



UNIVERSITY
OF WOLLONGONG
AUSTRALIA

University of Wollongong
Research Online

Faculty of Business - Economics Working Papers

Faculty of Business

2003

Korea, the Pharmaceutical Industry and Non-Commercial Use in the TRIPS Agreement

D. Shanker

University of Wollongong

Publication Details

Shanker, D, Korea, the Pharmaceutical Industry and Non-Commercial Use in the TRIPS Agreement, Working Paper 03-15, Department of Economics, University of Wollongong, 2003.

Research Online is the open access institutional repository for the University of Wollongong. For further information contact the UOW Library:
research-pubs@uow.edu.au



**University of Wollongong
Economics Working Paper Series
2003**

<http://www.uow.edu.au/commerce/econ/wplist.html>

**Korea, the Pharmaceutical Industry and Non-
Commercial Use in the TRIPS Agreement**

Daya Shanker

WP 03-15

December 2003

Korea, the Pharmaceutical Industry and Non-commercial Use in the TRIPS Agreement

Daya Shanker

Abstract

In 2002, a number of associations requested the Korean Patent Office to issue a compulsory license for the manufacture of a drug under the Korean patent provision which permits the issue of compulsory licensing for public non-commercial use. This provision in the Korean patent act was introduced in 1995 ostensibly to comply with Article 31 of the TRIPS Agreement which permits the issue of compulsory licenses without prior consultations with the patent holder. In a change of strategy, the objection to the issue of a compulsory license for the drug, Gleevec, was filed not by the patent holder or by PhRMA, the association and lobby group of the pharmaceutical industry, but by certain individuals claiming to have legal expertise, and sympathizers of the pharmaceutical industry. The objection raised was based on the concept of legitimate expectation, a concept not applicable in the case of the TRIPS Agreement. The objections raised do not appear to be supported by a legal argument and appear to be arbitrary in nature. In addition, they appear to reflect PhRMA's aims of curtailing the flexibility inherent in the TRIPS Agreement.

Introduction

The issue of non-commercial working of patent in Korea became a prominent one when Hee Seob Nam and SungHo Park filed a request on behalf of the People's Health Coalition for Equitable Society, the Association of Physicians for Humanism, and Korean Pharmacists for Democratic Society on Jan. 30, 2002 for issue of a compulsory license under non-commercial working of Gleevec under Article 107(1)(iii) of the Korean Patent Law, the patent for which is owned by Novartis, a Swiss pharmaceutical company.¹

The main argument of Nam and Park was that under Article 36.6 of the Korean Constitution, "the Government of Korea has a duty to establish a comprehensive and systematic health policy for the benefit of its own people (People's Right to Health)" and the exceptionally high price charged by Novartis for Gleevec amounts to ignoring the Korean government's public health policy and threatening "Koreans' fundamental right to seek a healthy life." In an unusual development, Dr. Jacques Gorlin, a consulting economist and Vice-chair of the Industrial Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters, which advises the U.S. Secretary of Commerce and the U.S. Trade Representative on Trade Policy, filed an affidavit against the Nam-Park request² on a number of grounds. The major ones were the doctrine of legitimate expectations, a doctrine not applicable to the provisions of the TRIPS Agreement as decided by the Appellate Body in India-Patent Protection³, and the negotiating history of the TRIPS Agreement based on the EC and Swiss proposals during the TRIPS negotiations.

¹ See Request for a Compulsory License by Hee Seob Nam and Sung Ho Park on Behalf of People's Health Coalition for Equitable Society, Association for Physicians for Humanism, and Korean Pharmacists for Democratic Society. The request was filed before the Commissioner of KIPO (Korean Intellectual Property Office) on January 30, 2002. The request is available at http://glivec.jinbo.net/REquest_for_CL_Final_version.htm (visited on 3/07/2002)

² See Jacques Gorlin, Affidavit "to Clarify Certain Requirements of the TRIPS Agreement with respect to granting of Compulsory licenses." Dated May 28, 2002. Available at <http://www.cptech.org/ip/health/gleevec/gorlin05282002.html> (visited on 5.10.2002). Provided to the author by Hee Seob Nam.

³ India-Patent Protection for Hermetical and Agricultural Products, Report of the Appellate body, WT/DS50/AB/R, Adopted by the Dispute Settlement Body on 16 January 1998

Since the public non-commercial working is part of the Article 31 exception of the TRIPS Agreement and does not require prior consultation with the patent holder to obtain a license on “reasonable commercial terms,” it has become quite a sensitive issue with the patent holders and countries like the USA and the EC which are in favour of strict patenting regimes. The filing of the affidavit by Jacques Gorlin and Dohi Kozuhemi in favour of the pharmaceutical industry appears to be part of a changed strategy adopted by the members of PhRMA to avoid inviting public condemnation by not opposing the issue of compulsory licensing directly. The presence of non-commercial use in Article 31 also has a corresponding presence in Article 27.2 of the TRIPS Agreement which permits exclusion of patentable invention if the prevention of the commercial exploitation of which is necessary to protect human, animal or plant life or health or to avoid serious prejudice to the environment. This exclusion has two implications: first, the exclusion of patenting relating to nuclear matters as in the USA⁴ and other patentable subjects which are covered by the public safety; and, second, the practice that has been followed by a large number of countries which did not permit patenting of inventions related to food and medicines.⁵ The prevention of commercial exploitation does not prevent non-commercial exploitation of such inventions.

The term public-non commercial use has a number of implications. Is public non-commercial use exclusively meant for non-profit purposes as the term non-commercial suggests? Is the non-commercial exemption confined only to government use and no private party can engage in such activity? Hee Seob Nam raised issue of highly profit making activities as excluded from non-commercial use under Article 31 of the TRIPS Agreement. The definitional problem inherent in the label of non-commercial use or purposes raises a number of other issues also

⁴ 42 USCS s. 2181. Inventions relating to atomic weapons, and filing of reports

(a) Denial of Patents; revocation. No patent shall hereafter be granted for a y invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon. Any patent granted for any such invention or discovery is hereby revoked, and just compensation shall be made therefore.

⁵ See F. M. Scherer, *The Pharmaceutical Industry and World Intellectual Property Standards*, 56 *Vanderbilt Law Review* 2245, 2247-48 (2000), “Many nations excluded drug products from patentability because they considered drugs (and for analogous reasons, food products) to be of such great importance to the national welfare. Even Switzerland, home to three of the world’s leading pharmaceutical companies, abstained until 1977 from granting drug patents.”

whether the central purpose of the actor is not to achieve profit or whether the underlying activity is commercial in character. This article will discuss the meaning of public non-commercial use and its limitations if any both in terms of profitability and its scope.

Public Non-commercial Purposes

This term has been used regularly in copyright disputes. Recently it has been discussed in the case of domain name disputes.⁶ Any contribution to the cost of expenses coming from anywhere would not be counted as profitable transaction. This type of situating normally arises in case of insurance when a transport is used for pure personal use or for commercial gain. Where the cost is shared to cover the cost of running the transport, there is no commercial transaction. These types of situations have been discussed in a series of cases particularly in the insurance of automobiles⁷ and in airplanes⁸ where the insurers prohibited the use of such transport for commercial purposes. The courts have observed that sharing for the cost of running the transport would not convert the use of automobile or the airplanes into a commercial activity.

The other use is that of 28 USC Sec. 1498 dealing with government use which permits the US government or its agencies to use and manufacture any patented invention whether or not developed with federal funds and authorize its use and manufacture by others for the United States subject to liability for “reasonable and entire compensation.”⁹ Gorlin¹⁰ in his affidavit argued that

⁶ See *Ford Motor Company v. 2600 Enterprises*, 177 F. Supp. 2d 661; 61 U.S.P.Q. 2D (BNA) 1757); *Nissan Motor v. Nissan Computer Corporation* 231 F. Supp. 2d 977; 65 U.S.P.Q. 2D (BNA) 2008

⁷ See *Christensen v. State Farm Auto. Ins.*, 52 Hawaii 80, 470 P.2d 521 (1970), “On balance, we think that the language of the policy excludes coverage only where a rental is commercial in nature. Visualizing a spectrum between simple permissive use (which clearly is covered under the policy) and commercial rental for a profit (which clearly is excluded), we view the present facts as being more in the nature of permissive use. ****”

⁸ See *Cammack v. Avemco Insurance Company*, 264 Ore. 287, p. 292; 505 P.2d 348, The court observed that “In light of these decisions we construe the transaction to a payment of expenses in a noncommercial context and we agree with the trial court that Rutledge’s use was not “any operation for which a charge is made.”

⁹ 28 U.S.C. Sec. 1498. – Patent and Copyright Cases

- (a) Whenever an invention described in and covered by a patent of the United States issued or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims of the recovery of his reasonable and entire compensation for such use and manufacture. ...
“Notwithstanding”

“public non-commercial use” provision in Article 31 of the TRIPS Agreement was based on US Section 1498 and can be used for only legitimate government functions which, according to him, are confined to defence and space. The point of discussion here is that whenever a government contractor uses the patent under this section, the profit for the contractor and other agencies are not to be taken into consideration. The only limitation is the remuneration to be paid which does not depend “on what the owner has lost, not what the taker has gained.”¹¹ Thus the profit has not been totally excluded from the public non-commercial purposes. Similar exceptions are not only present in the USA, but are present in each and every country’s patent act. Section 1498 came into prominence in the USA when the USA threatened Bayer¹² with issue of compulsory license for manufacture of ciprofloxacin (Cipro) during anthrax crises. Although Harvey Bale from PhRMA tried to project the low cost at which Bayer agreed to supply cipro i.e. less than one fifth price it charges from customers to the government as a commercial transaction,¹³ the fact that the Government of USA was keen to have access to such methods confirms that getting the medicines is not prohibited even in the USA from compulsory license under Article 31 of the TRIPS Agreement.¹⁴ The US government provided substance to its threat by extending national defense contracting authority to the Department of Health and Human Services (DHHS).¹⁵

For the purposes of this section, the use or manufacture of an invention conceived in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States. ...

¹⁰ See Jacques Gorlin Affidavit, supra note 2

¹¹ See Hughes Aircraft v. Y United States, 86 F.3d 1566, quoting Leeson (599 F. 2d at 969)

¹² Deborah Socolar and Alan Sager, Cipro Price: Windfall Profits Despite discounted Price: Small Manufacturing Cost for Cipro Yields Estimated \$70 Million Windfall, www.healthreformprogram.org, 28th June, 2002

¹³ See United States Department of Health and Human Services, HHS Bayer Agree to CIPRO Purchase, dt. 24 Oct. 2001 at <http://www.hhs.gov/news/press/2001press/20011024.html>

¹⁴ United States Department of Health and Human Services, HHS, Bayer Agree to CIPRO Purchase dated 24th October 2001, <http://www.hhs.gov/news/press/2001press/20011024.html> ; Martiga Lohn, A Bitter Pill for the WTO, MoJournal, 9th November 2001 at http://www.motherjones.com/web_exclusives/features/news/cipro.html

¹⁵ Executive Order for Department of Health and Human Services, press release on 20 October 2001, available at <http://www.whitehouse.gov/news/releases/2001/10/20011022-15.html>

Berger¹⁶ discussed the public noncommercial use in connection with similar provision in Article 27.2 of the TRIPS Agreement. Berger argued that the presence of the term “commercial exploitation” in Article 27.2 is to be read as different from “normal exploitation” mentioned in Article 30 and non-commercial use in Article 31. Article 27.2 of the TRIPS Agreement permitting the WTO Members to exclude inventions from patentability to protect *ordre public*, human, animal or plant life or health or to avoid serious prejudice to the environment supports that comparatively milder provision of non-commercial use in Article 31 cannot be restricted to defense and space programs. Berger noted that “A prohibition on commercial exploitation would in effect amount to more than extinction of any rights of exclusivity-it would constitute an effective expropriation of property without any compensation.”¹⁷

Gold and Lam¹⁸ recently discussed the role of public non-commercial use in the TRIPS Agreement. They have brought out the facts of specific inclusion of the term “public non-commercial use” in the Brussels Draft¹⁹ only as this term had not been included at all in the previous drafts to confirm that public non-commercial use is not to be constructed in terms of any negotiating history previous to the Brussels Draft.

Korean Patent Act dealing with compulsory licensing

Article 107 of the Korea Patent Act permitting the issue of compulsory licensing in enumerates the situations required for the issue of compulsory licensing. These are:

¹⁶ See Jonathan M. Berger, “Tripping Over Patents: AIDS, ACCESS to Treatment and the Manufacturing of Scarcity”, Symposium – The Global AIDS Crisis: Human Rights, International Pharmaceutical Markets and Intellectual Property, 17 Connecticut Journal of International Law 157, 228-229 Spring, (2002)

¹⁷ See Berger, supra note 16, p. 229, Berger pointed out that, “a country would be able to invoke Article 27.2 where it was shown, for example, that even making use of compulsory licensing would not be sufficient to avert the pending public health or environmental disaster, either because of an inability to finance compensation or else because the procedures under the required compulsory licensing provisions would not allow for a sufficiently timely response. The result of such a move would be to open the market to competition immediately, which would allow for the erstwhile patent holder, generic manufacturers and the state (if it had the capacity) to produce the required invention.”

¹⁸ E. Richard Gold and Danial K. Lam, Balancing Trade in Patents: Public Non-commercial use and Compulsory licensing, 6 Journal of World Intellectual Property 5 (2003)

¹⁹ See Agreement on trade Related Aspects of Intellectual Property, including Trade in counterfeit Goods in Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT Doc. No. MTN.TNC/W/35/Rev.1, 3 December 1990, reproduced in part in Gervais at p. 161 (hereinafter Brussels Draft)

- 107(i) Where the patented invention has not been worked for more than three consecutive years in the Republic of Korea, except in the case of a natural disaster, unavailable circumstances or other justifiable reasons prescribed by Presidential Decree;
- 107(ii) Where the patented invention has not continuously been worked commercially or industrially for more than three consecutive years in the republic of Korea on a substantial scale during a period of three years or more without justification, or where the domestic demand for the patented invention has not been satisfied to an appropriate extent and under reasonable conditions;
- 107(iii) Where the non-commercial working of a patented invention is necessary in the public interest
- 107(iv) where the working of a patented invention is necessary to remedy a practice determined to be anti-competitive after the judicial or administrative process.

Article 107(iii) permitting the issue of compulsory licensing was incorporated in the Korean Patent Act only in 1995 apparently to comply with the TRIPS Agreement. Its predecessors Article 101 and 102, Article 44 of Law No. 950 enacted December 31, 1961), Article 44 of Law No. 1293 (enacted March 5, 1963), Article 50 of Law No. 2505 (enacted February 8, 1978) and Article 50 of Law No. 3891 (enacted December 31, 1986) permitted use of compulsory licenses only in the case of national defense or for public purposes.²⁰

In Article 2 “working” has been defined as

- (iii)a in the case of an invention of a product, acts of manufacturing, using, assigning, leasing, importing, or offering for assigning or leasing (including displaying for the purpose of assignment or lease) the product.

In Article 31 of the TRIPS Agreement, there is no provision or even mention of working of the patent. The working of the patent comes from Article 5A of the Paris Convention. The period of three years and four years also come from Article 5A(4) of the Paris Convention as mentioned below.

²⁰ See Nam and Park, *supra* note. 1

Articles 5A(1) and 5A(2) of the Paris Convention deal with compulsory licenses and abuse of patent. The provisions are

- Article 5A(1) Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.
- Article 5A(2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, **failure to work**.
- Article 5A(3) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.
- Article 5A(4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before 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; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable even in the form of grant of a sub-license, except with that part of the enterprise or goodwill, which exploits such license.'

The grant of compulsory license has been specifically mentioned for non-working of the license in Article 5A(2).

The working has been defined by Bodenhausen:

'The Member states are also free to define what they understand by 'failure to work'. Normally working a patent will be understood to mean working it industrially, namely by manufacture of the patented product, or industrial application of a patented process. Thus, importation or sale of the patented article, or of the article manufactured by a patented process, will not normally be regarded as 'working the patent'²¹

²¹ See Bodenhausen, G.H.C., Guide to the Application of the Paris Convention for the Protection of Industrial Property, as revised at Stockholm in 1967, 1968, p-71, WIPO

The term “working” has been defined in all the countries of Europe including the Community Patent Convention. Only in the year 2000, in the Community Patent Convention²² on the basis of the panel report in Canada-Patent Protection²³ the concept of importation as constituting working of the patent was introduced. It was based on the premises that Article 27.1 of non-discrimination is applicable to Articles 30 and 31 of the TRIPS Agreement.

South Korea has introduced importation as working against the concept of working in the Paris Convention which is an integral part of the TRIPS Agreement through Article 2 of the TRIPS Agreement.

Article 2(1) of TRIPS reads as under

1. In respect of Parts II, III, and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).

Article 2(2) of TRIPS states

2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

²² See Proposal of a Council Regulation on the community Patent Amendments (2000) Legislation under Preparation: commission Proposals, Document 500PC041217.20-Intellectual Property Law, http://europa.eu.int/eur-lex/en/com/dat/2000/en_500PC0412.html

Article 47 of the Community Patent Convention renumbered as Article 46[1989] reads

“A compulsory license may not be granted in respect of a Community patent on the ground of lack of or insufficiency of exploitation if the product covered by the patent, which is manufactured in a contracting state, is put on the market in the territory of any other Contracting State, for which such a licence has been requested, in sufficient quantity to satisfy needs in the territory of that other Contracting State. This provision shall not apply to compulsory license granted in the public interest.”

The Proposed Legislation under Preparation says “The Commission may grant compulsory licences for lack of or insufficiency of exploitation of a Community patent to any person filing an application four years after the patent application was filed and three years or later after the patent was granted if the patent proprietor has not exploited the patent in the Community on reasonable terms or has not made effective and serious preparations to do so, unless he provides legitimate reasons to justify his inaction. In determining the lack or insufficiency of exploitation of the patent, no distinction shall be made between products originating within the Community and imported products.”

²³ See Report of the Panel in Canada-Patent Protection for Pharmaceutical Products, WT/DS114/R dated 17th March, 2000 (hereinafter Canada-Patent Protection)

The dictionary meaning of the phrase 'derogate from' is 'detract from' and the dictionary meaning of derogate is 'to cause to seem inferior'.²⁴ Article 2 of TRIPS makes it clear that the Paris Convention dealing with local working is applicable in its totality to the TRIPS Agreement and the obligations under the Paris Conventions and other relevant conventions shall not become of less value because of the presence of any provision in Parts I to IV of the TRIPS Agreement. The concept of local working and its applicability has been discussed in detail by Daya Shanker.²⁵

In case the cost of patented medicines is exorbitant, it would have been covered by the condition insufficient working and a compulsory licensing could have been issued without raising any issue of compensation to the patent holder. Other alternative, is to treat high prices of the patented product as anti-competitive as has been done in Argentinean Patent Act. The Argentinean Patent Act says:

“Article 44 of Argentinean Patent Law in line with anti-competition provisions of Article 31 and has outlined certain practices as anti-competitive per se. These are

“For the purposes of this Law, the following practices among others shall be considered anti-competitive:

- (a) the setting of prices for the patented products that are excessive in relation to the market average or discriminatory, particularly where alternative proposals exist for supplying the market at prices significantly lower than those charged by the patent owner for the same product;
- (b) refusal to supply the local market on reasonable commercial terms;
- (c) the slowing down of marketing or production activities

Jacques Gorlin's Objection

Gorlin objected to the request of Nam and Park on a number of grounds some of them do not appear to be legal while others were bald assertions without any supporting documents. Some of the major grounds in Gorlin's affidavit to oppose the issue of compulsory licensing for Gleevec are

²⁴ Collier's Dictionary, Simon & Schuster, Inc. 1994

²⁵ See Daya Shanker, Brazil, the Pharmaceutical Industry and the WTO, 5 Journal of Intellectual Property 53, (2002); India, the Pharmaceutical Industry and the Validity of TRIPS, 5 Journal of World Intellectual Property 315 (2002)

- a. Relevance of the concept of legitimate expectation where Gorlin argued that “Under the TRIPS Agreement, when considering the grant of a compulsory license for a non-commercial working of a patented invention that is necessary for the public interest, the expectations of those who require the protection and enforcement of intellectual property right and the public benefits that derive from such protection must be taken into account.”²⁶

Gorlin also contented that “rules and disciplines governing the multilateral trading system serve to protect legitimate expectations of members as to the competitive relationship between their products and those of other Members” on the basis of the Panel report in *India Patent Protection*

- b. Use of proposals from the EC²⁷ and Switzerland²⁸ as defining the meaning of the term “public non-commercial use” in terms of negotiating history
- c. Limiting the use of provisions of Articles 30 and 31 of the TRIPS Agreement for individuals only.

The first major weakness in Gorlin’s arguments pertains to the concept of “legitimate expectations”.

The legitimate expectation was discussed by the WTO panel in *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products* (WT/DS50/R) in paras 7.20 and 7.21.

Para 7.20 says:

The Protection of legitimate expectations of members regarding the conditions of competition is a well-established GATT principle which derives in part from the Article XXIII, the basic dispute settlement provisions of GATT (and the WTO). Regarding Article III of GATT, the panel on *Italian Agricultural Machinery*²⁹ stated that “the intent of the drafters was to provide equal conditions of competition once goods had been cleared through customs.” This principle was later elaborated by the Superfund panel, which stated

²⁶ See Gorlin, *supra* note 2

²⁷ See Draft Agreement on Trade Related Aspects of Intellectual Property, Communicating from the European Community, GATT Doc. No. MTN.GNG/NG11/W/68, dated 29th March 1990- (hereinafter EC Draft Text)

²⁸ See Draft Agreement on Trade Related Aspects of Intellectual Property, Communication from Switzerland, GATT Doc. MTN.GNG/NG11/W/73 dated 14th May, 1990

²⁹ See Panel Report on “Italian Discrimination against Imported Agricultural Machinery”, adopted on 23 October 1958 BISD 7S/60, para 12-13.

that “[t]he general prohibition of qualitative restrictions under Article XI ... and the national treatment obligations of Article III ... have the same rationale, namely to protect expectations of the contracting parties as to the competitive relationship between their products and those of the other contracting parties.”³⁰ The panel on Section 337, which dealt with issues involving protection of intellectual property at the border, also reached similar conclusions.”^{31 32},

Para 7.21 of the above panel report further says:

The protection of legitimate expectations is central to creating security and predictability in the multilateral trading system. In this connection, we note that disciplines formed under GATT 1947 (so called GATT acquis) were primarily directed at the treatment of the goods of other countries, while rules under the TRIPS Agreement mainly deal with the treatment of nationals of other WTO members. While this calls for the concept of the protection of legitimate expectations to apply in the TRIPS areas to the competitive relationship between domestically produced goods and the goods of other members, as in the goods area), it does not in our view make inapplicable the underlying principle. The Preamble to the TRIPS Agreement, which recognizes the need for new rules and disciplines concerning “the applicability of the basic principles of GATT 1994” provides a useful context in this regard.³³

India went against these observations of the panel to the Appellate Body, which found the above contention of the Panel inapplicable in the case of the TRIPS Agreement.³⁴ Paras 32 to 48

³⁰ See Panel Report on “United States – Taxes on Petroleum and Certain Imported Substances”, adopted on 17th June 1987 BISD 34S/136, para 5.2.2..

³¹See Panel Report on “United States – Section 337 of the Tariff Act of 1930”, adopted on 7th November 1989, BISD 36S/345, para 5.13

³² See Report of the Panel in *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products* (WT/DS50/R), para 20

³³ See Panel Report in *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products* (WT/DS50/R), para 7.21

³⁴ See Report of the Appellate Body in *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products* WT/DS50/AB/R dt. 16th Jan, 1998

of the Appellate Body Report deal with the panel's interpretation of "legitimate expectations" and concluded that the concept of "legitimate expectations" was applicable only in cases of non-violation complaint and Article 64.2 of the TRIPS Agreement had explicitly excluded application of these provisions to the settlement of disputes under the TRIPS Agreement.

In paras 41 and 42, the Appellate Body actually discussed the use of doctrine of "reasonable expectations". In para 41, it says

The doctrine of protecting the "reasonable expectations" of contracting parties developed in the context of "non-violation" complaints brought under Article XXIII:1(b) of the GAT 1947. Some of the rules and procedures concerning "non-violation" cases have been codified in Article 26.1 of the DSU. "Non-violation" complaints are rooted in the GATT's origins as an agreement intended to protect the reciprocal tariff concessions negotiated among the contracting parties under Article II.³⁵ In the absence of substantial legal rules in many areas relating to international trade, the "non-violation" provision of Article XXIII:1(b) was aimed at preventing contracting parties from using non-tariff barriers or other policy measures to negate the benefits of negotiated tariff concessions. Under Article XXIII:1(b) of the GATT 1994, a Member can bring a "non-violation" complaint when the negotiated balance of concessions between members is upset by the application of a measure whether or not this measure is inconsistent with the provisions of the covered agreement. The ultimate goal is not the withdrawal of the measure concerned but rather achieving a mutually satisfactory adjustment, usually by means of compensation.³⁶

The Appellate Body made its point clear that non-violation complaint under Article XXIII:1(b) dealing with "reasonable expectations" as asserted by the Panel in *India-Patent Protection* was applicable only to negotiated tariff concessions. Articles 64.2 and 64.3 of the TRIPS Agreement say:

- Article 64.2 "Subparagraph 1(b) and 1(c) of Article XXIII of GATT 1994 shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement."

³⁵ See E.-U. Petersman, "Violation Complaints and Non-violation Complaints in International Law" (1991) German Yearbook of International law 175

³⁶ This is codified in Article 26.1(b) of the DSU.

- Article 64.3 “During the time period referred to in paragraph 2, the Council for TRIPS shall examine the scope and modalities or complaints of the type provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 made pursuant to this Agreement, and submit its recommendations to the Ministerial Conference for approval”.

In 1999, the Council for Trade Related Aspects of Intellectual Property Rights prepared a factual background note on “Non-violation Complaints and the TRIPS Agreement.”³⁷ The TRIPS Council, although under Adrian Otten is in general leans towards pharmaceutical industry, by and large picked up the Appellate Body Report in *India-Patent Protection*³⁸ and quoted para 42 to confirm that the Panel’s assertion of ‘reasonable expectation’ in case of the TRIPS Agreement was unfounded and wrong.³⁹ The 1998 Panel Report on *Japan – film* considered that “the non-violation remedy should be approached with caution and should remain an exceptional remedy.”⁴⁰ So far, the TRIPS Council has not taken any decision on this issue. The matter came up for discussion in the Doha Conference in November, 2001, but any decision was postponed. The Doha Ministerial Conference on 14 November asked for continuation of the non-application of Article XXIII:1(b) in the TRIPS dispute and it addressed the issue in following

³⁷ See Council for Trade Related Aspects of Intellectual Property Rights, “Non-violation Complaints and the TRIPS Agreement, (IP/C/W/124) dated 28th January 1999.

³⁸ See Report of the Appellate Body, supra note 34

³⁹ See Report of the Appellate Body Report, supra note 34. In para 42, the Appellate Body observed

The meaning of this provision is clear: the only cause of action permitted under the TRIPS Agreement during the first five years after the entry into force of the WTO Agreement is a violation complaint under Article XXIII:1(a) of the GATT 1994. This case involves allegations of violation of obligations under the TRIPS Agreement. However, the Panel’s invocation of the “legitimate expectations” of Members relating to conditions of competition melds the legally-distinct bases for “violation” and “non-violation” complaints under Article XXIII of the GATT into one uniform cause of action. This is not consistent with either Article XXIII of the GAT 1994 or Article 64 of the TRIPS Agreement. Whether or not “non-violation complaints should be available for disputes under the TRIPS Agreement is a matter that remains to be determined by the Council for Trade related Aspects of Intellectual Property (the Council for TRIPS) pursuant to Article 64.3 of the TRIPS Agreement. It is not a matter to be resolved through interpretation by panels or by the Appellate Body.

⁴⁰ See Japan-Measures Affecting Consumer Photographic Film and Paper, Report of the Panel, WT/DS44/R dated 31st March 1998

“The TRIPS Council is directed to continue its examination of the scope and modalities for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 and make recommendations to the fifth Session of the Ministerial Conference. It is agreed that in the meantime, members will not initiate such complaints under the TRIPS Agreement.”⁴¹

The latest document to come from the TRIPS Council on Non-Violation was on 19th June 2002 (IP/C/W/349 dated 19th June 2002) and it conforms to the Appellate Body Report in *India-Patent Protection*.

Another aspect of “legitimate expectation” used by the Panel in *India-Patent Protection* was the use of Article 31 of the Vienna Convention. The Appellate Body castigated the Panel by calling the Panel’s approach a total misapplication. The Appellate Body observed in para 45:

The Panel misapplies Article 31 of the Vienna convention. The Panel misunderstands the concept of legitimate expectations in the context of the customary rules of interpretation of public international law. The legitimate expectations of the parties to a treaty are reflected in the language of the treaty itself. The duty of the duty interpreter is to examine the words of the treaty to determine the intention of the parties. This should be done in accordance with the principles of treaty interpretations set out in Article 31 of the Vienna Convention. But these principles of interpretation neither require nor condone the imputation into a treaty of words that are not there or the importation into a treaty of concepts that were not intended.⁴²

If any doubt was left in the inconsistency of “reasonable expectations” with the TRIPS Agreement in *India-Patent Protection*, it was removed by the Appellate Body’s observation in para 46 when it said:

“The Panel in this case has created its own interpretation of public international law nor established GATT/WTO practice. Both panels and the Appellate Body must be guided by the

⁴¹ See Declaration on the TRIPS Agreement and Public Health, Ministerial Conference , WT/MIN(01)/DEC/2 dated 20th November 2001

⁴² See The Report of the Appellate Body, supra note 34, para 45

rules of treaty interpretation set out in the Vienna Convention, and must not add or diminish rights and obligations provided in the WTO Agreement.”⁴³

The contention of Dr. Jacques Gorlin that “rules and disciplines governing the multilateral trading system serve to protect legitimate expectations of members as to the competitive relationship between their products and those of other Members” on the basis of the Panel report in *India Patent Protection* has been found to be inconsistent with the provisions of GATT 1994 and inapplicable to the TRIPS Agreement disputes by the Appellate Body in *India Patent Protection*.⁴⁴ The theory of legitimate expectations has no place in the TRIPS Agreement at all, at least till, the next Ministerial Conference, and that too only in the cases of non-violation complaints.

The next issue raised by Gorlin is the use of Ambassador Zoellick’s letter written to US congressman to arrive at the interpretation of the TRIPS Agreement as decided by the Ministerial Conference at Doha in an attempt to downplay the Doha Declaration. Gorlin stated, “It was not the intent of the Ministers that the Doha Ministerial Declaration would repudiate, rescind or contradict the basic objectives of the TRIPS Agreement, as set forth in Article 7 thereof. The US Trade Representative Zoellick is on record as declaring: Some WTO members and non-governmental organizations did exert considerable pressure on the United States to agree to clarification language at Doha that would have severely undermined obligations in the Agreement. In the end, no clarifications of this nature were included in the Declaration on the TRIPS Agreement and Public Health. (Letter from Ambassador Zoellick to US Congressman Pete Sessions, December 5, 2001).”⁴⁵

The International Treaty interpretations do not depend on a letter written by one government official to his Congressman. Whatever, the Ministerial Declaration at Doha said is to be interpreted in the light of customary rule of treaty interpretation.

Gorlin in his affidavit has raised a number of other issues but he has not taken any step to substantiate his interpretations of the TRIPS Agreement. These interpretations pertain to Article 7

⁴³ Ibid, para 46

⁴⁴ Ibid

⁴⁵ See Gorlin’s Affidavit, supra note 2

and Article 8 of the TRIPS Agreement, the Doha Declaration, Articles 30 and 31 of the TRIPS Agreement. Gorlin's interpretation regarding Doha Declaration⁴⁶ says:

“The Ministerial Declaration on TRIPS and Public Health, adopted by the WTO Ministers in Doha, Qatar on November 14, 2001 (Doha Ministerial Declaration) merely clarifies the basic theoretical principal that members may grant compulsory licenses in order to protect public health and enumerates the conditions under which such compulsory licenses may be issued and does not amend, revise or replace the TRIPS Agreement. It was not the intent of Ministers that the Doha Declaration would repudiate, rescind or contradict the basic objectives of the TRIPS Agreement, as set forth in Article 7 thereof.”

What the Doha Declaration has actually said in its paragraphs 5(a) and 5(b) is that

- “5(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
- 5(b) Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”

Paragraph 5(a) entered into the picture because the Panel under Robert Hudec in Canada – Patent Protection of Pharmaceutical Products⁴⁷ at the behest of the EC, ruled that objectives and principles have no role at all in interpretation of the TRIPS Agreement that Article 27.1 of the TRIPS Agreement would be applicable to the exceptions under Articles 30 and 31 of the TRIPS Agreement. The Panel observed that

“Moreover, to the extent prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8. It is quite possible that, as the EC argued, that the TRIPS Agreement would want to require governments to apply exceptions in a non-discriminatory manner, in order to ensure

⁴⁶ Declaration on the TRIPS Agreement and Public Health, Ministerial Conference, WT/MIN(01)/DEC/2 dated 20th November 2001, paras 5(a) and 5(b)

⁴⁷ Canada-Patent Protection WT/DS/114/R dated 17th March 2000, supra note 24

that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers.”⁴⁸

The EC had argued that “While issues of health care and costs of drugs played an important role in the domestic policy discussion in many if not all societies, including of course the European Communities and their member states, these considerations appeared to be of little, if any, relevance for the purpose of interpreting the TRIPS Agreement.”⁴⁹

EC further argued

It was one of the major features of the TRIPS Agreement that its implementation was in principle neutral vis-à-vis societal values. This principle was most clearly expressed in Article 8.1 of the Agreement: “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition and technological development, provided that such measures are consistent with the provisions of this Agreement” (emphasis added by the EC). This provision made it clear that none of the public policy considerations, referred to in the first half sentence, could be invoked to justify measures which were consistent with provisions of the TRIPS Agreement. This principle of neutrality vis-à-vis societal values was also confirmed if one compared the exception provision in Article 30 with the exception provisions contained in Article XX of the GATT.

The Panel’s decision in Canada-Patent Protection is quite puzzling in that the Panel not only improvised the arguments of the disputants but many times even reconstructed the arguments of the parties to arrive at some of the quite discombobulated conclusion.⁵⁰

Developing countries introduced the Draft Ministerial Declaration⁵¹ to deal with this misuse of the Dispute Settlement System by the Panel in Canada-Patent Protection⁵² where a

⁴⁸ See supra note 24, Canada-Patent Protection, para 7.92

⁴⁹ See supra note 24, Canada-Patent Protection, para 4.30(a) , p. 50.

⁵⁰ See Daya Shanker, The Vienna convention on the Law of Treaties, the Dispute Settlement System of the WTO and the Doha Declaration on the TRIPS Agreement, 36 Journal of World Trade 721 (2002)

⁵¹ See TRIPS: Proposal-Draft Ministerial Declaration: Proposal from a group of Developing Countries, IP/C/W/312 dated 4th October 2001 addressed to General Council and Council for Trade-related Aspects of Intellectual Property

number of like minded countries got together to amend the TRIPS Agreement by removing object and purpose of an international treaty from the treaty interpretation. The Doha Declaration on the objective and principle was to eliminate the aberration introduced by the EC and the panel in the TRIPS Agreement. The Ministerial Conference is the final authority for interpretation of the provisions in terms of Article IX(2) of the Marrakesh Agreement. Article IX(2) of the Marrakesh Agreement says:

“The Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements. In the case of an interpretation of a Multilateral Trade Agreement in Annex 1, they shall exercise their authority on the basis of recommendations by the Council overseeing the functioning of that Agreement.”

Para 5(b) of the Doha Declaration saying “Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted” removes any doubt regarding the decision making powers of the government in issuing compulsory licensing and that freedom cannot be curtailed by other governments or individuals acting on behalf of certain interested firms. Para 5(b) of the Doha Declaration is just an extension of para 5(a) in that the TRIPS Agreement gives the governments power to issue compulsory licensing without being dragged before any court or tribunal or dispute settlement body.

In view of the fact that the Ministerial Council adopted interpretation of the TRIPS Agreement through the Doha Declaration correcting the aberration introduced by the Panel headed by Prof. Robert Hudec and bringing objective and principles as narrated in Articles 7 and 8 of the TRIPS Agreement back in international treaty interpretations, the Ministerial Council was trying to introduce integrity into the TRIPS Agreement by reemphasizing the fundamental basis of international treaty interpretation.⁵³ These issues have been analysed in detail by Shanker.⁵⁴

Rights: Proposals by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela

⁵² See supra note 24, Canada-Patent Protection, (WT/DS/114/R dated 17th March 2000)

⁵³ See Daya Shanker, “The Vienna Convention on the Law of Treaties, the Dispute Settlement System of the WTO and the Doha Declaration on the TRIPS Agreement.”. 36 *Journal of World Trade* 721, 721-722

⁵⁴ See Ibid

Gorlin's Affidavit and Article 30 of TRIPS

Regarding Article 30 of the TRIPS Agreement, Gorlin in para 4 of his affidavit⁵⁵ insisted that “The TRIPS Agreement, as set forth in Article 7 thereof, requires that the system for the granting of a compulsory license for the public interest not be intended as a sanction against the abuse of the patent right relative to a specific person.” The confusion regarding “relative to a specific person” was attempted to be removed in the subsequent lines by Gorlin by saying that

“The TRIPS negotiators did consider the relationship between the exclusive patent rights enumerated in TRIPS Article 28 and a specific person but it was in the context of drafting TRIPS Article 30 (Exceptions to rights conferred) and not article 31, which contains the TRIPS obligations on compulsory licensing. The July 23, Draft Text of the TRIPS Agreement, for example, listed preparation on a pharmacy in individual cases as one of the possible acts that would generate an acceptable limited exception and, hence, not upset the balance found in the TRIPS Agreement. (Jacques J. Gorlin, *An Analysis of the Pharmaceutical –related provisions of the WTO TRIPS (Intellectual Property Agreement, London, Intellectual Property Institute, 1999, page, 29).*)

The negotiators, however, considered that acts taken on behalf of more than one person impaired the balance set out in the TRIPS Agreement and could not be justified under Article 30.” From what can be understood from the above, according to Gorlin, TRIPS Article 30 is applicable only when the benefit is applicable to one specific person. Apart from the novelty of the argument, it appears to be an attempt to misinterpret the TRIPS Agreement.

The application of Article 30 of the TRIPS Agreement, arrived either through negotiating history or through the recent interpretation by the Panel in *Canada-Patent Protection* including the argument of the EC in this dispute, nothing even remotely suggests that Article 30 of the TRIPS Agreement is applicable only in case where the beneficiary is only one single person.

The negotiating history of Article 30 has been compiled by the Secretariat for Canada-Patent Protection Panel and is available as Annex 6 of the Panel Report.⁵⁶ The Chairman's text of July 23, 1990 (Document MTN.GNG/NG11/W/76 dated 23rd July 1990) essentially was nothing

⁵⁵ See Jacques Gorlin, *supra* note 2, para 4

⁵⁶ See *Canada-Patent Protection*, *supra* note 24, Annex 6

more than a collection of all the proposals submitted by the EC, the USA, developing countries, Austria and Switzerland. It says in its relevant paragraph:

Section III.5.2.2

Exceptions to rights conferred

[Provided that legitimate interests of the proprietor of the patent and the third parties are taken into account] limited exceptions to the exclusive rights conferred by a patent may be made for certain acts, such as:

- 2.2.1 Rights based on prior use
- 2.2.2 Acts done privately and for non-commercial purposes
- 2.2.3 Acts done for experimental purposes
- 2.2.4 Preparation in a pharmacy in individual cases of a medicines in accordance with prescription or acts carried out with a medicine so prepared

In fact, the weakest exception during the argument to support the EC's contention of applicability of non-discrimination clause in Article 27.1 to Article 30 of the TRIPS Agreement in *Canada-Patent Protection* was para 2.2.4 dealing with pharmacy exceptions because it was a discriminatory exception and was attempted to be justified by the EC on the plea that it was like reservation on the bus for old and disabled. Rest, all of them were for general purpose. However, this limitation was not accepted during the negotiations of Article 30. Moreover, the negotiating history cannot be used under Vienna Convention on the Law of Treaties,⁵⁷ unless meaning under Article 31 of the Vienna Convention

- (a) Leaves the meaning ambiguous or obscure; or
- (b) Leads to a result, which is manifestly absurd or unreasonable.

As stipulated in the Vienna Convention on the Law of Treaties, Article 31,

1. A treaty is to 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.

⁵⁷ See Vienna Convention on Law of International Treaties, done at Vienna, 25th May 1969, 1155 UNTS 331 (hereinafter Vienna Convention)

2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:
3. There shall be taken into account with the context:
 - (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;
 - (b) any subsequent practice in the application of the parties regarding its interpretation; any relevant rules of international law applicable in the relations between the parties.

A treaty is to 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.

The US practice under the Bolar Exemptions,⁵⁸ where generic manufacturers are allowed to manufacture and import patented products for getting the approval from the Food and Drug Authority is not confined to one specific person for its benefits. The Panel in *Canada Patent Protection* in spite of the fact that the Panel justified societal neutrality of the TRIPS Agreement, conceded that the Canadian provision under Section 55.2(1) of Canada's Patent Act saying

“It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development an submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product” was consistent with Article 30 exceptions to rights conferred.

Gorlin's interpretation of Article 30 of the TRIPS Agreement is inconsistent with the legal interpretation arrived at by the Panel Report in *Canada –Patent Protection* and practices followed by different countries including the United States.

⁵⁸ Bolar Exemption was added to the United States patent statute in 1984 following the ruling of the Court of Appeals for the Federal Circuit in *Roche Products Inc. v. Bolar Pharmaceuticals Co. Inc.* (733 F.2d 858; cert. denied 221 USPQ 937; 469 US 856 (1984)) stipulating that the common law “experimental use” defence would not cover generic manufacturers who had used patented invention to test and apply for marketing authorization of their version of patented medicines. Bolar Exemptions in part provides “[I]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention [...] solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.” (35 U.S.C. Section 271(e))

Gorlin's Affidavit and Article 31 of TRIPS

Gorlin's main argument is around Article 31(b) of the TRIPS Agreement. Article 31(b) of the TRIPS Agreement says

“such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization 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 other circumstances of extreme urgency or in case of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonable practical. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;”

The issue revolves around “public non-commercial use” i.e. the compulsory license should be used for public purpose, and it should be non-commercial. The normal definition or dictionary meaning of commercial is “made, done or operating primarily for profit”. The compulsory license is not to be used for profitable purposes. It is difficult to visualize any other interpretation. However, Gorlin insisted that

“The TRIPS Agreement also applies the same rationale to situations of public non-commercial use, where it also permits the waiver of prior consultations. However, it would not be reasonable to wave prior consultations in instances in which a compulsory license is being sought for pubic health reasons that are not of extreme urgency. In such instances it is reasonable to understand the TRIPS Agreement as requiring prior consultation with the right holder before a compulsory license may be sought from the government.”⁵⁹

To bolster, his assertion, Gorlin has quoted from the EU and Swiss submissions in the year 1990 during the initial phase of TRIPS negotiations to say that “Except in the case of manifest national emergency, a compulsory license may only be issued after unsuccessful efforts made by the

⁵⁹ See Gorlin's Affidavit, supra note 2, para 5

applicants in line with normal commercial practices to negotiate a voluntary license with the right holder (Submission of the Delegation of the European Communities, March 27, 1990, Document MTN.GNG/NG11/68).”⁶⁰

Gorlin did not appreciate that a proposal from one country or a group of countries does not form negotiating history which can be used in the treaty interpretation.

While discussing the relationship of the WTO Agreement to customary international law and use of negotiating history in the Panel in *Korea –Government Procurement*⁶¹ observed that the language of Article 3.2 of the DSU that “the customary rules of interpretation of public international law” was incorporated to deal with the specific problem “that has arisen under the GATT to the effect that, among other things, reliance on negotiating history was being utilized in a manner arguably inconsistent with requirement of the rules of treaty interpretation of customary international law.”⁶²

In fact, the term “customary rules of interpretation of public international law” in Article 3.2 of the DSU was specifically introduced to stop the practice of relying on negotiating history for treaty interpretation. Another reason for inconsistent argument of Gorlin is that it is not only the TRIPS Agreement but whole of the WTO does not have any official negotiating history or travaux préparatoires.

The use of negotiating history has always led to distortion in the interpretation of an international treaty as there are always more than one version of negotiating history. The Appellate Body in *European Communities–Customs classification of Certain Computer Equipment* very categorically observed that only when “if after applying Article 31 [of the Vienna Convention] the meaning of the term remains ambiguous or obscure or leads to a result which is manifestly absurd or unreasonable, Article 32 allows a treaty interpreter to have recourse to “supplementary means of interpretation, including preparatory work of the treaty and the circumstances of its conclusion.”with regard to “the circumstances of [the] conclusion” of a treaty,

⁶⁰ See Gorlin’s Affidavit, supra note 2, para 5

⁶¹ See Panel Report in *Korea –Government Procurement* WT/DS163/R, dated 1st May 2000, page 181

⁶² See note 753 in Report of the Panel in *Korea-Government Procurement* WT/DS163/R page 181

this permits, in appropriate cases, the examination of the historical background against which the treaty was negotiated.”⁶³

Only when, the interpretation as per Article 31 fails to arrive at an unambiguous meaning in the light of its object and purpose of a treaty, read in its context, Article 32 of the Vienna Convention would come into play. There has never been any need “to bear constantly in mind the historical background against which the treaty has been negotiated” as suggested by Sinclair.⁶⁴ In fact, in *Sections 301-310 of the US Trade Act, 1974*,⁶⁵ the US insisted that there was no decision to create any official *travaux préparatoires* for the Marrakesh Agreement Establishing the WTO. On the basis of the US submission the Panel observed

The discussion of October and November, 1993, when the most contentious and politically sensitive issues in the WTO Agreements text were settled, were conducted orally in small meetings that did not include all delegations. Some issues, including the final wording of Article XVI:4, were resolved in plurilateral working groups that were smaller still. When the plurilateral subgroups reported to the larger Institutions Group, some delegations objected to having written documents become part of a negotiating history, because if there were to be an official negotiating history, its importance would be such that its contents would have to be negotiated line by line, and this added burden was clearly impossible given the November 15 deadline for finishing the Institution’s work. In any event, absent a complete picture of every note and proposal from every delegation, it would be difficult to obtain an accurate picture of the parties’ intentions. For these reasons, the Chairman, Ambassador Juliono Lacarte, announced during these discussions that no negotiating history would be issued and all trade-offs had to be made in the text of the agreement itself.⁶⁶

The preparatory work has not been defined in Article 32 of the Vienna Convention as the International Law Commission was under the impression that defining the *travaux préparatoires*

⁶³ See *European Communities–Customs classification of Certain Computer Equipment*, WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68/AB/R dated 5th June 1998, p. 38, para 86

⁶⁴ I. Sinclair, *The Vienna Convention on the Law of Treaties*, 2nd Edition, Manchester University Press, 1984, p. 141

⁶⁵ See Report of the Panel in *Sections 301-310 US Trade Act, 1974*, WT/DS152/R dated para 4.450

⁶⁶ Ibid

may lead to exclusion of relevant evidence.⁶⁷ However, it includes the record of negotiations between the states who participated in the drafting of the treaty in certain circumstances and the records of the work of the independent bodies of experts such as the International Law Commission and the United Commission on Human Rights. At times unilateral statements of the governments have also been treated as *travaux préparatoires* but McNair⁶⁸ was against such wider inclusion when he observed that, “Surely whatever value there may be in preparatory work is that it may afford evidence of the common intention of the parties.”

The need to limit the use of preparatory work in treaty interpretation was also voiced by both the British and French delegates. The British delegate during the negotiation of the Vienna Convention observed that

“...preparation work was almost invariably confusing, unequal and partial: confusing because it commonly consisted of the summary records of statements made during the process of negotiations, and early statements on the positions of delegations might express the intention of the delegation at that stage, but bear no relation to the ultimate text of treaty; unequal, because not all delegations spoke on any particular issue; and partial because it excluded the informal meetings between heads of delegations at which final compromises were reached and which were often the most significant feature of any negotiation.”⁶⁹

France also supported this position by observing

“It was much less hazardous and much more equitable when ascertaining the intention of the parties to rely on what they had agreed in writing, rather than to seek outside the text elements of intent which were far more unreliable, scattered as they were through incomplete or unilateral documents.”⁷⁰

In *Fothergill v. Monarch Airlines*, while discussing the rules on the interpretation of treaties in the Vienna Convention, the House of Lords held that:

“These cases [of recourse to *travaux préparatoires*] should be rare, and only where two conditions are fulfilled, first, that the material involved is public and accessible, and,

⁶⁷ Commentary, Year Book of International Law Commission, 1966, II, p. 223

⁶⁸ Arnold McNair, *The Law of Treaties*, 2nd Ed., Oxford University Press, 1986, p. 421

⁶⁹ See Treaty Conference Records, 1968, p. 178

⁷⁰ *Ibid*, p. 176

secondly, that the *travaux préparatoires* clearly and indisputably point to a definite legislative intention.”⁷¹

In *Border and Transborder Armed Actions (Nicaragua/Honduras)*,⁷² the International Court of Justice observed:

“Further confirmation of the Court’s reading GOF Article XXXI is to be found in the *travaux préparatoires*. In this case these must of course be resorted to only with caution, as not all the stages of the drafting of the texts at the Bogota Conference were the subject of detailed records.”

The USA was quite opposed to restrictive use of preparatory documents and insisted that such restrictive use does not represent established practice⁷³ but the International Law Commission preferred overwhelmingly the textual approach.

The Vienna Convention although not signed by the USA has been accepted as providing the basis for interpretation of the provisions of the WTO and its associated agreements and understandings. It specifically adopted the textual approach and permitted use of preparatory documents only as a last resort and only when such documents should be public and accessible. In view of the above discussion and the interpretation of Article 32 of the Vienna Convention, the negotiating history as exemplified by the preparatory documents and the circumstances of its conclusion should be used very restrictively not only when Article 31 of the Vienna Convention fails to provide an unambiguous meaning but only when the preparatory work can point to a definite legislative intent and should provide all the stages of the drafting of the text.

If one resorts to Gorlin’s use of negotiating history, then document MTN.GNG.NG11/W/76 dated July 1990 also says:

- 5A.3.1 A compulsory license may only be granted after unsuccessful efforts have been made by the applicant to negotiate a voluntary license in line with normal commercial practices with the right holder, [except in the case of a manifest national emergency]

⁷¹ [1981] A.C. 251, 283

⁷² *Border and Transborder Armed Actions (Nicaragua/Honduras)*, 72 Jurisdiction and Admissibility, Judgement, I.C.J. Reports 1988, p. 69

⁷³ See Treaty Conference Records, 1968, p. 167

- 5A.3.2 Compulsory licenses for non-working or insufficiency of working on the territory of the granting authority shall not be granted if the right holder can show that the lack of insufficiency of local working is justified by the existence of legal, technical or commercial reasons.

Article 31 of the TRIPS Agreement does not even mention local working. Preparatory work cannot be used on the basis of one or two selective proposals of one or two selective documents.

Although negotiating history does not have any relevance in the case of the TRIPS Agreement, King and Lam⁷⁴ discussed the circumstances in which the term “public non-commercial use” was introduced in the TRIPS Agreement. They observed

“Not only was public non-commercial use included as an explicit ground for a license in the final drafts of the TRIPS Agreement (where it had not been included in the earlier drafts), but other articles emerged to flesh out the concept of public interest. Article 8(1) of TRIPS extends, in particular, public interest to contemplated areas such as public health, nutrition and sectors required for socio economic and technical developments. That Article 8(1) articulates principles that apply to the TRIPS Agreement as a whole, including Article 31, means that public non-commercial use should be liberally interpreted with these principles in mind.”⁷⁵

Document MTN.GNG/NG11/W/76 dated 23rd July 1990 was a combination of all the proposals submitted by different countries by then Chairman of Negotiating Group on Trade-Related Aspects of Intellectual Property Rights where those from developed countries were marked A and those from developing countries were marked B. The draft Article 5A.2.2b and 5A.2.2c were submitted by developed countries. These articles say

- “5A.2.2b On the grounds of the public interest concerning national security, or critical peril to life of the general public or body thereof.

⁷⁴ See E. Richard Gold and Danial K. Lam, Balancing Trade in Patents: Public Non-commercial use and Compulsory licensing, *Journal of World Intellectual Property*, Vol. 6 No. 1, 2003, pp. 5-31

⁷⁵ See *Ibid*, p. 30

- 5A.2.2c Where the exploitation of the patented invention is required by reason of an overriding public interest, the possibility of exploitation of the patented invention by the government, or by third persons authorized by it.”⁷⁶

Developing countries had a similar proposal which had segregated governmental use and compulsory license granted for preparation and distribution of food and medicines. The Draft Article 5B says

“Nothing in this Agreement shall be construed to prevent any PARTY from taking any action necessary: (i) for the working or use of a patent for governmental purposes; or (ii) where a patent has been granted for an invention capable of being used for this preparation or production of food or medicine, for granting to any person applying for the same a license limited to the use of the invention for the purposes of the preparation or precaution and distribution of food and medicines.”⁷⁷

During their discussion, King and Lam⁷⁸ missed this point that this document was nothing but a simple collection of all the proposals submitted.

The term public non-commercial purposes appeared for the first time in the Brussels Draft⁷⁹ in December, 1990 which distinguished it from other reasons such as circumstances of national emergency and extreme urgency in the case of exempting compulsory licences from prior negotiations. The relevant part of the clause says

“Notwithstanding the provision of subparagraphs (a)-(k) above, where such use is made for public non-commercial purposes by the government or by any third party authorized by the government, PARTIES are not obliged to apply the conditions set forth in sub-paragraphs [...] above in such cases...”⁸⁰

⁷⁶ See Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Status of Work in the Negotiating Group, MTN.GNG/NG11/W/76 dated 23rd July 1990

⁷⁷ See Ibid, MTN.GNG/NG11/W/76 dated 23rd July 1990

⁷⁸ See Gold and Lam, supra note 74, p. 16

⁷⁹ See Agreement on Trade Related Aspects of Intellectual Property including Trade in Counterfeit Goods in Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Negotiations, GATT Doc. No. MTN.TNC/W/35/Rev.1, 3 December 1990, reproduced in part in Danielle Gervais, *The TRIPS Agreement: Drafting History and Analysis*, Sweet and Maxwell, London, 1998, subparagraph (o), at pp. 162-163

⁸⁰ Ibid

Gorlin's approach to the use of the negotiating history appears to be misplaced. On 29th March, 1990, the EC in its attempt to force the issue of inclusion of the patenting monopoly in the Uruguay Round negotiations introduced a draft⁸¹ having far more stringent provisions than were present in its Members' patent acts. Another reason as discussed by Daya Shanker was the attempt by countries such as the EC and the USA to introduce changes in their internal patent acts through the use of international treaty negotiations.⁸²

Legitimate Functions of the Government and Public Non-commercial Use

In para 6 of his affidavit, Gorlin, for the first time discussed the meaning of Public Non-Commercial use as "only after the government has demonstrated that an entity on its behalf is undertaking the infringement and that the unauthorized use is non-commercial in nature. This would appear to bar failure to supply a pharmaceutical at a reasonable price, which clearly involves a commercial finding, as a rationale for seeking a public non-commercial use compulsory license."⁸³

He further asserted that "the government may only undertake activities that are part of its legitimate functions. Hence, the TRIPS Agreement specified that the unauthorized use permitted under the public non-commercial use exception must be and for the government."⁸⁴

Although there is no documentary evidence, Gorlin asserted that "During TRIPS negotiations, US negotiators informally provided the following pharmaceutical-related description of the difference between public commercial use and public non-commercial use: supplying the general public with a drug that it manufactures or has manufactured on its behalf is not a

⁸¹ See Draft Agreement on Trade Related Aspects of Intellectual Property, Communicating from the European Community, GATT Doc. No. MTN.GNG/NG11/W/68, dated 29th March 1990- (hereinafter EC Draft Text) at Article 26 which states "Compulsory licences may not be issued for non-working or insufficiency of working on the territory of the granting authority if the right holder can show that the lack or insufficiency of local working is justified the existence of legal, technical or commercial reasons" when such compulsory licensing provisions were present in each and every EC member's patent acts.

⁸² Daya Shanker, Para 6 Solution of the Doha Declaration, Article 30 of TRIPS and Non-Prohibition of Exports under the TRIPS Agreement, Working Paper, University of Wollongong, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=377160

⁸³ Gorlin, supra note 2, para 5

⁸⁴ Gorlin, supra note 2, para 5

legitimate function of the government and would not fall under the exception. On the other hand, supplying drugs to soldiers in the army could be considered a legitimate function of government that might be permitted under the public non-commercial use exception.”⁸⁵

The biggest achievement of the Doha Declaration has been para 5(b) which categorically asserts that “Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”⁸⁶ It is the right of the South Korean government to determine the grounds upon which such licenses are granted. It is not left to outside experts to say what constitute legitimate government functions accepting the contention of Gorlin that “public non-commercial use” would cover only legitimate government functions. The USA’s threat during the anthrax crisis to use Section 1498 to issue compulsory licensing to manufacture ciprofloxacin is too recent to forget although in his authorization to the Secretary Health to use Section 1498, the USA used the term defense.⁸⁷ It has been discussed already that negotiating history does not exist in the Vienna Convention on the Law of Treaties. What is there is the preparatory work and the circumstances of negotiations and this can be used only after Article 31 of the Vienna Convention fails to provide meaningful interpretation.⁸⁸ In fact the USA has always prided itself that it does not have compulsory licensing provisions in its patent act and Section 1498 is in the realm of “eminent domain.” Menell⁸⁹ alleged that in terms of the decision of the US Supreme Court in *Florida Prepaid*⁹⁰ and even before that, notification to patent owners was not incumbent on the US states and its institutions.

Gorlin appeared to have confused the issues while discussing the legitimate function of the government in relation to the TRIPS Agreement. The first issue he insists that public non-

⁸⁵ See Gorlin’s Affidavit, supra note 2, para 5

⁸⁶ See Declaration on the TRIPS Agreement and Public Health, Ministerial Conference , WT/MIN(01)/DEC/2 dated 20th November 2001

⁸⁷ Executive Order for Department of Health and Human Services, press release on 20 October 2001, available at http://www.whitehouse.gov/news/releases/2001/10/2001_1022-15.html

⁸⁸ See Daya Shanker, Vienna Convention on the law of Treaties, the Dispute Settlement System of the WTO and the Doha Declaration on the TRIPS Agreement, 36 *Journal of World Trade* 721 (2002)

⁸⁹ Peter S. Menell, Economic Implications of State Sovereign Immunity from Infringement of Federal Intellectual Property Rights, 33 *Loyola of Los Angeles Law Review* 1399 (2000)

⁹⁰ See *College Sav. Bank v. Florida Prepaid Postsecondary Educ. Expense Board*, 119 S. Ct 2219, 2231 (1999)

commercial use is confined to the governmental use only and the second issue he asserts that government use should be restricted to legitimate government functions which according to Gorlin are confined to defense and space. The fact that public non-commercial working is not confined to government use and that too particularly to defense and space is evident from reading of Article 31© of the TRIPS Agreement which excluded semiconductor technology from general application of Article 31 except for public non-commercial use and for anticompetitive practices.⁹¹

It appears that Gorlin's attempt to limit public non-commercial use to the government use was based on last sentence of Article 31.b of the TRIPS Agreement which says

“In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.”

This sentence does not suggest that the public non-commercial use must be confined to the government only. All that it says that in case the government uses this provision, the right holder should be informed. The Brussel's Draft⁹² where public non-commercial use was introduced for the first time specifically tried to limit the public-non commercial use to the government but this limitation was not accepted in the final treaty and any reference to the government was specifically removed.

Reference to the UK Patent Act which is based on the European Patent Code dealing with government use would explain if any doubt is left what constitute the legitimate government function. Section 55(1) of the UK Patent Act, 1977 says

“Notwithstanding anything in this Act, any government and any person authorized in writing by a government department may, for the services of the Crown and in accordance with this section, do any of the following acts in the United Kingdom in relation to a patented invention without the consent of the proprietor of the patent, that is to say –

(a) where the invention is a product, may –

⁹¹ Article 31© of TRIPS in relevant part says, “the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semiconductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive.”

⁹² See Brussel's Draft, supra note 79. The original version says

“Notwithstanding the provision of subparagraphs (a)-(k) above, where such use is made for public non-commercial purposes by the government or by any third party authorized by the government, PARTIES are not obliged to apply the conditions set forth in sub-paragraphs [...] above in such cases”.

- (i) make, use, import or keep the product, or sell or offer to sell it where to do so would be incidental or ancillary to making, using, importing or keeping it: or
- (ii) in any event, sell or offer to sell it for foreign defense purposes or for the production or supply of specified drugs and medicines, or dispose or offer to dispose of it (otherwise than by selling it) for any purpose whatever;
- (b) where the invention is a process, may use it or do in relation to any product obtained directly by means of the process anything mentioned in paragraph (a) above;
- (c) without prejudice to the foregoing, where the invention or any product obtained directly by means of the invention is a specified drug or medicine, may sell or offer to sell the drug or medicine;
- (d) ...
- (e) ...

and anything done by virtue of this subsection shall not amount to an infringement of the patent concerned.

The term “for the services of the crown” has been explained in section 56.2 and section 56.03 although that list is not exhaustive. Section 56.2 of the UK Patent Act says

“In this Act, except so far as the context otherwise requires, “the services of the Crown” includes –

- (a) the supply of anything for foreign defense purposes;
- (b) the production or supply of specified drugs and medicines; and
- (c) such purposes relating to the production or use of atomic energy or research into matters connected therewith as the Secretary of State thinks necessary or expedient;

and “use for the services of the Crown” shall be construed accordingly.”

Sections 55.1 and 55.2 of the UK Patent Act specifically states that the production or supply of specified drugs and medicines under compulsory licensing provisions do not constitute any violation of the UK Patent Act and is one of the legitimate function of the UK government.

In fact, Article 31(b) of the TRIPS Agreement is drafted on the UK Patent Act and not on section 1498 of the US Patent Act. Production or supply of specified drugs and medicines constitute a legitimate function of the government of the United Kingdom. In practically all the countries of the European Community, similar provisions are available.

Even in the USA itself, the use of public non-commercial use is not confined to defense becomes evident by the EC's complaint, the relevant part of which says

“Under U.S. law (28 US Code Section 1498) a patent owner may not enjoin or recover damages on the basis of his patents for infringements due to the manufacture or use of goods by or for the US Government Authorities. This practice is particularly frequent in the activities of the [Department of Defense] but is also extremely widespread in practically all government departments.”⁹³

Gorlin's interpretation does not appear to have a legal basis when one examines the US Federal Acquisition Regulation: FAR Part 27 which has been recently attempted to be amended for clarification, streamlining, and updating guidance and clauses on patents, data and copyrights.⁹⁴ This deals with the US government's 28 U.S.C. 1498 which permits use of Section 1498 in the USA apart for the Department of Defense and NASA, also for the General Services Administration, responsible for a totally commercial transaction of acquiring and providing goods, services, and facilities to support the needs of other Federal agencies. In its 2002, Annual Report, GSA claims that although Federal agencies comprise the majority of GSA's customers, the client base include State and Local governments, international partners, thousand of vendors and the US citizens.⁹⁵

PhRMA made similar allegations against s. 102 of the Indian Patent Act.⁹⁶ PhRMA⁹⁷ stated that

‘Section 102 authorizes the Central government to exercise what amounts to ‘eminent domain’ of a patent. The provision specified that if the Central Government concludes “it is necessary that an invention, which is the subject of an application for a patent or a patent,

⁹³ See European Commission, Report on United States Barriers to Trade and Investment s 6.1 (1997)

⁹⁴ Federal Acquisition Regulation: FAR Part 27, Department of Defense, General Services Department, and NASA, Federal Register / Vol. 68, NO. 102, Wednesday, May 28, 2003 / Proposed Rules

⁹⁵ See US General Services Administration, Annual Report, 2002, p. 9

⁹⁶ See Daya Shanker, India, the Pharmaceutical Industry and the Validity of TRIPS, Journal of World Intellectual Property, vol. 5, No. 3, 2002, pp. 315-371

⁹⁷ See PhRMA, 2001, India: A Cautionary Tale on the Critical Importance of the IP Protection, Backgrounder and Facts, (PhRMA Special 301 Submission: Appendices, pp. 182-187), available at <http://www.phrma.org/publications/documen5ts/backgrounders/2001-03-01.202.phtml>

should be acquired from the patentee” then, after publishing a notice, the patent shall be deemed to be transferred to the Government. The authority is inconsistent with most of Article 31, particularly paragraph (e), which forbids exclusive compulsory licenses (e.g. which operate to deprive the patentee to use the patented invention), and paragraph (c), (d) and (f), which impose other general conditions with a license. The provision is also inconsistent with Article 5A of the Paris Convention, incorporated through Article 2 of TRIPS, which forbids forfeiture of a patent other than to remedy a working-related abuse of the patent. Under a more general construction of a TRIPS Agreement, forfeiture or revocation of a patent is forbidden unless it is on the grounds that there is some defect of patentability of the invention (e.g. lack of novelty).’

What actually Section 102 of Indian Patent Act says is

‘(1) The Central government may, if satisfied that it is necessary that an invention is the subject of an application for a patent or a patent should be acquired from the applicant or the patentee for a public purpose, publish a notification to that effect in the Official Gazette, and thereupon the invention or patent and all rights in respect of the invention or patent shall, by force of this action, stand transferred to and vested in the Central Government.

(1) The Central Government shall pay to the applicant, or as the case may be, the patentee and other persons appearing on the register as having an interest in the patent such compensation as may be agreed upon between the Central Government and the applicant, or the patentee and other persons, or, as may, in default of agreement, be determined by the High Court on reference under Section 103 to be just having regard to the expenditure incurred in connection with the invention and in the case of a patent, the term thereof, the period during which and the manner in which it has already been worked (including the profits made during such period by the patentee or by his licensee whether exclusive or otherwise) and other relevant factors.

No part of Section 102 of the IP Act is violative of Article 31 of TRIPS, particularly Article 31(e) of TRIPS which just says ‘such use shall be non-assignable, except with that part of enterprise or goodwill which enjoys such use’

Apart from HR 1498 which deals with eminent domain, the Eleventh Amendment of the U.S. constitution states that “The judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another state, or by Citizens or Subjects of any foreign State.” The US Congress

passed Patent and Plant Variety Protection Remedy Clarification Act (P.L. 102-500, enacted Oct. 28, 1992) ostensibly because it got concerned that some of the US states were claiming immunity when sued of intellectual property infringement in federal court. However, in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*, 527 U.S. 627 (1999), the Supreme Court struck down the Patent and Plant Variety on the ground that the US Congress did not have the powers to enact such law. (United States General Accounting Office 2001).

Volokh⁹⁸ went to the extent that state sovereign immunity violates TRIPS which generally requires that governments at least to give notice before infringing a patent. The same situation would prevail in case of 28 U.S.C. s. 1498. Menell⁹⁹ citing 28 U.S.C. 1498 claimed “Even before the *Florida Prepaid* decision, it is questionable whether the United States fully adhered to Article 31 with regard to notification of patent owners that their inventions were being used by government entities.”

In *King Instrument Corporation v. Perego*, Circuit Judge observed that government can simply “take” the invention where warranted by public interest concerns and provide “adequate compensation” to the patent holder (28 U.S.C. Section 1498 (1988) *Special Equip. Co. v. Coe*. 324 U.S. 370, 378 (1945). The Circuit Court in *Kings Instruments* observed, ‘As long as the patentee receives a proper economic return on its investment in the acquisition of a patent, the Act does not require that return to come from sale of a patented products. (F.2d 1573) (Cert. Denied 493 U.S. 1022 (1990) *Rite Hite v. Kelly* 56 F.3d 1538 (Fed. Cir. 1995) (in banc)

Section 1498 of US Patent Act nowhere suggests that this section is for legitimate function of the government such as defense and space program. Sec. 1498 also covers copyright and plant variety protected by a certificate of plant variety protection under the laws of the United States and it is not confined to defense and space. The Appellate Body specifically prohibited any “imputation into a treaty of words that are not there or the importation into a treaty of concepts that were not intended.”¹⁰⁰

⁹⁸ Eugene Volokh, *Sovereign Immunity and Intellectual Property*, 73 *Southern California Law Review* 1, 2000

⁹⁹ Peter S. Menell, *Economic Implications of State Sovereignty from Infringement of Federal Intellectual Property Rights*, 33 *Loyola of Los Angeles Law Review* 1399 (2000)

¹⁰⁰ See Report of the Appellate Body in *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R adopted on 16th January 1998, para 45; See Daya Shanker, *Vienna Convention*, supra note 50, pp. 723-725

Conclusion

Public non-commercial use in Article 31 of the TRIPS Agreement became a contentious issue when a group of social workers made an application before the Korean Patent Office to issue compulsory licence under public non-commercial use for Gleevec a medicine the patent of which is held by Novartis. The objection to this application was not filed either by Novartis or by PhRMA but by two individuals claiming to be experts in the TRIPS Agreement. The objection was on the ground that a compulsory license is to be issued only for individual cases, the proposals at the time of the TRIPS negotiations submitted by the EC and reproduced by Switzerland as constituting the preparatory documents for interpretations of the term public noncommercial use and the assertion that the public non-commercial use is confined only to the legitimate government use such as sending space shuttle to the moon and defense and the production of medicines is not part of the legitimate government function. The last assertion is not based on any documentary evidence.

The analysis in this article suggests that the proposals from one or two nations during the international treaty negotiations do not constitute travaux préparatoires and in the context of the WTO and the TRIPS Agreement, there has been no preparatory document at all as the most contentious and politically sensitive issues in the WTO were settled orally in small meetings and no consistent record has been kept for these discussions. For these reasons, then Chairman Ambassador Julio Lacarte decided not to keep any negotiating history and insisted that all trade offs had to be made in the text of the agreement itself. The concept of legitimate expectation was never part of the TRIPS Agreement as per the Appellate Body Report in *India-Patent Protection* and when it would be made applicable, it would be meant only for non-violation disputes. Public non-commercial use was incorporated in the TRIPS Agreement in the Brussels Draft and it neither eliminates profitability completely nor is confined to the use by the government. Even if it is accepted that public non-commercial use is to be used only for legitimate government functions, the government use is not limited to defense and space program as insisted by Gorlin as even in the UK Patent Act, it is specifically mentioned that the use of crown is to provide medicines. The issue of public non-commercial use in Korea apparently enjoined the pharmaceutical industry to change the strategy to avoid public relations disaster by not filing objection opposing the compulsory licensing directly but use the services of their sympathizers to bring in the arguments, some of which borders on dishonesty.

The affidavit of Jacques Gorlin in particular appears to have been used to convey the displeasure of the USTR and the US objection to convert the Doha Declaration as an aberration in international treaty negotiations. The fact that the Korean Patent Office rejected the application without discussing the issue of public non-commercial use suggests that Western pharmaceutical industries succeeded in introducing limitations in the TRIPS Agreement where it is not there.