaliate against any unreasonable, unjustifiable, or discriminatory foreign practices that burden or restrict US commerce.<sup>91</sup>

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<sup>85</sup> Abbott, Kenneth W., 'Defensive Unfairness: The Normative Structure of Section 301', in Bhagwati and Hudec (eds.), *Fair Trade and Harmonisation – Prerequisites for Free Trade?* Vol. 2: Legal Analysis, Cambridge: The MIT Press, 1996, op. Cit., p. 449.

<sup>86</sup> Abbot, Frederick M., 'Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework', *Vand JTL*, 22(4), 1989, pp. 689-745.

<sup>87</sup> Hart, Michael M., 'The WTO and the Political Economy of Globalisation', *JWT*, 31(5), 1997, pp. 37-61.

<sup>88</sup> Feketekuty, note 83 above, p. 91.

<sup>89</sup> Section 302(a)(2), 19 U.S.C. § 2412(a)(2).

<sup>90</sup> Section 302(b), 19 U.S.C. § 2412(b). The USTR is a cabinet level official serving at the pleasure of the US president. Its office is located within the Executive Office of the president. See Section 19 U.S.C. § 2171(a), (b)(1)(1998).

<sup>91</sup> 19 U.S.C. § 2411(a) 1988. The statutory definition of "unjustifiable", "discriminatory" and "unreasonable" were given in the 1984 Trade and Tariff Act. An "unjustifiable" foreign practice is an act, policy, or practice that is in violation of or inconsistent with the international legal rights of the US. "Discriminatory" is defined to include an act, policy, or practice that denies MFN or NT to US goods, services, or investment. The term "unreasonable" is defined to include an act, policy, or practice that might

The 1988 Act contains three Section 301 provisions. They are known as Regular 301, Special 301, and Super 301. Regular 301 was first enacted in the Trade Act of 1974<sup>92</sup> and had been revised in the Trade Agreement Act of 1979,<sup>93</sup> the Trade and Tariff Act of 1984,<sup>94</sup> the Omnibus Trade and Competitiveness Act of 1988,<sup>95</sup> and the Uruguay Round Agreements Act of 1994.<sup>96</sup> Special 301 and Super 301<sup>97</sup> were newly introduced in the 1988 Act. Special 301 deals specifically with intellectual property issues. It is designed to improve foreign IPP through bilateral negotiations with the threat of retaliation in the form of restriction on access to the US market. Under Special 301, the USTR must prepare an annual report entitled National Trade Estimate<sup>98</sup> and identify and analyse the acts, policies, or practices of each country which constitute significant market access barriers to or distortions of US exports of goods or services.<sup>99</sup> No later than thirty days after the submission of National Trade Estimate to Congress, the USTR must identify those foreign countries that “deny adequate and effective protection of intellectual property rights or deny fair and equitable market access to US persons that rely upon

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not be in violation or inconsistent with the international legal rights of the US but is deemed unfair or inequitable. See The Trade and Tariff Act of 1984, Pub. L. No. 98-573, §304, 98 Stat. 2948, 3002 (1984).

<sup>92</sup> The Trade Act of 1974, Pub. L. No. 93-618, §§ 301-302, 88 Stat. 1978 (1975). The first appearance of Section 301 was in the Trade Act of 1974. One of the stated legislative purposes was to harmonise, reduce, or eliminate trade barriers so to assure “substantially equivalent commercial opportunities” for US commerce. It was introduced to enforce legal rights conferred by GATT and bilateral treaties. And it was directed at foreign government trade barriers restricting US trade. Its complaint procedures were GATT – consistent in principle as it is expected to first invoke GATT dispute settlement mechanism Bhagwati, Jagdish, ‘An Overview’, in Bhagwati and Patrick (eds.), *Aggressive Unilateralism – America’s 301 Trade Policy and the World Trading System*, London: Harvester Wheatsheaf, 1991, p. 4.

<sup>93</sup> The Trade Agreement Act of 1979, Pub. L. No. 96-39, title IX, 93 Stat. 144, 295 (1979).

<sup>94</sup> The Trade and Tariff Act of 1984, Pub. L. No. 98-573, §304, 98 Stat. 2948, 3002 (1984).

<sup>95</sup> The Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, §§ 1301-1302, 102 Stat. 1107, 1164-79 (1988).

<sup>96</sup> The Uruguay Round Agreements Act, Pub. L. No. 103-465, § 314(f), 108 Stat. 4809 (1994).

<sup>97</sup> Super 301 is the most controversial provision which requires the USTR to prepare an inventory list of foreign trade barriers, establish a priority list of countries and their unreasonable practices, and set a deadline for their removal. Failure to comply with the US demand will be met by retaliations. A specific sector will be targeted and its access to the US market denied.

<sup>98</sup> 19 U.S.C. §2241(6) (1988).

<sup>99</sup> 19 U.S.C. §2241(a)(1)(A)(i) (1988).

intellectual property protection.”<sup>100</sup> Unless they have entered into good faith negotiations or made significant progress in negotiations to provide adequate intellectual property protection,<sup>101</sup> those that have “most onerous or egregious acts, policies, or practices that deny adequate and effective intellectual property rights” and whose acts have “the greatest adverse impact on the relevant US products” will be designated as “priority foreign countries”<sup>102</sup> for possible retaliatory actions.

Section 301 procedures have three controversial characteristics: 1) the agenda for Section 301 negotiations is set by the US. It decides which foreign practices to be considered unfair.<sup>103</sup> The unilateral nature of the judgement as to what is fair or not makes the US both the prosecutor and judge.<sup>104</sup> 2) the negotiations take place with the threat of trade retaliation to obtain one-way trade concessions or policy changes from the designated country. By singling out a country for its unfair trade practices, the threat of unilateral retaliation is discriminatory and inconsistent with the multilateral dispute settlement mechanism under GATT;<sup>105</sup> 3) a different concept of reciprocity applies under Section 301. It puts emphasis on equal market access as the benchmark to evaluate the extent of success in trade liberalisation. And continued access to the US market depends upon the growth of market share of the US companies in the designated country. The threat of

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<sup>100</sup> 19 U.S.C. §2242(a)(1) (1988).

<sup>101</sup> 19 U.S.C. §2241(b)(1) (1988).

<sup>102</sup> 19 U.S.C. §2242(a)(2) (1988).

<sup>103</sup> Abbott, 1996, note 85 above, p. 417.

<sup>104</sup> Hudec, Robert, *The GATT Legal System and World Trade Diplomacy*, 2<sup>nd</sup> ed., New Hampshire:

Butterworth Legal Publishers, 1990 and Milner, note 81 above, p. 176.

<sup>105</sup> *Ibid.*, p. 163.



retaliatory actions often involves the reduction of existing access to the US market by the designated country.<sup>106</sup>

The demand for reciprocal market access first appeared in the Trade Agreement Act of 1979 implementing the agreements reached in the Tokyo Round.<sup>107</sup> Traditionally, market access has been referred to as the tariff treatment import country governments give to industrial products imported from other countries. But in the context of IPP, the demand for market access on a reciprocal basis is to mean that US firms should be given equivalent access to or commercial opportunities in a foreign market as firms from that particular foreign country have been offered in the US market.<sup>108</sup> This demand turns on the concept of fairness that has underlined the majority of US trade law.<sup>109</sup>

Section 301 was amended in the Trade and Tariff Act of 1984.<sup>110</sup> The 1984 Act expands the application of Section 301 and sets out the negotiating objectives for IPRs.<sup>111</sup> It also authorises the President to impose trade sanctions against any countries that inadequately protect IP and engage in “unreasonable or unjustifiable” trade practices. It further adds IPP as one of the considerations to determine a country’s eligibility for GSP.<sup>112</sup> The

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<sup>106</sup> Bhagwati, 1991, note 92 above, p. 5.

<sup>107</sup> Trade Agreement Act of 1979, Pub. L. No. 96-39, § 2(b)(2), 93 Stat. 144, 295 (1979). The 1979 Act provides that a foreign country could benefit from agreements reached in the Tokyo Round only when it has accorded adequate benefits, including substantially equal commercial opportunities, to the US.

<sup>108</sup> Abbott, 1996, note 85 above, p. 449.

<sup>109</sup> Ibid., pp. 417-422. See further discussion on the concept of fairness in Chapter 3.3.

<sup>110</sup> 19, USCA 2462 (c) (5) (West Supp. 1987).

<sup>111</sup> The expanded application of Section 301 also covers trade-related investment measures, trade in high technology products, services, and FDI.

<sup>112</sup> The Trade and Tariff Act of 1984, Pub. L. No. 98-573, §§ 503 and 505, 98 Stat. 2948, 3019-23 (1984), (codified at 19 U.S.C. §§ 2462(c)(5), 2464(c)(3)(B)(ii)).

Generalised System of Preferences Renewal Act of 1984 directs the US president, when considering the renewal of GSP, to

“give great weight to...the extent to which such country provides adequate and effective means under its law for foreign nationals to secure, to exercise, and to enforce exclusive rights in intellectual property...”,<sup>113</sup>

This has caused much concern among GATT contracting parties who were the beneficiaries of the US GSP.<sup>114</sup>

Following the enactment of the 1984 Act, Section 301 cases involving subjects not covered by GATT have appeared with greater frequency.<sup>115</sup> But the Brazil Pharmaceutical case<sup>116</sup> had resulted in actual retaliation by the US Executive branch. This case concerns the US's retaliation against Brazil for its failure to offer adequate process and product patent protection to pharmaceuticals. The petition was filed in June

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<sup>113</sup> Section 505, Trade and Tariff Act of 1984, 19 U.S.C. 2464(c)(B)(ii) (Supp. III 1985). See discussion in Bradley, note 73 above, pp. 73-74.

<sup>114</sup> Bhagwati explains that, these countries with trade surplus were targeted because, having been given DMFT by GATT thus were free to use tariffs and other trade barriers, and profited from the general reduction in trade barriers from ICs because of the unconditional MFN, they have secured unbalanced trade concessions and made overall access to their market significant restricted than their access to the market of ICs. Instead of allowing the US to use the leverage of its large market to address the imbalance in market access caused by perceived NTBs caused by inadequate or ineffective IPP, it should be the GATT to establish graduation guidelines for those DCs who had been successful in expanding their exports. Bhagwati, 1991, note 92 above, p. 29.

<sup>115</sup> Hudec, 1991, note 72 above, p. 124.

<sup>116</sup> This case was only part of a growing trade dispute between the US and Brazil in the mid-1980s. Other source of growing tension between the two countries derived from the US's reduction of Brazil's benefits under the GSP by virtue of Trade and Tariff Act 1984. Getland, Myles, 'TRIPS and the Future of Section 301: A Comparative Study of Trade Dispute Resolution', *Columbia Journal of Transnational Law*, 34(1), 1995, p. 185.

1987 by the Pharmaceutical Manufacturers' Association (PMA), a trade association representing pharmaceutical companies exporting to Brazil. The USTR accepted the PMA's petition and initiated a Section 301 investigation in July 1987. At that time, Brazil agreed to debate the issue of patent protection, assuring the US that it had fulfilled its treaty obligation of NT under the Paris Convention.

After allowing for public comment, President Reagan decided to impose retaliatory trade sanctions in October 1988 imposing an ad valorem tariff on certain Brazilian imports that had little or no relation to the pharmaceutical industry.<sup>117</sup> The value of the tariff was about the equivalent of the USTR's estimate of financial injury suffered by the US pharmaceutical industry resulting from Brazil's failure to provide patent protection.<sup>118</sup> The USTR indicated that retaliatory measures would be lifted once Brazil addressed the problem by introducing new patent legislation. Brazil in reply described the US action as a hostile act against Brazil and was GATT-inconsistent.

In 1989, Brazil asked a GATT panel to be set up to adjudicate the dispute, but panel proceedings were suspended by mutual agreement. In June 1990, when President de Mello of Brazil came to power, it was announced that patent protection for pharmaceuticals would be adopted as part of an overall economic reform. The USTR lifted the sanctions and terminated the Section 301 investigation in the following month. But Brazil failed to deliver the promise due to domestic legislative problems, which caused the USTR to name it as a priority foreign country in April 1993 and initiated a

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<sup>117</sup> Hudec, 1991, note 72 above, p. 34.

<sup>118</sup> Getlan, note 116 above, p. 188.

Super 301 investigation. It was not until February 1994 that the USTR terminated the Super 301 investigation when Brazil introduced amendments to its pending industrial property law.

Hudec points out that the US action against Brazil was GATT-illegal because GATT did not allow governments to use trade retaliation to attack inadequate IPP regimes.<sup>119</sup> The US occasionally suggested that it might have a claim of non-violation nullification and impairment under Article XXIII:1(b) of GATT<sup>120</sup> on the ground that inadequate IPP deprived it of the benefit of GATT trade obligations on pharmaceuticals, but the claim has no substance. The remedy of non-violation nullification and impairment is based on the notion that a reasonable expectation at the time one makes a concession has been frustrated by some unexpected action of the other government.<sup>121</sup> Brazil's policy was well known from the beginning of US-Brazil GATT relations, the US had no ground for any reasonable expectations.<sup>122</sup>

A group of prominent economists, led by Bhagwati, condemned the GATT illegality of 301 retaliation and the US's departure from GATT multilateralism in favour of bilateral

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<sup>119</sup> Hudec, 1993, note 13 above, p. 227-229.

<sup>120</sup> Article XXIII: 1(b) states that:

“1. If any contracting party should consider that any benefit accruing to it directly or indirectly under this Agreement is being nullified or impaired or that the attainment of any objective of the Agreement is being impeded as the result of ...

(b) the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement, ...”

Jackson points out that there is no satisfactory definition to the concept of “nullification or impairment”. But nullification may stem from a breach of “reasonable expectations” at the time the concession was considered. See Jackson, John H., *World Trade and the Law of GATT*, NY: The Bobbs – Merrill Co. Inc., 1969, pp. 178-187.

<sup>121</sup> See discussion in Chapter 4.4.

initiatives based on bullying small trading partners.<sup>123</sup> But Hudec is of the view that if GATT is in fact unable to rule, the complainant may be free to resort to "self-help" in some circumstances.<sup>124</sup> The disobedience of GATT rules is justified "where the dangers to the legal system caused by inaction in the face of a deadlock will exceed the damage caused by some disobedient actions trying to force a correction."<sup>125</sup> But the one-sidedness of the Section 301 simply cannot justify disobedience.<sup>126</sup>

Feketekuty argues that Section 301 provisions provide a mechanism to deal with trade issues that were not yet covered by GATT at the time of enactment of the 1988 Act.<sup>127</sup> By linking trade policies of Section 301 provisions with US negotiating objectives in the Uruguay Round,<sup>128</sup> he claims that bilateral negotiations carried out under Section 301 provisions could be seen as complementing and reinforcing the MTNs in the Uruguay Round. And it sent the signal to GATT contracting parties that the US government would have to address IP issues bilaterally if they were not covered by the Uruguay Round MTNs.<sup>129</sup>

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<sup>122</sup> See also Abbott, 1989, note 86 above, p. 693.

<sup>123</sup> 'Statement of Forty economists on American Trade policy', *The World Economy*, 12, 1989, pp. 263-265.

<sup>124</sup> Hudec, 1991, note 72 above, p. 21.

<sup>125</sup> Hudec, 1990, note 104 above, p. 127.

<sup>126</sup> Ibid.

<sup>127</sup> Feketekuty, note 83 above, p. 91.

<sup>128</sup> Ibid., p. 100. Special 301 deals exclusively with IP issues. Super 301 deals with five areas of trade barriers: quantitative restrictions, government procurement policies, technical barriers to trade, trade related investment measures, and barriers to trade in services. Subsidies and Agricultural policies were dealt with outside Super 301 process.

<sup>129</sup> Ibid., p. 92.

The effects of the Section 301 actions had not been proven wholly satisfactory because the impact is limited to those countries which rely heavily on exports to US market,<sup>130</sup> and it is less potent against larger DCs which are less dependent on trade.<sup>131</sup> Bhagwati's description that minor players will succumb while major players will be spared under Section 301 actions<sup>132</sup> is manifested in the examples involving Taiwan, South Korea which belong to the league of minor players, and the EC and Japan. In order to avoid being named as unfair traders, Taiwan and South Korea had initiated negotiations with the US to liberalise sectors demanded by the US, import more US goods, or to freeze their trade surplus with the US.<sup>133</sup> But the EC announced that it would refuse to negotiate if named as an unfair trader, that Section 301 provisions were a violation of international law, and it was unilateralism at its worst; if the US sanctioned it, it would retaliate in full force.<sup>134</sup> The Japanese government declared that it had no intention to negotiate with the US when Japan was named an unfair trader under Super 301 in 1989. In the wake of Japan's refusal to negotiate, the USTR claimed that "the Super 301 framework was found to be excessively rigid and confrontational" and initiated a set of

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<sup>130</sup> Evenson, Robert E., 'Intellectual Property Rights, R&D, Inventions, Technology Purchase, and Piracy in Economic Development: An International Comparative Study', in Evenson and Ranis (eds.), *Science and Technology – Lessons from Development Policy*, Boulder, Colorado: Westview Press, 1990b, p. 325 and Reichman, J. H., 'Intellectual Property in International Trade: Opportunities and Risks of a GATT Connection', *Vand JTL*, 22(4), 1989, p. 756. Individual DCs have responded to US pressure over IPP issues in proportion to their overall export dependence on the US market. For example, Taiwan and South Korea had revised their IPP law considering 29.9% and 14.5% of GNP constituting export to the US respectively. India with its 2.1% of GNP as exports to the US had not revised patent law. See Gadbow, Michael and Timothy J. Richard (eds.), *Intellectual Property Rights – Global Consensus, Global Conflict*: Boulder, Colorado: Westview Press, 1988b.

<sup>131</sup> Kastenmeier Robert W. and David Beier, 'International Trade and Intellectual property: Promise, risks, and Reality', *Vand JTL*, 22(2), 1989, p. 302.

<sup>132</sup> Bhagwati, 1991; note 92 above, p. 38.

<sup>133</sup> New York Times, May 13, 1989.

<sup>134</sup> New York Times, May 20, 1989, Sec. A.

talks with Japan outside the 301 framework covering issues which were initially to be negotiated under Super 301.<sup>135</sup>

When challenged by trading nations during the Uruguay Round MTNs of the unilateral nature of Section 301 actions, the US took the stance that many problems dealt with in the 1988 Act, for example IP issues, were not yet covered by GATT law so they had to be handled bilaterally.<sup>136</sup> The official line remained adamant that the multilateral approach was only complementary to the unilateral and bilateral approaches.<sup>137</sup> Following the conclusion of TRIPS, the US government reaffirmed its intention to retain freedom for unilateral actions under Section 301 provisions,<sup>138</sup> and declared that no provision in any of the Uruguay Round agreements would prevail over any inconsistent US law, or is to be construed as modifying any US law.<sup>139</sup>

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<sup>135</sup> In May 1989, the USTR named Japan as an unfair trader under super 301 for its procurement practices in supercomputers and satellite and technical barriers in lumber. *New York Times*, May 27, 1989, Sec. A.

<sup>136</sup> GATT, C/M/224, for the meeting of 22 September, 1988.

<sup>137</sup> Gadbow and Gwynn, note 84 above, p. 64. Also USTR, Web Site, 9 April, 1996.

<sup>138</sup> The Uruguay Round Agreements Act, Pub. L. No. 103-465, § 314(f), 108 Stat. 4809 (1994).

<sup>139</sup> The Uruguay Round Agreements Act, Pub. L. No. 103-465, § 102, 108 Stat. 4809 (1994).

## 2.4 DCs' position on TRIPS in MTNs

DCs viewed the introduction of IPP into the Uruguay Round MTNs as a weapon in the struggle of "haves" against "have nots" in the diffusion of technology.<sup>140</sup> It was also seen as a way to establish a linkage between extraneous issues and trade in goods which might lead to the withdrawal of concessions on goods given by ICs in the previous rounds of MTNs.<sup>141</sup> From the DCs' perspective, the substantive standards of IP are related to socio-economic, industrial, and technological developments.<sup>142</sup> Imposing higher levels of IPP on DCs infringes the right of self-determination<sup>143</sup> and freedom to pursue national economic goals.<sup>144</sup> They considered the approach under the Convention more desirable whereby a gradual elevation of minimum standards enables the members to the Union to determine the desired balance between monopoly and competition for

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<sup>140</sup> D'Amato, Anthony and Doris Estelle Long (eds.), *International Intellectual Property Law*, The Hague: Kluwer Law International, pp. 457-458 and Stern, note 3 above, p. 203. It was also suspected that, by bringing IPP negotiations in the Uruguay round, ICs tried to introduce the subject of FDI in the GATT in an indirect way fuelling the year-long differences between DCs and ICs in their emphasis vis-à-vis FDI (DCs are largely concerned with the protection from FDI while ICs are interested in the promotion of it).

<sup>141</sup> The representatives from India and Argentina expressed this concern in the Preparatory Committee meeting of August 1986. See GATT, PREP.COM(86)SR/9, 26 August 1986, p. 8.

<sup>142</sup> GATT, MTN.GNG/NG11/14, 12 September 1989, p. 5.

<sup>143</sup> Self-Determination is a legal principle which forms part of jus cogens (rule of customary law that cannot be set aside with the status of peremptory norms). With reference to Article 1, Paragraph 2 and Article 55 of the UN Charter, the practice of the UN organs has established the principle as a part of the law of the UN. See Brownlie, Ian, *Principles of Public International Law*, 4<sup>th</sup> ed., Oxford: Oxford University Press, pp. 512 and 596-599.

<sup>144</sup> See the Declaration on Principles of International Law Concerning Friendly Relations and Co-operation Among States in Accordance with the Charter of United Nations, GA Res. 2625 (XXXV), 25 UN GAOR Supp. (No.28), UN Doc A/8028 (1970). Three principles stated in the Declaration are of relevance: The first principle concerns the duty not to intervene in matters within the domestic jurisdiction of any state in accordance with the UN Charter, i.e., each state has an inalienable right to choose its political, economic, social, and cultural systems without interference in any form by another state. The second one is the principle of equal rights and self determination of peoples enshrined in the UN Charter. It is the right of all peoples to pursue their economic, social, and cultural development without external interference. Lastly, under the principle of sovereign equality of states, each state has the right freely to choose and develop its political, social, economic, and cultural system; see Evans (ed.), *Blackstone's International Law Documents*, 3<sup>rd</sup> ed., London: Blackstone Press Ltd., 1996.



themselves.<sup>145</sup> DCs pointed out that the standards currently prevailing in DCs resembled those prevalent in ICs when ICs were at a similar stage of development.<sup>146</sup> As Raghavan points out, historically, countries in the process of industrialisation always limited the scope of protection granted to foreign technologies or excluded whole areas of activity on the view that a weak technological capacity cannot take advantage of the IPR regime.<sup>147</sup> For example, on patentable subject matters, ICs had been able to exclude sectors such as pharmaceuticals on public interest, health care, and social grounds.<sup>148</sup> And the introduction of patent protection for pharmaceuticals is a fairly recent phenomenon in many ICs.<sup>149</sup> DCs argued that they should be able to adjust their IP legislation in accordance with their development needs as ICs have done at their earlier stage of development.<sup>150</sup>

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<sup>145</sup> Reichman, 1989, note 130 above, p.867.

<sup>146</sup> Some industrial countries have only recently introduced patent protection in pharmaceutical and chemicals after ensuring the development of their own domestic industry. Ringo, Frederick, 'The Trade-Related Aspects of Intellectual Property Rights Agreement in the GATT and Legal Implications for Sub-Saharan Africa', *JWT*, 28(6), 1994. Also Reichman, 1989, note 130 above.

<sup>147</sup> Raghavan, note 72 above, p. 134.

<sup>148</sup> GATT, MTN, GNG/NG11/14, 12 September 1989, p. 34.

<sup>149</sup> Patent protection for pharmaceuticals was introduced in the UK in 1949, France in 1960, Germany in 1968, Japan in 1976, Switzerland in 1977, Italy in 1978, and Spain in 1992.

<sup>150</sup> Gadbow and Gwynn, note 84 above, p.63-64 and Bradley, note 73 above, p.68-69 and 78-80. And see Maskus in support of this argument, Maskus, K.E., 'Normative Concerns in the International Protection of Intellectual Property Rights', *The World Economy*, 12, 1990, pp. 387-409. Switzerland is often quoted as an example. It was one of the original signatories to the Convention in 1883, but its Patent Act of 1888 provided a very limited scope of protection to pharmaceuticals. Because of its free access to technologies others have developed, Swiss consumers paid no increased price for new technology, thus minimised outflow of its wealth to importers and removed all the social costs of patenting. By adhering to the principle of NT under the Convention and denied patent protection to domestic nationals and foreigners, it guaranteed Swiss industries receiving NT from foreign countries and ensuring them patent profits from exports. It was not until 1907 that Switzerland amended its 1888 Act under the pressure from Germany. See Oddi, Samuel A., 'The International Patent System and Third World Development: Reality or Myth?' *Duke Law Journal*, 1987, p. 869 and Moy, Carl R., 'The History of the Patent Harmonisation Treaty: Economic Self-Interest as an Influence', *John Marshall Law Review*, 26, 1993, p. 457.

DCs take a zero-sum approach<sup>151</sup> and implicitly consider losses suffered by ICs from the absence of adequate IPP as net benefits to DCs' economies.<sup>152</sup> The accusation that some DCs have a deliberate policy to pirate and counterfeit<sup>153</sup> has been rebutted on the ground that when a country chooses not to introduce IP, there is no breach of obligations under the Convention as long as NT is implemented.<sup>154</sup> There is no such an issue as infringement of IP in countries where an IPP system is not in place.<sup>155</sup>

Concerns have been expressed of the appropriateness of subjecting IPP to the negotiation process and trading private rights against commercial advantages in the form of quid-pro-quo trade concessions. IPP policy has to balance a wide variety of elements and interests including the public interest in competition and consumer welfare.<sup>156</sup> Patent protection could play a useful and important role in an economic system constructed upon private initiative and competition;<sup>157</sup> but in a nation structured along socialist lines, foreign

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<sup>151</sup> Zero-sum approach involves the notion that one's loss is the gain of the other as opposed to positive-sum approach whereby all people involved are to gain from the participation. See Finger, Michael J. and Paula Holmes, 'Unilateral Liberalisation and the MTNs', in Finger and Olechowski (eds.), *The Uruguay Round – A Handbook for the Multilateral Trade Negotiations*, Washington, D.C.: The World Bank, 1987.

<sup>152</sup> Cottier, note 61 above, p.385.

<sup>153</sup> Gadbow and Richards, 1988a, note 71 above, pp. 12-17. But Meessen opposes to this view and pointed out that there was no apparent government collusion but private acts, see Meessen, Karl M., 'Intellectual Property Rights in International Trade', *JWTL*, 21(1), 1987, pp. 69 and 73.

<sup>154</sup> Primo Braga, 1989, note 6 above, pp. 243-264.

<sup>155</sup> *Ibid.*, p. 259 and Schumann, Gunda, 'Economic Development and Intellectual Property Protection in Southeast Asia: Korea, Taiwan, Singapore, and Thailand', in Rushing and Brown (eds.), *Intellectual Property Rights in Science and Technology and Economic Performance*, Boulder, Colorado: Westview Press, ch.9.

<sup>156</sup> Ullrich, Hanns, 'GATT: Industrial Property Protection, Fair Trade and Development', in Beier and Schriker (eds.), *GATT or WIPO? New Ways in the International Protection of Intellectual Property*, Munich: Max Planck Institute, 1989, op. cit.

<sup>157</sup> Kunz-Hallstein, Hans Peter, 'The Revision of the International System of Patent Protection in the Interest of Developing Countries', *IIC*, 10, 1979, p. 670.

technology could be acquired by the conclusion of government or private contract, or by the simple theft of foreign technology.<sup>158</sup>

The possible consequences of failure in IPP negotiations in the Uruguay Round also caused some concerns. Many believed that if no agreement was reached, ICs would seek to establish a set of IPP standards on their own. Such an agreement is likely due to the similarity among ICs' relative level of development, domestic legal systems and their existing IPP legislation.<sup>159</sup> The failure to reach an agreement would also run the risk of increasing unilateral or bilateral actions when dealing with IPP issues.<sup>160</sup> The possibility of unilateral or bilateral trade retaliation must be included in the economic analysis of the costs and benefits of IPP reform.<sup>161</sup> Instead of being exposed to unilateral or bilateral actions, Cottier believes that it is more desirable to defend one's interest based on a set of multilaterally negotiated and well-defined trade rules and principles as under GATT.<sup>162</sup> Despite the US's relative decline and its diminished power on the world scene, Low felt that the order in international trade relations would be difficult to maintain without the participation of the US and its commitment to preserve multilateralism.<sup>163</sup>

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<sup>158</sup> Lall, Sanjaya, 'The Patent System and the Transfer of Technology to LDCs', *JWTL*, 10(1), 1976, pp. 649-670.

<sup>159</sup> Kastenmeier and Beier, note 131 above, p.300. This could happen, for example, among OECD countries. See also Emmert, Frank, 'Intellectual Property in the Uruguay Round – Negotiating Strategies of the Western Industrialised Countries', *MJIL*, 11(4), 1990, p. 1397.

<sup>160</sup> In an interview on September 1986, the USTR Yuetter made it clear that the US would turn to bilateral and plurilateral arrangements if IPP issues are not included in the Uruguay Round. See Bradley, note 73 above, p. 85 and Gibbons, Sam M., 'US Trade Legislation and Intellectual Property Rights', in Walker and Bloomfield (eds.), *Intellectual Property Rights and Capital Formation in the Next Decade*, Lanham, MD.: University Press of America, 1988, p. 170.

<sup>161</sup> Primo Braga, Carlos Alberto, 'Intellectual Property Rights in NAFTA: Implications for International Trade', in Riggs and Velk (eds.), *Beyond NAFTA: An Economic, Political and Sociological Perspective*, Vancouver: The Fraser Institute, 1993, p. 107.

<sup>162</sup> Cottier, note 61 above, p. 389.

A rule-based global trading system that provides transparency and certainty is essential in an increasingly interdependent global economy<sup>164</sup> where national markets are practically border-less. The rule-based system also needs to have the built-in capability to respond to the fast changing world trading environments. Long observes that the relatively rigid system of GATT made it difficult to adapt to changes so that GATT adopted a pragmatic approach allowing governments to deviate from its provision so as to accommodate divergent national trade interests.<sup>165</sup> This pragmatism had led to the deviation from the adherence to the rule of law towards a more power-oriented approach<sup>166</sup> in dealing with trade relations. The result was that participants in the global market lost confidence in the effectiveness and validity of GATT. And it was against this macro-environment background that the Uruguay Round MTNs commenced, with its overriding objective to reform the system.

By giving the principle of reciprocity a modern interpretation and re-defining the benchmark for trade liberalisation, the US's justification for the legality of their legislation had also affected the conduct of MTNs. Its domestic trade legislation introducing IPP as one of the considerations for unilateral and bilateral retaliations signaled their commitment to take up IPP issue unilaterally with or without a TRIPS

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<sup>163</sup> Low, note 5 above, p. 140.

<sup>164</sup> Jackson, John H., 'The Crumbling Institutions of the Liberal Trade System', *JWTL*, 12(2), 1978, p. 97.

<sup>165</sup> Long, Olivier, *Law and its Limitations in the GATT Multilateral Trade System*, Dordrecht: Martinus Nijhoff Publishers, 1987, p. 22.

<sup>166</sup> According to Jackson, the power-oriented approach involves the diplomacy of asserting the power of a nation so that it can be brought to bear to win advantage in particular negotiations. See Jackson, 1978, note 164 above, p. 98.

agreement.<sup>167</sup> It exerted considerable pressure to compel CPs of GATT to persevere with TRIPS MTNs in the Uruguay Round and pushed the pace of negotiations forward.

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<sup>167</sup> Getlan, note 116 above, pp. 173-218.

## Chapter III

### GATT and TRIPS

This chapter discusses the three underlying legal principles of GATT, MFN, NT, and reciprocity, based on which the assessment is made whether GATT provides the legal framework within which a multilateral agreement on TRIPS could be achieved.

Particular attention is paid to the evolution of these legal principles in terms of how they have responded to demands from governments and business constituencies in an increasingly integrated global market.

#### 3.1 Introduction

Long, the former Director-General of GATT, comments that, when dealing with trade problems, a balance has to be struck between the legal approach and pragmatism.<sup>1</sup> It is difficult to adhere strictly to legal interpretations in the application of trade rules and principles because of the political factors involved.<sup>2</sup> He further points out that, trade policies conducted by governments often faced a conflict between their international legal obligations and the demands of national interest, and that the limitations are merely a reflection of the difficulties inherent in any attempt to regulate within a legal framework something as dynamic and fluctuating as world trade.<sup>3</sup> A trading system has to be

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<sup>1</sup> Long, Olivier, *Law and its Limitations in the GATT Multilateral Trade System*, Dordrecht: Martinus Nijhoff Publishers, 1987, pp. 61-62.

<sup>2</sup> Ibid, pp. 7-8. The Economist points out that trade liberalisation is politically demanding because it could harm focused vested interests. The Economist, December 4, 1999, p. 116.

<sup>3</sup> Long, note 1 above, pp. 7-8 and 61-62.

capable of accommodating different trading interests as what goes on in GATT almost daily.<sup>4</sup>

Supporters of the global trading system believe that GATT has built in both the pragmatic and judicial features. The pragmatic approach in the process of MTNs entails a rule-based global trading system capable of accommodating different domestic economic and political agenda. Its strict judicial pursuit of multilateral legal principles provides binding obligations and yields the transparency the business community looks for.<sup>5</sup>

The GATT system has evolved considerably since it was applied provisionally in 1947. MFN, NT, and Reciprocity have withstood the test of time. With the revised applications of these principles and the introduction of GATT-sanctioned exceptions in the consecutive rounds of MTNs, the system has responded to demands from governments and business communities in an increasingly integrated global trading environment. But faced with CPs' reduced level of tolerance with deviations from GATT provisions in recent years, the pragmatic approach of the GATT system to accommodate different national trade interests would require a rethink.

How to eliminate the disparity existing among national IP system was another challenge CPs faced in the Uruguay Round which was specific to TRIPS MTNs. GATT contains rules that allow CPs to take defensive and compensatory actions when adversely affected

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<sup>4</sup> Jackson, John H., *World Trade and the Law of GATT*, NY: The Bobbs-Merrill Co. Inc., 1969, p. 763.

<sup>5</sup> Ibid.

by domestic policies of their trading partners,<sup>6</sup> but it made no attempt to harmonise domestic policies.<sup>7</sup> Solutions needed to be found to the problem of to what extent CPs could exercise their regulatory autonomy in deciding their policies which have cross-border effects.<sup>8</sup> If the purpose of GATT is the elimination of market distortions at source, it has to consider covering domestic policies.<sup>9</sup>

### 3.2 The creation of GATT

Wilcox, in his book *A Charter for World Trade*, described the 1930s and the devastation brought by the World War II in the following terms:

“The foundations of economic liberalism were shaken by the First World War. The economy of Europe was disorganised, productive facilities were destroyed; channels of trade were broken; heavy debts were incurred. Nationalism and protectionism were stimulated by the revision of boundaries and the creation of new states. Economic and political uncertainty weakened devotion to principles that were once unquestioned. Governments assumed increasing responsibility for the direction of economic life...

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<sup>6</sup> GATT, *Trade Policies for a Better Future – The “Leutwiler Report”, The GATT and the Uruguay Round*, Dordrecht: Martinus Nijhoff Publishers, 1987 (hereinafter *The Leutwiler Report*), pp. 76-77.

<sup>7</sup> *Ibid.*

<sup>8</sup> This question has added significance in a global market where economic activities among nations are highly interdependent. See discussion in Chapter 5.1.

<sup>9</sup> See discussion in Chapter 3.3.2.

<sup>10</sup> Wilcox, Clair, *A Charter for World Trade*, NY: Arno Press, Inc., 1949, pp. 5-9.



The foundations of economic liberalism, badly shaken by the First World War, were all but demolished by the Great Depression... There was a sharp contraction in the volume of the world's trade. The attention of governments turned inward... Each for himself and the devil take the hindmost became the general rule...

Intensive economic nationalism marked the rest of the decade. Exports were forced; imports were curtailed. All of the weapons of commercial warfare were brought into play: currencies were depreciated, exports subsidised, tariffs raised, exchanges controlled, quotas imposed, and discrimination practised through preferential systems and barter deals. Each nation sought to sell much and buy little. A vicious restrictionism produced a further deterioration in world trade.”<sup>10</sup>

During that period of time, governments engaged in beggar-thy-neighbour policies, attempting to obtain economic advantages at the expense of others by restricting imports and subsidising exports.<sup>11</sup> Consequently, it triggered off retaliatory actions among nations and depressed the world economy. It was against this background that the three institutions of Brentton Woods were conceived to rebuild the post-war international order: the International Trade Organisation (ITO) for trade, the International Monetary Fund (IMF) for finance, and the World Bank for reconstruction.<sup>12</sup>

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<sup>11</sup> Rooseler, Frieder, 'The Scope, Limits, and Function of the GATT Legal System', in GATT, *Trade Policies for a Better Future – The "Leutwiler Report", The GATT and the Uruguay Round*, Dordrecht: Martinus Nijhoff Publishers, 1987, p. 84.

<sup>12</sup> It was called International Bank for Reconstruction and Development when it was first established.

GATT, when first drafted, was intended to be a multilateral treaty administered by the ITO, designed to facilitate multilateral negotiations on the reduction of tariffs and to secure the liberalisation and expansion of world trade. The ITO never came into being mainly due to the failure of the United States government to seek congressional approval of the Havana Charter establishing the ITO.<sup>13</sup> Since January 1948, GATT has been applied through a "Protocol of Provisional Application".<sup>14</sup> Legally, GATT has established a consensual framework of rules and principles for the conduct of world trade.<sup>15</sup> Politically, GATT has provided a framework of self-imposed constraints that enables CPs to regulate conflicts of interests among states, and to defend against protectionist lobbies from competing importers and interest groups within one's own country. Through time, GATT has evolved and adopted salient functions of an organisation for consultation, negotiation, and the application of rules and principles of international trade law, and governments have turned to GATT as a forum to handle trade disputes, although the drawbacks of its not being an organisation are well recognised.<sup>16</sup>

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<sup>13</sup> For the origins of GATT 1947, see Jackson, John H., *Restructuring the GATT System*, London: Royal Institute of International Affairs, 1990, pp. 9-15, and Stewart, Terence P. (ed.), *The GATT Uruguay Round: A Negotiating History (1986-1992)*, vol. 2, Deventer: Kluwer Law and Taxation Publishers, 1993, pp. 1986-1990.

<sup>14</sup> It ended with the establishment of the WTO in January 1995.

<sup>15</sup> The GATT system consists of a series of over one hundred agreements including those which amended the articles of the General Agreement, those which admitted new members, the agreements for the revision of and addition to the tariff schedules, and the side agreements and understanding completed in the Tokyo Round. Deardorff, Alan V. and Robert M. Stern, *Multilateral Trade Negotiations and Preferential Trading Arrangements*, in Deardorff and Stern (eds.), *Analytical and Negotiating Issues in the Global Trading System*, Ann Arbor: The Michigan University Press, 1994, ch. 2, p.29 and Jackson, 1990, note 13 above, p. 27.

<sup>16</sup> The functioning of the GATT system was one of the agenda items for the Uruguay Round MTNs. As a result of the negotiations in the Functioning of the GATT System Negotiating Group (FOGS) in the Uruguay Round, the World Trade Organisation was established which came into force on January 1, 1995. The WTO transformed the GATT into a full-fledged world trade organisation. It provides an institutional framework for the administration and implementation of the agreements reached in the Uruguay Round. The constitutional flaws of GATT system were therefore rectified. See UNCTAD, *The Outcome of the*

As stated in the preamble of GATT, the objectives of GATT are:

“to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, developing the full use of the resources of the world and expanding the production and exchange of goods”.

It was to secure the liberalisation and expansion of world trade in tangible goods <sup>17</sup> and to further the economic and social development of member countries. By entering into reciprocal and mutually advantageous arrangements, the objectives would be achieved by gradually removing and eliminating tariffs <sup>18</sup> and other barriers to trade and discriminatory treatments in international commerce. Tariff barriers were to be reduced through MTNs on the basis of reciprocity and MFN. Non-Tariff barriers (NTBs) were to be reduced based on the principle of good faith as manifested through the principle of non-discrimination and have objectivity and transparency in the administration of government regulations.

The two principles of non-discrimination, namely MFN and NT, and reciprocity are the cornerstones of GATT. They were conceived by the post-war planners in the US and

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*Uruguay Round: An Initial Assessment – Supporting Papers to the Trade and Development Report 1994*, NY: UN, 1994, ch. 1, Stewart (ed.), note 13 above, pp. 1943-1948 and Jackson, 1990, note 13 above, Part VIII.

<sup>17</sup> Havana Charter had an entire chapter (Chapter V) devoted to restrictive business practices that included provisions relating to rights under patents, trademarks, and copyrights, but GATT 1947 only deals with trade in tangible goods. See Jackson, 1969, note 4 above, p. 511. It excludes trade in intangible technology and services and foreign direct investment.

<sup>18</sup> Tariffs are custom duties on imports, the only form of protection permitted by GATT (Article I).

Britain<sup>19</sup> as the vehicle to eradicate the discriminatory system that dominated the international trade relations at that time. Reinforced by the application of reciprocity, MFN and NT were intended to help ensure that market access and equal competition opportunity commitments were implemented and maintained.<sup>20</sup>

### 3.3 GATT principles discussed

#### 3.3.1 The principle of Most-Favoured-Nation Treatment (MFN)

MFN<sup>21</sup> as stated in Article I of GATT requires each CP to grant to every other CP the most favourable treatment which it grants to any country with respect to imports and exports of products.<sup>22</sup> It deals with issues of external discrimination. This principle of non-discrimination confers on CPs equal rights of market access irrespective of their size and bargaining power. It was conceived, at the time the General Agreement was drafted, as the best means of ensuring equality of competition within an economic framework inspired by the ideas of free trade.<sup>23</sup>

When GATT was first drafted, MFN applied unconditionally, which meant that CPs are under the obligation to grant equivalent preferential treatments to other CPs without receiving anything in return, and that each CP accords access to its market independently

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<sup>19</sup> It was mainly the US and the UK which laid the ground work for the 1946-1948 GATT/ITO negotiations. See discussion in Hudec, Robert E., *The GATT Legal System and World Trade Diplomacy*, 2<sup>nd</sup> ed., New Hampshire: Butterworth Legal Publishers, 1990, p. 9.

<sup>20</sup> Hoekman, Bernard and Michael Kosteci, *The Political Economy of the World Trading System from GATT to WTO*, Oxford: Oxford University Press, 1995, p. 27.

<sup>21</sup> Or it is referred to by the US as the principle of Normal Trade Relations.

<sup>22</sup> Jackson, 1990, note 13 above, p.106.

<sup>23</sup> Espiell, Hector Gros, 'The Most-Favoured-Nation Clause – Its Present significance in GATT', *JWTL*, 5(1), 1971, p. 35.

of the domestic policies of its trading partners.<sup>24</sup> Amid concerns over the problems of free riders and foot draggers,<sup>25</sup> a code approach was introduced in the Tokyo Round in dealing with agreements relating to NTBs. It constitutes a departure from the unconditional MFN and introduced the element of discrimination in the GATT system in so far as only the signatories to the agreement can benefit from it.

The pragmatic aspect of the GATT system has seen several exceptions to the MFN sanctioned by GATT. They include the Waiver provision (Article XXV), the Generalised System of Preference, Customs Union, Free Trade Area, and interim agreement (Article XXIV), Balance-of-Payment provisions (Article XII), the escape clause (Article XIX), national security exceptions (Articles XX and XXI), and grandfather clause exceptions derived from protocols of accession.<sup>26</sup> The waiver provision, the GSP and the code approach will be discussed here for their particular relevance.

**The waiver provision (Article XXV:5) – This provision legalises a CP's request to derogate from any obligations imposed by GATT**

“..in exceptional circumstances not elsewhere provided for in the agreement so long as the necessary votes are obtained.”

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<sup>24</sup> Rooseler, Frieder, 'Diverging Domestic Policies and Multilateral Trade Integration', in Bhagwati and Hudec (eds.), *Fair Trade and Harmonisation*, Vol. 2: Legal Analysis, Massachusetts: The MIT Press, 1996, p. 31.

<sup>25</sup> A foot dragger refers to a country that is influential enough that other countries are reluctant to subscribe to an agreement and accord the MFN without its participation. It has the effect of strengthening the bargaining power of the influential country.

<sup>26</sup> For detailed discussion of these exceptions, see Jackson, 1969, note 4 above.

It has been utilised in some controversial cases such as the US's obtaining a waiver in its agricultural products in 1955<sup>27</sup> which not only put trade liberalisation of agricultural sector in jeopardy but also put to the test the effectiveness of GATT in regulating trade in agricultural products. The other two commonly known examples are the waiver granted in 1971 to DCs to confer preferential treatment on one another, and the operation of the GSP between 1971 and 1981.

The waiver provision is subject to broad interpretation. "Exceptional circumstances" is not defined, and there is no stipulation of rules or principles under which a waiver shall or shall not be granted. Furthermore, the absence of an expiration date has led a number of waivers to becoming an almost permanent feature of the GATT system.<sup>28</sup> All these criticisms were met with rectification in the Uruguay Round MTNs. The Understanding<sup>29</sup> on the Interpretation of Article XXV:5 reached not only fixes expiry dates for the existing waivers but also requests the member states who apply for a waiver or for an extension of an existing waiver to describe the measures, the specific policy objectives, and the reasons for utilising the waiver provision.

**Generalised System of Preference (GSP)** – The GSP is a scheme that authorises ICs to derogate from MFN and provide differential and more favourable treatments (DMFT) to DCs in regard to, among others:

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<sup>27</sup> The 1955 waiver was applied in order to implement Section 22 of the US Agricultural Adjustment Act of 1933 which deals with imposition of import fees and quotas. GATT, BISD 3<sup>rd</sup> Supp. 1955, p. 32.

<sup>28</sup> GATT, MTN/GNG/NG7/W/69, 23 February 1990.

2. (a) preferential tariff treatment accorded by developed contracting parties to products originating in developing countries in accordance with the Generalised System of Preferences;

(b) differential and more favourable treatment with respect to the provisions of the General Agreement concerning non-tariff measures governed by the provisions of instruments multilaterally negotiated under the auspices of the GATT...<sup>30</sup>

The GSP was initially adopted as a policy by the United Nations Conference on Trade and Development (UNCTAD)<sup>31</sup> in 1968<sup>32</sup> as the result of a general movement toward more favourable treatment to DCs in aspects of economic relations. This movement gained momentum in the 1960s with the recognition that preferences should be accorded because of the differences that existed in the level of development among CPs, which resulted in economic inequality that could only be corrected through unequal treatment.<sup>33</sup>

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<sup>29</sup> "Understanding" is used to designate a statement to set forth an interpretation of a treaty provision. It is not intended to alter or limit the effect of a treaty. See D'Amato, Anthony and Doris Estelle Long (eds.), *International Intellectual Property Law*, The Hague: Kluwer Law International, 1997, p. 224.

<sup>30</sup> GATT, BISD 26<sup>th</sup> Supp., 1980, p. 202, paragraph 2 of the 1979 Decision. Also GATT, *The Tokyo Round of Multilateral Trade Negotiation, Report by the Director-General of GATT*, Geneva: GATT, 1979, p.149.

<sup>31</sup> UNCTAD was set up by UN General Assembly in 1964 and became an organ of the General Assembly in 1995 (GA resolution 1995 (XIX) of 30 December 1964, as amended). Its major functions are to promote international trade between countries at different stages of development, between DCs and between countries with different systems of economic and social organisation, and to formulate principles and policies on international trade and related problems of economic development. UNCTAD Website, <http://www.unctad.org>, 29 January, 1999.

<sup>32</sup> The UNCTAD II meeting was held in New Delhi, see UNCTAD, TD/B/330, 1968, Part I.

<sup>33</sup> Espiell, note 23 above, p. 36.

Granting DMFT to DCs was therefore viewed as a means of overcoming underdevelopment and economic backwardness.<sup>34</sup>

The GSP was incorporated into the GATT system by the Decision of CONTRACTING PARTIES of 25 June 1971<sup>35</sup> which made it possible for ICs to rely on the waiver provision to deviate from unconditional MFN and to grant GSP in favour of DCs for an initial period of ten years. In 1979, as a part of the outcome of the Tokyo Round of MTNs, Another Decision was adopted<sup>36</sup> which gave GSP a legal basis for implementation in the GATT system.<sup>37</sup> Under the scheme, a beneficiary country is selected according to the criteria of the donor country.<sup>38</sup> It is unilateral and temporary in nature because ICs are not obliged to offer any concessions and they can abandon the scheme at will. It does not establish a legal obligation,<sup>39</sup> but it was given a contractual

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<sup>34</sup> Yusuf, Abdulqawi A., 'Differential and More Favourable Treatment – The GATT Enabling Clause', *JWTL*, 14(5), 1980, pp.488-507.

<sup>35</sup> GATT, BISD 18<sup>th</sup> Supp., 1972, p. 26.

<sup>36</sup> The decision of 28 November 1979 was titled "Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries" (commonly referred to as "the enabling clause"). GATT, BISD 26th Supp., 1980, p. 203.

<sup>37</sup> *Ibid.* Paragraph 5 of the 1979 Decision reads as followed:

"The developed countries do not expect reciprocity for commitments made by them in trade negotiations to reduce or remove tariffs and other barriers to the trade of developing countries, i.e., the developed countries do not expect the developing countries, in the course of trade negotiations, to make contribution which are inconsistent with their individual development, financial and trade needs. Developed contracting parties shall therefore not seek, neither shall less-developed contracting parties be required to make concessions that are inconsistent with the latter's development, financial and trade needs."

<sup>38</sup> It is an arbitrary self-selection process under the GATT to decide whether a CP is a DC or not. The selection or identification of least LDCs under the GATT follows the UN definition.

<sup>39</sup> Long, note 1 above, p. 102.



status that ICs prefer in the form of a permissive clause as an exception to MFN<sup>40</sup> which fell short of the demand from DCs to amend the GATT.

The impact of GSP had been minimised after several rounds of MTNs which have resulted in significant reduction of tariffs. The necessity and the format of conferring differential and more favourable treatment were much discussed in view of NIEs' playing increasingly active roles in the world trading system following their progressive improvement in trade and their competitiveness in the world market.

The GSP was challenged by the concept of "graduation" introduced by ICs during the Tokyo Round which refers to the removal from the GSP of a beneficiary country or specific products from a beneficiary country which deemed to have achieved a degree of competitiveness in the world market. It was a call for the fuller participation of DCs and the termination of DMFT when their economic status had improved. As stated in the Paragraph 7 of the 1979 Decision:<sup>41</sup>

“ Less-developed contracting parties expect that their capacity to make contributions or negotiated concessions or take other mutually agreed action under the provisions and procedures of the general agreement would improve with the progressive development of their economies and improvement in their trade situation and they would accordingly expect to participate more fully in the framework of rights and obligations under the

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<sup>40</sup> Yusuf, 1980, note 34 above, p.506.

<sup>41</sup> GATT, 1980, note 36 above, p. 203.

general agreement”.

The call for fuller participation of LDCs was also reiterated as one of the general principles governing MTNs in the Punta del Este Declaration launching the Uruguay Round MTNs.<sup>42</sup> The Ministerial Declaration further committed CPs to apply DMFT in the Uruguay Round MTNs. But the political climate of the 1980s was such that CPs became less tolerant toward any departure from the legal rules and principles of GATT, and that other alternatives might have to be found in substitution of any scheme that might allow CPs to enjoy the benefits of MTNs without taking up corresponding obligations.

**The Code Approach and NTBs** – As tariff escalation was blamed as one of the major causes of the great depression before the World War II, the removal and reduction of tariff barriers became the focus of negotiations in the first six major rounds of MTNs conducted under the auspices of the GATT.<sup>43</sup> With the impressive accomplishment in tariff reductions in these rounds,<sup>44</sup> NTBs became alternative measures for governments to protect domestic economic interests and to counter competition from imports in the

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<sup>42</sup> The Punta del Este Declaration. See GATT, MIN.DEC, 20 September 1986.

<sup>43</sup> The six major rounds are Geneva Round (1947), Annecy Round (1949), Torquay Round (1950), Geneva Round (1956), Dillon Round (1961), Kennedy Round (1962-1967). Kennedy Round was the first round of MTNs that discussed NTBs in the Anti-Dumping Code with very little success. The seventh round of MTNs, the Tokyo Round, was the first in placing NTBs at the centre of MTNs.

<sup>44</sup> From an average tariff of 40% in the mid-1930s before the creation of GATT to 4%-8% on the manufactured products of ICs after the Tokyo Round. Olechowski, 'Andrzej, Non-tariff Barriers to Trade', in Finger and Olechowski (eds.), *The Uruguay Round: A Handbook for the Multilateral Trade Negotiations*, Washington, D.C.: The World Bank, 1987, p. 122.

1970s.<sup>45</sup> They often appeared to be legitimate domestic policy but, when implemented, they could have significant market distortion effects.<sup>46</sup>

The emphasis of MTNs on NTBs<sup>47</sup> distinguished the Tokyo Round from earlier trade rounds. In the absence of detailed rules for the conduct of negotiations on NTBs, a Code approach was introduced to deal with agreements reached on NTBs. The Code (or referred to as the side agreement) forms a separate legal instrument and exists side by side with the General Agreement.<sup>48</sup> The existing GATT provisions were neither amended nor were new provisions added to accommodate the side agreement.<sup>49</sup> Each Code has established its own institutional framework to facilitate regular meetings of the signatories, and the procedures for handling disputes and regular exchanges of information.

The code approach was introduced by the US, with the support of the EC, to eliminate the problems of free-riding and non-participation by DCs<sup>50</sup> Under the Code, only the signatories who submit to the discipline could enjoy the benefits of the subscribed

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<sup>45</sup> By 1973, an inventory of 800 NTBs, listed by countries, was established by cps for dealing with notification in the Tokyo Round from countries whose exports were adversely affected by their use. See discussion in Long, note 1 above, p. 74 and Ray, Edward J., 'Protection of Manufacturers in the US Protectionism', in Greenaway, Hine, O'Brien, and Thornton (eds.), *Global Protectionism*, Hampshire: MacMillan Academic and Professional Ltd., 1991, pp. 13-17. By 1982, there remained as many as over 600 NTBs included in GATT Inventory List, see GATT, Focus, #11, 1982.

<sup>46</sup> Stewart (ed.), note 13 above, p.707.

<sup>47</sup> It involved a process of identifying negotiable NTBs from the GATT Inventory List of NTBs. See discussion in Nau, Henry R., 'Bargaining in the Uruguay Round', in Finger and Olechowski (eds.), *The Uruguay Round: A Handbook for the Multilateral Trade Negotiations*, Washington, D.C.: The World Bank, 1987, p. 76 and GATT, 1979, note 30 above, pp. 49-87.

<sup>48</sup> Long, note 1 above, pp. 26-28.

<sup>49</sup> Six codes were agreed in the Tokyo Round. They relate to government procurement, technical barriers to trade, import licensing, customs valuation, anti-dumping, and subsidies and countervailing duty measures. Code-conditionality was applied only in the subsidies code and the code on government procurement.

agreement. This approach is described by Jackson as code-conditionality,<sup>51</sup> which constitutes a departure from unconditional MFN,<sup>52</sup> but is different from conditional MFN. Jackson explained that, under conditional MFN, when country A grants a privilege to country C while owing MFN to country B, country A must grant the equivalent privilege to country B but only after country B has given country A some reciprocal privilege.<sup>53</sup>

For a departure from unconditional MFN to be GATT-legal, amending the general agreement was one of the options. Any amendment to MFN requires unanimity among CPs, which is very difficult to reach.<sup>54</sup> Furthermore, some felt that the code-approach seemed a feasible alternative taking into consideration the diversified nature of NTBs. NTBs are erected for different purposes by national governments ranging from national security to infant industry protection. The mechanism of MTNs becomes burdensome when it is difficult to draw uniformity among these non-standard government measures.<sup>55</sup> It is not at all an easy task to identify the tariff equivalent value of NTBs and conversion factors in the exercise of ensuring the mutuality of concession.<sup>56</sup>

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<sup>50</sup> Hudec, 1990, note 19 above, p. 129.

<sup>51</sup> Jackson, *The World Trading System – Law and Policy of International Economic Relations*, Massachusetts: The MIT Press, 1992, p. 137.

<sup>52</sup> Long, note 1 above, p.30.

<sup>53</sup> Ibid.

<sup>54</sup> Amendments to Article II (Schedules of Concessions) and Article XXX (Amendments) require unanimity. Amendments to other provisions of GATT require a two-third majority (Article XXVI), and as the case may be, the two-third majority has to constitute 50 per cent or more of the CPs.

<sup>55</sup> Stern, Robert and Hoekman, Bernard, 'The Code Approach', in Finger and Olechowski (eds.), *The Uruguay Round - A Handbook on the Multilateral Trade Negotiations*, Washington, D.C.: The World Bank, 1987.

<sup>56</sup> Olechowski, note 44 above, p. 126.

The elimination or removal of trade distortions caused by NTBs in the form of inadequate and ineffective IPP was the focal point of TRIPS MTNs in the Uruguay Round. Although the existing international Conventions dealing with IP do not contain MFN, the major trading nations such as the US and the EEC proposed the adoption of conditional MFN.<sup>57</sup> Many other nations called for unconditional MFN to be applied to all agreements<sup>58</sup> in view of the US and some other ICs' demand of reciprocal market access concession as a condition for access to their markets. They believed that the unconditional nature of MFN would limit the possibility of GATT CPs to use the threat of discriminatory withdrawal of market access to induce other CPs to accept new commitments which affect their domestic policies, or to use them for bargaining purposes.<sup>59</sup> Furthermore, the application of unconditional MFN might make bilateral arrangement less attractive because any advantage obtained from bilateral negotiations have to be passed on to all other CPs. In addition, the application of unconditional MFN coupled with the introduction of technical or other forms of assistance<sup>60</sup> in lieu of the differential and more favourable treatment DCs enjoyed under the GATT system was seen as the way forward to equip DCs to fulfil their treaty obligations in order to bring

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<sup>57</sup> See GATT, MTN.GNG/NG11/W/70, 11 May 1990, Draft Agreement on Trade-Related Aspects of Intellectual Property Rights: Communication by the US, GATT, MTN.GNG/NG11/W/68, 29 March 1990, and Cottier, 'The Prospects for Intellectual Property in GATT', *CMLR*, 28, 1991, p. 300. According to Cottier, the EEC advocated conditional MFN because it wished to reserve IPP as an area for bilateral preferential treatment to selected countries.

<sup>58</sup> The call came toward the end of the Uruguay Round when free-rider was brought up as an issue. See Hudec, *Enforcing International Trade Law – The Evolution of the Modern GATT Legal System*, New Hampshire: Butterworth Legal Publishers, 1993, p. 123.

<sup>59</sup> Roessler, 1996, note 24 above, p. 53.

<sup>60</sup> Kastenmiere Robert W. and David Beier, 'International Trade and Intellectual Property: Promise, Risks, and Reality', *Vand JTL*, 22(2), 1989, p. 306.

DCs in from the fringe of the international trading system by participating more fully in the mainstream.<sup>61</sup>

### 3.3.2 The principle of National Treatment (NT)

NT as stated in Article III(4) of GATT<sup>62</sup> obliges CPs to apply domestic law in a non-discriminatory manner and accord no less favourable treatment to imported products as it has conferred on like products of domestic origin. It is not only to prevent domestic taxes and government regulations from being used “so as to afford protection to domestic productions”,<sup>63</sup> but is relevant to the reduction and elimination of NTBs operating within the territory of the importing country.<sup>64</sup> Its application is therefore to ensure “effective equality of opportunity”<sup>65</sup> for imported products to compete once the foreign products have crossed the border for legitimate sale in the domestic market. In a situation when

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<sup>61</sup> As elaborated in both the 1979 Decision (see note 36 above) and the Punta del Este Declaration (see note 42 above).

<sup>62</sup> Article III(4) of GATT states that:

“The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements ...”

<sup>63</sup> Article III (1) of GATT.

<sup>64</sup> NT traditionally confines its application to the issue of internal discrimination. But in the case of economic integration arrangement such as the European Union, NT applies at the border as well as in the territory of each member state.

<sup>65</sup> A 1990 Panel Report concerning the definition of words “treatment no less favourable” in Article III(4) states that:

“... The words ‘treatment no less favourable’ in paragraph 4 call for effective equality of opportunities for imported products in respect of the application of laws, regulations and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use of products. This clearly sets a minimum permissible standard as a basis. On the one hand, contracting parties may apply to imported products different formal legal requirements if doing so would accord imported products more favourable treatment. On the other hand, it also has to be recognised that there may be cases where application of formally identical legal provisions would in practice accord less favourable treatment to imported products and a contracting party might thus have to apply different legal provisions to imported products to ensure that the treatment accorded them is in fact no less favourable.”

imported products are subject to different legal provisions from those applying to products of national origin, it in itself is not conclusive to establish inconsistency with Article III:4. An assessment has to be made whether differences in the legal provision in practice discriminate against imported products.<sup>66</sup> And the onus of proof is on the contracting party applying differential treatment to prove that it is not the case.<sup>67</sup>

NT is also the pivotal principle of the Paris Convention (the Convention).<sup>68</sup> Its definition is substantially the same as that in the GATT. The difference is that NT provides no less favourable property protection to IP holders, legal or nature, under the Convention, while it deals with goods under the GATT system. Its application under the Convention does not take into account disparity among member states domestic legislation, i. e., it is not a concern whether a host country offers similar or equivalent protection to its nationals as in the home country. Under these circumstances, MNCs have to be content with the treatment offered in the host country even if the standard might be much lower than in the home country. The principle of state sovereignty is thus observed and the states to the Convention mutually recognise each other's system.<sup>69</sup> This comity approach recognises

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See United States – Section 337 of the Tariff Act of 1930, GATT, BISD 36<sup>th</sup> Supp., 1990, p. 345.

<sup>66</sup> Ibid.

<sup>67</sup> Ibid.

<sup>68</sup> Article 2 of the Paris Convention.

<sup>69</sup> Ullrich, Hanns, 'GATT: Industrial Property Protection, Fair Trade and Development', in Beier and Schriker (eds.), *GATT or WIPO? New Ways in the International protection of Intellectual property*, Munich: Max Planck Institute, 1989, p. 138.

each country's laws and judicial decisions <sup>70</sup> but has its limitation on eliminating the disparity existed among national laws. <sup>71</sup>

Any suggestions of harmonising IP standard among nations <sup>72</sup> could lead to the curtailment of regulatory autonomy, which the GATT system had been reluctant to allow. <sup>73</sup> GATT contains rules which allow cps to take defensive and compensatory

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<sup>70</sup> Dhanjee, Rajan and Laurence Boisson de Chazournes, 'Trade Related Aspects of Intellectual Property Rights (TRIPS): Objectives, Approaches and Basic Principles of the GATT and of Intellectual Property Convention', *JWT*, 24, 1990, p. 6, and Stern, Richard H., 'Intellectual Property', in Finger and Olechowski (eds.), *A Handbook for the Multilateral Trade Negotiations*, Washington, D.C.: The World Bank, 1987, pp. 198-206.

<sup>71</sup> Stern, note 70 above, p. 205, and Primo Braga, Carlos, 'Trade Related Intellectual Property Issues: The Uruguay Round Agreement and its Economic Implication', in Martin and Winters (eds.), *The Uruguay Round and the Developing Countries*, Cambridge: Cambridge University press, 1996, p. 342.

<sup>72</sup> The US proposed the code approach with the obligation of applying same domestic IPP standard among the signatories. See Ullrich, note 69 above, p. 132.

<sup>73</sup> Two GATT panel reports could provide illustration as to how GATT would deal with the question of regulatory autonomy. In the GATT Panel Report (United States – Measures Affecting Alcohol and Malt Beverage, GATT, BISD 39<sup>th</sup> Supp., 1993.) concerning the definition of "like products" in Article III:4, the panel stated that:

"...The Panel recognise that the treatment of imported and domestic products as like products under Article III may have significant implication ... for the regulatory autonomy of contracting parties with respect to their international tax laws and regulations... In the view of the Panel, it is imperative that the like product determination in the context of Article III be made in such a way that it does not unnecessarily infringe upon the regulatory authority and domestic policy option of contracting parties."

Another 1993 Panel Report examining Article III: 4 relates to the US' restrictions on imports of tuna from Mexico which permit fishing methods endangering dolphins (United States -- Restrictions on Imports of Tuna, GATT, BISD 39<sup>th</sup> Supp., 1993.) The Panel stated that:

"Article III calls for a comparison of the treatment of imported tuna as a product with that of domestic tuna as a product. Regulations governing the taking of dolphins incidental to the taking of tuna could not possibly affect tuna as a product. Article III:4 therefore obliges the United States to accord treatment to Mexican tuna no less favourable than that accorded to United States tuna, whether or not the incidental taking of dolphin by Mexican vessels corresponds to that of United States vessels."

The Panel rejected the US's justification based on Article XX(b), which exempts CPs from the obligations under GATT "measures...necessary to protect human, animal, or plant life or health" and stated that:

"..It seemed evident to the Panel that, if the Contracting Parties were to permit import restrictions in response to differences in environmental policies under the General Agreement, they would need to impose limits on the range of policy differences justifying such response and to develop criteria so as to prevent abuse. If the Contracting Parties were to decide to permit trade measures of this type in particular circumstances it would therefore be preferable for them to do so not by interpreting Article XX, but by amending or supplementing the provisions of the General Agreement or waiving obligation thereunder."



actions when their trading interests are adversely affected by domestic policies of their trading partners,<sup>74</sup> but it made no attempt to harmonise domestic policies when dealing with tariff or non-tariff measures.<sup>75</sup> Furthermore, there have been no provisions in the General Agreement that deal with harmonisation of domestic policies, and no effort had ever been made to do so. CPs had retained freedom as regards their domestic trade policies and they have been reluctant to accept any specific rules that go beyond border measures.<sup>76</sup>

The issue of harmonisation was a challenge CPs faced in the TRIPS MTNs. It touches upon the sensitive issue of national sovereignty. The respect for sovereignty and the principle of territoriality are closely linked, which underpin the system of IPP under the Convention. It is this respect for state sovereignty which gives effect to the territorial nature of patent protection. If the objective of the TRIPS MTNs is to eliminate at source trade distortions caused by disharmony of national IP systems, a multilateral agreement covering domestic policies must be considered.<sup>77</sup> The ability of governments to determine their national policies within their own territory would invariably be affected if the obligation of NT is to be fully complied with.<sup>78</sup>

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In this case, the Panel did not allow the US to apply import restrictions to force Mexico to change their domestic policies. It resisted the pressure from the US to apply GATT provisions in such a way to offset differences in domestic policies and affirmed CPs' regulatory autonomy.

<sup>74</sup> The Leutwiler Report, note 6 above, pp. 76-77.

<sup>75</sup> Ibid.

<sup>76</sup> Ibid., p. 76.

<sup>77</sup> Ibid.

<sup>78</sup> Hart, Michael M., 'The WTO and the Political Economy of Globalisation'. *JWT*, 31(5), 1997, p. 38, and Jackson, 1992, note 51 above, p. 189.

### 3.3.3 Reciprocity

Reciprocity is pivotal in the removal and elimination of trade barriers under GATT. As stated in Article XXVIII<sup>bis</sup>:1:

“... negotiations on a reciprocal and mutually advantageous basis, directed to the substantial reduction of the general level of tariffs and other charges on imports and exports ... are of great importance to the expansion of international trade...”

The traditional concept of reciprocity in GATT applies through mutually accepted tariff and non-tariff concessions across negotiated sectors based on an overall balance of rights and obligations. It serves to limit the scope for free-riding that may arise from the application of unconditional MFN in a multilateral setting.<sup>79</sup> The mutuality of concession suggests fairness, which makes adjustment to trade liberalisation potentially more acceptable to domestic politicians who oppose such changes.<sup>80</sup> And reciprocal trade liberalisation provides a political counterweight when governments are faced with oppositions from industries negatively affected as political supports could be expected from industries benefiting from such a policy.<sup>81</sup>

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<sup>79</sup> Hoekman and Kostecki, note 20 above, p. 27.

<sup>80</sup> Roessler, 1987, note 11 above, p. 83 and Jackson, 1992, note 51 above, p. 125.

<sup>81</sup> Ibid.

Reciprocity is not defined in GATT, and there are conflicting arguments whether it is a legal principle.<sup>82</sup> As stated by Arthur Dunkel,<sup>83</sup> the former Director-General of GATT: “Reciprocity cannot be determined exactly; it can only be agreed upon.”<sup>84</sup> According to Jackson, GATT does not require reciprocity but the practice in GATT among the major negotiation parties for tariff reductions was always to seek reciprocity.<sup>85</sup> Espiell comments that the principle of reciprocity is implicit in GATT and that the General Agreement is founded de facto on this principle applicable to the granting of trade concessions when substantially equivalent advantages are exchanged on a reciprocal basis.<sup>86</sup>

Historically, reciprocity is an instrument for bilateral negotiations.<sup>87</sup> The basic assumption underlying this principle is the equal bargaining power between negotiating parties. It would be a concept difficult to apply in a multilateral setting if the parties involved are of unequal bargaining power. Khan observes that the assumption of economic equality did have its validity in the early stages of GATT when the majority of its CPs were ICs.<sup>88</sup> But this assumption was later proven to be dubious when more and more DCs joined the GATT in the 1950s.

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<sup>82</sup> See Hudec, Robert H., *Developing Countries in the GATT Legal System*, London: Trade Policy Research Centre, 1987.

<sup>83</sup> Arthur Dunkel was the Director General of GATT from 1980-1993.

<sup>84</sup> GATT, Press Release no. 1312, 5 March, 1982.

<sup>85</sup> Jackson, 1992, note 51 above, p. 123.

<sup>86</sup> Espiell, note 23 above, p. 36.

<sup>87</sup> The concept of reciprocity in GATT was introduced by the US based on their Reciprocal Trade Agreements Act of 1934. In the 1934 Act, the US president was authorised to negotiate reciprocal reduction of tariffs mostly on bilateral basis with the aim to improve market access and increase exports, see Winters, ‘Reciprocity’, in Finger and Olechowski (eds.), *The Uruguay Round: A Handbook for the Multilateral Trade Negotiations*, Washington D.C.: The World Bank, 1987.

<sup>88</sup> Khan, K. R., ‘International Law of Development and the Law of the GATT’, in Snyder and Slinn (eds.), *International Law of Development: Comparative Perspectives*, Abingdon: Professional Books, 1987. The twenty three founding members of GATT 1947 were: Australia, Belgium, Brazil, Burma, Canada, Ceylon,

DCs were of the view that they were placed in a disadvantaged position in reciprocal trade negotiations. Depressed prices and demand for primary commodities relative to industrial products in the late 1950s<sup>89</sup> highlighted the intrinsic weakness of DCs' economic dependence on primary commodities such as agricultural products and raw materials as their major export interests.<sup>90</sup> The virtual exclusion of these products from GATT MTNs had been seen as protectionist measures adopted by ICs and legitimised by GATT to the detriment of DCs.<sup>91</sup>

It was not until 1958 that, for the first time, the Haberler Report documented the fact that DCs had failed to benefit from the tariff reductions and that DMFT were necessary to redress the balance which could not be achieved by the normal operation of trading rules alone. The response from CPs was the adoption of Part IV of GATT entitled "Trade and Development" which came into force in June 1966.<sup>92</sup> The adoption of Part IV resulted

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Chile, China, Cuba, Czechoslovakia, France, India, Lebanon, Luxembourg, Netherlands, New Zealand, Norway, Pakistan, Southern Rhodesia, Syria, South Africa, United Kingdom, and the United States.

<sup>89</sup> The Haberler Report noted that:

"..since the end of 1955, and leaving aside the effects of the Suez crisis, the slowing down in economic activity in North America and Western Europe has given rise to an average decline in the prices of primary products which in early 1958 reached five per cent. Its impact upon the position of non-industrial countries taken as a whole is aggravated by the simultaneous rise—by about six per cent—in the prices of manufactured goods."

See GATT, *Trend in International Trade (The Haberler Report)* (hereinafter The Haberler Report), Geneva: GATT, 1958, pp.3, 6, and 189-230. For further discussion of the report, see Jackson, 1969, note 4 above, ch. 25.4.

<sup>90</sup> Barry Jones, R. J., *Globalisation and Interdependence in the International Political Economy*, London: Pinter Publishers, 1995.

<sup>91</sup> The Haberler Report had highlighted the problem of agricultural protectionism of ICs as one of the contributory factors to DCs' failure to develop international trade. The Report was commissioned by the Ministers in the 12<sup>th</sup> Ministerial Meeting in 1957. See The Haberler Report, note 89 above.

<sup>92</sup> Part IV was prepared by a Committee on the Legal and Institutional Framework of GATT in Relation to Less-Developed Countries, and was adopted as an amendment to the GATT articles for the cps who had accepted it and signed up to a 'Declaration De Facto Implementation', Jackson, note 4 above, p.646.

in the amendment of the basic principle of reciprocity and introduced the concept of non-reciprocity into the GATT system. As a result, ICs would no longer expect reciprocity for commitments they made in trade negotiations to reduce or remove tariffs and other barriers to the trade of less developed CPs.<sup>93</sup>

Criteria?

There was controversy relating to the nature and legal effects of Part IV. The prevailing view in the western countries was that it did not create any new legal obligation<sup>94</sup> but simply put an economic and political agenda for future negotiations in legal terminology.<sup>95</sup> On the other hand, the Development School advocated a functional approach recognising that the provisions of Part IV did not create a fully developed legal obligation, but it did formally recognise inadequacies of reciprocity and a need for providing concessions to DCs on a non-reciprocal basis.<sup>96</sup> Consequently, it corrected the false assumption of equal bargaining powers among the CPs on which the original provisions of GATT were established, and recorded ICs' commitments to give concessions to DCs on a non-reciprocal basis.

During the era of "new protectionism" in the 1970s,<sup>97</sup> reciprocity was given a new interpretation of ensuring equal market access among trading countries, which was

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<sup>93</sup> Article XXXVI:8 of GATT states that:

"The developed contracting parties do not expect reciprocity for commitments made by them in trade negotiations to reduce or remove tariffs and other barriers to the trade of less-developed contracting parties."

<sup>94</sup> Jackson, 1969, note 4 above, pp. 646-647.

<sup>95</sup> Takase, T., 'The Role of Concessions in the GATT Trading System and Their Implications for Developing Countries', *JWTL*, 1987, pp. 67-89.

<sup>96</sup> Hudec, 1987, note 82 above.

<sup>97</sup> See discussion in Chapters 2.2 and 2.3.

consistent with the US domestic trade legislation. It puts emphasis on the equivalent market access of a specific sector<sup>98</sup> as the benchmark to evaluate the extent of success in trade liberalisation. The US defined it to mean that its trading partners should accord equal market access to American exports as what the US had accorded to the imports of its trading partners in the US.

This revised application of reciprocity is synonymous with the concept of fair trade. This concept of fair trade is different from its counterpart contained in the safeguard provisions of the General Agreement.<sup>99</sup> According to the General Agreement, when imports are considered to be fair trade practices but are deemed to have harmed a importing country's economy, or domestic competing industries, and caused burdens of adjustment, a importing country could impose border-import restraints as a temporary relief when imports.<sup>100</sup> When unfair trade practices such as dumping or subsidies are the issue, an importing country is allowed to take import restraining actions if such practices cause domestic industries temporary difficulty in adjusting to fair competition and are being injured by a sudden surge in imports at artificially low or subsidised price. The traditional GATT system tried to distinguish between the rules dealing with fair and unfair trade policies by requiring a higher standard of harm to domestic competing

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<sup>98</sup> Sector harmonisation was introduced in the US Trade Act of 1974. See the Trade Act of 1974, Title I, §104, 88 Stat. 1985, 19 USCA §2114 (1980 and Supp. 1988). With the perceived weakening of the competitiveness of the US, suffering from what Bhagwati describes as Diminishing Giant Syndrome, the US again switched the emphasis of its trade policy from the balance of rights and obligations to the notion of reciprocity that leads to equal levels of market access. See Bhagwati, J., 'The Demands to Reduce Domestic Diversity Among Trading nations', in Bhagwati and Hudec (eds.), *Fair Trade and Harmonisation*, vol. 1, Ch. 9, Massachusetts: The MIT Press, 1996 and Bhagwati, J., *Protectionism*, Massachusetts: The MIT Press, 1988, pp. 35-36.

<sup>99</sup> They relate to Anti-dumping and Countervailing Duties (Article VI) and Subsidies (Article XVI).

<sup>100</sup> Jackson, 1992, note 51 above, p. 149-152.

industries and a more stringent requirement of causal effect between imports and the resultant harm.

When applying the new concept of fair trade in the context of IPP, any attempt by foreign sellers to evade legitimate IPP regulations in the importing country could be regarded by the US as unfair trade practices which justified the imposition of import restraining actions by the importing country.<sup>101</sup> The perception of unfairness derives from differences in domestic legal systems, and could lead to political pressures from importing countries to change their systems.<sup>102</sup> What constitutes fair trade, from the US' perspective, is for its trading partners to accord American exports substantially equivalent treatments as what the US gives to imports. These exporting countries have to consider harmonising their domestic IP legislation to mirror those of the US<sup>103</sup> if they wish to maintain market access to the vast US market.

The harmonisation of IPP in the TRIPS MTNs would be the equivalence of introducing substantive reciprocity into an international agreement on IPP for the first time. It highlights a different interface between NT and Reciprocity from the existing IP Conventions. Any reciprocity built into the Convention derives from those minimum standards contained within the agreement,<sup>104</sup> which serve as the basis of NT.<sup>105</sup> But

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<sup>101</sup> Ibid.

<sup>102</sup> Ibid., p. 152.

<sup>103</sup> Hay, Keith and B Andrei Sulzenko, 'U.S. Trade Policy and 'Reciprocity'', *JWTL*, 1982, p. 472-476.

<sup>104</sup> Bodenhausen's view serves as the basis for the present discussion here. See discussion in Chapter 2.5.

<sup>105</sup> What is prohibited by NT under the Convention is for members to take unilateral measures of substantive reciprocity. See Kunz-Hallstein, Hand Peter, 'The United States Proposal for a GATT Agreement on Intellectual Property and the Paris Convention for the Protection of Industrial Property', *Vand JTL*, 22(2), 1989, p. 87, Reichman, J. H., 'Intellectual Property in International Trade: Opportunities

when NT is to be applied under the premise of harmonised national IP system, it would then work within the context of substantive reciprocity. Only by moving forward from a NT based on the standard of protection of individual countries to the one that required substantive reciprocity by harmonising domestic IPP on a level found in most of the advanced countries,<sup>106</sup> could ICs be successful in their pursuit of an effective and adequate IP protection in the Uruguay Round.

### 3.4 GATT provisions relating to intellectual property protection

Although IPP was present in the Havana Charter,<sup>107</sup> the General Agreement did not incorporate any substantive standards with respect to IPP.<sup>108</sup> It dealt with IPP in a permissive manner<sup>109</sup> allowing CPs to adopt IP-related measures or legislation, provided that such measures were not inconsistent with GATT.<sup>110</sup> Primo Braga interprets this permissive approach as the result of a lack of concern for IP in trade in 1940s.<sup>111</sup>

Another plausible explanation put forward by Reichman is that the drafters of GATT decided to place the traditional institutions of the world's IP system beyond GATT in order to avoid potential conflict or overlap between GATT and the international unions

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and Risks of a GATT Connection', *Vand JTL*, 22(4), 1989, p. 779, and Dhanjee and de Chazournes, note 70 above, p. 9.

<sup>106</sup> Ullrich, Hanns, 'TRIPS: Adequate Protection, Inadequate Trade, Adequate Competition Policy', *Pacific Rim Law & Policy Journal*, 4(1), 1995, pp. 172 and 184.

<sup>107</sup> The Havana Charter drafted for the defunct ITO had an entire chapter V devoted to Restrictive Business Practices which included provisions relating to rights under patents, trademarks, and copyrights. Hartridge, David and Arvind Subramanian, 'Intellectual Property Rights: The Issues in GATT', *Vand JTL*, 16(6), 1982 and Reichman, 1989, note 105 above.

<sup>108</sup> Primo Braga, Carlos Alberto, 'Guidance from Economic Theory', in Siebeck, Evenson, Lesser and Primo Braga (eds.), *Strengthening Protection of Intellectual Property in Developing Countries – A Survey of the Literature*, Part VII, World Bank Discussion Papers #112, Washington, D.C.: The World Bank, 1990a.

<sup>109</sup> Cottier, note 57 above.

<sup>110</sup> Dhanjee and de Chazournes, note 70 above, p.6.



already regulating IP.<sup>112</sup> Yusuf believes that the rapid technological changes and the competitive importance of technology to international trade means that trade distorting effects are more likely to arise from the application and enforcement of domestic IP legislation these days, so that a multilateral agreement on trade-related IP provisions thus becomes more important.<sup>113</sup>

In contrast to the permissive approach adopted by the Convention, GATT embraces a comparatively more prescriptive approach stipulating relatively clearly the rules and principles CPs have to abide by.<sup>114</sup> But the language of GATT is broad enough to be capable of covering new subjects such as IPP.<sup>115</sup> Two categories of GATT provisions have been identified by the GATT Secretariat as relevant to IPP. The first category contains four articles with specific reference to IPP: Articles XX(d), IX, XII:3(c)(iii), and XVIII:10,<sup>116</sup> and the second category encompassing the consultation provision (Article XXII) and the dispute settlement provision in Article XXIII:<sup>117</sup>

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<sup>111</sup> Primo Braga, 1990a, note 108 above.

<sup>112</sup> Reichmen, 1989, no53 105 above, p. 833. He also pointed out that in the 1940s, the ICs involved in the drafting of the GATT were all parties to the Paris Convention, and except the US, all signatories to the Berne Convention.

<sup>113</sup> Yusuf, Abdulqawi A., 'Developing Countries and Trade-Related Aspects of Intellectual Property Rights', in UNCTAD, *Uruguay Round: Papers on Selected Issues*, NY: UN, 1989, p. 197.

<sup>114</sup> Dhanjee and de Chazournes, note 70 above, p. 6.

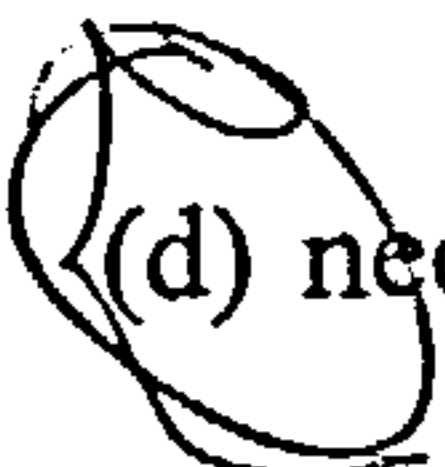
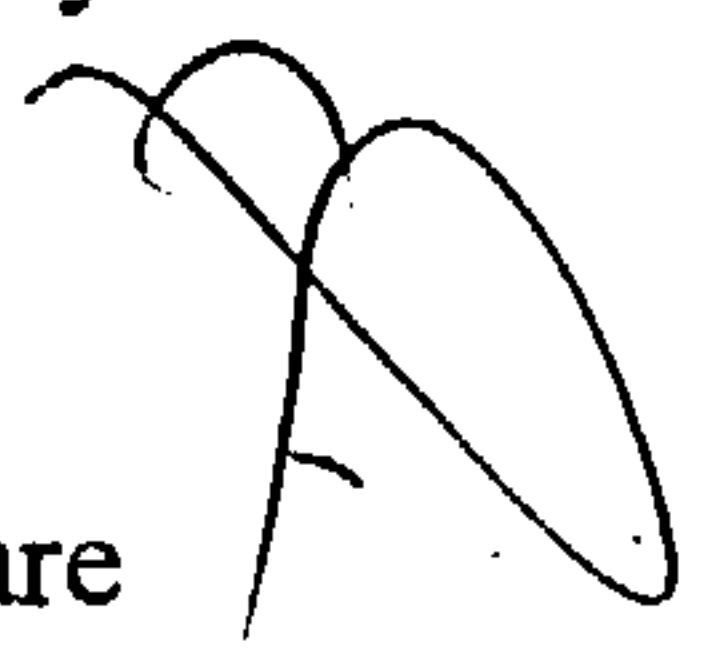
<sup>115</sup> See Jackson, 1992, note 51 above, p. 136. Hartridge and Subramanian observe that MFN under Article I should be capable of covering relevant actions of government in the area of IPP (see Hartridge and Subramanian, note 107 above, p. 899). And Abbott gives the example of private petitions under Section 301 legislation in the US to demonstrate that NT under Article III is capable of conferring the same degree of IPP to both domestic and foreign nationals as the majority of petitions involved alleged violation of the General Agreement, and most of the NTBs reported in the area of IP were discriminatory in the NT sense. Abbott, Kenneth W., 'Defensive Unfairness: The Normative Structure of Section 301' in Bhagwati and Hudec (eds.), *Fair Trade and Harmonisation – Prerequisites for Free Trade? Vol. 2: Legal Analysis*, Cambridge: The MIT Press, 1996, pp. 420-422.

<sup>116</sup> GATT, MTN.GNG.NG11/W/6, 22 May 1987, on GATT Provisions bearing on Trade-Related Aspects of Intellectual Property Rights – Note by the Secretariat (hereinafter GATT Note on Provisions).

<sup>117</sup> Ibid.

**Article XX(d)** is a general exception provision which allows actions to be taken to secure compliance with patent, trademark, and copyright laws, which would otherwise be inconsistent with the provisions of GATT. The provisions of Article XX(d) reads as follows:

“Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

 (d) necessary to secure compliance with laws or regulation which are not inconsistent with the provisions of this Agreement, including those relating to...the protection of patents, trade marks and copyrights, and the prevention of deceptive practices.” 

According to Article XX(d), three conditions have to be met in order for the exceptional measures to be justified under the GATT: Firstly, the measures relating to IPP must not be inconsistent with the provisions of the General Agreement. Secondly, the measures taken to secure compliance with laws and regulations relating to IPP must be “necessary”. Thirdly, the measures must not be applied in such a manner so to constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or become a disguised restriction on international trade. Article XX(d)

does not oblige CPs to adopt any enforcement measures.<sup>118</sup> It only ensures that GATT obligations do not stand in the way of effective enforcement of domestic IP legislation.<sup>119</sup>

**Article IX** is entitled “Marks of Origin”. Its first five paragraphs are to ensure that marking requirements and marks of origin are not used in such a way so as to hamper unnecessarily international trade or discriminate between CPs:

Each contracting party shall accord to the products of the territories of other contracting parties treatment with regard to marking requirements no less favourable than the treatment accorded to like products of any third country.

The contracting parties recognise that, in adopting and enforcing laws and regulations relating to marks of origin, the difficulties and inconveniences which such measures may cause to the commerce and industry of exporting countries should be reduced to a minimum, due regard being had to the necessity of protecting consumers against fraudulent or misleading indications.

Whenever it is administratively practicable to do so, contracting parties should permit required marks of origin to be affixed at the time of importation.

The laws and regulations of contracting parties relating to the marking of imported products shall be such as to permit compliance without

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<sup>118</sup> Jackson, 1969, note 4 above, p. 743.

<sup>119</sup> Hartridge and Subramanian, note 107 above, p. 900.

seriously damaging the products, or materially reducing their value, or unreasonably increasing their costs.

As a general rule, no special duty or penalty should be imposed by any contracting party for failure to comply without marking requirement prior to importation unless corrective marking is unreasonably delayed or deceptive marks have been affixed or the required marking has been intentionally omitted.

Article IX: 6 is essentially concerned with the protection of geographical indications. It requires CPs to co-operate to prevent the use of trade names "in such a manner as to misrepresent the true origin of a product, to the detriment of such distinctive regional or geographical names of products of the territory of a contracting party as are protected by its legislation..." This is the only GATT provisions that obliges cps to take actions against the deceptive use of names of products if so required.<sup>120</sup>

Articles XII:3(c)(iii) and XVIII:10 both require import restrictions aimed at safeguarding the balance of payments not to be applied in such a manner so as to "prevent compliance with patent, trademark, copyright, or similar procedures."

The other type of provisions in the General Agreement that could be invoked in IPP matters are the principle of non-discrimination which encompasses MFN (Article I) and

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<sup>120</sup> Yusuf, 1989, note 113 above, p. 196.

NT (Article III), and the two relevant procedural provisions, the consultation provision (Article XXII) and the consultation provision (Article XXII).<sup>121</sup>

**The consultation provision in Article XXII** requires CPs to afford adequate opportunity for consultation with respect to any matter affecting the operation of the General Agreement. This provision could be interpreted to cover matters related to IPP which affect the operation of the General Agreement.

**The nullification or impairment provision contained in Article XXIII: 1** states that:

“1. If any contracting party should consider that any benefit accruing to it directly or indirectly under this Agreement is being nullified or impaired or that the attainment of any objective of the Agreement is being impeded as the result of

- (a) the failure of another contracting party to carry out its obligations under this Agreement, or
- (b) the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement, or
- (c) the existence of any other situation, ....”

According to Article XXIII: 1, there are three circumstances under which claims of nullification or impairment could be brought. The vast majority of cases involve Article

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<sup>121</sup> GATT Note on Provisions, note 116 above.

XXIII: 1(a).<sup>122</sup> When a member state adopts measures that have de facto, if not de jure discrimination against foreign products, and the relevant government measures are inconsistent with GATT, a violation complaint under Article XXIII:1(a) could be filed by the representative government of foreign products.<sup>123</sup> If the relevant government measures are not inconsistent with GATT, but nullify or impair “reasonable expectations” at the time trade concessions were considered,<sup>124</sup> a non-violation complaint under Article XXIII: 1(b) could be filed. And Article XXIII: I(c) is similar to the frustration clause often seen in contracts, it deals with “situation complaints”, which CPs have never based any ruling or recommendation on.<sup>125</sup>

There is no definition of the concept of “nullification or impairment” in the General Agreement nor in subsequent GATT practices.<sup>126</sup> In the case of a violation complaint, the concept of nullification or impairment was introduced to protect contracting parties from the failure of other parties to carry out their obligations under the General Agreement.<sup>127</sup> The proof of a violation is in itself sufficient to prove a prima facie

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<sup>122</sup> See the analysis of past GATT panel reports in Hudec, 1993, note 58 above, pp. 375-383.

<sup>123</sup> Violation complaints often involve the violation of Articles III (national treatment), XVII (rules on state trading enterprises), and XI (quantitative restrictions) of GATT 1994. Article XI refers to quantitative restrictions exercised by business entities but enforced by government to restrict market access. Under XVII, member states are obliged to ensure that state trading enterprises covered by the provision do not act in a manner inconsistent with the general principles of non-discrimination. See discussion in Hoekman, Bernard M. and Petros C. Mavroidis, ‘Competition, Competition Policy and the GATT’, *The World Competition*, 1994, p. 129.

<sup>124</sup> GATT, MTN.GNG/NG13/W/31, 14 July 1989, Non-Violation Complaints Under GATT Article XXIII:2 – Note by the Secretariat (hereinafter Note on Non-Violation Complaints) and Jackson, 1969, note 4 above, pp. 178-187.

<sup>125</sup> *Ibid.*, p. 30.

<sup>126</sup> The legal uncertainty caused has been criticised as reducing the legal predictability of GATT dispute settlement proceedings.

<sup>127</sup> Jackson, John H., William Davey and Alan O. Sykes Jr., *Legal Problems of International Economic Relations – Cases, Material and Text on the National and International Regulation of Transnational Economic Relations*, 3<sup>rd</sup> ed., St Paul: West Publishing Co., 1995 (hereinafter Jackson et al), ch. 7 in general, and specifically p. 350.

case.<sup>128</sup> The impact of a measure inconsistent with GATT is not relevant for a determination of nullification or impairment.<sup>129</sup>

In the case of non-violation complaints, the objective is to protect the balance of reciprocal exchanges of tariff concessions.<sup>130</sup> According to past panel reports, there is an assumption of *prima facie* nullification or impairment of benefits when competitive benefits deriving from tariff concessions were upset as a result of subsequent unexpected government measures.<sup>131</sup> And the proof of cause-and-effect trade damage was not required in the case of non-violation complaints.<sup>132</sup>

On the question of the applicability of non-violation complaints to disputes involving IPP, various commentators have expressed different opinions. Petersmann argues that Article XXXIII: 1(b) is to protect the balance of reciprocal tariff concessions and competitive opportunities from being impaired by unforeseen measures that do not

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<sup>128</sup> And the initial burden of proof is on complaining party. See GATT, BISD 34<sup>th</sup> Supp., 136, (1988), *United States – Taxes on Petroleum and Certain Imported Substances*. This case involves the US's Superfund Act dealing with the cleanup of hazardous waste sites. The legislation imposes a tax of 8.2 cents per barrel on domestically refined crude oil and 11.7 cents on imported petroleum products. The US argued that the tax indeed violates national treatment obligations under Article III:2. But the tax differential is so small that its trade effects were minimal, that it did not nullify or impair benefits accruing to Canada, the EEC and Mexico.

<sup>129</sup> *Ibid.*

<sup>130</sup> GATT, BISD 37<sup>th</sup> Supp., 228, 261, (1990). There were thirteen cases of non-violation complaints out of 130. Only one panel report did not base its non-violation finding on Schedule of Concessions (Article II).

<sup>131</sup> Hudec, 1993, note 58 above, pp. 268-269 and Hoekman and Kostecki, note 20 above, p. 46, where the three conditions required to bring a non-violation complaints are set out: firstly, the measure must be applied by a government; secondly, it must alter the competitive conditions established by the agreed tariff bindings; and thirdly, the measure must be unexpected in that it could not have been reasonably foreseen at the time the concessions were negotiated.

<sup>132</sup> *Ibid.* Hudec, in support of the decision, commented that it is difficult to prove that a particular trade measure had any cause-and-effect impact on trade, that one can identify the trade measure and gather the trade data, but there is no way to link the two in a logically valid manner.

violate GATT provisions.<sup>133</sup> But an agreement containing substantive standard of IPP does not provide for reciprocal tariff bindings, nor guarantee market access for IP-protected goods. It is more likely that disputes will arise from the direct breach or bad-faith implementation of treaty provisions.<sup>134</sup>

Jackson opines that an IP agreement which contains substantive rules and standards should not need to allow non-violation claims, and that problems of protecting legitimate expectations should be resolved through the application of legal principles.<sup>135</sup> But Lee and von Lewinski argue that the non-violation provision should remain available to deal with cases such as when a national regime requiring an excessively high level of inventive step as a criterion for patentability which, in the absence of bad faith, could be subject to a non-violation complaint.<sup>136</sup>

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<sup>133</sup> Petersmann, Ernest-Ullrich, 'The Dispute Settlement System of the World Trade Organisation and the Evolution of the GATT Dispute Settlement System since 1948'. *CMLR*, 31, 1994, pp. 1230-1233.

Pescatore comments that a legal judgement is to decide who is right and who is wrong. The consideration of maintaining a balance between the rights and obligations of members is criticised by him as contributed to the incoherent legal patchwork of GATT dispute settlement system, see Pescatore, Piere, 'The GATT Dispute Settlement Mechanism', *JWT*, 27(1), 1993, pp. 13 and 18.

<sup>134</sup> Petersmann, 1994, note 133 above, pp. 1232-1233.

<sup>135</sup> Jackson et al, note 127 above, ch. 7. See also discussion in Lee, Karen and Silke von Lewinski, 'The settlement of International Disputes in the Field of Intellectual Property', in Beier and Schriker (eds.), *From GATT to TRIPS*, IIC Studies in Industrial Property and Copyright Law, Munich: Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, 1996, pp. 278-328.

<sup>136</sup> Lee and von Lewinski, note 135 above, p. 313.



## Chapter IV

### Patent Protection for Pharmaceuticals under the TRIPS Agreement

This chapter begins by setting out the negotiation history of the TRIPS Agreement to illustrate the interface of political, legal, and economic dimensions of MTNs and how it has influenced the result of the Agreement. The substantive provisions of the TRIPS Agreement are then discussed, with particular reference to the patent system for pharmaceuticals.

#### 4.1 Introduction

The TRIPS Agreement was completed as part of the Uruguay Round MTNs in April 1994.<sup>1</sup> Its completion was held as a significant achievement for the global trading system in light of the North-South dimensions of the subject.<sup>2</sup>

NT, unconditional MFN and reciprocity form the backbone of the TRIPS Agreement. And the Agreement contains a set of minimum IPP standards, domestic enforcement procedures, and the inter-governmental dispute settlement mechanism. The set of minimum IPP standards are at a level which approximates to what could be found in the major western countries at the time of the Uruguay Round MTNs.<sup>3</sup> The TRIPS Agreement continues on with the tradition of the Convention leaving the implementation

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<sup>1</sup> GATT, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiation, 15 April 1994 (hereinafter the Final Act).

<sup>2</sup> See discussion in Chapters I and II. Also Hoekman Bernard M. and Michael M. Kostecky, *The Political Economy of the World Trading System – From GATT to WTO*, Oxford: Oxford University Press, 1995, p. 151 and Zutshi, B. K., 'Bringing TRIPS into the Multilateral Trading System', in Bhagwati and Hirsch (eds.), *The Uruguay Round and Beyond*, Heidelberg: Springer, 1998, p. 40.

of the Agreement to the discretion of national governments,<sup>4</sup> and does not propose to achieve the harmonisation of domestic intellectual property legislation among WTO members.<sup>5</sup>

According to a 1996 UNCTAD report:<sup>6</sup> the strengthening of IP regime is expected to engender a greater degree of uncertainty to DCs depending upon their economic policy and the stage of development they are in. The positive impacts are likely to be more local innovation and inward FDI and technology transfer,<sup>7</sup> but these benefits will only incur if DCs co-ordinate IPP with a broader modernisation programmes for technology development. The negative impacts could include higher prices for protected products and technologies, and restricted abilities to achieve diffusion through imitation or copying.

The negotiation history of the TRIPS Agreement has seen the working of the power-oriented approach in the global trading system. It was illustrated by the initiative and insistence of major trading nations on the inclusion of IPP as a subject for the Uruguay

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<sup>3</sup> WTO, Press/57, October 9, 1996, p. 49.

<sup>4</sup> Article 1.1 of the TRIPS Agreement.

<sup>5</sup> But UNCTAD 1994 report regards TRIPS as providing a harmonised legal protection system. It could be argued that the element of harmonisation goes so far as to bind all WTO members of the provisions contained in TRIPS. See UNCTAD, *The Outcome of the Uruguay Round: An Initial Assessment – Supporting Papers to the Trade and Development Report*, NY: UN, 1994 (hereinafter UNCTAD 1994 Report), pp. 185-190.

<sup>6</sup> UN, *The TRIPS Agreement and Developing Countries – Prepared by the UNCTAD Secretariat*, NY: UN, 1996, pp. 1 and 18.

<sup>7</sup> UNCTAD 1994 Report, note 5 above. The UNCTAD report further points out that the effect of strengthened IPP on the decision of technology transfer is dependent on its interrelation with other factors such as the size of the domestic market, local infrastructure, and the degree of stability of the macroeconomic environment, etc.

Round MTNs,<sup>8</sup> and the similarity between proposals submitted by ICs and the final agreement.<sup>9</sup> During the Uruguay Round MTNs, countries such as India sought to exclude pharmaceutical products from patent protection to avoid the impact of predicted price rises and to ensure the accessibility and affordability of advance medicines.<sup>10</sup> But it was the insistence of some ICs to cover pharmaceuticals in TRIPS MTNs, coupled with the change of attitude from some DCs to accept the subject which carried the day.<sup>11</sup>

The Uruguay Round MTNs also saw the dissolution of DCs acting as a group with an unified negotiation stance,<sup>12</sup> with many DCs co-operated with ICs on issues important to their own domestic interests.<sup>13</sup> It demonstrated that common grounds could be found among DCs and ICs in the process of MTNs even on controversial issues. With a shift in many DCs' attitudes towards favouring inward FDI in the 1980s,<sup>14</sup> they came to realise

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<sup>8</sup> Srinivasan, T. N., *Developing Countries and the Multilateral Trading System – From the GATT to the Uruguay Round and the Future*, Boulder, Colorado: Westview Press, 1998, p. 34

<sup>9</sup> *Ibid.* And Zutshi, note 2 above, p. 44.

<sup>10</sup> The pharmaceutical industry was of particular concern to DCs in respect of higher drug prices and more strict terms of access to technology following the introduction of patent protection. See UNCTAD 1996 Report, pp. 18-19. See also the statement made by Dr. Subramanian Swamy of India in GATT, MTN.GNG/MIN(90)/ST/46, 4 December 1990, the statement made by India in US v India Appellate Body Report and Zutshi, note 2 above, p. 43.

<sup>11</sup> The inclusion of pharmaceuticals in the TRIPS negotiation was considered non-negotiable for many ICs such as the US, the European Economic Community, and Switzerland. Cottier, Thomas, 'The Prospects for Intellectual Property in GATT', *CMLR*, 28, 1991, p. 406.

<sup>12</sup> Cottier comments that TRIPS MTNs could not be generalised in a simplified manner as constituting a north-south divide. Domestic political resistance to changes was foreseeable in many ICs because legislative changes are required as the result of an IPP agreement. See *Ibid.*, p. 389 and Zutshi, note 2 above, p. 49.

<sup>13</sup> Cottier, note 11 above, pp. 390 and 391.

<sup>14</sup> Haggard describes the situation in a nutshell: During the borrowing boom of the 1970s, the middle income DCs could depend on easy access to external financing through the Eurocurrency markets. With the evaporation of international commercial lending after debt crisis and severe balance-of-payments constraints, governments became more sensitive toward the interests of foreign investors with the aim to attract foreign investment. Efforts to attract foreign investment spilled over into the deep integration in ways such as bringing domestic IPP legislation into conformity with international standard. See Haggard, Stephan, *Developing Nations and the Politics of Global Integration*, Washington D.C.: The Brookings Institution, 1995, p. 19. Also Hoekman, Bernard, 'Services and Intellectual Property Rights', in Collins and Bosworth (eds.), *The New GATT – Implications for the United States*, Washington D.C.: The Brookings Institution; 1994, p. 106.

that the introduction of adequate IPP standards was necessary to compete successfully for foreign investment in a world economy,<sup>15</sup> especially if they wish to attract FDI in high-tech industries.<sup>16</sup> On the home front, strengthened IPP would also likely to encourage domestic research in the process of building up knowledge capital essential for economic development.<sup>17</sup> Furthermore, major DCs such as India had also come to accept that it was in their own interest to provide IPP. They are not just users of foreign technology but also producers of IP in areas such as software<sup>18</sup> and pharmaceuticals,<sup>19</sup> and their innovators would benefit from strengthened IPP when competing in export markets.<sup>20</sup>

By bringing IPP issues into the global trading system, DCs believe that the WTO's one member one vote majority decision making in the absence of a consensus<sup>21</sup> has a better prospect of keeping powerful trading nations in check.<sup>22</sup> A multilateral trading system underpinned by NT, unconditional MFN and reciprocity is necessary, given the political influence of domestic industry lobby in many ICs<sup>23</sup> and the continuing threat of

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<sup>15</sup> Mansfield, *Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer*, International Financial Corporation, Discussion Paper #19, Washington D.C.: The World Bank, 1994. The set of minimum IPP standards will be regarded as the common denominator when MNCs evaluate their choice of location for foreign investment.

<sup>16</sup> Hoekman, note 14 above.

<sup>17</sup> Srinivasan, note 8 above, p. 52.

<sup>18</sup> Bhagwati, Jagdish, comment given to Hoekman's article 'Services and Intellectual Property Rights', in Collins and Bosworth (eds.), *The New GATT – Implication for the United States*, Washington D.C.: The Brookings Institution, 1994 (hereinafter Bhagwati Comment), p. 114. The growth of the Indian software industry since the late 1980s has been a remarkable success, and has emerged as a leading offshore software development centre in the fast-growing global information technology market. And in the wake of the success came the demand from the industry for IPP. See discussion in FT, FT Survey – South Asian Software and Services, June 2, 1999, p. I and FT, October 25, 1999, p. 22.

<sup>19</sup> FT, Life Sciences 4 – Asia, July 15, 1999, p. IV and FT, August 30, 1999, p. 8.

<sup>20</sup> Jackson, John, comment given to Hoekman's article 'Services and Intellectual Property Rights', in Collins and Bosworth (eds.), *The New GATT – Implication for the United States*, Washington D.C.: The Brookings Institution, 1994 (hereinafter Jackson Comment), p. 118.

<sup>21</sup> Article IX of the Agreement Establishing WTO.

<sup>22</sup> In contrast to the dominance of ICs in the World Bank and IMF because of the weighted voting system. See discussion in Srinivasan, note 8 above, p. 34.

<sup>23</sup> Bhagwati Comment, note 18 above, p. 113.

unilateral and bilateral actions. By bringing inter-governmental disputes into a rule-based multilateral regime where unilateral actions are outlawed,<sup>24</sup> there is a better chance of keeping unilateralism at bay.<sup>25</sup>

The TRIPS Agreement, along with all other multilateral agreements concluded in the Uruguay Round, forms an integral package that all WTO members have to adhere to.<sup>26</sup> And the WTO provides the common institutional framework for the conduct of trade relations among WTO members in matters relating to these agreements.<sup>27</sup> This Single Undertaking approach makes trade-off between negotiated subjects possible and paves the way for engaging in reciprocal exchange of concessions.<sup>28</sup> It also facilitates the application of cross-sectoral retaliation under the dispute settlement mechanism<sup>29</sup> when the offending party to a dispute fails to implement rulings or recommendation contained in panel or Appellate Body Reports.<sup>30</sup>

Specific provisions on patent protection for pharmaceuticals have been provided in the TRIPS Agreement. Under the TRIPS regime, both product and process are subject to IPP, the term of protection is for the minimum of twenty years from the date of filing, and the burden of proof for process patent has been reversed. If DCs and LDCs take advantage of transitional arrangements available to them under TRIPS, they are obliged

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<sup>24</sup> Article 23 of The Understanding on Rules and Procedures Governing Settlement of Disputes, Annex 2 to the Agreement Establishing the WTO.

<sup>25</sup> Haggard, note 14 above, p. 111.

<sup>26</sup> Article 2.2 of the Agreement Establishing WTO.

<sup>27</sup> Article 2.1 of the Agreement Establishing WTO.

<sup>28</sup> Hoekman and Kostecki, note 2 above, p. 241, and Hartridge, David and Arvind Subramanian, 'Intellectual Property Rights: The Issues in GATT', *Vand JTL*, 22(4), 1989, p. 898.

<sup>29</sup> See discussion in Chapter 4.3.

to implement the pipeline provision to allow patent applications filed after TRIPS comes into operation to retain their novelty and priority of filing for patent consideration when domestic patent systems come into operation. They are also under legal obligation to confer a five-year marketing exclusivity a product which has been granted patent protection and marketing approval in another WTO member country during the period of dispensation.

During the Uruguay Round MTNs, ICs strived for a broad and comprehensive multilateral agreement on the protection of IPRs, while DCs sought latitude in the implementation of the agreement so as to maintain the consistency with their economic development goals and their legal obligations under the TRIPS Agreement. The result is an agreement which provides a legal framework of substantive norms, enforcement and dispute settlement mechanisms of ICs' standard, and the enunciation of broad principles and non-specific rules and guidelines capable of broad interpretation. For the pharmaceutical industry, the full impact of the TRIPS Agreement will not be seen until 2003-2005 if the development time for new drugs remains averaging 8-10 years.<sup>31</sup> But as WTO members have competency to determine the appropriate methods of implementing TRIPS domestically, it has already given rise to uncertainty the degree of stringency in their implementation of the Agreement and the effect on IP right holders.

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<sup>30</sup> Petersmann, Ernest-Ullrich, 'The Dispute Settlement System of the World Trade Organisation and the Evolution of the GATT Dispute Settlement System since 1948', *CMLR*, 31, 1994, p. 1161.

<sup>31</sup> Redwood, Heinz, *New Horizons in India*, Suffolk: Oldwicks Press, 1994, p. 52.

## 4.2 The negotiation history of the TRIPS Agreement

The Punta del Este Ministerial Declaration formally opened the Uruguay Round in September 1986. The Ministers agreed to conclude the round within four years.<sup>32</sup> TRIPS was one of the subjects for MTNs under Trade in Goods<sup>33</sup> mandated in the first part of the Punta del Este Declaration.<sup>34</sup> The Ministers stated the negotiation mandate for TRIPS as follows:

“In order to reduce the distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines.

Negotiations shall aim to develop a multilateral framework of principles,

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<sup>32</sup> At the institutional level, the Trade Negotiations Committee was set up to oversee the entire round of negotiations which was divided into MTNs on Trade in Goods and trade in Services. The chairman of the Committee was Arthur Dunkel, Director-General of GATT at that time. See GATT, MIN.DEC, 20 September 1986 for The Punta del Este Declaration.

<sup>33</sup> The subjects covered are: Tariffs, Non-Tariff Measures, Natural Resource-Based Products, Textiles and Clothing, Agriculture, Tropical Products, GATT Articles, MTN Agreements and Arrangements, Safeguards, Subsidies and Countervailing Measures, TRIPS, Trade-Related Investment Measures, Dispute Settlement, Functioning of the GATT System.

<sup>34</sup> The Punta del Este Declaration, note 32 above. A Group of Negotiations on Goods was established to carry out the programme of negotiations contained in Part I for Negotiations on Trade in Goods. It reports directly to the Trade Negotiations Committee. Part II of the Declaration deals with Negotiations on Trade in Services. A Group of Negotiations on Services was set up and reports to the Trade Negotiations Committee as well. MTNs on services were conducted outside GATT separated from MTNs on goods. This is described as the twin track approach to gain support from DCs for the inclusion of services on the agenda of the Uruguay Round.

rules and disciplines dealing with international trade in counterfeit goods, taking into account work already undertaken in GATT.

These negotiations shall be without prejudice to other complementary initiatives that may be taken in the World Intellectual Property Organisation and elsewhere to deal with these matters.”

This negotiation mandate was seen as a political compromise between DCs' opposition and US' insistence to include IPP on the negotiation agenda.<sup>35</sup> There were different opinions as to what the negotiating objectives for the TRIPS are based on the reading of the negotiation mandate. DCs held the view that norms and standards per se were not trade related, therefore they were not covered by the mandate.<sup>36</sup> Raghavan agrees with the DCs' interpretation and suggests that the three indents should be read separately: the first indent is to ensure that the enforcement of GATT Articles relating to IPRs does not hamper or retard international trade, the second indent is to develop a multilateral framework to deal with international trade in counterfeit goods, and the last indent is to ensure that the effort under the first and the second indents are complimentary to the initiatives taken by other world organisations.<sup>37</sup> But ICs interpreted the Declaration to cover the norms and standards of IPRs. And as Stewart states, the goal of the negotiation was a multilateral agreement on minimum levels of protection for intellectual property

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<sup>35</sup> Cottier, note 11 above, p.387.

<sup>36</sup> Zutshi, note 2 above, p. 40.

<sup>37</sup> Raghavan, hakravarthi, *Recolonisation – GATT, the Uruguay Round & the Third World*, London: Zed Books Ltd. And Third World Network in Malaysia, 1990, pp. 127-128.



rights.<sup>38</sup> These divergent views persisted during the early stage of TRIPS MTNs and led to very little progress made during the first phase of the TRIPS MTNs which commenced in 1987.

During the initial phase of the TRIPS MTNs, many participating countries, such as the US,<sup>39</sup> Switzerland,<sup>40</sup> Japan,<sup>41</sup> the EC,<sup>42</sup> Nordic Countries,<sup>43</sup> Mexico,<sup>44</sup> and Brazil,<sup>45</sup> submitted proposals on how to achieve the negotiation objective based on their understanding of the negotiation mandate. With the aim to persuade countries to negotiate a multilateral framework of substantive standards on IPP, the US 1987 proposal states that IPRs promote innovation and intellectual creativity, the protection and enforcement of which are essential to the expansion of international trade, investment, economic development and the diffusion of technology. It calls for, among others, the introduction of more stringent standards and norms of IPP, the provision of a basis for an effective enforcement mechanism, and an extension of international dispute settlement procedures to protect and enforce IPRs.<sup>46</sup> The Swiss proposal suggested a framework

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<sup>38</sup> Stewart, Terence P. (ed.), *The Uruguay Round: A Negotiating History (1986-1992)*, vol. I & II, Deventer: Kluwer Law and Taxation Publishers, 1993, p.2265.

<sup>39</sup> Suggestion by the United States for Achieving the negotiating Objective, GATT, MTN.GNG/NG11/W/14, 20 October 1987, (hereinafter US 1987 Proposal).

<sup>40</sup> Suggestion by Switzerland for Achieving the Negotiating Objective, GATT, MTN.GNG/NG11/W/25, 29 June 1988.

<sup>41</sup> Suggestion by Japan for Achieving the Negotiating Objective, GATT, MTN.GNG/NG11/W/17, 23 November 1987.

<sup>42</sup> Guidelines Proposed by the EC for the Negotiations on Trade-Related Aspects of Intellectual Property Rights, GATT, MTN.GNG/NG11/W/16, 20 November 1987 and EC 1988 Guidelines, op. Cit..

<sup>43</sup> Suggestion by the Nordic Countries for Achieving the negotiating Objective, GATT, MTN.GNG/NG11/W/22, 12 February 1988, (hereinafter Nordic Countries 1988).

<sup>44</sup> Statement Made by the Delegation of Mexico at the Meeting of 17, 18, and 21 October 1988, GATT, MTN.GNG/NG11/W/28, 19 October 1988, (hereinafter Mexico 1988).

<sup>45</sup> Submission from Brazil, GATT, MTN.GNG/NG11/W/30, 31 October 1988, (hereinafter Brazil 1988).

<sup>46</sup> The US also gave assurance that that measures of protection or enforcement would not become barriers to legitimate trade. And it called upon non-signatory government to join the agreement, as at this stage, the US advocated a code approach to an IP agreement by which only the signatories to the agreement would be bound. See US 1987 Proposal. The code-approach has been discussed in details in Chapter 2.4.2.

for a TRIPS agreement and mentioned the need to improve the enforcement of IPP. Japan's submission was similar to that of the US. While the EC suggested that the TRIPS Agreement should cover new subjects of intellectual property such as semiconductor layouts along with patents, trademarks, industrial designs, geographical descriptions, designations of origin, new plant varieties, and copyright, and that the agreement should also incorporate GATT principles of NT and MFN.

The Mexican submission cautioned that the negotiating objective regarding the improvement of intellectual property rights should not become a barrier to access technologies produced in developed countries.<sup>47</sup> The Brazilian proposal stated that the negotiations seemed to be on the side of the owners of IPRs. If DCs were to have a realistic and balanced analysis of the implications of IPP on their growth and development, it is fundamental to give due consideration to aspects relevant to the users of the IPRs.<sup>48</sup> The representative from Brazil further made the point that other proposals submitted did not establish the link between granting of IPR and the promotion of domestic technological development.<sup>49</sup> This missing link was significant to DCs because "the furtherance of the public interest was the fundamental goal pursued by governments when granting IPRs."<sup>50</sup>

The failure to resolve the disagreement on the interpretation of TRIPS negotiation mandate meant that no agreement was reached in preparation for the Montreal Mid-Term

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<sup>47</sup> Mexico 1988, note 44 above, p. 2.

<sup>48</sup> Brazil 1988, note 45 above, p. 3.

<sup>49</sup> GATT, MTN.GNG/NG11/10, 30 November 1988, p. 4.

<sup>50</sup> Ibid.

Review in December 1988.<sup>51</sup> It was not until April 1989 when the Trade Negotiations Committee met again in Geneva that the disagreement was resolved, and a framework agreement for TRIPS MTNs was reached.<sup>52</sup> What remained unresolved was the question of whether GATT was the preferred forum for implementing a TRIPS agreement.<sup>53</sup>

The framework agreement for TRIPS sets out the issues for subsequent MTNs:<sup>54</sup>

- (a) the applicability of the basic principles of the GATT and of relevant international intellectual property agreements or conventions;
- (b) the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;
- (c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems;
- (d) the provision of effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments, including the applicability of GATT procedures;
- (e) transitional arrangements aiming at the fullest participation in the

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<sup>51</sup> See GATT, MTN.TNC/7, 9 December 1988 for the Trade Negotiations Committee Meeting at ministerial level in Montreal. There were no agreements reached for TRIPS, Agriculture, Textiles, and Safeguards in Montreal. Negotiation progress in Textiles and Safeguards was seen to be contingent on progress in TRIPS and Agriculture. But negotiations in Agriculture reached a deadlock because the US and the EEC refused to compromise their positions on agricultural subsidies. See Ford Foundation, *op. Cit.*, p. 107 for detailed discussion.

<sup>52</sup> GATT, MTN.TNC/11, 21 April 1989, (hereinafter Mid-Term Meeting 1989).

<sup>53</sup> Zutshi, note 2 above.

<sup>54</sup> Mid-Term Meeting 1989, note 52 above, p. 21 and GATT, Focus – GATT Newsletter, May 1989, p. 8.

results of the negotiations.<sup>55</sup>

It was also agreed that considerations would be given to the underlying public policy objectives of national IP systems, such as developmental and technological objectives.<sup>56</sup>

In June 1991, a "Chairman's Draft" was distributed.<sup>57</sup> It identified the proposals submitted by ICs<sup>58</sup> and a group of fourteen DCs based on the framework agreement,<sup>59</sup> and set out the substantive differences among them. It later became a formal document<sup>60</sup> and served as the basis of the agreement reached in TRIPS MTNs.

By December 1990, most of the negotiation subjects had reached agreements, including TRIPS. But the Brussels Ministerial Meeting failed to complete the round of MTNs as scheduled because the US and the EC failed to reach an agreement on Agriculture.<sup>61</sup>

One year later, the Draft Final Act Embodying the Results of the Uruguay Round of

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<sup>55</sup> Ibid.

<sup>56</sup> Ibid.

<sup>57</sup> See GATT, MTN.GNG/NG11/W/76, 23 July 1990. The document was prepared by then Negotiating Group Chairman Lars Anell from Sweden.

<sup>58</sup> It included the EEC (Draft Agreement on Trade-Related Aspects of Intellectual Property, GATT, MTN.GNG/NG11/W/68, 29 March 1990, the US (Draft Agreement on Trade-Related Aspects of Intellectual Property Rights, GATT, MTN.GNG/NG11/W/70, 11 May 1990, Switzerland (Draft Amendment to the General Agreement on Tariffs and Trade on the Protection of Trade-Related Intellectual Property Rights, GATT, MTN.GNG/NG11/W/73, 14 May 1990, Japan (Main Elements of a Legal Text for TRIPS, GATT, MTN.GNG/NG11/W/74, 15 May 1990.

<sup>59</sup> See GATT, MTN.GNG/NG11/W/71, 14 May 1990.

<sup>60</sup> The July draft had been revised in October. The October draft retained most of the text from July draft with two additions. One is the sentence to make the provisions in the Agreement the minimum GATT, MTN.TNC/11, 21 April 1989, requirements CPs have to abide by. It also added a new section on Exhaustion. It became a formal document known as the Chairman's Report to the Group of Negotiation on Goods. See GATT, Doc. 2341, October 1, 1990, Status of Work in the Negotiating Group. Also Gervais, Daniel J., 'The TRIPS Agreement', *EIPR*, 21(3), 1999, p. 157.

<sup>61</sup> Low, Patrick, *Trading Free – The GATT and US Trade Policy*, NY: The Twentieth Century Fund Press, 1993, p. 229 and Srinivasan, note 8 above, p. 33.

Multilateral Trade Negotiations was tabled for approval.<sup>62</sup> It was only after the renewal of the US president's fast track procedure was approved by the Congress in June 1993<sup>63</sup> and the new Director General of GATT taking office<sup>64</sup> in July of the same year that the negotiation momentum was regained.<sup>65</sup> With minor changes, the Dunkel Draft was finally agreed in December 1993 and adopted by Ministers in April 1994 in Marrakesh.<sup>66</sup>

After seven torturous years of negotiations, the Uruguay Round finally came to a

successful end.

### 4.3 Salient features of the TRIPS Agreement

The TRIPS Agreement, which came into effect on 1 January 1995, is the most comprehensive multilateral agreement on IPP to date. It contains NT and unconditional MFN as its two basic principles,<sup>67</sup> substantive standards concerning the availability, scope and use of IPRs,<sup>68</sup> procedures for enforcement<sup>69</sup> and dispute prevention and settlement,<sup>70</sup> acquisition and maintenance of IPRs,<sup>71</sup> transitional arrangements,<sup>72</sup> and

<sup>62</sup> GATT, MTN.TNC/W/FA, 20 December 1991. The document was commonly referred to as "the Dunkel Draft" because it was prepared by Arthur Dunkel, then Director-General of GATT. It included a new TRIPS text which contained an arbitrated resolution to issues undecided by the negotiation parties. The pharmaceutical industry was quite negative toward the Dunkel Draft for various reasons, the main one being the absence of pipeline protection, see Stewart (ed.), note 38 above, pp. 2313 and 2282, note 267.

<sup>63</sup> The US president's fast-track authority expired in February 1993, and was renewed by the Congress on June 30, 1993.

<sup>64</sup> Peter Sutherland took over as the new Director-General of GATT from Arthur Dunkel in July 1993.

<sup>65</sup> GATT, GATT-WTO News, GW/11, 21 December, 1994, pp. 10-11.

<sup>66</sup> Ministers representing 124 governments and the EC participated in the Marrakesh Ministerial Meeting to mark the conclusion of the Uruguay Round MTNs, and the Final Act of the Uruguay Round was signed on 15 April, 1994.

<sup>67</sup> General Provisions and Basic Principles, Articles 1 to 8 in Part I of the TRIPS Agreement.

<sup>68</sup> Standards Concerning the Availability, Scope and Use of Intellectual Property Rights, Articles 9 to 40 in Part II of the TRIPS Agreement.

<sup>69</sup> Articles 41 to 61 in Part III of the TRIPS Agreement.

<sup>70</sup> Articles 63 to 64 in Part V of the TRIPS Agreement.

<sup>71</sup> Article 62 in Part IV of the TRIPS Agreement.

<sup>72</sup> Articles 65 to 67 in Part VI of the TRIPS Agreement.

institutional arrangements.<sup>73</sup> And it provides legal protection to Copyright and related rights, Trade marks, Geographical Indications, Industrial Designs, Patents, Lay-Out Designs of Integrated Circuits, and the Protection of Undisclosed Information.<sup>74</sup>

The WTO provides an institutional framework for the implementation, administration, and operation of the TRIPS Agreement.<sup>75</sup> It is also a negotiation forum for future MTNs on the TRIPS Agreement.<sup>76</sup> As Jackson points out, the provision of an institutional framework is essential to provide a rule-based multilateral mechanism to ensure the highest possible degree of adherence to the agreed rules and to resolve trade conflicts.<sup>77</sup> The establishment of the WTO rectifies the constitutional limitations of GATT.<sup>78</sup> Much of the discussed inadequacy of the absence of a formal institutional framework under GATT was eradicated.<sup>79</sup>

In establishing the substantive norms of IPP, the Agreement incorporates the main rules in the existing Conventions administered by WIPO,<sup>80</sup> and adds a substantial number of

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<sup>73</sup> Articles 68 to 73 in Part VII of the TRIPS Agreement.

<sup>74</sup> In relation to other part of the TRIPS Agreement, Part I, III to VII are applicable to the seven IPRs covered in the Agreement.

<sup>75</sup> Article III.1 of the Agreement Establishing the WTO.

<sup>76</sup> Article III.2 of the Agreement Establishing the WTO.

<sup>77</sup> Jackson, John H., 'The Crumbling Institutions of the Liberal Trade System', *JWTL*, 12(2), 1978, p. 99.

<sup>78</sup> *The Economist*, Forty Years on from GATT, October 24, 1987.

<sup>79</sup> See discussion in Long, Olivier, *Law and its Limitations in the GATT Multilateral Trade System*, Dordrecht: Martinus Nijhoff Publishers, 1987, ch. 4 and Jackson, John H., *Restructuring the GATT System*, London: Royal Institute of International Affairs, 1990, part VIII.

<sup>80</sup> The Doctrine of Incorporation was applied to promote the complementarity and consistency between the work of GATT and WIPO. By doing so, it ensures that WIPO members who are also members of the WTO could subscribe to the TRIPS Agreement without being in breach of their legal obligations under the Conventions administered by WIPO. According to Article 19 of the Paris Convention, member states to the Convention could choose to enter into a "special agreement" if the provisions of the new agreement do not contravene with those contained in the Convention, and it contains further substantive obligations designed to improve the system of the Union. The existing Conventions which have been incorporated into the TRIPS Agreement include: the Paris Convention for the Protection of Industrial Property; as revised in Stockholm in 1967, (hereinafter Paris Convention); Berne Convention for the Protection of Literary and

obligations on matters that the Conventions are silent or seen as being inadequate. It does not seek to achieve a global harmonisation of domestic IP law.<sup>81</sup> But by incorporating the minimum standards stipulated in the Agreement in their domestic legislation, WTO members are obliged to take positive actions to protect IP.<sup>82</sup> With the Council for TRIPS monitoring the compliance of the Agreement,<sup>83</sup> member states are free to determine the appropriate methods of implementation so long as their legal system and practices are consistent with the TRIPS Agreement.<sup>84</sup>

As IPRs are private rights, NT and unconditional MFN contained in the TRIPS Agreement confer the protection to legal and natural persons.<sup>85</sup> NT forbids discrimination between one's own nationals<sup>86</sup> and nationals of other member states so as to confer no less favourable treatment than that is accorded to its own nationals.<sup>87</sup> This definition is underpinned by the principle of reciprocity in that the rules and standards set

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Artistic Works (1971), (hereinafter Berne Convention); The International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisation (1961) (hereinafter Rome Convention); the Treaty on Intellectual Property in respect of Integrated Circuits (1989) (hereinafter IPIC Treaty).

<sup>81</sup> UNCTAD, *The TRIPS Agreement and Developing Countries*, NY; UN, 1996, p. 29.

<sup>82</sup> Other agreements reached in the Uruguay Round, namely GATT 1994 and GATS, contain lists of practices members should not implement or rules which allow members to take defensive and compensatory actions when their trade interest is adversely affected, negative list of practices member states should not implement. See GATT, *Trade Policies for a Better Future – The 'Leutwiler Report'*, *The GATT and the Uruguay Round*, Dordrecht: Martinus Nijhoff Publishers, 1987 (hereinafter the Leutwiler Report), p. 77 and Hoekman, Bernard, 'Services and Intellectual Property Rights', in Collins and Bosworth (eds.), *The New GATT – Implications for the United States*, Washington, D.C.: The Brookings Institution, 1994, p. 100.

<sup>83</sup> Article 68 in Part VII of the TRIPS Agreement.

<sup>84</sup> Article 1.1 of the TRIPS Agreement.

<sup>85</sup> Article 1.3 of the TRIPS Agreement.

<sup>86</sup> "Nationals" refer to persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in a separate customs territory Member of the WTO. See Footnote 1 of the TRIPS Agreement.

<sup>87</sup> But subject to the exceptions provided in other international agreements which have been incorporated into the TRIPS Agreement. See Article 3 of the TRIPS Agreement.

out in the TRIPS Agreement serve as the minimum levels of protection under domestic laws.

Unconditional MFN contained in Article 4 is a new addition to an international IP agreement. Under this principle, any advantage, favour, privilege or immunity granted to any nationals should be accorded immediately and unconditionally to nationals of other member countries.<sup>88</sup> By introducing unconditional MFN into the TRIPS Agreement, WTO members might be discouraged from making trade concessions bilaterally, and it could help to dispel fears of small countries being left out of bilateral agreements between major trading nations.<sup>89</sup>

In the area of Copyright and related rights, the TRIPS Agreement requires member states to comply with the substantive provisions of Berne Convention except for the protection of moral rights.<sup>90</sup> It further confers copyrights on computer programs and treats them as literary works,<sup>91</sup> and provides authors and their successors in title exclusive rental rights to authorise or prohibit the commercial rental of their works to the public.<sup>92</sup> Title holders of sound recordings could also benefit from exclusive rental rights but only when “.. such rental has led to widespread copying of such works which is materially impairing

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<sup>88</sup> For the purpose of Articles 3 and 4, “protection” is to include matters affecting the availability, acquisition, scope, maintenance and enforcement of IPRs as well as other matters affecting the use of IPRs addressed in the TRIPS Agreement. See Footnote 3 in the TRIPS Agreement.

<sup>89</sup> Any benefit accrued from bilateral negotiations has to be made available to WTO member states under unconditional MFN obligation. Ullrich, Hanns, ‘TRIPS: Adequate Protection, Inadequate Trade, Adequate Competition Policy’, *Pacific Rim Law & Policy Journal*, 4(1), 1995, p. 183.

<sup>90</sup> Article 9.1 of the TRIPS Agreement. Moral rights are the rights to claim authorship and to object to any derogative actions in relation to a work which would be prejudicial to the author’s honour or reputation. It was conferred under Article 6<sup>bis</sup> of the Berne Convention.

<sup>91</sup> Article 10.1 of the TRIPS Agreement.

<sup>92</sup> Article 11 of the TRIPS Agreement.



the exclusive right of reproduction conferred: on authors and their successors in title”.<sup>93</sup>

Performers, producers of phonograms and broadcasting organisations are also protected for the term of at least fifty years for the former and two and twenty years for the latter.<sup>94</sup>

Trademarks are defined, for the first time in a multilateral treaty, to include “any sign, or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings”.<sup>95</sup> The protection under the TRIPS Agreement covers both goods and services,<sup>96</sup> and the term of protection is for a minimum period of seven years with indefinite renewals if renewal conditions are met.<sup>97</sup>

Well-known marks of goods and services<sup>98</sup> are also protected even if they are not used in a country.<sup>99</sup> The knowledge of the trademark in the relevant sector of the public is to be taken into account when determining whether a particular trademark is well-known or not.<sup>100</sup>

The TRIPS Agreement is the first multilateral treaty to recognise geographical indications<sup>101</sup> as an IP.<sup>102</sup> The Agreement requires WTO members to legislate to

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<sup>93</sup> Ibid.

<sup>94</sup> Article 14.5 of the TRIPS Agreement.

<sup>95</sup> Article 15:1 of the TRIPS Agreement.

<sup>96</sup> Article 16.2 of the TRIPS Agreement.

<sup>97</sup> Article 18 of the TRIPS Agreement.

<sup>98</sup> Article 16.3 of the TRIPS Agreement.

<sup>99</sup> Article 16 of the TRIPS Agreement.

<sup>100</sup> Article 16.2 of the TRIPS Agreement.

<sup>101</sup> In Article 22 of the TRIPS Agreement, geographical indications are defined as:

“ indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.”

From the reading of this provision, quality, reputation, or other characteristics of a good can each be a sufficient basis for eligibility as a geographical indication. See WTO, WTO Intellectual Property – An Overview of the Agreement on Trade-Related Aspects of Intellectual Property Rights, <http://www.wto.org>, February 2, 1998.

prevent the use of any designations or presentations which could mislead the public as to the true geographical origin of a good <sup>103</sup> or yield unfair competitive advantages as a result. <sup>104</sup> The registration of a trademark must be refused or invalidated *ex officio* if a geographical indication is used which misleads the public as to the true place of origin if the legislation so permits or at the request of an interested party. <sup>105</sup>

Article 23 provides additional protection for geographical indications for wines and spirits, according to which interested parties must be provided the legal means to prevent the usage of a geographical indication identifying wines or spirits not originated from a place as indicated by the geographical indication, regardless of whether or not the true origin of the good is indicated or the geographical indication is accompanied by expressions such as “kind”, “type”, “style”, “imitation” or the like. <sup>106</sup> Further negotiations are mandated to be undertaken in the Council for TRIPS to establish a multilateral system of notification and registration for wines eligible for protection. <sup>107</sup>

Article 25.1 mandates protection for independently created industrial designs that are new or original. Taking into consideration short life cycle and sheer number of new designs in the textile sector, <sup>108</sup> Article 25.2 requires member states to design a system of protection for textile design which will not fail the application due to requirements on cost, examination or publication.

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<sup>102</sup> Article 22 of the TRIPS Agreement.

<sup>103</sup> Article 22.2(a) of the TRIPS Agreement.

<sup>104</sup> Article 22.2(b) of the TRIPS Agreement.

<sup>105</sup> Article 22.3 of the TRIPS Agreement.

<sup>106</sup> Article 23.1 of the TRIPS Agreement.

<sup>107</sup> Article 23.4 of the TRIPS Agreement.

<sup>108</sup> WTO. Website, <http://www.wto.org>, 2 February 1998.

The Treaty on Intellectual Property in respect of Integrated Circuits (IPIC Treaty) serves as the foundation for the protection of layout designs of integrated circuits in the TRIPS Agreement,<sup>109</sup> with further elaboration on the term of protection for layout designs to be for the duration of ten years,<sup>110</sup> the treatment of innocent infringements in Article 37.1, and the application of the compulsory licensing provision (Article 31) in the event of non-voluntary licensing of a layout design or of its use by or for the government without the right holder's authorisation.<sup>111</sup>

Article 39.1 of the TRIPS Agreement provides protection for undisclosed information, commonly known as trade secret or know-how. Although the Agreement does not require undisclosed information to be treated as a form of property, it is the first time undisclosed information is protected in a multilateral treaty.<sup>112</sup> Trade secret protection is increasingly important in ICs<sup>113</sup> because patent protection and trade secret are mutually reinforcing.<sup>114</sup> Any persons in lawful control of such information should have the possibility of preventing it from being disclosed to, acquired by, or used by others

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<sup>109</sup> Article 35 of the TRIPS Agreement.

<sup>110</sup> Article 38.1 of the TRIPS Agreement.

<sup>111</sup> Article 37.2 of the TRIPS Agreement.

<sup>112</sup> Although the North America Free Trade Agreement (NAFTA) guarantees the protection of trade secrets, it is a regional agreement. The Paris Convention deals with unfair competition (Article 10<sup>bis</sup>), and it is for the domestic legislation to determine what constitute acts of unfair competition. It does not deal with trade secret directly. See Bodenhausen, G. H. C., *Guide to the Application of the Paris Convention for the Protection of Industrial Property*, Paris: BIRPI, 1968, p. 144

<sup>113</sup> Clemente, C. L., 'A Pharmaceutical Industry Perspective', in Walker and Bloomfield (eds.), *Intellectual Property Rights and Capital Formation in the Next Decade*, American Centre for Capital Formation Centre for Policy Research, Lanham, MD: University Press of America, 1988, p. 127.

<sup>114</sup> Patent protection provides safeguard for a invention from the discovery of NCE to the launch of the new drug in the market. Trade Secret comes into play, for example, to prevent participants of R&D from leaking valuable information before patent application can be filed or during the period after filing of patent protection and before the commercial scale production. If a product could be copied easily by reverse

without consent in a manner contrary to honest commercial practices.<sup>115</sup> To qualify for the protection, the information has to be of commercial value and is perceived as secret to those who are within the business circles dealing with the kind of information in question, and the person in control of the information has taken reasonable steps to keep it secret.<sup>116</sup>

Article 39.1 also provides protection for test data, under which governments have legal duty to protect undisclosed clinical test data submitted by pharmaceutical companies for marketing approval of new chemical entities (NCEs) from unfair commercial use or disclosure.<sup>117</sup> It is an important area of protection for pharmaceutical companies to prevent rivals from free-riding on the confidential information to undermine the competitive position of the original manufacturers.<sup>118</sup>

Prior to the completion of the TRIPS Agreement, various Conventions only imposed general obligations for legal remedies in case of infringement<sup>119</sup> and left the enforcement of IPRs to domestic legislation. The lack of recourse in domestic courts was heavily

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engineering, patent protection is preferred because trade secret only has a delaying effect, See Sherwood, *Intellectual Property and Economic Development*, Boulder, Colorado: Westview Press, 1990, pp. 55-57.

<sup>115</sup> According to Footnote 10 of the TRIPS Agreement, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition. Does it preclude continued use or further discrimination of a trade secret by an innocent third party when improper practices were involved in the acquisition of the trade secret by the second party? See Hufbauer, Gary Clyde and Jeffrey J. Schott, *NAFTA – An Assessment*, Washington, D.C.: Institute for International Economics, 1993, p. 89.

<sup>116</sup> Article 39.1 of the TRIPS Agreement.

<sup>117</sup> The International Federation of Pharmaceutical Manufacturers Association (IFPMA) which represents the major global research-based pharmaceutical companies calls for a ten-year right of data exclusivity for the data files compiled for applications for drug regulatory approval. See IFPMA Position Paper: WTO Millennium Round, Geneva: IFPMA, 1999.

<sup>118</sup> "... except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.", see Article 39.2 of the TRIPS Agreement.

criticised by governments and MNCs alike, and regarded national legislation redundant when it is unenforceable, and the rectification of which was a must if IPP is to be strengthened.

The result is the enforcement procedures contained in Part III of the TRIPS Agreement. It imposes the obligation on all member states to provide for civil, administrative and criminal proceedings and border measures, allowing private parties to contest alleged violation of IPRs domestically. In order for private parties to invoke the TRIPS Agreement provisions before national courts, the implication is that its provisions are capable of becoming part of, and interact with, domestic legal order.<sup>120</sup> But the current status of the direct applicability of the TRIPS Agreement remains that private individuals cannot invoke its disciplines in domestic litigation because the Agreement only addresses member states and sets out the contractual rights and obligations between them.

WTO member states are obliged to ensure that fair and equitable domestic enforcement procedures are in place<sup>121</sup> so as to permit effective actions against any act of infringement of IPRs covered by the TRIPS Agreement.<sup>122</sup> Any decision made should

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<sup>119</sup> Articles 9, 10, 10<sup>bis</sup>, and 10<sup>ter</sup>(1) of the Paris Convention.

<sup>120</sup> Hoekman, Bernard M. and Petros C. Mavroidis, 'Policy Externalities and High-Tech Rivalry: Competition and Multilateral Co-operation Beyond the WTO', in OECD, *Market Access after the Uruguay Round: Investment, Competition and Technology Perspectives*, Paris: OECD, 1996, p. 213.

<sup>121</sup> Article 41.2 of the TRIPS Agreement.

<sup>122</sup> See Article 41.1 of the TRIPS Agreement. Under Article 41.5, members are not under obligations to set up separate legal system or reserve special resources for the legal protection of IP.

be based on the merit of individual cases.<sup>123</sup> And the opportunity for a judicial review has to be provided in civil cases.<sup>124</sup>

Article 42 provides civil judicial proceedings for the enforcement of IPRs. The civil remedies available include injunctions,<sup>125</sup> adequate damages,<sup>126</sup> the destruction of infringing goods or the disposal of them outside the channel of commerce.<sup>127</sup> As it may take time to reach decisions in judicial proceedings, provisional measures are available to enable judicial authorities to order prompt and effective actions to prevent an infringement from occurring or to prevent infringing goods from entering into the channels of commerce, and to preserve relevant evidence in regard to the alleged infringement.<sup>128</sup> Provisional measures could be adopted without prior hearing of the other party,<sup>129</sup> but such a decision is subject to judicial review.<sup>130</sup>

The enforcement measures discussed above only deal with domestic infringing activities at the point of production. In dealing with counterfeit and pirated goods presented for importation, it is compulsory to apply border measures to suspend the release of these

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<sup>123</sup> Article 41.3 of the TRIPS Agreement.

<sup>124</sup> But there is no obligation to provide a judicial review in criminal cases. See Article 41.4 of the TRIPS Agreement.

<sup>125</sup> Article 44:1 provides injunctive relief as "... to desist from an infringement, *inter alia* to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involves the infringement of an intellectual property rights..." which has to be available immediately after customs clearance of the goods.

<sup>126</sup> Article 45 authorises the judicial authority to order the infringer who knowingly, or with reasonable ground to know, engaged in infringing activity to pay adequate damages to compensate for the injury the right holder has suffered.

<sup>127</sup> Article 46 of the TRIPS Agreement. When considering this remedy, the test of proportionality applies, under which the judicial authority has to take into consideration the seriousness of the infringement, the remedies ordered, and the interests of third parties.

<sup>128</sup> Article 50.1 of the TRIPS Agreement.

<sup>129</sup> It is an *ex-parte* action. And parties affected have to be notified no later than when the measures are executed. Article 50.2 of the TRIPS Agreement.

goods into free circulation.<sup>131</sup> Criminal procedures and penalties are also available when it involves a willful commission on a commercial scale.<sup>132</sup>

Article 62.2 provides that the procedure for reviewing applications and registering an IPR should be completed within a reasonable period of time so to prevent unwarranted curtailment of the duration of protection. And any procedures concerning the acquisition or maintenance of IPRs should be fair, equitable, and based on the merit of individual cases.<sup>133</sup> This provision provides a legal basis to challenge practices such as burdensome or lengthy acquisition procedures which could constitute disguised restrictions to trade for protectionist reasons.<sup>134</sup>

According to Article 64.1 of the TRIPS Agreement:

“The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement ...”<sup>135</sup>

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<sup>130</sup> Article 50.4 of the TRIPS Agreement.

<sup>131</sup> Article 51 of the TRIPS Agreement. And it requires the co-operation between IP right holders and customs authorities.

<sup>132</sup> The remedies available include fines and imprisonment sufficient to provide a deterrent, seizure, forfeiture and destruction of the infringing goods, see Article 61 of the TRIPS Agreement. Furthermore, it is a matter for individual members whether to subject goods which infringe other IPRs to the same measures, see Articles 51 and 61 of the TRIPS Agreement.

<sup>133</sup> Article 62.4 of the TRIPS Agreement.

<sup>134</sup> Wineberg, Arthur, ‘The Japanese Patent System: A Non-Tariff Barrier to Foreign Businesses?’ *JWT*, 22(1), 1988, pp. 11-12. It has been common for MPCs to claim the erection of non-tariff barriers when product registration process in a country takes longer than the industry average.

<sup>135</sup> But Article 64.2 excludes non-violation complaints (Article XXIII: 1(b) being brought under the TRIPS Agreement until January 2000. What happened in January 2000 was that many DCs claimed that they were still not ready to fully implement the TRIPS Agreement, hence technically in violation of the Agreement.

It is important to point out that private entities could not be held as infringing international obligations under the TRIPS Agreement because it is an inter-state agreement.<sup>136</sup> And it is difficult to establish liability of states for the independent action of private entities on the basis of WTO laws.<sup>137</sup> Anti-competitive practices pursued by private entities without the support from governments cannot be challenged under Article XXIII: 1(a).<sup>138</sup> Only if it involves positive actions or specific support from governments that nullify or impair established domestic competition conditions<sup>139</sup> could a non-violation complaint be brought. Otherwise, private restrictive business practices (RBPs) that are not subject to any government involvement are excluded from the scope of Article XXIII: 1(b).

The Understanding on Rules and Procedures Governing Settlement of Disputes (DSU) is contained in Annex 2 to the Agreement Establishing the WTO. It is an integrated system applicable to all multilateral trade agreements covered by the WTO.<sup>140</sup> It provides a

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The US and the EU have agreed to exercise restraint in filing complaints against these offenders and expressed their willingness to consider extending the transitional period on a case-by-case basis. See *Financial Times*, January 20, 2000. It is not clear whether Article XXIII: 1(b) would be available under the TRIPS Agreement as in January 2000.

<sup>136</sup> Hoekman, Bernard M. and Petros C. Mavroidis, 'Competition, Competition Policy and the GATT', *The World Competition*, March 1994, p. 145, Malaguti, Maris-Chiara, 'Restrictive Business Practices in International Trade and the Role of the World Trade Organisation', *JWT*, 1998, pp. 137-138, and Scherer, F. M., *Competition Policies for an Integrated World Economy*, Washington, D.C.: The Brookings Institution, 1994, pp. 105-107.

<sup>137</sup> *Ibid.*

<sup>138</sup> Hoekman and Mavroidis, 1994, note 136 above, p. 129, and Scherer, note 136 above, p. 105.

<sup>139</sup> Private RBPs producing extra-territorial effects cannot be brought before the DSB. See Hoekman and Mavroidis, 1994, note 136 above, pp. 140-141.

<sup>140</sup> Article 1.1 of the DSU reads that:



legal framework for third-party adjudication<sup>141</sup> in disputes brought by governments,<sup>142</sup> and all WTO members are bound by it.<sup>143</sup>

The DSU is administered by the WTO.<sup>144</sup> The Dispute Settlement Body (DSB) is set up with the authority to establish panels, adopt Panel and Appellate Body reports, maintain surveillance of implementation of rulings and recommendations, and authorise suspension of concessions and other obligations under the covered agreement.<sup>145</sup> The DSB reach their decisions by the principle of consensus,<sup>146</sup> which is the continuation of the pre-existing GATT practice.<sup>147</sup>

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“The rules and procedures of this Understanding shall apply to disputes brought pursuant to the consultation and dispute settlement rules and procedures of the agreements listed in Appendix 1 to this Understanding, hereinafter referred to as the “covered agreements.” The rules and procedures of this Understanding shall also apply to consultations and the settlement of disputes between Members concerning their rights and obligations under the provisions of the Agreement Establishing the World Trade Organisation and of this Understanding taken in isolation or in combination with any other covered agreement.”

The Agreements covered by the Understanding are: the Agreement Establishing the World Trade Organisation, the Agreements on trade in goods, the General Agreement on Trade in Services, the TRIPS Agreement, the DSU, the Agreement on Trade in Civil Aircraft, the Agreement on Government Procurement, International Dairy Arrangement, and Arrangement Regarding Bovine Meat.

<sup>141</sup> Hudec, Robert, ‘The Role of the GATT Secretariat in the Evolution of the WTO Dispute Settlement Procedure’, in Bhagwati and Hirsch (eds.), *The Uruguay Round and Beyond – Essays in Honour of Arthur Dunkel*, Berlin: Springer-Verlag, 1998, pp. 101-122, p. 107.

<sup>142</sup> Article 1.1 of the DSU. Private parties are not allowed recourse under the WTO dispute settlement mechanism. It is up to their respective governments to take up the issue and act on their behalf.

<sup>143</sup> Article 2 of the Agreement Establishing the WTO states that “The agreements and Associated legal instruments included in Annexes 1, 2, and 3 are integral parts of this Agreement, binding on all Members”.

<sup>144</sup> Article III: 3 of the Agreement Establishing the WTO.

<sup>145</sup> Article 2:1 of the DSU.

<sup>146</sup> Article 2.4 of the DSU states that “Where the rules and procedures of this Understanding provide for the DSB to take a decision, it shall do so by consensus.” And in Footnote 1 of the DSU, it further states that:

“The Dispute Settlement Body shall be deemed to have decided by consensus on a matter submitted for its consideration, if no Member, present at the meeting of the Dispute Settlement Body when the decision is taken, formally objects to the proposed decision.”

<sup>147</sup> UNCTAD 1994 Report, note 5 above, p. 207. According to Jackson, there was little or no formal voting system at the CPs’ sessions under GATT that actions were frequently taken by consensus as interpreted by the Chairman in the absence of objection from any CP on the floor. Even though “consensus” is defined in Article 2.4 of the DSU, it is not the same as unanimity, since consensus is defeated only by a formal objection by a member present at the meeting. Thus those absent do not prevent a consensus, nor does an

As stated in Article XVI: 1 of the Agreement establishing the WTO, the global trade organisation shall be guided by the decisions, procedures, and customary practices established under GATT. In the context of dispute settlement, the past GATT dispute settlement practices remain relevant.<sup>148</sup> It therefore lays the groundwork for the establishment of a rule-based approach which will promote predictability expected of a legal system.

The legal features of the WTO dispute settlement mechanism are to affirm due process of law with the rights to the establishment of a panel and the right to appeal. And panels and appellate bodies operate within defined terms of reference.<sup>149</sup> There are three areas in the DSU which have been held as significant improvements in comparison with the dispute settlement mechanism under GATT:<sup>150</sup> (1) the first area is to do with the application of negative consensus<sup>151</sup> at four different stages of the dispute settlement process. It first appears in the process when a complaining party requests the

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abstention prevent a consensus. The practice in GATT was that some countries that had difficulty with a particular decision would remain silent out of deference to countries with a substantially higher stake in the pragmatic economic consequences of a decision, therefore, the practice of consensus itself involves some deference to economic power. See Jackson, John H., 'The World Trade Organisation, Dispute Settlement, and Code of Conduct', in Collins and Bosworth (eds.), *The New GATT – Implication for the United States*, Washington, D.C.: The Brookings Institution, 1994, p. 68, and Jackson, John H., *World Trade and the Law of GATT*, NY: The Hobbs-Marrill Co. Inc., 1969, p. 123, and WTO, Focus, May 1998, p. 6.

<sup>148</sup> The most important GATT document relevant to the DSU is The Understanding Regarding Notification, Consultation, Dispute Settlement and Surveillance, adopted in the Tokyo Round MTNs on 28 November 1979, codified GATT dispute settlement procedures (GATT, BISD 26<sup>th</sup> Supp., 210, 1980). Other document includes the Decision on Procedures under Article XXII on Questions Affecting the Interests of a Number of Contracting Parties, approved by CPs on November 1958,

<sup>149</sup> Articles 3(2) and 19(2) of the DSU.

<sup>150</sup> For example, see Hudec, Robert, *Enforcing International Trade Law – The Evolution of the Modern GATT Legal System*, New Hampshire: Butterworth Legal Publishers, 1993, pp. 235-238, UNCTAD 1994 Report, note 5 above, pp. 205-219.

<sup>151</sup> With the application of negative consensus, a decision is deemed to have been reached by consensus if no member present at the meeting objects to the proposal put forward. See, for example, discussion in Qureshi, Asif H., *International Economic Law*, London: Sweet & Maxwell, pp. 295-296.

establishment of a panel either after the failure to settle the dispute by consultations,<sup>152</sup> or the other party fails to reply to the request for consultations.<sup>153</sup> A panel is to be set up as promptly as possible unless the DSB decides by consensus not to do so.<sup>154</sup> Such a negative consensus could be blocked by one of the parties involved in the dispute, it is in effect an automatic procedure for the establishment of a panel; (2) when it comes to the adoption of the panel report, Article 16.4 stipulates that:

“Within sixty days of the issuance of a panel report to the Members, the report shall be adopted at a DSB meeting unless one of the parties to the dispute formally notifies the DSB of its decision to appeal or the DSB decides by the consensus not to adopt the report...”

Therefore, unless the complaining party decides to appeal, a panel report should be adopted by the DSB unless they veto the adoption by consensus. The adoption of panel reports can no longer be blocked by the losing party as often happened under the GATT system; (3) the establishment of an Appellate Body is an innovation in the GATT dispute settlement mechanism. On appeal, the Appellate Body will only consider legal issues covered in the panel report and the legal interpretation developed by the panel.<sup>155</sup> And, as stated in Article 17.14, an appellate report is binding unless overturned by the DSB by consensus,<sup>156</sup> (4) when a member involved in a dispute is found to be in breach of its legal obligation, but fails to bring the measure concerned into conformity with the rulings

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<sup>152</sup> Article 4.7 of the DSU.

<sup>153</sup> Articles 4.1, 4.2, and 4.3 of the DSU.

<sup>154</sup> Article 6.1 of the DSU.

<sup>155</sup> Article 17.6 of the DSU.

or recommendations of the panel or appellate report, the other party to the dispute may request the DSB to authorise the suspension of concessions or other obligations<sup>157</sup> unless the DSB rejects the request by consensus.<sup>158</sup>

The second area of improvement is the stipulation of specific time frames for different stages of the dispute settlement process. For example, according to Article 12.9, the panel is to conclude its work within six months from the time the composition and terms of reference of the panel have been agreed upon to the time when the final report is provided to the parties to the dispute. And in no case should the period exceed nine months in case of delay.<sup>159</sup> In case of appeal, the appeal procedure shall not exceed 60 days from the date a party formally notifies the intention to appeal to when the Appellate Body issues its decision.<sup>160</sup>

The third area of improvement is the availability of cross-sector retaliation in which the suspension of concessions is allowed across covered agreements. The suspension of concessions is a temporary remedy available if the party found to be in breach fails to comply fully with the rulings or recommendations of the panel or Appellate Body within a reasonable period of time.<sup>161</sup> The complaining party should first seek to suspend concessions within the same sector where the breach is found.<sup>162</sup> When it is impracticable or ineffective to do so, the complaining party may seek to suspend

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<sup>156</sup> The decision whether to adopt the Appellate Report has to be made within 30 days following its issuance to the WTO members, see Article 17.14 of the DSU.

<sup>157</sup> Article 22.3 of the DSU.

<sup>158</sup> Article 22.6 of the DSU.

<sup>159</sup> Article 12.9 of the DSU.

<sup>160</sup> Article 17.5 of the DSU.

<sup>161</sup> Article 22.1 of the DSU.

concessions in another sector within the same agreement.<sup>163</sup> For example, with respect to the TRIPS Agreement, the IPRs covered in Part II, the enforcement obligations under Part III, and Part IV are regarded as separate sectors for the purpose of cross-sector retaliation.<sup>164</sup> Only if the circumstances are serious enough and seeking suspension of concessions from other sectors are not practical or effective, the complaining party may seek an authorisation to suspend concessions made in another covered agreement.<sup>165</sup> For example, when a breach of obligations under the TRIPS Agreement is found, market access concessions in one of the Agreements on Trade in Goods might be targeted for the suspension of trade concessions.<sup>166</sup>

The comprehensiveness of the dispute settlement mechanism exceeded the negotiating mandate articulated in the Punta del Este Declaration.<sup>167</sup> It brings all grievances within the WTO system so that the WTO members could not justify resorting to unilateral actions.<sup>168</sup> And for small countries, the strengthened mechanism might redress some of the imbalance of power when it comes to handling disputes.<sup>169</sup> Unilateralism was one of

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<sup>162</sup> Article 22.3(a) of the DSU.

<sup>163</sup> Article 22.3(b) of the DSU.

<sup>164</sup> The definition of "sector" with respect to trade-related IPRs is found in Article 22.3(f) of the DSU. It means each of the categories of IPRs covered in Section 1, or Section 2, or Section 3, or Section 4, or Section 5, or Section 6, or Section 7 of Part II, or the obligations under Part III, or Part IV of the TRIPS Agreement.

<sup>165</sup> Article 22.3(c) of the DSU. The definition of "agreement" could be found in Article 22.3(g) to include Agreements on Trade in Goods, General Agreement on Trade in Services, and the TRIPS Agreement.

<sup>166</sup> Examples can be drawn from the unilateral retaliation the US imposed on Brazil in 1988 for the alleged infringement of patents on products and processes of US pharmaceutical companies. Retaliations were imposed on products such as pulp and paper and electronic appliances exported to the US from Brazil, see Moreira, Marcilio Marques, 'The Point of View of an Emerging Trading Nation: Brazil', in Bhagwati and Patrick (eds.), *Aggressive Unilateralism – America's 301 Trade Policy and the World Trading System*, London: Harvester Wheatsheaf, 1991, pp. 257-258.

<sup>167</sup> Stewart (ed.), note 38 above, p. 2913.

<sup>168</sup> Hudec, 1993, note 150 above, p. 237.

<sup>169</sup> Jackson, John, 'The Uruguay Round Results and National Sovereignty', in Bhagwati and Hirsch (eds.), *The Uruguay Round and Beyond – Essays in Honour of Arthur Dunkel*, Berlin: Springer-Verlag, 1998, pp. 293-304, p. 296.

the major concerns expressed by many participating countries during the Uruguay Round MTNs as undermining the integrity of the global trading system. Incorporating a treaty commitment to curtail unilateral actions, such as Section 301 actions imposed by the US on its trading partners,<sup>170</sup> was seen as necessary after the Montreal Mid-Term meeting.<sup>171</sup> This demand was duly incorporated into the DSU that obliges WTO members to bring all grievances rising from the covered agreements within the WTO system.<sup>172</sup> Any member who takes unilateral retaliations could be in violation of the treaty obligations under Article 23.1, and is itself an actionable offence.

Under the TRIPS Agreement, time-limited derogation in the form of different transitional periods is available depending upon the development status of a country,<sup>173</sup>. By delaying the full implementation of TRIPS obligations, the arrangement allows WTO members time to effect legal, institutional, and administrative reforms required.<sup>174</sup> However, the obligation to provide NT and unconditional MFN came into effect when the Agreement Establishing WTO entered into force in January 1995.<sup>175</sup>

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<sup>170</sup> See discussion in Chapter 2.3.1.

<sup>171</sup> Hudec, 1993, note 150 above, p. 237.

<sup>172</sup> Reading Articles 1.1 and 23 of the DSU jointly, it is mandatory to bring trade disputes relating to covered agreement to the WTO dispute settlement mechanism. Article 23 reads that:

“When Members seek the redress of a violation of obligation or other nullification or impairment of benefits under the covered agreements or an impediment to the attainment of any objective of the covered agreements, they shall have recourse to, and abide by, the rules and procedures of this Understanding.”

And members shall not make an unilateral decision that a violation has occurred without following the rules and procedures of the DSU (Article 23.2(a)).

<sup>173</sup> The status of DCs is determined on the basis of self-selection process existed under the UN system. In determining the status of LDCs, the WTO follows the UN list of LDCs. See UNCTAD, *The Least Developed Countries: 1993-1994 Report*, UN: NY, 1994, p. xi, and WTO Website for the WTO's adoption of the UN list for the purpose of effecting transitional arrangements.

<sup>174</sup> Srinivasan, note 8 above, p. 53.

<sup>175</sup> Article 65.2 of the TRIPS Agreement.

Following the date of entry into force of the Agreement Establishing WTO, ICs were given one year to bring their domestic legal and administrative apparatus into line with the TRIPS Agreement.<sup>176</sup> DCs and countries in transition<sup>177</sup> are given the option of four more years until 2000 to implement the TRIPS Agreement.<sup>178</sup> For DCs who did not provide patent protection in their domestic legislation in January 1995, they have to fully comply with the patent protection under TRIPS in 2005.<sup>179</sup> LDCs are not required to apply the provisions of the TRIPS Agreement until 2006.<sup>180</sup> However, during the transitional period, WTO members are obliged to ensure that any changes in their laws, regulations, and practice made during that period do not result in a lesser degree of consistency with the provisions of the TRIPS Agreement.<sup>181</sup>

#### **4.4 The legal provisions of patent protection for pharmaceuticals under the TRIPS Agreement**

By incorporating the main rules of patent protection from the Paris Convention,<sup>182</sup> and adding further obligations of its own, the substantive norms of patent protection contained in the TRIPS Agreement go beyond what is stipulated in the Convention. They

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<sup>176</sup> Article 65:1 of the TRIPS Agreement states that "...no Member shall be obliged to apply the provisions of this (TRIPS) Agreement before the expiry of a general period of one year following the date of entry into force of the Agreement Establishing the WTO," which was January 1, 1995. See GATT, Focus, The Marrakesh Declaration, May 1994, p. 7.

<sup>177</sup> Countries in transition include those which are "in the process of transformation from a centrally-planned into a market, free-enterprise economy...", see Article 65.3 of the TRIPS Agreement.

<sup>178</sup> Articles 65:2 and 65:3 of the TRIPS Agreement

<sup>179</sup> Article 65:4 of the TRIPS Agreement.

<sup>180</sup> And the Council for TRIPS should accord LDCs further extensions upon their request. Article 66:1 of the TRIPS Agreement.

<sup>181</sup> See Article 65.5 of the TRIPS Agreement which came into effect on 1 January 1995.

<sup>182</sup> See Articles 1.3 and 2.1 of the TRIPS Agreement.

are expressed in abstract legal concept and principles,<sup>183</sup> which gives a general understanding of the legal framework, but does little in the way of harmonising domestic practices.<sup>184</sup>

Article 27.1 of the TRIPS Agreement deals with patentable subject matters. It states that “.. patent shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application...” It further stipulates that patents should be available without discrimination as to the place of invention, which effectively repudiates the US domestic legislation of limiting evidence used in support of patent applications to be solely of domestic origin.<sup>185</sup>

There are three exceptions to Article 27 which exclude inventions from patent protection:

1) when the commercial exploitation of an invention is necessary to protect *ordre public* or morality, including to protect human, animal, plant life, health, or to avoid serious prejudice to the environment, WTO members may exclude the invention from being

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<sup>183</sup> In contrast with the protection of Trademarks where TRIPS requires a fairly precise mode of implementation as the standard of protection is built upon the elaborate rules on the subject found in the Paris Convention.

<sup>184</sup> UNCTAD, 1996, note 81 above, pp. 29 and 32. Concurrent to MTNs on TRIPS, WIPO has been working on a Patent Law Harmonisation Treaty. It sets forth a number of concrete provisions that will have the effect of harmonising certain administrative and substantive rules for obtaining and enforcing patents in countries subscribed to it. See Gorlin, Jacques J., ‘Updating on International Negotiations on Intellectual Property Rights’, in Wallerstein, Moguee and Schoen (eds.), *Global Dimensions of Intellectual Property Rights in Science and Technology*, Washington, D.C.: National Academy Press, 1993, pp. 179-180.

<sup>185</sup> Under the first-to-invent system in the US, Section 104 of the US patent law states that “In patent interference proceedings...an applicant for a patent...may not establish a date of invention by reference to knowledge or use of the invention...in a foreign country”. It effectively restricts the evidence of inventive acts to the territory of the US. See 35 U.S.C. § 104 (1988), which was superseded by 35 U.S.C. § 104(a) (1993) that permits proof of inventive activity in Mexico and Canada.



patentable;<sup>186</sup> 2) diagnostic, therapeutic and surgical methods for the treatment of humans or animals could also be excluded from patentability;<sup>187</sup> 3) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes could both be considered to be excluded from patentability.<sup>188</sup> But plant varieties should be protected by patents or by an effective *sui generis* system or a combination of both.<sup>189</sup>

Article 29 concerns the requirement of disclosure of the nature of patentable invention.

It requires the disclosure in a patent application to be sufficiently clear and complete for the invention to be carried out by a person skilled in the art. How specific or detailed the disclosure has to be is a matter for domestic law. The time-frame for the publication of patent application after filing could also have a direct consequence on the speed of diffusion of technological information.<sup>190</sup>

A process patent provides protection not only for use of the process but also for products derived directly from the process.<sup>191</sup> And the burden of proof has been reversed in cases of civil proceedings involving process patent. It is now on the defendant to prove that the process to obtain an identical product to the patented one is different from the patented process.<sup>192</sup> When the product obtained by the patented process is new,<sup>193</sup> or if there is a

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<sup>186</sup> Article 27.2 of the TRIPS Agreement.

<sup>187</sup> Article 27.3(a) of the TRIPS Agreement.

<sup>188</sup> Article 27.3(b) of the TRIPS Agreement.

<sup>189</sup> Article 27.3(b) of the TRIPS Agreement. This provision does not cover genetically engineered plant life, it is subject to review four years from the date of entry into force of the WTO Agreement.

<sup>190</sup> Oddi, Samuel A., 'TRIPS – Natural Rights and a 'Polite Form of Economic Imperialism'', *Vand JTL*, 29(3), 1996, p. 463.

<sup>191</sup> Article 28.1(b) of the TRIPS Agreement.

<sup>192</sup> Article 34.1 of the TRIPS Agreement.

substantial likelihood that the identical product was made by the process and the patent owner has not been able to determine the process actually used through reasonable efforts,<sup>194</sup> any identical product produced without the consent of the patent owner will be deemed to have been obtained by the patented process in the absence of proof to the contrary.

A product patent confers on the patent owner the exclusive rights to prevent third parties from making, using, offering for sale, selling, or importing<sup>195</sup> the patented product without authorisation.<sup>196</sup> Importation is one of the exclusive rights conferred by patent protection, but whether importation itself constitutes working is left unanswered by the TRIPS Agreement. What is clear is that if a patent holder supplies a domestic market by import only, it does not constitute a ground for granting compulsory licences as in Article 5A(1) of the Paris Convention.<sup>197</sup>

Compulsory licenses and government use without the authorisation of the right holder remains available under TRIPS, but are subject to safeguard clauses contained in Article 31 to protect the legitimate interests of the right holders. Prior negotiations with the right holder to negotiate a licensing agreement on reasonable commercial terms and conditions

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<sup>193</sup> Article 34.1(a) of the TRIPS Agreement.

<sup>194</sup> Article 34.1(b) of the TRIPS Agreement.

<sup>195</sup> While the TRIPS Agreement recognises the exclusive right of patent owners to use, sell, import or distribute the patented products, these exclusive rights are subject to Article 6 of the TRIPS Agreement, the provision dealing with the Doctrine of Exhaustion. See Footnote 6 of the TRIPS Agreement. The Doctrine of Exhaustion will be discussed in Chapter 5.3.

<sup>196</sup> Article 28.1(a) of the TRIPS Agreement.

<sup>197</sup> See discussion in Chapter 1.5.

is necessary.<sup>198</sup> Failing that, the authorisation of compulsory licences should be based on the merit of each case.<sup>199</sup> Once granted, the compulsory licence should be non-exclusive<sup>200</sup> and non-assignable.<sup>201</sup> Any use of the licence should be limited to predominantly supplying the domestic market of the host country.<sup>202</sup> The right holder is entitled to adequate remuneration<sup>203</sup> taking into account the economic value of the authorisation.<sup>204</sup> Furthermore, the legal validity of the authorisation should be subject to judicial review.<sup>205</sup> But when anti-competitive practices are established which forms the ground for the granting of a compulsory licence, the requirement of prior negotiations with the right holder is waived, and its use is not restricted to the supply of the domestic market of the host country only.<sup>206</sup>

Article 33 provides a minimum of 20 years of patent protection from the date of filing. It does not deal with the extension of patent term to compensate for delays caused by governmental regulatory approval processes.<sup>207</sup> Some countries have introduced patent

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<sup>198</sup> Prior negotiations with the right holder may be waived in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. Article 31(b) of the TRIPS Agreement.

<sup>199</sup> Article 31(a) of the TRIPS Agreement.

<sup>200</sup> Article 31(d) of the TRIPS Agreement.

<sup>201</sup> Article 31(e) of the TRIPS Agreement.

<sup>202</sup> Article 31(f) of the TRIPS Agreement.

<sup>203</sup> The concept of "adequate" compensation derives from the Hull Formula which was initially designed by capital exporting countries to 'legalise' the taking of foreign property by host countries. Under the formula, compensation should be paid adequately (fully), promptly and effectively, the property is taken for public interest, and the principle of non-discrimination was observed. But the Charter of Economic Rights and Duties (UN General Assembly Resolution 3281 (1974)) recognises the right of a state to take foreign property on the payment of "appropriate" compensation, which is considered to be less than what is provided by the Hull Formula.

<sup>204</sup> Article 31(h) of the TRIPS Agreement.

<sup>205</sup> Article 31(i) of the TRIPS Agreement.

<sup>206</sup> Article 31(k) of the TRIPS Agreement.

<sup>207</sup> In some countries, health authorities demand extra local clinical trial to be conducted on the basis that genetic and metabolic differences limit the validity of the evidence of a drug's safety and efficacy gathered in the west. Extra local clinical trials could take up 2 to 3 years to complete. Ullrich, 1995, note 89 above, p. 177, note 106.

term restoration measures to compensate for the time lost on conducting pre-marketing clinical trials and waiting for regulatory approval.<sup>208</sup> This is seen by the pharmaceutical industry as the recognition by governments of the importance of patent protection to pharmaceuticals.<sup>209</sup>

Patent protection under the TRIPS Agreement does not apply retrospectively.<sup>210</sup> It therefore does not cover products which existed prior to the application of the Agreement.<sup>211</sup> But with regard to pharmaceutical and agricultural chemical pipeline products,<sup>212</sup> Articles 70.8 and 70.9 operate in tandem to impose special obligations on WTO members who choose to delay the introduction of patent protection by making use of transitional arrangements available to DCs and LDCs.

Article 70.8 states that:

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<sup>208</sup> *De jure* patent term extensions have been enacted by the EC, Switzerland, the US, Japan, Australia and Israel. Under the US Drug Price Competition and Patent Restoration Act of 1984, the patent term could be extended for the duration of the drug application review time by the Federal Drug Administration plus one and a half of clinical test time. The maximum extension is five years with no extension allowed beyond 14 years of effective patent life. See discussion in WTO, WT/DS114/R, the Panel Report on Canada – Patent Protection of Pharmaceutical Products, pp. 153-154 and Nogues, Julio, *Patents and Pharmaceutical Drugs: Understanding the Pressures on Development Countries*, International Economic Department, Washington, D.C.: The World Bank, p. 100.

<sup>209</sup> Redwood, 1994, note 31 above, p. 18.

<sup>210</sup> Article 70.1 of the TRIPS Agreement.

<sup>211</sup> Article 70(3) of the TRIPS Agreement states that “existing products and pipeline products with patents that have been published abroad will not be qualified for protection”. Therefore, for leading drugs with development time averaging 8-10 years, the full impact of TRIPS will be seen in 2003-2005. See Redwood, 1994, note 31 above, p. 52.

<sup>212</sup> Pipeline products include those whose patent applications are being evaluated by the national patent office, products that are in the development stage, and products that are not yet sold in countries that are updating their intellectual property laws. See Industry Functional Advisory Committee for Trade in Intellectual Property Rights, Report of the Industry Functional Advisory Committee for Trade in Intellectual Property Rights (IFAC-3) on the North American Free Trade Agreement, September 1992, p. 17 and Hoekman, 1994, note 14 above, p. 105.

“Where a Member does not make available as of the date of entry into force of the Agreement Establishing the WTO patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

- (i) Notwithstanding the provisions of Part VI above, provide as from the date of entry into force of the Agreement Establishing the WTO a means<sup>213</sup> by which applications for patents for such inventions can be filed;
- (ii) apply to these applications, as of the date of application of this agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the

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<sup>213</sup> The “means” under Article 70.8(i) is the equivalent of a sound legal base for the filing of patent applications. What constitutes a sound legal basis is a matter of domestic law (Article 1.1 of the TRIPS Agreement.) See WTO, WT/DS50/AB/R, 19 December 1997, Report of the Appellate Body on India -- Patent Protection for Pharmaceutical and Agricultural Chemical Products (hereinafter US v India Appellate Body Report), p. 22. The US v India case was the first IP dispute before the DSB, brought by the US against India on two accounts. Firstly, India was accused of failing to establish a means for the filing of patent application for pharmaceutical and agricultural chemical products pursuant to the mail box provision of Article 70.8. Secondly, India also failed to establish a mechanism for the granting of exclusive marketing rights effective from the date of entry into force of the Agreement Establishing WTO pursuant to Article 70.9.

application;

- (iii) provide patent protection in accordance with this agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in sub-paragraph (ii) above.”

Starting from January 1995,<sup>214</sup> any member who opts to benefit from transitional arrangements is under the obligation to provide the pipeline protection for pharmaceutical and agricultural chemical products. DCs’ obligations under Article 70.8 is “to provide a legal mechanism for the filing of mailbox applications that provide a sound legal basis to preserve both the novelty of the inventions and the priority of the applications<sup>215</sup> as of the relevant filing and priority date.”<sup>216</sup> When the domestic patent system is implemented in full upon the expiration of the transitional period, these patent applications are to be treated as normal applications. If and when a patent is granted, it

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<sup>214</sup> The ordinary meaning of the term “notwithstanding the provisions of Part VI” in Article 70.8(I) of the TRIPS Agreement is to be interpreted as indicating that transitional arrangements do not apply to the implementation of Article 70.8. See WTO, WT/DS79/R, 24 August 1998, Report of the Panel on India -- Patent Protection for Pharmaceutical and Agricultural Chemical Products (hereinafter EC v India Panel Report), p. 66. The EC v India case concerns a complaint brought by the European Community against India in India’s failure to implement Articles 70.8 and 70.9 of the TRIPS Agreement.

<sup>215</sup> For patent protection, the right of priority, as stipulated in Article 4 of the Paris Convention, is incorporated into the TRIPS Agreement by virtue of Article 1.3 of the TRIPS Agreement.

<sup>216</sup> See US v India Appellate Body Report, note 213 above, pp. 6 and 22.

will be for the remainder of the twenty-year patent term from the date the application was filed.<sup>217</sup>

For pharmaceutical products which are granted marketing approval during the transitional period, Article 70:9 confers on them exclusive marketing rights for the duration of five years, or until a product patent is granted or rejected, whichever period is shorter. In order to be eligible for this protection, the relevant product has to have been granted patent and free sales certificate in another member state.<sup>218</sup> This exclusive marketing rights are a *quid pro quo* for the delay of the availability of product patents for pharmaceutical and agricultural chemical products until January 2005 based on a careful balancing of obligations between interested parties participated in the Uruguay Round MTNs.<sup>219</sup>

The emphasis on striking a balance between rights and obligations permeates through the whole negotiation process of the TRIPS Agreement. It is reflected in the negotiation mandate for TRIPS MTNs<sup>220</sup> and the preamble of the TRIPS Agreement.<sup>221</sup> They

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<sup>217</sup> Article 70:8(c) of the TRIPS Agreement.

<sup>218</sup> Free sales Certificate is issued by governments as a proof of granting marketing approval to a product in the issued country. Under usual circumstances, NCEs are first marketed in ICs where MPCs' target customers are. Most of ICs have patent system in place, NCEs with marketing approval from them should have gone through regulatory scrutiny to prove their efficacy, quality and safety, which provide the assurance DCs seek.

<sup>219</sup> The Panel made this observation by looking into the drafting history of the TRIPS Agreement, see EC v India Panel Report, note 214 above, p. 68.

<sup>220</sup> The Punta del Este Declaration states that:

“In order to reduce the distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines...”

See note 32 above.

address the need to strengthen IPP in order to reduce distortions and impediments to international trade, and the importance of ensuring that the negotiated measures and procedures themselves do not become barriers to legitimate trade. They also acknowledge the interface between IPP, international trade, and competition law.<sup>222</sup>

#### 4.5 Post-TRIPS Agreement uncertainties

In the era of post-TRIPS Agreement, MPCs are concerned with how individual governments will implement the provisions which contain broad language, and consequential impacts on competition.

The compulsory licensing provision is one example in point. There have been criticisms of the vagueness of the wording,<sup>223</sup> such as the absence of the actual wording “compulsory licence” in Article 31. But some argue that it then gives the flexibility needed when member states implement their domestic patent legislation. To prevent potential licensing abuses<sup>224</sup> is very much on the agenda when DCs could design their patent legislation for fears of unequal bargaining power between themselves as buyers of technology, and sellers. Especially when many DCs have no sophisticated domestic anti-

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<sup>221</sup> The first paragraph of the preamble of the TRIPS Agreement reads:

“Members, desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;”

<sup>222</sup> In the current discussion, competition policy and anti-trust law are used interchangeably.

<sup>223</sup> See, for example, Redwood, 1994, note 31 above, p. 48.

<sup>224</sup> One examples of potential licensing abuse is when an agreement is used as a vehicle for a cartel arrangement to fix prices, limit output or divide markets, see OECD, *Competition Policy and Intellectual Property Rights*, Paris: OECD, 1989, pp. 23-26 for further details.



competitive legislation to control restrictive business practices of MPCs. UNCTAD 1996 Report advises against DCs' applying compulsory licensing provisions too stringently, or the innovation could be held in the form of trade secret rather than as patents, and the diffusion of technological knowledge would likely to be restricted.<sup>225</sup> The Report also points out that strengthened patent protection could induce more use of licensing agreements by MPCs to facilitate monitoring of drug quality in order to elevate quality standards of drug production in DCs. Stringent compulsory licensing provisions are often a deterrent for MPCs to do so.<sup>226</sup>

Article 27 dealing with patentable subject matters is another provision capable of broad interpretation. With no international standard of absolute novelty or non-obviousness,<sup>227</sup> member countries could apply the criteria of patentability in accordance with their domestic patent law.<sup>228</sup> Whether a country allows second uses of known products when stringent novelty criteria are applied could have direct consequences on MPCs' development of "me-too drugs".<sup>229</sup> Since no definition of "invention" is provided in Article 27, WTO members are relatively free to draw the line between non-patentable discovery and actual inventions.<sup>230</sup> They could be construed to allow, for example, the

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<sup>225</sup> UNCTAD, 1996, note 81 above, p. 13 and Taylor C. T. and Z. H. Silberstone, *The Economic Impact of the Patent System: A Study of British Experience*, Cambridge: Cambridge University Press, pp. 350 and 359.

<sup>226</sup> Ibid.

<sup>227</sup> It was in November 1963 when inventive step and non-obviousness were recognised by the European Patent Convention and the Strasburg Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions as the common standards of patentability. Other countries not members to the Conventions are free to specify their own criteria.

<sup>228</sup> UNCTAD, 1996, note 81 above, p. 32.

<sup>229</sup> See discussion in Oddi, 1996, note 190 above, pp. 464 and 465.

<sup>230</sup> UNCTAD, 1996, note 81 above, p. 34.

exclusion of eligibility of biotechnology inventions from patent protection.<sup>231</sup> Such a policy will have significant effects on the future of new drug introduction and competitive strength of the research-based pharmaceutical industry.<sup>232</sup>

Articles 27.2 allows WTO members to exclude inventions from patentability for the protection of human, animal, plant life, health, or environment. It is difficult to predict how broadly these exceptions will be applied. For those economies dependent on agriculture, for example, the issue of patenting plant life in food industry has been controversial.<sup>233</sup> Despite the claim that genetically engineered plants are commercially more viable, DCs argue that patented genetically engineered plant life would be

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<sup>231</sup> Ullrich comments that the TRIPS Agreement left open the issue of patent protection for genetic engineering inventions because ICs had not yet decided on the proper policy to deal with it domestically. See Ullrich, 1995, note 89 above, p. 175. There are many problems surrounding patent protection for bio-pharmaceutical inventions. For example, genetic engineering involves replicating a natural compound already existed in nature, its patentability per se is dealt with differently in ICs. Furthermore, patent protection for these products is not strong because patent claims for bio-pharmaceutical products are often defined in broad terms, which leads to difficulty in proving an infringement. See discussion in Correa, Carlos M., 'The Pharmaceutical Industry and Biotechnology Opportunities and Constraints for Developing Countries', *World Competition*, vol. 15, no. 42, 1992, pp. 43-63.

<sup>232</sup> *Ibid.*, pp. 44-47 and FT, The New Drug Race, June 1, 1999, p. 19. Biotechnology products are the application of genetics in human medicine, which is based on biology. Instead of testing thousands of molecules until a useful one is identified, which is costly and time-consuming, biotechnology enables researchers to target the biochemical reaction that a disease triggers and devise a chemical compound to stop them. As pharmaceutical companies' competitiveness is partly based on the introduction of new chemical entities, the industry sees the development in biotechnology as their future. If biopharmaceuticals are excluded from patent protection, the future of new drug development will be put in jeopardy. See also OECD, TD/TC/WP99815FINAL, February 2, 1999, p. 9. In the preparatory stage for the Ministerial Meeting in Seattle in November 1999, Canada, Australia and Japan were pushing for a working group on biotechnology to examine how WTO rules could be applied to genetically modified products, especially regarding the issue of safety of GM products. See *The Economist*, November 27, 1999, p. 26.

<sup>233</sup> See FT, December 3, 1999, p. 13 and Ringo, Frederick, 'The Trade-Related Aspects of Intellectual Property Rights Agreement in the GATT and Legal Implications for Sub-Saharan Africa', *JWT*, 28(6), 1994, p. 131. According to FT, The EC faced opposition from its member states of its attempt to endorse the US's demand that the WTO sets up a working group on biotechnology as part of a new world trade round. Many DCs support a separate initiative on a bio-safety protocol negotiated under the aegis of the United Nation bio-diversity convention

expensive, damaging to the environment, and it is unsustainable as it does not have drought or sickness resistant strains found in crops cultivated by traditional method.<sup>234</sup>

The desire to seek a rule-based global trading system reflects MPCs preference for an open global market with a minimum of intervention by national governments as demonstrated by the support they have given to inter-governmental free trade agreements aimed at reducing jurisdictional conflicts.<sup>235</sup> What MPCs also recognise is the legitimacy of nation states as economic units in international relations who assert their sovereignty by participating in the setting of global trading rules.<sup>236</sup> And that host governments' domestic policy-making power will affect how MNCs conduct their business and utilise their created assets in host countries.<sup>237</sup>

The last two decades has also seen a shift of governments' efforts from regulating the behaviours of MNCs to conform to national or regional economic objectives to encouraging cross-border mechanisms that promote a positive interaction between national governments and MNCs.<sup>238</sup> The globalisation of economic activities brought about the realisation by governments that the success of their domestic economic policies will be judged on the strength of the country's international competitive position. Faced

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<sup>234</sup> Ibid., p. 132 and UNCTAD, 1996, note 81 above, Annex 2.

<sup>235</sup> Vernon, Raymond, *In the Hurricane's Eye – The Troubled Prospects of Multinational Enterprises*, Massachusetts: Harvard University Press, 1998, p. 150 and Vernon, Raymond, 'Research on Transnational Corporations: Shedding Old Paradigms', *Transnational Corporation*, 3(1), 1994, p. 152.

<sup>236</sup> Vernon, 1998, note 235 above, p. 8 and FT, December 3, 1999, p. 19. The other side of the coin is that any international agreement affecting MNCs will need MNCs' support if it is to be adopted and applied. See Vernon, 1994, note 235 above, p. 152.

<sup>237</sup> Dunning, John H., *Multinational Enterprise and the Global Economy*, Reading Mass: Addison-Wesley Publishing Company, 1993, pp. 528-529 and Vernon, 1998, note 235 above, p. 8.

<sup>238</sup> Dunning, 1993, note 237 above, ch. 19 and Barry Jones, R. J., *Globalisation and Interdependence in the International Political Economy*, London: Pinter Publishers, pp. 177-178.

with the limit of their economic boundaries and the susceptibility of their domestic policies to international economic events, they found it necessary to attract MNCs' inward investment<sup>239</sup> and to foster the unique technological and organisational assets of MNCs to optimise the contribution of MNCs to the competitiveness of nation states.<sup>240</sup> They also need to effectively influence MNCs' patterns of behaviour and to ensure that MNCs' activities are in support of their economic and social goals.<sup>241</sup> A co-operative approach thus has emerged between host governments and MNCs to strive for mutually beneficial outcome in their interaction.

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<sup>239</sup> Cross-border investments by MNCs often create jobs, upgrade the quality of local workforce, and strengthen host governments' currency on the foreign exchange markets, for example. See Vernon, 1998, note 235 above, p. 31.

<sup>240</sup> Ibid., pp. 575-616.

<sup>241</sup> But as Vernon points out, in comparison with domestic firms that are confined to a single national market, host governments tend to be uncertain about how MNCs are likely to behave. One of the reasons is the lack of transparency in the availability of operational data of MNCs. Ibid., pp. 14, 22, 207, and 219 and Barry Jones, ote 238 above, p. 176. Nonetheless, some governments have learned that their actions toward MNCs are the outcome of their own past economic and political strategies, and are now appraising their policies in the light of globalisation of markets and productions. As explained by Dunning, the structure and performance of foreign-owned firms in a particular host country in time  $t$  is partly a function of the macro and micro economic policies pursued by the government in time  $t-1$ . See Dunning, 1993, note 237 above, p. 547.

## Chapter V

### Unresolved Issues

This chapter starts by looking into the roles multinational corporations and nation states play in an increasingly integrated global economy, and how globalisation has affected these two major players in their participation of shaping the rules governing the global market. It is against this background that this chapter proceeds to discuss how the two major areas of concern expressed by MPCs would affect the adequacy and effectiveness of the TRIPS Agreement in ensuring the legal recognition of the exclusive marketing rights conferred by patent protection among WTO member states.

#### 5.1 Introduction

The global market is now dominated by MNCs, the catalyst of the globalisation of economic activities.<sup>1</sup> They are wealth creators accounting for an increasing proportion of value-added activities in the global economy, with influence reaching beyond their national borders.<sup>2</sup> Since the configuration of their activities depends less on the availability of unimproved national resources, and more on knowledge-based created

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<sup>1</sup> Despite the number of MNCs being only in the thousands, they account for about half of the world trade in goods, with about two-third of their trade taking place between related units of the same enterprise. Their role in international markets has been concentrated in the more dynamic sectors of the world economy which are technology-related and information-based networks of value-added activities such as pharmaceuticals, chemicals, and electronic products. See Lipsey, Robert E., 'Outward Direct Investment and the US Economy', in Feldstein, Hines, and Hubbard (eds.), *The Effects of Taxation on Multinational Corporations*, Chicago: University of Chicago Press, 1995, pp. 7-33 and Dunning, John H., *Multinational Enterprise and the Global Economy*, Reading, Mass: Addison-Wesley Publishing Company, 1993, p. 602.

<sup>2</sup> An example of MNCs' influence is their contribution in the shaping of inter-governmental trade agreements by assisting in the drafting of the fine print of WTO and NAFTA Agreements. See Vernon, Raymond, *In the Hurricane's Eye – The Troubled Prospects of Multinational Enterprises*, Massachusetts: Harvard University Press, 1998, p. 144.

assets,<sup>3</sup> they are able to shift value-added activities across national borders, which distinguishes them from traditional trade involving simple import-export of physical goods.

Cross-border investment challenges the assumption of immobility of factors of production in the theory of comparative advantage.<sup>4</sup> Natural endowments such as labour, land, and minerals have assumed second place and in their place are the “created assets” in assessing the competitiveness of both firms and nations. Created assets can be tangible and intangible. Tangible created assets include the stock of financial and physical assets such as communication infrastructure or marketing networks. While the intangible created assets encompass knowledge as the common denominator and include, for example, R&D and technological and innovative capabilities.<sup>5</sup> These created assets

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<sup>3</sup> Dunning, 1993, note 1 above. The accessibility and quality of these created assets in a country reflect government policies in areas such as education, science and technology, trade, transport and communication.

<sup>4</sup> David Ricardo’s theory of comparative advantage shows that countries benefit not by focussing on absolute advantage in production efficiency but on their comparative advantages; even where a country is more efficient in producing all goods than its neighbours, it still pays to trade by concentrating on where its advantage is the greatest and importing other goods where its advantage is less even if they could be made more efficiently domestically. With the assumption of the immobility of assets crossing borders, this theory assumes that market forces will allocate a nation’s resources to those relatively productive industries. See Rowthorn, Robert and Richard Kozul-Wright, *Globalisation and Economic Convergence: An Assessment*, Discussion Paper no. 131, Geneva: UNCTAD, February 1988, p. 5, The Economist, A Survey of World Trade, October 3, 1998, p. 5, Porter, Michael E., *The Competitive Advantage of Nations*, London: MacMillan, 1990, p.11, and Kogut, Bruce, ‘Designing Global Strategies: Comparative and Competitive Value-Added Chains’, in Vernon-Wortzel and Wortzel (eds.), *Global Strategic Management – The Essential*, 2<sup>nd</sup> ed., NY: John Wiley & Sons, 1990, p. 86. Based on this theory, governments measure national competitiveness in terms of trade performance as shown in the balance of payment, particularly in current assets and the presumed effect on the exchange rate. See Stopford, John M., ‘The Growing Interdependence between Transnational Corporations and Governments’, in Vernon-Wortzel and Wortzel (eds.), *Strategic Management in a Global Economy*, 3<sup>rd</sup> ed., NY: John Wiley & Sons, 1990, p. 61.

<sup>5</sup> UN, *World Investment Report: Trends and Determinants*, NY: UN, 1998, p. 114. They could be in the form of human capital – the stock of knowledge, technology, infrastructure, and governing policies, see Stopford, note 4 above, p. 61.

are not naturally endowed. Their mobility is evidenced by the increase in MNCs' cross-border investment as an alternative to trade.<sup>6</sup>

The advancement of information technology,<sup>7</sup> the integration of global capital markets,<sup>8</sup> and the increase in cross-border trade and investment by MNCs have facilitated the globalisation of economic activities among nations in the past two decades and put on track the acceleration of a long-term trend toward greater economic interdependence among nation states.<sup>9</sup> During the last decade and a half, global integration has proceeded at a faster pace through cross-border investment than through trade which made FDI flows and stocks an important benchmark along side the traditional trade.<sup>10</sup> The impact of FDI on globalisation is best described by UNCTAD as follows:

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<sup>6</sup>As foreign direct investment has grown four times faster than trade since 1982.

<sup>7</sup>The accelerated advancement of information technology came about mainly as the result of privatisation and deregulation of telecommunication industry in recent years. It effectively removed the geographical and political distance of conducting business and contributed to the integration of global markets. See Kinnock, Neil, 'Beyond Free Trade to Fair Trade', *California Management Review*, 1994, p. 126.

<sup>8</sup>The mid-1970s saw the dismantling of exchange controls on capital movement by countries such as the US, Japan, and UK. Coupled with further deregulation of national financial services markets in ICs and DCs, it reflected governments' realisation that relaxation of regulatory control was necessary if they were not to lose valuable business to overseas financial centres. These change of government policy contributed to the increase of cross-border financial flows and unify world financial market. The result was an increased share of international capital flow and the flows within national markets in the form of transaction in securities instead of bank lending with the implication on the private capitals available for DCs which was not there before. As UNCTC points out: falling communication costs have strengthened the trend of large number of banks locating themselves in the least regulated environment. This has been a powerful incentive for national authorities to deregulate their domestic markets to attract bank business to home centres. Some DCs have adopted more a liberal stance particularly in respect of setting up establishments specialised in off-shore banking. See UNCTC, *Foreign Direct Investment, the Service Sector, and International Banking*, NY: UN, 1987, Rowthorn and Kozul-Wright, note 4 above, P. 3, and Pecchioli, R.M., *The Internationalisation of Banking: The Policy Issues*, Paris: OECD, 1983.

<sup>9</sup>Vernon, 1998, note 2 above, pp. 1-29, Dunning, 1993, note 1 above, pp. 474-482, Barry Jones, R. J., *Globalisation and Interdependence in the International Political Economy*, London: Pinter Publishers, 1995, and UNCTAD, *World Investment Report 1995*, NY: UN, 1995.

<sup>10</sup>The growth of world trade is the traditional indicator of global economic integration. According to World investment Report 1998: for the world as a whole, the ratio of FDI stock (inward plus outward) to Gross Domestic Product (GDP) has increased steadily since 1980; the ratio of world FDI flows (inflows plus outflows) to GDP has also risen although not steadily (For example, in 1997, the FDI inflows grew by 19% to US\$400 billion and the FDI outflows rose by 27% to reach US\$424 billion). The ratio of world

“ The relationship...runs both ways: each affects the other. It was the liberalisation of national policy frameworks that helped unleash one of the key driving forces of globalisation as we know it today with increasing international production by transnational corporations (TNCs). At the same time, progress in the liberalisation of trade, as well as technological progress in telecommunications and transportation permits TNCs to pursue increasingly regional and global strategies, and to integrate their production structures on regional or global bases, which in turn creates incentives to liberalise FDI policies. This mutually reinforcing process has in fact shaped international production in recent years and led to its integration at a deeper level than the shallow integration based on arm's length trade and flows of financial capital.”<sup>11</sup>

The globalisation of economic activities have had a profound influence on national economies.<sup>12</sup> The success of domestic economic policy will be judged on the strength of the country's international competitive position.<sup>13</sup> In a practically border-less world

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trade (imports plus exports) to world GDP has remained relatively constant during the same period. UN, 1998, note 5 above, pp. 7-8.

<sup>11</sup> UNCTAD, *World Investment Report 1993*, NY: UN, 1993.

<sup>12</sup> For some, “globalisation” marks the hegemony of transnational capitalism in general, and institutional primacy of multinational corporations in particular. It marks the general progress of the internationalisation of finance, production, and economic transactions to a level that challenges the traditional functioning of nation states, and exposes them to a similar set of competitive economic pressure. It renders national economies sensitive to international externalities and increasingly dependent upon sympathetic external conditions. See Gill, S and David Law, *The Global Political Economy*, Hempstead: Harvester Wheatsheaf, 1988, chs. 7 and 11, Barry Jones, note 9 above, pp. 93-95 and 131.

<sup>13</sup> See Drucker, Peter F., ‘The Changed World Economy’, in Vernon-Wortzel and Wortzel (eds.), *Global Strategic Management – The Essential*, 2<sup>nd</sup> ed., NY: John Wiley & Sons, 1990, p. 17.



where economic interdependence reins,<sup>14</sup> nation states can no longer be considered as distinct economic entities with autonomous decision making power in their pursuit of national objectives because of extra-territorial effects of domestic policies.<sup>15</sup> The “public goods” of maintaining a free global trading system, such as IPRs and competition policy,<sup>16</sup> becomes a global responsibility.<sup>17</sup> Co-ordinated efforts among governments to establish multilateral discipline in these areas are therefore necessary.<sup>18</sup>

Following the incorporation of trade-related aspects of IPP into the global trading system, there are calls for incorporating competition rules into GATT.<sup>19</sup> One important reason is because national competition policy<sup>20</sup> needs to complement international treaty obligations so to protect and promote competition in the global level.<sup>21</sup> But past efforts to include competition in GATT had not been successful<sup>22</sup> because the political economy

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<sup>14</sup> Ohmae, Kenichi, *The Borderless World – Power and Strategy in the Interlinked Economy*, London: Collins, 1990, p. 173.

<sup>15</sup> Stopford, note 4 above, p. 66, Jackson, *Restructuring the GATT System*, London: Royal Institute of International Affairs, 1990, pp. 91-103, and FT, March 2, 1998, p. 21.

<sup>16</sup> According to Barry Jones, globalisation is a direct function of the growth of competition in an international free trade system. Barry Jones, note 9 above, p. 12.

<sup>17</sup> Rowthorn and Kozul-Wright, note 4 above, p. 4 and FT, March 2, 1998, p. 21.

<sup>18</sup> Stopford, note 4 above, p. 66. According to Scherer, there are three approaches to manage interdependence: 1. By upholding the principle of national sovereignty, governments make decisions with little or no consultation or co-operation with other nations; 2. Mutual recognition presumes decentralised decisions by national governments and relies on market competition to guide the process of international convergence. It also entails exchanges of information of national policies with explicit acceptance by each member state of the regulatory standards of others; and 3. Agreements of co-ordination promote inter-governmental co-operation. They involve jointly designed adjustments of national policies as governments agree to behave differently from the way they would have behaved without any agreement. Scherer, F. M., *Competition Policies for an Integrated World Economy*, Washington, D.C.: the Brookings Institution, 1994, pp. xx-xxi.

<sup>19</sup> Ibid., p. 92 and Petersmann, Ernest-Ullrich, “International Competition Rules for the GATT-MTO World Trade and legal System”, *JWT*, 27(6), 1993, pp. 41 and 75. Securing an international agreement on competition policy has been identified by the Uruguay Round negotiators as a high-priority items for the next round of MTNs. It is reflected in the establishment of a Working Group on the Interaction between Trade and Competition Policy during the Singapore Ministerial Conference held in December 1996.

<sup>20</sup> Competition policy and competition law are used synonymously in the discussion.

<sup>21</sup> UNCTAD, TD/B/COM.2/EM/2, 28 August 1996, p. 37.

<sup>22</sup> Past efforts to include competition rules into GATT started from the drafting of Chapter V of the Havana Charter on restrictive business practices as, for example, Article 46 contained in Chapter V requests each

of co-operation on competition policy is different from the more traditional trade liberalisation under GATT.<sup>23</sup> Furthermore, the recent trend of increasing unpopularity of trade liberalisation and hostility toward MNCs has been fuelled by the opponents of globalisation<sup>24</sup> accusing the WTO of intruding on national sovereignty by enforcing global trade rules which interfere with domestic political considerations.<sup>25</sup> The US

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member state to take appropriate measures and to co-operate to prevent business practices on the part of public or private commercial enterprises from affecting international trade by restricting competition, limiting market access, or fostering monopolistic control. In 1955, CPs rejected a proposal to add Chapter V to the General Agreement. In 1960, CPs adopted a report by an Expert Group on restrictive business practices, but the arrangements for inter-governmental consultation have never been put into practice (see GATT, BISD 9<sup>th</sup> Supp., 1961, the Decision of 18 November 1960). During the Tokyo Round, a notification on restrictive business practices of MNCs was included in the Inventory of Non-Tariff Measures, but the issue was not examined. During the preparatory work of the Uruguay Round, a proposal by least-developed countries to include restrictive business practices as one of the negotiation topic. No consensus was reached because of ICs' rejection (GATT, GATT Activities 1986, p. 29). See discussion in Malaguti, 1998, pp. 120-122 and Petersmann, 1993, note 19 above, pp. 38-40.

<sup>23</sup> Despite one of the objectives of GATT trade rules being to maintain equal competition opportunities in the market place, GATT does not regulate government policies affecting exports. It allows liberalisation to occur by inducing export oriented industry and consumer groups to offset the political power of protected import competing interest group. See Hoekman, Bernard and Petros C. Mavroidis, 'Competition, Competition Policy and the GATT', *The World Competition*, 1994, p. 128 and GATT, BISD 37<sup>th</sup> Supp., 86, 1990, Panel Report on EEC, Payments and Subsidies Paid to Processors and Producers of Oilseeds and Related Animal-Feed Proteins, a case relating to the violation of Article III: 4 and XXIII:1(b). Fox also rejects the suggestion of a multilateral agreement in light of recent failed attempts. See Fox, Eleanor M., 'Trade, Competition, and Intellectual Property – TRIPS and its Antitrust Counterparts', *Vand JTL*, 29(3), 1996, pp. 495-501. Two examples of recent failure to reach an international antitrust agreement are 1) the Munich Group Draft (A Draft International Anti-trust Code as a GATT-Multilateral Trade Organisation Plurilateral Trade Agreement), prepared by a private International Antitrust Code Working Group, which was submitted to Peter Sutherland, then GATT Director-General in 1993, and 2) the co-ordination of competition policies in the framework of the Organisation for economic Co-operation and Development (OECD), mainly due to the objection from the US. Fox further points out that, to have a meaningful internationalised IP-anti-trust law, nations have to be able to agree on a set of rules with a meaningful level of specificity, the law has to be pre-emptive, and the enforceable mechanism has to be creditable, but these conditions are unlikely to achieve. See also See Petersmann, 1993, note 19 above, p. 37.

<sup>24</sup> Many opponents of globalisation are non-governmental organisations (NGOs) with political or social objectives, such as preventing environmental deterioration or promoting human rights. The confrontation was magnified in the street protests in Seattle during the third WTO Ministerial Conference held between 30 November and 3 December 1999. The Conference failed to reach an agreement for a new round of MTNs. See Vernon, 1998, note 2 above, p. 219 and FT, December 3, 1999, p. 19.

<sup>25</sup> The Economist observes that if competition is to be incorporated into the WTO, two agreements must be reached, one being a transatlantic deal between the EU and the US, the two most influential players in global trade who account for nearly two-fifth of world trade, and another one between North and South. (See The Economist, November 27, 1999, pp. 25-29). The failure of the recent Ministerial Meeting in Seattle demonstrates the difficulty for the EU and the US to reach an agreement on this issue (See FT, December 3-6, 1999, The Economist, November 27, 1999, and Vernon, 1998, op. cit., pp. 211-219). They both agree that the aim of competition policy is to get other countries to improve access to their markets by punishing local RBPs, but both are not keen for WTO DSB to be empowered to overrule their anti-trust decisions. . It is an issue which concerns national sovereignty. (See FT, July 27, 1998 and October 26,

Congress has expressed their refusal to relinquish policy-making power.<sup>26</sup> And the reluctance of the EU to comply with rulings of panel reports on its banana regime and ban on hormone-treated beef<sup>27</sup> demonstrates the increasing difficulty governments face in defending domestically the legitimacy of unpopular dispute rulings by an international institution. As such, a multilateral agreement to regulate or harmonise domestic policies which will interfere with regulatory autonomy of states looks difficult.<sup>28</sup>

## 5.2 Global trade in IPP and competition policy

The major objective of the global trading system is to liberalise trade. It is to be achieved by two inter-linked mechanisms. One is to secure market access and fair competition

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1999). The EU seeks a WTO agreement on competition policy with agreed common basic principles for incorporating into members' domestic competition policies. But the US does not want a global anti-trust policy for fear that it could only result in political compromises which could lower standard and weaken enforcement, and the scope for its unilateral actions could be constrained (The Economist, November 27, 1999, p. 26). An agreement between North and South is even more unlikely as DCs have a very different perspective in relation to the role the WTO competition policy. For them, competition policy is implemented to stop MNCs from dominating their markets and to tackle rich economies' use of anti-dumping measures against low cost imports. See FT, December 6, 1999, p. 18.

<sup>26</sup> Especially toward the strengthened DSM under the WTO system which might adjudicate unfavourably in the area of Section 301 trade policy. Jackson, 1994, op. Cit., pp. 74-81. It should be noted that Article XV: I of the Agreement Establishing WTO does provide member states with the right to withdraw from the trade organisation with a six months notice.

<sup>27</sup> The two cases do not just involve economic issues, they are also social issues with political elements involved. The ban on hormone-treated beef is in response to public fears about food safety, but also is to protect inefficient European farmers. See The Economist, May 8, 1999, p. 22. See also WTO, WT/DS27/RW/ECU, 12 April, 1999, the Panel Report on European Communities' Regime for the Importation, sales and Distribution of Bananas – Recourse to Article 21.5 by Ecuador and WTO, WT/DS26/ARB, 12 July, 1999, the Decision by the Arbitrators on the European Communities' Measures Concerning Meat and Meat Products (hormones).

<sup>28</sup> Mutual recognition of each other's law and regulations might then be a way forward. For example, negotiations on mutual recognition agreements between the US and EU to dismantle barriers to transatlantic investment and trade in pharmaceuticals and medical devices. See FT, March 2, 1998, p. 21. Mutual recognition does not require acceptance of another country's standards or technical regulations for products. It involves two parties agreeing to recognise, for example, test reports issued by agreed and accredited bodies located in each other's territory. It could then waive the need for repetitive testing when products are destined for different markets. For discussion on the approach of mutual recognition on transatlantic registration dossier for new chemical entities, see Stephenson, Sherry M., 'Mutual Recognition and its Role in Trade Facilitation', *JWT*, 33(2), April 1999, pp. 141-150.

opportunity commitments through MTNs under the legal framework of the WTO. And the other is to ensure the efficient functioning of domestic markets through domestic competition policy to give effect to trade liberalisation commitments.<sup>29</sup> The introduction of domestic competition policy in this context is to minimise or eliminate trade restricting practices engaged by both government and private enterprises which have anti-competitive effects.<sup>30</sup> Its implementation must complement and reinforce international treaty obligations so to protect and promote competition in the global market.<sup>31</sup>

The interface between IPP and domestic competition policy comes in two strata: almost all competition policies expressly or implicitly exempt the exclusive rights inherent in IPP from their application.<sup>32</sup> But the majority of them do regulate the use of IPRs in the areas of contractual licensing agreements and commonly provide compulsory licensing as a remedy for abuses or anti-competitive practices in the exercise of the exclusive rights.<sup>33</sup>

With regard to patent protection conferred by the TRIPS Agreement, the Agreement does not expressly define to what extent the exclusive rights should be recognised in domestic

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<sup>29</sup> OECD, *Competition Policy and Intellectual Property Rights*, Paris: OECD, 1989, p. 12 and UNCTAD, *The TRIPS Agreement and Developing Countries*, NY; UN, 1996, p. 53. See also Vernon, 1998, note 2 above, p. 212 and Hoekman and Mavroidis, note 23 above, p. 128.

<sup>30</sup> According to UNCTAD report, the introduction of competition policy is to minimise restrictions on free competition caused by restrictive business practices engaged in by private firms, and by governmental measures which unjustifiably distort competition. See UNCTAD, TD/B/COM.2/2/Add.1, 26 September 1996, p. 1. Petersmann and Khemani also acknowledge that private restraints and government policies could impede competition, and there is the need for competition policy to relate to government as well as private distortion. The comment was made in a symposium on Competition Policy, Economic Development and International Trade that took place at the WTO headquarters on 29 November 1997. It was organised by the Secretariats of the WTO, UNCTAD, and the World Bank (hereinafter 1997 Symposium). See WTO, Focus, February 1998, p. 11. Fox further points out that the implication for IP on market access come in two strains. One is the formation of cartel and monopoly by private firms which has an international dimension. The other side of the spectrum is strict rules governments apply in interpreting TRIPS provisions which might hinder market access as a result. See also Fox, 1996, note 23 above, p. 501.

<sup>31</sup> UNCTAD, TD/B/COM.2/EM/2, 28 August 1996, p. 37.

<sup>32</sup> The lack of explicit provisions or guidelines in relation to the competition policy treatment of the exclusive rights creates uncertainties. Ibid., p. 20.

<sup>33</sup> OECD, 1989, note 29 above, p. 12.

policy. It does acknowledge the interface by providing a framework to deal with private anti-competitive practices in contractual licensing agreements,<sup>34</sup> but it does not contain checks and balances to ensure that government measures do not unjustifiably distort trade and affect the exercise of the exclusive marketing rights conferred by patent.<sup>35</sup>

Under the TRIPS Agreement, governments may adopt “appropriate measures”<sup>36</sup> to prevent, among others, practices which unreasonably restrain trade or adversely affect international transfer of technology.<sup>37</sup> As not every competitive practice has anti-competitive effects, UNCTAD 1996 Report interprets the wording “appropriate measures” as meaning that measures taken by governments have to meet some sort of proportionality test to prevent governments from introducing an overly broad concept of restrictive conduct and excessive remedies. The TRIPS Agreement also authorises

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<sup>34</sup> It is important to point out that private entities could not be held as infringing international obligations under TRIPS because it is an inter-state agreement. And it is difficult to establish liability of states for the independent action of private entities on the basis of WTO laws. Anti-competitive practices pursued by private entities without the support from governments cannot be challenged under Article XXIII: 1(a). Only if it involves positive actions or specific support from governments that nullify or impair established domestic competition conditions can a non-violation complaint be brought. Otherwise, private RBPs that are not subject to any government involvement are excluded from the scope of Article XXIII: 1(b). Hoekman and Mavroidis, 1994, note 23 above, pp. 121-150, p. 129, and Scherer, note 18 above, p. 105-107 and Malaguti, note 22 above, pp. 137-138.

<sup>35</sup> Fox, 1996, note 23 above, pp. 487, 491, and 505. For example, licensors see governments’ over-zealous application of competition policy as the most important disincentive to technology licensing activities, according to the result of an OECD survey, see OECD, *International Technology Licensing and Survey Results*, Paris: OECD, 1987, Table 40 and further discussion on this issue in OECD, 1989, note 29 above, pp. 12-14.

<sup>36</sup> UNCTAD, 1996, note 29 above, p. 54.

<sup>37</sup> In order to achieve the objective of the TRIPS Agreement set out in Article 7, which states that:

“The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”

Article 8(2) reads:

“appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”

See fn 34

national governments to regulate private restrictive business practices (RBPs) which affect contractual licences,<sup>38</sup> and calls for a case-by-case approach so as to prevent the enactment of licensing rules which might outlaw some forms of licensing without looking into the existence of anti-competitive effects. And recognising that many anti-competitive practices could have cross-border effects,<sup>39</sup> an inter-governmental consultation mechanism is provided for<sup>40</sup> in cases involving private licensing practices that restrain competition and adversely affect trade.<sup>41</sup>

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<sup>38</sup> Article 40.2 reads:

“Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market...”

The Article also gives examples of exclusive grant-back conditions, conditions preventing challenges to validity and coercive package licensing. The list of examples should be seen as non-exhaustive. It is up to national governments to specify what constitute anti-competitive practices. See discussion in UNCTAD, 1996, note 29 above, p. 54. There are fourteen practices which have been identified by an international draft code of conduct on the transfer of technology as anti-competitive: grant-back provisions, challenges to validity, exclusive dealing, restrictions on research, restrictions on use of personnel, price fixing restrictions on adaptations, exclusive sales or representation agreements, tying arrangements, export restrictions, patent pool or cross-licensing agreements and other arrangements, restrictions on publicity payments and other obligations after expiration of industrial property rights, and restrictions after expiration of arrangement. See UNCTAD, TD/CODE TOT/56, Further Consultations on a Draft International Code of Conduct on the Transfer of Technology – Report by the Secretary General of UNCTAD, 1990a, pp. 8-10.

<sup>39</sup> When dealing with business practices occurring in one state which produce restrictive effects in another, the international co-operation on the enforcement of competition regulations is in the form of bilateral agreement between governments, for example, of the US and the EC (Agreement between the Government of the United States of America and the Commission of the European communities regarding the application of their competition law, reached on 23 September 1991, 30 I.L.M. (1991) 1487) and Canada and the US (Canada – United States Agreement regarding the application of their competition and deceptive marketing practices laws, reached in August 1995, 35 I.L.M. (1996) 309).

<sup>40</sup> Most national competition policies do not apply to RBPs which solely affect foreign markets. It is often difficult if not impossible for countries whose markets are affected to gather the necessary evidence from where restrictive practices originated. Full cooperation from the authority of the country where the RBPs originated is therefore necessary. But Petersmann comments that different degree of market integration does affect the extent of co-operation in competition law enforcement. See 1997 Symposium, note 30 above.

<sup>41</sup> Article 40(3) of the TRIPS Agreement reads:

“Each Member shall enter, upon request, into consultations with any other Member which has cause to believe that an intellectual property right owner that is a national or domiciliary of the Member to which the request for consultations has been addressed is undertaking practices in violation of the requesting Member’s laws and regulation...”

Any anti-competitive practices outside the context of licensing are not subject to this provision. See discussion in Fox, 1996, note 23 above, p. 486 and UNCTAD, 1996, note 29 above, pp. 3,7, and 54.

The TRIPS Agreement further provides compulsory licensing as a remedy when private anti-competitive practices are established.<sup>42</sup> As it is within the domestic jurisdiction to define what constitute anti-competitive practices, concerns have been raised that governments might rely on the compulsory licensing provisions to implement measures which deny the exercise of the exclusive rights conferred by patent protection.<sup>43</sup>

Since the protection of public health is a common socio-economic goal among nations, it could be taken up as a consideration in formulating or amending domestic licensing legislation. The availability and affordability of modern medicines for AIDS is a poignant example in that AIDS is a common disease in both ICs and DCs, but the most advanced medicines are in the hand of MPCs, and are protected by patent.<sup>44</sup> With 95% of HIV positive sufferers living in DCs,<sup>45</sup> countries such as South Africa try to find a way to improve access to these expensive medicines and solve the problem of affordability for the poor population as a matter of urgency.<sup>46</sup> In the search for solutions that are TRIPS-consistent, Article 8.1 provides the first step forward. It states that

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UNCTAD 1996 Report describes inter-governmental consultation in Article 40:3 as providing a comity approach with respect to possible extra-territorial effects of national anti-trust enforcement.

<sup>42</sup> Article 31(k) of the TRIPS Agreement states that:

“Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use (without authorisation of the right holder) is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases...”

See Chapter 4.4 for the discussion on Articles 31(b) and 31(f) of the TRIPS Agreement.

<sup>43</sup> See IFPMA, *IFPMA Position Paper – WTO Millennium Round*, Geneva: IFPMA, 1999.

<sup>44</sup> MPCs market their advanced medicines in ICs for those affluent patients who can afford to pay.

<sup>45</sup> The Economist, August 14, 1999, p. 11.

“ Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health..., provided that such measures are consistent with the provisions of this Agreement.”

If a product is needed in case of national emergency <sup>47</sup> or if it is for public non-commercial use, the requirement of prior negotiations with the right holder for a licensing agreement on reasonable commercial terms could be waived. <sup>48</sup> Compulsory license could therefore be granted to allow local manufacturers to produce generic versions of the patented product to cope with the epidemic through the public healthcare system. <sup>49</sup>

Limiting the exercise of the exclusive marketing rights conferred by a patent is an alternative to secure the availability and affordability of modern medicines in many countries. The TRIPS Agreement does allow limited exceptions to the exclusive rights conferred by a patent, as states in Article 30:

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<sup>46</sup> The government of South Africa acknowledged that they face a national emergency as the HIV epidemic and AIDS-related diseases poise to kill millions of people in the country. See FT, December 1, 1999, p. 20 and The Economist, August 14, 1999, p. 70.

<sup>47</sup> The government of South Africa has wanted the WTO to declare AIDS a medical emergency, giving it the right to disregard patent rules so to manufacture or import cheap copies of HIV drugs, see FT, May 19, 2000.

<sup>48</sup> Article 31(b) of the TRIPS Agreement states that other use without authorisation of the right holder should respect the following provision:

“such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency... or in case of public non-commercial use...”



“.. providing that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”<sup>50</sup>

Under Article 30, limited exception may be provided when three cumulative conditions are met, each being a separate and independent requirement that must be satisfied.<sup>51</sup> Firstly, the exception must be “limited”, a condition neither designed nor intended to address the issue of economic impact directly.<sup>52</sup> The term “limited exception” expresses a requirement that the exception makes only a narrow curtailment of the legal rights Article 28.1 of the TRIPS Agreement requires to be granted to patent owners. The curtailment of legal rights cannot be measured by the size or extent of the economic impact or by counting the number of legal rights impaired by an exception.<sup>53</sup> It is to be measured by the extent to which the exclusive rights of the patent owner have been curtailed.<sup>54</sup> Secondly, the exception “must not unreasonably conflict with normal exploitation of the patent.” And the normal practice of exploitation by patent owners is to exclude all forms of competition that could detract significantly from the economic

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<sup>49</sup> The assumption is made that medicines are for non-commercial use when they are available through a non-profit making national health scheme.

<sup>50</sup> Article 30 of the TRIPS Agreement. This Article contains broad language and political. It is left to individual governments to define what constitute *normal exploitation of the patent* and unreasonable prejudice? Who are the third parties and how to justify their legitimate interests taking precedent over legal rights conferred by patent protection?

<sup>51</sup> WTO, WT/DS114/R, 17 March 2000, the report of the Panel on Canada – Patent Protection of Pharmaceutical Products (hereinafter the EC v Canada Panel Report), p. 138.

<sup>52</sup> Ibid., p. 146.

<sup>53</sup> Ibid., p. 141.

<sup>54</sup> Ibid.

returns anticipated from a patent's grant of market exclusivity.<sup>55</sup> Thirdly, the exception "must not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties."<sup>56</sup> The term "the legitimate interests" is construed as a concept broader than legal interests.<sup>57</sup> It is defined as a normative claim calling for protection of interests that are justifiable in the sense that they are widely recognised and supported by relevant public policies or other social norms.<sup>58</sup>

UNCTAD suggested that one exception relating to the exclusive right of using the patented product is to allow third parties, such as generic manufacturers, to use the pharmaceutical patented invention to obtain regulatory approval for the commercialisation of generic versions prior to the expiry of patent.<sup>59</sup> The legality of such a government policy has been challenged by the EC in 1998 under the WTO DSM<sup>60</sup> against Canada. In this case, the EC challenged Article 55.2(1) of Canada's Patent Act (the so called regulatory review exception) which allows all activities relating to the development and submission of information required to obtain regulatory approval for

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<sup>55</sup> Ibid., p. 147.

<sup>56</sup> Ibid., pp. 147-149. The Panel is of the opinion that the weight of legitimate interests of third party interests cannot be appraised after the identification of "the legitimate interests" and the appraisal of whether they have been prejudiced. The EC argued that, pursuant to Article 28.1 of the TRIPS Agreement, "legitimate interests" is the full enjoyment of one's patent rights during the entire term of the patent, and the only relevant third parties for the purpose of Article 30 are the patent owner's competitors, the generic drug producers. But Canada defined "legitimate interests" as the norms or policies that are deduced from the patent laws that create those rights. And by relying on Articles 7 and 8.1 of the TRIPS Agreement, Canada regarded the legitimate interests of third parties as representing general societal interests, particularly interests connected with health policy.

<sup>57</sup> Ibid., pp. 151-154.

<sup>58</sup> Ibid. An example given by the Panel is that both society and the scientists have a legitimate interest in using the patent disclosure to support the advance of science and technology.

<sup>59</sup> UNCTAD, 1996, note 29 above, p. 34.

<sup>60</sup> MPCs have also challenged in national courts the legality of the domestic legislation allowing generic manufacturers to produce chemical substances within the technical scope of the patent holder's invention for the purpose of conducting clinical trials and to gain regulatory approval during the patent life of a product. In a recent case between Ono Pharmaceutical Co. Ltd. v. Kyoto Pharmaceutical Co. Ltd.,

pharmaceutical products to be carried out by third parties without the consent of the patent holder at any time during the patent term,<sup>61</sup> therefore in breach of Articles 30 and 28(1) of the TRIPS Agreement. Canada argued that, by doing so, it was maintaining the balance between the protection of patent and the promotion of public welfare. Canada further argued that Article 55.2(1) sought to protect public health, as recognised in Article 8.1 of the TRIPS Agreement, through promoting access to cost-effective generic medicines following patent expiry, taking into account the legitimate interests of individuals, private insurers, and public sector entities that financed health care in maintaining access to affordable medicines.<sup>62</sup>

The Panel to the case concluded that Article 55.2(1) of Canada's Patent Act does satisfy all three conditions of Article 30 of the TRIPS Agreement, and does not prejudice "the legitimate interests" of affected patent owners within the meaning of Article 30, thus it is not inconsistent with Canada's obligations under Article 28.1 of the TRIPS Agreement.<sup>63</sup>

This decision will clear the way for more governments adopting legislations containing similar regulatory review exception because the introduction of generic competition is a practice governments are keen to emulate as a means to control healthcare costs.<sup>64</sup>

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Japanese Supreme Court affirmed that such a conduct by generic manufacturers does not infringe Japanese patent law. See National Reports, *EIPR*, 8, 1999, N 140-141.

<sup>61</sup> The EC also challenged Articles 55.2(2) and 55.2(3) of Canada's Patent Act that allow manufacturing and stockpiling products during the six months immediately prior to the expiration of the twenty-year patent term (the so called stockpiling exceptions). See the EC v Canada Panel Report, note 51 above.

<sup>62</sup> *Ibid.*, p. 15 and WTO, Focus, November 1998, pp. 2 and 35, p. 2.

<sup>63</sup> But the stock piling exceptions constitute a substantial curtailment of the exclusive rights and are inconsistent with Article 28.1 of the TRIPS Agreement. *Ibid.*, pp. 143-144.

<sup>64</sup> The US, Argentina, Australia, Hungary, Israel, Japan and Portugal all allow research and product testing before patents expire, see FT, March 8, 2000 and the EC v Canada Panel Report, note 51 above, p. 144. Furthermore, the participation of eleven WTO members in the panel proceedings of this case as third parties (they are Australia, Brazil, Colombia, Cuba, India, Israel, Japan, Poland, Switzerland, Thailand and the US) by virtue of Article 10 of the DSU demonstrated the interest governments have in the legal status of this practice under WTO rules.

### 5.3 The doctrine of exhaustion and the issue of parallel importation

The absence of any provisions under the TRIPS Agreement to explicitly define the extent of the exclusive marketing rights conferred by patent protection<sup>65</sup> should be recognised in domestic legislation exposes the contradiction between trade liberalisation and domestic competition policy promoting free trade, and trade restricting effects arising from the exercise of the exclusive rights conferred by patent protection. The doctrine of exhaustion<sup>66</sup> and the related issue of parallel importation for pharmaceuticals are the prime examples to illustrate this interface. As the scope of exemption of the exclusivity of the rights conferred by patent protection from competition rules varies among countries,<sup>67</sup> and parallel importation is often encouraged to complement an array of other domestic economic, health care or social policies,<sup>68</sup> no party in the TRIPS MTNs was willing to make any commitment in the areas of exhaustion of rights and parallel importation even though they are very important trade-related issues in the field of IPP.<sup>69</sup>

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<sup>65</sup> This might trace back to the Paris Convention that does not contain explicit provisions about exhaustion and parallel importation either. Under the Convention, it is for individual states to legislate whether patent holders could rely on domestic patent systems to block parallel imports.

<sup>66</sup> It is referred to as the doctrine of first sale in the US.

<sup>67</sup> See UNCTAD, TD/B/COM.2/EM/2, 28 August 1996.

<sup>68</sup> Rothnie, W. A., *Parallel Imports*, London: Sweet & Maxwell, 1993, pp. 501-508.

<sup>69</sup> As Cottier points out, many participants in the TRIPS MTNs thought it necessary to include an explicit guarantee of sovereignty in the area of exhaustion of rights and parallel importation if the topics were to be negotiated. See Cottier, Thomas, 'The Prospects for Intellectual Property in GATT', *CMLR*, 28, 1991, p. 399. Cornish comments that because they are very political issues. See Cornish, W. R., *Intellectual Property: Patents, Copyrights, Trade Marks and Allied Rights*, 4<sup>th</sup> ed., London: Sweet & Maxwell, 1999, p. 47 and Straus, Joseph, 'Implications of the TRIPS Agreement in the Field of Patent Law', in Beier and Schriker (eds.), *From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property*

The word “exhaustion” is used to mean that a patent holder is not entitled to any legal control over the subsequent commercialisation<sup>70</sup> of the patented product within the territory of the state granting the protection following the first authorised domestic sale of the patented product. This concept is underpinned by the assumption that a patent holder would have been rewarded for his or her creative efforts through the first exclusive sale by charging higher economic rents to recoup R&D investment,<sup>71</sup> and that he or she should not be allowed to further economic rents from subsequent commercialisation of the product.<sup>72</sup>

Parallel importation of pharmaceuticals involves the importation of patented drugs, lawfully put on the market in the place of export, by third parties, without patent holders’ consent, to countries where identical products have been legitimately put onto the markets but are selling at a higher price.<sup>73</sup> The application of the doctrine of territorial exhaustion is limited to the territory of the state granting the protection,<sup>74</sup> under which parallel importation constitutes an infringement of the patent holder’s exclusive rights. Parallel importation is allowed in countries where a patent system does not exist or the

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*Rights*, Munich: The Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, 1996.

<sup>70</sup> The doctrine of exhaustion does not affect the exclusive rights of manufacturing or production of patented products. But it applies to the commercialisation stage in relation to sales, marketing, distribution and importation of patented products.

<sup>71</sup> When parallel importation is allowed, the assumption that a patent holder could charge a premium price and be expected to recoup R&D investment at the initial sale of the patented product in country A can be easily rebutted if country A is not the first market the MPC launches this product, and parallel imported products are waiting in the wing to compete.

<sup>72</sup> Yusuf, Abdulqawi and Andres Moncayo von Hase, ‘Intellectual Property Protection and International Trade – Exhaustion of Rights Revisited’, *World Competition*, 16(1), 1992, pp. 116-119 and 129,

<sup>73</sup> Rothnie, note 68 above, p. 1 and FT, December 16, 1997. The parallel importation on a commercial scale is under discussion here. It does not concern private individuals purchasing a small quantity from abroad for private use.

doctrine of international exhaustion applies. The EU is an exception where community exhaustion is applied to uphold the principle of free movement of goods among the EU member states.<sup>75</sup>

In the EU, the disparity of national legislation among its member states did not prevent the European Court of Justice (ECJ) from applying the exhaustion of IPP on a community basis with respect to the distribution of patented products. When parallel importation was from outside the common market, it could be stopped by patent holders relying upon patent protection of individual member states.<sup>76</sup> For parallel importation of pharmaceuticals from within the community, the ECJ formulated the principle<sup>77</sup> in *Centrafarm v Sterling Drug* that a patent holder cannot not invoke the exclusive rights conferred in member states to prevent the importation and the sale of goods that have been placed on the market with consent in another member state.<sup>78</sup> Otherwise, it would create a barrier to free movement of goods,<sup>79</sup> and amounts to a quantitative restriction or

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<sup>74</sup> The territorial nature of the Doctrine of Exhaustion was developed at the end of the nineteenth century. It is consistent with the principle of territoriality applicable to IPP. Yusuf and von Hase, note 72 above, pp. 115-131, p. 116.

<sup>75</sup> Ibid.

<sup>76</sup> Bronckers, Marco C. E. J., 'The Impact of TRIPS: Intellectual Property Protection in Developing Countries', *CMLR*, 31, 1994, p. 1266.

<sup>77</sup> *Centrafarm BV v Sterling Drug BV*, (Case 15/74) [1974] ECR 1147 (hereinafter *Sterling Drug*). And the application of community exhaustion is GATT-legal by virtue of Article XXIV of GATT (customs unions and free trade areas), see discussion in Yusuf and von Hase, note 72 above, pp. 121 and 122 and Cottier, note 69 above, p. 400.

<sup>78</sup> Sales in other member states by a licensee or another member of the same corporate group is covered by the principle. See Rothnie, note 68 above, p. 384. The same principle was articulated in relation to trade marks in *Centrafarm BV v Winthrop BV* (Case 16/74) [1974] ECR 1183, and *Hoffmann-La Roche AG v Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse mbH* (Case 102/77) [1978] ECR 1139 (hereinafter *Hoffmann-La Roche*). In the latter case, Advocate General Capotorti explains that the decision was prompted "by the desire to eliminate any risk of the use of trade marks to establish artificial divisions within the common market", see *Hoffmann-La Roche*, p. 1173. The principle applicable to trade marks was later enshrined in Article 7 of the Trade Marks Harmonisation Directive (Directive 89/104).

<sup>79</sup> Shea, Nicholas, 'Parallel Importers' Use of Trade Marks: The European Court of Justice Confers Rights but also Imposes Responsibilities', *EIPR*, 3, March 1997, p. 103. In cases involving parallel importation, the ECJ applied the rules of competition under Articles 85 and 86 of the Treaty of Rome at the beginning to

a measure having equivalent effects within the meaning of Article 30 of the Treaty of Rome.<sup>80</sup> But derogation from the principle of free movement of goods allowed under Article 36 can be relied on only for the purpose of safeguarding rights which constitute “the specific subject matter” of the intellectual property in question.<sup>81</sup> In relation to patent, the specific subject matter is the guarantee that the patent holder has the exclusive rights to use the invention to manufacture and put them into circulation for the first time in order to reward the creative effort of the inventor.<sup>82</sup>

Both the EU and the US have refused to apply international exhaustion.<sup>83</sup> Straus argues that the substantive patent law under the TRIPS Agreement amount to a bar to international exhaustion. When Articles 27(1) and 28(1) are read jointly, they oblige

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emphasise the importance of market integration. But increasingly, it relied on the principle of free movement of goods as stated in Article 30 of the Treaty of Rome. See discussion in Cornish, note 69 above, ch. 1.

<sup>80</sup> Article 30 of the Treaty of Rome reads:

“Quantitative restrictions on imports and all measures having equivalent effect shall, without prejudice to the following provisions, be prohibited between Member States.”

Also consider the opinion expressed by Advocate General Jacobs in *Upjohn SA v Paranova A/S* case (Case C-379/97, delivered on 19 November 1998). He opines that if the patent owner is to seek to oppose imports from other EU member states, it is necessary to consider whether such an action is justified on grounds of the protection of industrial or commercial property by virtue of Article 36 of the Treaty of Rome. See <http://europa.eu.int/jurisp>. According to Article 36:

“The provisions of Arts. 30 to 34 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of .. the protection of health and life of humans, animals or plants; ... the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.”

<sup>81</sup> *Sterling Drug*, note 77 above, Judgement para 8.

<sup>82</sup> *Ibid.*, Judgement para 9. In a later case, the ECJ elaborates that patent is not a guarantee of a reward, it only offers a prospect; and that many factors influence patentees’ ultimate return, such as the availability of substitute products in the market. See *Merck & Co., Inc. v Stephar BV*, (Case 187/80) [1981] ECR 263 (hereinafter *Merck*). In the same case, the ECJ also specifies that patent protection can be relied on to block the free movement of goods when the imported goods are generic, see *Merck*, Judgement para 11 and *Rothnie*, note 68 above, pp. 339-352.

<sup>83</sup> See discussion in Broncker, note 76 above, p. 1268, Ullrich, Hanns, ‘TRIPS: Adequate Protection, Inadequate Trade, Adequate Competition Policy’, *Pacific Rim Law & Policy Journal* 4(1), 1995, p. 192, and Yusuf and von Hase, note 72 above, pp. 122 and 123. The community Patent Convention of 1975 as

member states to grant the patent holder the exclusive rights to prevent, for example, the importation by third parties of patented product regardless of where the products were produced.<sup>84</sup> In contrast, Yusuf and von Hase advocate the adoption of international exhaustion because parallel importation promotes free trade and encourages competition.<sup>85</sup> They regard national exhaustion as constituting a barrier to trade when legitimate goods are not allowed from entering into countries; and the discrimination against imports contravenes NT obligations under the TRIPS Agreement.<sup>86</sup> Bronckers is also in support of international exhaustion regarding it as more in line with the GATT spirit of banning import restrictions and ensuring free movement of goods in the promotion of global trade.<sup>87</sup> But any WTO member states applying it must do so on a MFN basis<sup>88</sup> without discriminating against imports based on the origin of the product and to whom the intellectual property belongs.<sup>89</sup>

Yusuf and von Hase argue that by allowing in parallel imports, it has a price leveling effect which could make the lowest price available for the benefit of domestic consumers.<sup>90</sup> And by introducing competition into a market, Ullrich believes that MPCs

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revised in 1989 will introduce a specific doctrine of exhaustion affecting community and national patent within the EU, see discussion in Cornish, note 69 above, ch. 6.

<sup>84</sup> The situation is not altered by Article 6 because it is not of a substantive legal nature. See Straus, note 69 above, pp. 160-215, p. 192.

<sup>85</sup> Yusuf and von Hase, note 72 above, p. 128

<sup>86</sup> Ibid. and Ullrich, 1995, note 83 above, p. 193.

<sup>87</sup> Bronckers, note 76 above, pp. 1267 and 1268. Ullrich also makes the point that the principle of territoriality has to be viewed critically because the application of which could interrupt the free flow of goods across borders, Ullrich, 1995, note 83 above, p. 193.

<sup>88</sup> The application of Article 6 is subject to NT (Article 3) and MFN (Article 4). See Article 6 of the TRIPS Agreement.

<sup>89</sup> Ullrich, 1995, note 83 above, p. 191.

<sup>90</sup> Yusuf and von Hase, note 72 above, p. 130. This statement could be challenged from two aspects: If the criteria of MPCs' pricing strategy hold true, drug prices in DCs would tend to be lower to start with. And if governments implement drug reimbursement schemes and healthcare service is delivered by private sector,



cannot profit from non-market rewards based on monopoly privileges.<sup>91</sup> But MPCs argue that, in recent years, government pressure to reduce health care expenditure has had significant impacts on the pricing of pharmaceutical products and the functioning of pharmaceutical markets.<sup>92</sup> Even though MPCs base their pricing strategy considerations on factors such as demand elasticity, purchasing power and the size of the market, conflicting government policies have also contributed to price differentials among countries<sup>93</sup> as some countries adopt a low price approach with stringent pricing control scheme in operation, while others allow MPCs greater pricing freedom as an incentive to encourage inward R&D investments.<sup>94</sup>

UNCTAD suggested the adoption of international exhaustion, especially in DCs, by relying on the exception provision of Article 30 to facilitate the availability of cheaper imports on the domestic market.<sup>95</sup> If this approach is adopted, government measures as such cannot be challenged under the TRIPS Agreement because Article 6 of the Agreement excludes disputes arising from exhaustion of IPRs from being brought in front

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any saving from drug prices would not pass on to consumers, but to benefit parallel importers or healthcare providers who are the purchasers.

<sup>91</sup> Ullrich, 1995, note 83 above, p. 194.

<sup>92</sup> This is acknowledged by the EU Commission in November 98 Communication on the Single Market in Pharmaceuticals (EU Commission, COM(98) 588 final). Also see Rothnie, note 68 above, p. 497.

<sup>93</sup> Ibid., pp. 505-508.

<sup>94</sup> Ibid.

<sup>95</sup> UNCTAD, 1996, note 29 above, p. 34. However, UNCTAD also points out that international exhaustion could bring the risk of MPCs withdrawing price discrimination in DCs favour. In the interest of consumers in poorer countries, some suggest an agreement with wealthier countries where sales by the patentee in the poorer countries does not lead to an exhaustion of patent rights in the wealthy countries. In return, it might persuade MPCs to price drugs at lower price in the poorer countries. See Adelman, Martin and Sonia Balda, 'Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India', *Vand JTL*, 29(3), 1996, p. 532.

of the DSB.<sup>96</sup> Some believe that if it can be substantiated that the introduction of international exhaustion has frustrate legitimate expectations created by the TRIPS Agreement, in which case it might be actionable under Article XXIII: 1(b) of GATT 1994.<sup>97</sup> But Hoekman and Mavroidis express reservation that the interpretation of TRIPS provisions could lead to the establishment of a non-violation complaint under GATT<sup>98</sup> as it involves the protection of competitive conditions established by agreed imported tariff concessions, but there is no agreed tariff concessions involved in TRIPS.

When disputes arise which concern the interpretation or application of the legal provisions of the TRIPS Agreement, the 1969 Vienna Convention on the Law of Treaties (Vienna Convention) applies.<sup>99</sup> Recent WTO panel reports<sup>100</sup> affirm that provisions of WTO agreements must be interpreted in accordance with customary rules of interpretation of public international law,<sup>101</sup> and Articles 31 and 32 of the Vienna

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<sup>96</sup> See Footnote 6 in the TRIPS Agreement which states that the right in respect of the use, sale, importation or other distribution of goods referred to in Article 28.1(a) is subject to the provisions of Article 6. And Article 6 of the TRIPS Agreement reads:

“For the purpose of dispute settlement under this Agreement... nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”

<sup>97</sup> Cottier, note 69 above, pp. 399 and 400, Broncker, note 76 above, p. 1268, and Yusuf and von Hase, note 72 above, p. 115. They also suggest to rely on Article XX of GATT as a possible defense if international exhaustion is challenged, based on the claim that the exclusive rights conferred constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade.

<sup>98</sup> Hoekman and Mavroidis, note 23 above, p. 140-141 and Hoekman, Bernard M. and Michael Kostecki, *The Political Economy of the World Trading System from GATT to WTO*, Oxford: Oxford University Press, 1995, p. 46.

<sup>99</sup> Article 3.2 of the DSU states that the WTO dispute settlement system is

“to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law...”

Furthermore, Article 19.2 of the DSU states that the panel and Appellate Body’s rulings or recommendations cannot add to or diminish the rights and obligations provided in the covered agreements.

<sup>100</sup> WTO, WT/DS79/R, 24 August 1998, the report of the Panel on India – Patent Protection for Pharmaceutical and Agricultural Chemical Products (hereinafter The EC v India Panel Report), p. 57-60.

<sup>101</sup> Article 3.2 of the DSU states that:

Convention have attained the status of customary international law.<sup>102</sup> According to Article 31, a treaty should be interpreted in good faith in accordance with the ordinary meaning of the terms of the treaty, the context, and its object and purpose.<sup>103</sup> And if necessary, the negotiating history of TRIPS could be used as a supplementary means of interpretation.<sup>104</sup>

The issue of whether adopted WTO panel reports are *stare decisis*, i.e. binding precedents, needs to be clarified. From the legal point of view, international legal system does not embrace the common law jurisprudence of strict adherence to precedent.<sup>105</sup> A

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“... The Member of the WTO recognise that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law...”

<sup>102</sup> WTO, WT/DS152/R, 22 December 1999, US – Sections 301-310 of the Trade Act of 1974 (hereinafter US Trade Act Panel Report), pp. 304-305.

<sup>103</sup> Article 31 of the Vienna Convention states that:

- “ 1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.
2. The context for the purpose of the interpretation of a treaty shall comprise, in addition and annexes:
  - (a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty;
  - (b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument relating to the treaty.....”

According to the panel report, the elements referred to in this Article, i.e., text, context and object and purpose as well as good faith, are to be viewed as one holistic rule of interpretation rather than a sequence of separate texts in a hierarchical order.

<sup>104</sup> Article 32 of the Vienna Convention on the Law of Treaties 1969 reads:

“Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion in order to confirm the meaning resulting from the application of article 31...”

<sup>105</sup> See discussion in Jackson, John H., ‘The World Trade Organisation, Dispute Settlement, and Codes of Conduct’, in Collins and Bosworth (eds.), *The New GATT – Implications for the United States*, Washington, D.C.: The Brookings Institution, 1994, p. 70 and Jackson John H., William Davey and Alan O. Sykes Jr., *Legal Problems of International Economic Relations – Cases, Material and Text on the National and International Regulation of Transnational Economic Relations*, 3<sup>rd</sup> ed., St Paul: West Publishing Co., 1995 (hereinafter Jackson et al), p. 348 et seq, and Brownlie, Ian, *Principles of Public International Law*, 4<sup>th</sup> ed., Oxford: Oxford University Press, pp. 21-23.

WTO panel confirmed that panels are not bound by previous decisions of panels or the Appellate Body even if the subject matter is the same.<sup>106</sup> However, the need to avoid inconsistent rulings so to give security and predictability to a rule-based multilateral trading system is very important.<sup>107</sup>

The territorial nature of the doctrine of exhaustion is consistent with the principle of territoriality applicable to IPP under which countries could legitimately take measures against import monopoly by introducing international exhaustion in their legislation.<sup>108</sup>

In deciding whether to adopt territorial or international exhaustion in their domestic legislation, member states are influenced by different legal traditions of dealing with patent protection,<sup>109</sup> and varying degrees of emphasis each country places on its health,<sup>110</sup> industrial<sup>111</sup> and economic policies.<sup>112</sup> They also need to strike a balance between short-term benefits of making available pharmaceuticals at lower prices and

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<sup>106</sup> The Panel states that:

“It can thus be concluded that panels are not bound by previous decisions of panels or the Appellate Body even if the subject-matter is the same.... Moreover, in our examination, we believe that we should give significant weight to both Article 3.2 of the DSU, which stress the role of the WTO dispute settlement system in providing security and predictability to the multilateral trading system, and to the need to avoid inconsistent rulings...”

See WTO, WT/DS50/AB/R, 19 December 1997, the report of the Appellate Body on India – Patent Protection for Pharmaceutical and Agricultural Chemical Products (hereinafter *The US v India Appellate Body Report*), p. 57.

<sup>107</sup> *Ibid.* So to be consistent with the central element of the WTO dispute settlement system. See Article 3.2 of the DSU.

<sup>108</sup> Broncker, note 76 above, p. 1270.

<sup>109</sup> If a country regards IP as public goods that, once created, should be made available at marginal cost, its competition policy will treat the question of reward-for-innovation differently from another country with the legal tradition of treating IP as private property.

<sup>110</sup> For example, the regulatory mechanism has to be in place to ensure that imported products from all sources meet the safety, quality and efficacy standards required of patented products marketed domestically.

<sup>111</sup> Such as incentives to attract foreign investment. See UNCTAD, TD/B/COM.2/2/Add.1, 26 September 1996.

<sup>112</sup> Consumer welfare is an area of concern. It could be protected by, for example, preventing practices that artificially raise price to consumers. See WTO, Focus, February 1998, p. 10. At the macro-economic

possible long term costs of discouraging MPCs from foreign investment if international exhaustion is adopted.<sup>113</sup> If it is perceived to be in the national interest to promote parallel importation, reciprocal bargaining in a multilateral setting on the issue will be politically difficult.

In the absence of a multilateral agreement on the exhaustion of the exclusive marketing rights, MPCs will continue to be exposed to diverse domestic legislation in regard to the exercise of exclusive marketing rights<sup>114</sup> and give rise to the claim of non-tariff barriers that cause trade distortion. If no satisfactory result is reached by negotiations between the pharmaceutical industry and the host government, it could result in MPCs' representative governments reverting to unilateral sanction as an alternative to resolve the issue.

The legitimacy of Section 301 provisions was confirmed in 1999 by a WTO panel report not to be inconsistent with the US's obligations under the WTO.<sup>115</sup> This decision will

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level, revenue from exports and foreign currency reserves could all play a part in shaping government policies.

<sup>113</sup> Rothnie, note 68 above, pp. 585-590.

<sup>114</sup> Vernon, 1998, note 2 above, pp. 213-219. Vernon explains that when an international agreement exists that addresses the substance of a problem, it reduces the frequency with which jurisdictional conflicts arise. If an agreement does not provide the necessary insulation to enable governments to fend off political pressures from, for example, interest groups who perceive the costs and benefits of opening the national economy being unfairly distributed, governments will often resist fiercely to the intrusion on their sovereignty.

<sup>115</sup> The US Trade Act Panel Report, note 102 above, pp. 6 and 300. In this case, the EC claims that by applying sections 301-310 of the 1974 Act after the entry into force of the Uruguay Round Agreement, the US breaches the deal struck between the US and the other Uruguay Round participants. The deal consists of a trade-off between the practical certainty of adoption by the DSB of panel and Appellate Body Reports and of authorisation for members to suspend concession on the one hand, and the complete and definitive abandoning by the US of its policy of unilateral actions on the other. One of the important conclusions made by the panel is that Section 304(a)(2)(A) of the 1974 Act which requires the USTR to determine whether another member state denies rights or benefits of the US under a WTO agreement irrespective of whether the DSB adopts a panel or Appellate Body's findings on the matter is not inconsistent with Article 23.2(a) of the DSU.

boost the US government's position in relying on them to deal with trade disputes arising within the WTO system or outside its coverage.<sup>116</sup> And these trade provisions will continue to play an influential role by providing the US citizens and private enterprises with a creditable route to petition the US government to investigate and act against potential violations of the TRIPS Agreement. The EC also has enacted a Trade Barrier Regulation (TBR) as a part of the Uruguay Round legislation package.<sup>117</sup> It enables industries and individual enterprises from the Community to lodge complaints and request the Commission to act<sup>118</sup> when they are faced with "obstacle to trade".<sup>119</sup> The Regulation could be seen as the counterpart of the US Section 301 provisions,<sup>120</sup> and will serve as the basis to impose unilateral sanctions on dispute relating to the exhaustion of IPRs in the absence of a multilateral resolution.

A multilateral solution to define the extent the exclusive marketing rights conferred by patent protection under the TRIPS Agreement should be recognised in domestic legislation so to settle the issue of exhaustion and parallel importation. MTNs under TRIPS is the preferred option because the principles of non-discrimination, namely NT and MFN, and reciprocity contained in the agreement would ensure the compliance of treaty commitments, and it offers a centralised enforcement mechanism that provides

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<sup>116</sup> Jackson et al., note 105 above, p. 817.

<sup>117</sup> Council Regulation 3286/94 lays down Community procedures in the field of commercial policy in order to ensure that exercise of the community's right under international trade rules, in particular, those established under the auspices of the WTO, see O.J. L349/71 of 31 December 1994, amended by the Council Regulation 356/95, O.J. L41/3 of 23 February 1995.

<sup>118</sup> Such as bringing actions under the WTO DSM.

<sup>119</sup> It could be either non-violation or outright violation of trade rules.

<sup>120</sup> There are at least two differences between the Regulation and Section 301 provisions: firstly, TBR does not intend to force trading nations into new concessions, and secondly, the WTO DSM has to be utilised first. See Van Eeckhaute, Jean Charles, 'Private Complaints against Foreign Unfair Trade Practices – The EC's Trade Barriers Regulation', 36(6), *JWTL*, 1999, pp. 199-213.

administrative simplicity and legal certainty.<sup>121</sup> Without a solution as such, it is difficult to see how the TRIPS Agreement could provide adequate or effective patent protection in securing patent holders' exercise of their exclusive marketing rights. The exercise of the exclusive rights should not be irreconcilable with, but complement trade liberalisation.<sup>122</sup> If the WTO is to manage increasingly complex trade relations in an interdependent global economy and to maintain the basic rationale of trade liberalisation,<sup>123</sup> it must address policies that, although remaining within the domestic jurisdiction at present, have a bearing on cross-border trade.<sup>124</sup>

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<sup>121</sup> The WTO might then be faced with the necessity of proving a case of anti-competitive behaviour that is harmful to the efficient function of markets. It often requires a highly developed investigative and adjudicatory capability which, according to Vernon, is one that exceeds anything that exists in the WTO. If the WTO does take up the challenge, the administrative burden placed on the WTO administration could be tremendous if the EU experience is a precedent. At the time of writing, the European Commission is proposing to leave all but the most serious infringements of European competition law to national authority in order to reduce its administrative burden. See Petersmann, 1993, note 19 above, p. 41 and 75, Vernon, 1998, note 2 above, p. 212 and FT, December 14, 1999, p. 22.

<sup>122</sup> IPP should be served as the groundwork to facilitate global trade in IP-endowed products and technology. In an Aluminum Wheel case, the Tokyo High Court in Japan upheld the doctrine of international exhaustion applicable to patent protection for the first time. However, the court also states that if the opportunity to take the compensation of the patented product is limited by some national price control or execution of compulsory licence, the court will not consider such a patent right as exhausted. See Yamamoto, Shusaku, 'A Reversal of Fortune for Patentees and Parallel Importers in Japan', *EIPR*, vol. 7, 1995, pp. 341-343.

<sup>123</sup> Also see the comment made by Petersmann that benefits of effective competition rules are an element of trade liberalisation in 1997 Symposium, note 30 above.

<sup>124</sup> UNCTAD, *The Outcome of the Uruguay Round: An Initial Assessment – Supporting Papers to the Trade and Development Report 1994*, NY: UN, 1994, p. 240.

## Conclusion

IPP has gained its prominence in legal, political and economic debates in recent years because of the increasing importance of intellectual property-endowed goods and technology in global trade.<sup>1</sup> Technology producers who participated in global trade, most of them MNCs, called for a rule-based trading environment in an increasingly integrated global economy where disparities in IP system among nations are eliminated, and IP products are bestowed due legal protection as in most of ICs. For MPCs, an adequate and effective patent regime that ensures the legal recognition of the exclusive marketing rights among nations was utmost in their mind.

The discussion of the legal framework of the Paris Convention in this thesis demonstrates that the Convention would have had difficulty in answering above-mentioned demands. Its legal framework was agreed upon at a time when economic debates dominated the design of the agreement. But IPP as a subject has evolved since then from a domestic economic policy issue to one that also affects cross-border trade with global ramifications.

The TRIPS Agreement has reflected, to a large extent, MPCs' concerns over the inadequacy and ineffectiveness of patent protection for pharmaceuticals under the Convention. With the emphasis on fair trade, it has incorporated unconditional MFN, NT, and reciprocity into the Agreement. And it has secured market access and equal



competition opportunity commitments by establishing a legal framework of substantive norms, enforcement and dispute settlement mechanisms of ICs' standard which binds all WTO members. But the Agreement did not address the issue of how to resolve potential conflicts between domestic competition policy and the implementation of treaty obligations under the TRIPS Agreement.<sup>2</sup>

An example in point is the different approach trading nations adopt in dealing with the exhaustion of the exclusive marketing rights conferred by patent protection for pharmaceuticals under the TRIPS Agreement. It is an issue with economic, political as well as legal connotations. Economically, international exhaustion legalises parallel importation of pharmaceuticals and has direct impact on MPCs' profitability because those targeted drugs tend to be the ones with more improved therapeutic benefits that MPCs rely on to sustain their level of profitability.<sup>3</sup> But countries might wish to rely on parallel importation as a mechanism to control the perceived monopoly patent holders enjoy, and to bring down prices of patented products. It is a legal issue in that, from IP holders' point of view, diverse domestic policies will be perceived as non-tariff barriers causing trade distortions especially if the exclusive marketing rights are compromised in the implementation of other government policies. Politically, it touches upon nations'

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<sup>1</sup> See World Bank, *World Development Report, 1998/1999*, NY: Oxford University Press for the World Bank, p. 27.

<sup>2</sup> IPP was introduced into the Uruguay Round MTNs at a time when GATT was confronted with increasing demands to bring domestic policy issues which affect cross-border trade into multilateral discipline. It inevitably involves interfering with governments' regulatory autonomy. Among different subjects dealt with by the global trading system in the Uruguay Round, MTNs on TRIPS, in particular patent protection for pharmaceuticals, pose a particular challenge in this respect because of diverse perspectives among ICs and DCs of the role patent protection for pharmaceuticals plays in both the spheres of domestic economy and global trade. By bringing an issue originally under domestic jurisdiction into multilateral discipline, the cohesion between the treaty obligation and other domestic policies cannot be totally ignored.

<sup>3</sup> Rothnie, W. A., *Parallel Import*, London: Sweet & Maxwell, 1993, pp: 506-508.

regulatory autonomy if a multilateral solution is to be sought to eliminate the discrepancy among domestic laws.<sup>4</sup>

This research has demonstrated that the failure to address the issues of exhaustion and parallel importation in the TRIPS Agreement is to put in doubt the adequacy and effectiveness of the patent system under the Agreement. The integrity of the patent system as a whole could be jeopardised if national governments are allowed to implement international exhaustion and limit the exercise of the exclusive marketing rights, justified on the ground of, for example, promoting free trade and competition.<sup>5</sup> The disparity among national policies will create distortion in global trade. Furthermore, the exclusion of the issue of the exhaustion of intellectual property rights for the purpose of dispute settlement under the TRIPS Agreement<sup>6</sup> might lead to governments representing MPCs reverting to unilateral actions for the resolution of grievances arising from the application of international exhaustion that permits parallel imports, an undesirable consequence TRIPS MTNs tried to prevent.

This thesis concludes that a multilateral solution needs to be found under the TRIPS Agreement to give legitimacy to the exclusive marketing rights in governments' domestic policy consideration. MTNs are the better option when it involves economic, legal, and

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<sup>4</sup> Hancher gives the example of the application of community exhaustion for the purpose of creating an internal market in pharmaceuticals within the EU, which has proven to be a difficult and slow process: the EU member states have to surrender their sovereignty in policy areas such as safety regulations on pharmaceuticals and the general economic policy of price control or national reimbursement rules. See Hancher, Leigh, *Regulating for Competition*, London: Clarendon Press, 1990, p. 152.

<sup>5</sup> When evaluating the desirability of bringing an issue into the jurisdiction of the WTO, the Economist suggests that it is necessary to ask whether the disparity among national policies in this area will distort global trade, and whether the existence of an international standard outweighs the benefits of accepting domestic rules which reflect local policy priorities. The Economist, January 15, 2000, p. 99.

political considerations. It may be argued that, in the absence of an agreement to secure the recognition in domestic policy of the exclusive marketing rights, it could still be possible for the DSB to fine-tune the point of contention while balancing the exercise of the exclusive rights with the objective the global trading system to liberalise trade. But to solve the issue through litigation would establish a set of rules in a piecemeal and protracted manner.<sup>7</sup> It will also put the global trading system in a reactive mode which does not serve the business community well in providing certainty and clarity to deal with new government or private business practices continuously emerging in response to market dynamics.

Inquiries into the impact on MPCs' commercial operations due to the absence of an agreement on how to secure the legal recognition of the exclusive marketing rights in the domestic policy are few and far between. As the TRIPS Agreement contains IPP of ICs' standards, the dislocating effects to the economy of DCs could be predicted with certainty in the short term, much of the post-TRIPS research in the area of patent protection for pharmaceuticals centre around economic impacts of the TRIPS Agreement on DCs and what TRIPS-consistent measures DCs could adopt to complement their development objectives so to alleviate negative impacts to their domestic economies.<sup>8</sup> It might also be

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<sup>6</sup> Article 6 of the TRIPS Agreement.

<sup>7</sup> Cornish, W. R., *Intellectual Property: Patents, Copyrights, Trade Marks and Allied Rights*, 4<sup>th</sup> ed., London: Sweet & Maxwell, 1999, ch. 1.

<sup>8</sup> See, for example, the following books, Srinivasan, T. N., *Developing Countries and the Multilateral Trading System – From the GATT to the Uruguay Round and the Future*, Boulder, Colorado: Westview Press, 1998, UNCTAD, *The TRIPS Agreement and Developing Countries*, NY: UN, 1996, and Martin, Will and L. Alan Winters (eds.), *The Uruguay Round and the Developing Countries*, Cambridge: Cambridge University Press, 1996. See also the following articles: Broncker, Marco C.E.J., 'The Impact of TRIPS: Intellectual Property Protection in Developing Countries', *CMLR*, 31, 1994, pp. 1245-1281, Oddi, Samuel A., 'TRIPS – Natural Rights and a 'Polite Form of Economic Imperialism'', *Vand JTL*, 29(3), 1996, pp. 415-469, and Subramanian, 1990a, note 1 above., pp. 252-265

because the assessment of the adequacy and effectiveness of the TRIPS Agreement is seen to be premature before it is fully implemented by all WTO members in 2005.<sup>9</sup>

The present evaluation of the adequacy and effectiveness of the patent system from the perspective of MPCs provides the assessment from the global business community of the workability of the international legal regime for the patent protection of pharmaceuticals. As in the supply of medicines for AIDS to DCs, MPCs have already encountered the issues of compulsory licensing<sup>10</sup> to facilitate the production of generic version of patented drugs which will lead to competition in the domestic market. They also face the demand for lowering the price of medicine<sup>11</sup> affordable to DCs which could lead to more products for parallel importation destined for ICs. This case goes to prove the necessity of addressing the uncertainty in relation to how governments exercise their discretion in implementing the contractual licensing provision contained in the TRIPS Agreement and the issues of international exhaustion and parallel importation irrespective of whether the TRIPS Agreement is fully implemented by all WTO members.

This thesis clearly identifies the parameters of the issue of how to establish the link between multilateral treaty obligations and domestic government policy portfolio in subsequent TRIPS MTNs. For the global trading system as a whole, the challenge remains to identify a equilibrium between the pragmatic approach that accommodates

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<sup>9</sup> Transitional arrangements are applicable to DCs if they opt to take advantage of them. See Article 65 of the TRIPS Agreement and discussion in Chapter 4.3 of the thesis.

<sup>10</sup> An organisation called South Africa's Treatment Action Campaign was about to start a legal action seeking a compulsory licence from Pfizer, a MPC, for the production of cheap copies of Pfizer's patented product fluconazole for the treatment of certain opportunistic infections that plague AIDS patients. See FT, July 12, 2000, p. 10.

different domestic economic and political agendas, and the judicial approach of establishing rule-based multilateral legal principles that provide binding obligations and yield the transparency and predictability global business communities look for. It is well recognised that the limitation of MTNs involves compromises and trade-offs in the negotiation process, and the necessity to respect national regulatory autonomy by allowing flexibility in the implementation of the agreement so to make it politically acceptable to domestic constituencies. But the process of globalisation and the integration of global economy mean that the shift toward a rule-based global trading system is an inevitable consequence, and the global trading system needs to evolve in response, if not to take the lead.

And with regard to future MTNs on TRIPS, ICs' spearheading the initiative remains a determined factor if they are to take place. They will involve a protracted series of negotiations among an extended set of bodies which includes governments, MPCs, the UN,<sup>12</sup> the World Health Organisation, and NGOs<sup>13</sup> with their own political agendas and priorities. A different negotiation dynamic has emerged which could impact on the role ICs play in future MTNs. It concerns the relationship between MPCs and their respective governments, in that, MPCs are faced with the need to call for their own governments to give full effect to the exclusive marketing rights conferred by the patent system under the

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<sup>11</sup> See reports on the biennial world Aids conference taken place in Durban, South Africa. Ibid., and FT, July 8/July 9, 2000, p. 12.

<sup>12</sup> The UN has established an umbrella group called UNAIDS to co-ordinate the anti-AIDS effort of various UN agencies. During the biannual conference on AIDS which took place in May 2000, five MPCs agreed with UNAIDS to slash the price of AIDS medicine for poor countries by 85%. Some commentators warned that, by doing so, MPCs run the risk of being asked to extend the price reduction to non-AIDS drugs, and that poor citizens in rich countries might also push for similar concessions. See The Economist, July 15<sup>th</sup>-21<sup>st</sup> 2000, p. 18 and FT, July 31, 2000, p. 18.

<sup>13</sup> Ibid.

TRIPS Agreement because encouraging competition by means of parallel importation to control health care costs is also an attractive policy option for ICs.<sup>14</sup> The issues of drug prices and supply have effect on how the compulsory licensing provision and the doctrine of exhaustion are to be implemented domestically. Engaging governments and MPCs in constructive dialogue is essential in this respect if there are to be meaningful negotiations, and to minimise the deviation of domestic policy remains an important objective in MTNs on TRIPS.

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<sup>14</sup> One recent example is the proposed US Senate amendment on legislation to allow drugs to be imported from any foreign factory approved by the Food and Drug Administration. It sends a clear message that patents in the US paying more for patented medicines than other western consumers is no longer acceptable. See FT, July 31, 2000, p. 18.

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