

Title: Remarks about the TRIPS Agreement with Particular Reference to Compulsory Licensing.

By: Dr. Mohamed Ibrahim M. Adam

Introduction

Trade Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement on protection of Intellectual Property Rights (IPRs) in International Trade. It was an outcome of negotiations of GATT members in the Uruguay Round. The Agreement was devised to seal a realized loophole in the GATT 1949 legal rules. The chief worry of industrialized countries, and in particular the U.S.A, was that World Intellectual Property Organization (WIPO) treaties, such as the Paris Convention on Industrial Property; and the Berne Convention on Literary and Artistic Works did not embrace adequate substantive standards of IPR protection, coupled with an inadequate mechanism for enforcing intellectual property rights. On the other hand the main interest of developing countries was to secure greater access to technology by limiting the scope of protection in developing countries. The ultimate goal is to enable developing countries to adjust their intellectual property protection system, in conformity to their needs and level of development conditions.¹

One of the cardinal contentions of developing countries was that: GATT was established with the objective to liberalize world trade; and not to deal in intellectual property protection. With earnest and justified insistence, developing countries resisted the industrialized countries approach, on the ground that the initiative, was made with a single-minded purpose of benefiting transnational corporations, owned by nationals of industrialized countries.² Industry groups of developed countries, with a view to accomplishing a strong multilateral enforcement mechanism of IPR, eschewed a positive

¹ Cf. *Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania & Uruguay, GATT Doc.No.MTN.GNG/NG11/2/71(May14, 1990)*, see also *Draft Agreement on Trade Related Aspects of Intellectual Property, Communication from the European Community, GATT Doc.No.MTN.GNG/NG11/W/68March29, 1990*, see also Gail. E. Evans, *Intellectual Property as a Trade Issue-The Making of the Agreement on Trade Related Aspects of Intellectual Property Rights*, L &Econ. Rev, Dec. 1994 at p.173, see also UNCTAD, *the TRIPS and Developing Countries*, New York and Geneva, 1996, see also UCTAD, *Training Tools on the TRIPS Agreement. The Developing Countries Perspective*, January, 2002 Geneva. See generally, Carlos M. Correa, *Intellectual Property Rights. The WTO and Developing Countries: The TRIPS Agreement and Policy Options*, Zed Books Ltd. In connection with counterfeiting see generally, "Global Counterfeiting & Piracy Update and Background Document" January 2005 world economic forum, 2005

² Cf. Generally Symposium, *Trade-Related Aspects of Intellectual Property*:23 Vand.J.Transna'l.Law (1989), see also J.H Reichman, *Implications of the Draft TRIPS Agreement for Developing Countries as Competitors in an Integrated World Market*, United Nations Conference on Trade and Development, Discussion Paper No. 73 at p 41-45. UN.Doc.UNCTAD/OSG/DP/73Nov.1993, see also Fredrick M. Abbott, *Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework*, 22 VAND. J. TRANSNA'L Law 689 (1989) see also Daniel Gervais, "The TRIPS Agreement: Drafting History and Analysis," Sweet and Maxwell, 1998, see also Bernard M.Hoekman & Michael M.Kostecki, "the political economy of world trading system: from GATT to WTO 156 {1995}, see also Raghavan Ghakravarthi, U.S s.301," threats raised in GATT Council" available at www.sunsonline.org, see also John Groome "Reshaping The World Trade System: A History of the Uruguay Round," Kluwer Law Int'l, 1999, see also Templeman, Lord Sydney, "Intellectual Property" *Journal of International economics* 603 (1998)

attempt to form a coalition of governments that would pursue the effort of shifting IPR from WIPO to GATT. The highest worries of multinational companies were related to trademark counterfeiting. The main participants in the coalition were the U.S.A, the European community, Japan and Switzerland. The said coalition maintained a firm approach as regards the coalition's strategic objectives throughout the negotiations, which culminated in prevailing over the resistance of the developing countries by threats of trade sanctions and trade-offs in connection with agriculture and traditional goods.³

It is pertinent to reiterate that the initial process in the direction of global harmonization of intellectual property protection started with the industrialized countries concern, particularly the U.S in combating counterfeit goods. In historical fact, a draft entitled "agreement on measures to discourage the importation of counterfeit goods" was prepared by the U.S.A and EU in 1979. The main purpose was to combat the unfavorable effect of counterfeiting on trade revenues.⁴ In 1982 some industrialized countries prepared a draft entitled "the anti-counterfeiting code." The U.S.A suggested that the said code should be adopted as part of the GATT. However, developing countries under the leadership of Brazil and India contended that intellectual property issues fall outside the ambit of physical goods. The only domain of GATT is to deal in physical goods. They argued that intellectual property deals with intangible property which falls within the jurisdiction of WIPO. The issue raised for consideration is this: what are the effects of importation of counterfeit goods on international trade and whether it could be quantified? The sub-committee on trade of the U.S House of Representatives on the basis of 1983 hearings issued a report supported by a report produced by the International Property Alliance showed huge losses.⁵

The U.S.A with a view to removing the deadlock at the GATT amended in 1984 section 301 of the Trade Act of 1974 authorizing the President to take measures conducive to eradicate "unjustifiable or unreasonable trade practices" to the effect of making intellectual property unambiguously actionable under Section 301⁶. The U.S.A Trade Representative was assigned the task to make an annual review in order to detect priority foreign countries which deny adequate and effective protection to intellectual property rights or which deny fair and equitable market access to U.S traders. The USTR is required to locate such countries on a priority watch list or a watch list followed by retaliation or sanctions in the form of increased duties, import restrictions and tariff exemptions. The issue of intellectual property protection including counterfeit goods was thoroughly discussed during the Uruguay Round trade negotiations continuing from September 1986 to April 1994 which changed the General Agreement on Tariffs and

³ Cf. Michael Blakeney, "Trade Related Aspects of Intellectual Property Rights: A Concise Guide To the TRIPS Agreement, London 1996, see also Paul.C.B.Liu, "Industry Influence on Intellectual Property Negotiations And Special 301 Actions," 13 UCLA/PAC.BASIN.L.J 87 (1994) see also Binswanger.H & Lutz.E, "Agricultural Trade Barriers, Trade Negotiations And Interests of Developing Countries," (1999) UNCTAD X High level Round Table on Trade and Development: Decisions for the Twenty first Century (TD(X)/RT.1/8) Geneva.

⁴ See Michael Blakeney *supra* note 3 at p.3

⁵ Cf. Bello and Homer, *Special 301: Its Requirements Implementation and Significance (1989-90)* 13 Fordham Int'l L.J at p 259

⁶ See Michael Blakeney *supra* note 3 at p. 4

Trade into the World Trade Organization (WTO). The Uruguay Round incorporated a resolution taken on January 28, 1987 under the title 'trade related aspects of intellectual property rights including trade in counterfeit goods'

The agreement of World Trade Organization (WTO) was signed on April 1994 by ministers of 125 participating countries at a meeting in Marrakech, Morocco⁷. The TRIPS Agreement was an Annex among a package of 20 agreements; however the phrase "including trade in counterfeit goods" was removed and substituted with a preamble carrying the same purport. The WTO Agreement entered into force on January 1, 1995.⁸ The negotiations surrounded the TRIPS Agreement demonstrate that a system of coercive economic retaliation measures could serve enforcement mechanism. The most powerful industrialized nations did not at all consider the ideal among conflicting interests, but elected pursuant to their national interests, coercive imposition of their position on countries that resisted their position. The TRIPS Agreement lays bare the mismatch between ideal concepts and the hard reality in international relations. It has raised many momentous issues in social and legal philosophy regarding the notions of equity and justice. This leads to the question whether power could be built up by justified ideals or only coercion?⁹ The TRIPS Agreement also demonstrates that a country's independence to control events within the ambit of its sovereignty is challenged by transnational corporations, economic globalization and trade.¹⁰

The sovereignty of a state dwindles, as the gap between the capabilities of the individual state, and the demands of the new economic threats placed on the state are disproportionate. It also demonstrates that developing and LDCs, in their present stage of development, are not in a position to prevail over current international problems. Globalization has augmented the magnitude of regional institutions for economic, political, juridical and social integration. The TRIPS Agreement deal shows that developing and LDCs have given up portions of their sovereignty, in exchange of proposed incentives in particular market access for agricultural products and technology transfer. It is submitted that the TRIPS Agreement has set up an international intellectual property regime that anchored the interests of key industrialized countries, and absolved their interests from the shackles of territorial sovereignty, which had been endorsed by the GATT under Article xx (d). However the nub is: would the deal bring in manifest economic advantages to developing and LDCs? This remains to be seen.

The main task of this piece is to address compulsory licensing as a public policy device to promote and protect public interest concerns. Intellectual property, in particular the patent regime, is a public policy instrument which must be tailored to respond to industrialization and development objectives. From this perspective, the patent regime

⁷ *The Agreement on Trade-Related Aspects of Intellectual Property, Apr.15, 1994 Marathas Agreement Establishing the World Trade Organization, Annex IC Legal Instruments-Results of the Uruguay Round Vol.31, 331.L.M81 (1994)*

⁸ Cf. Frederick. M. Abbott, *supra* note 2 at p.689

⁹ See generally, Harold Hongju Koh, *Why do Nations Obey International Law*, 106 *Yale law Journal*, 2599(1977) see also Thomas Frank, *Legitimacy in the International System*, 82 *American J. of Int'l law* 705 (1988), see also Robert. O. Keobane, *International Relations and International Law: Two Optics*, 38 *Harvard international L.J* 487(1997)

¹⁰ See generally Miguel De La Madrid H., *National sovereignty and Globalization*, 19 *HOUS J. Int'l L.*553 (1997) see also, Alex Y. Seita, *Globalization and the Convergence of Values*, 30 *Cornell. Int'l L.J* 429 (1997)

had to be considered in light of public interest. The phrase, “proposed user” as prescribed in paragraph 31(b) of the TRIPS Agreement must be interpreted as to embrace the public at large, taking into account the social impact of Intellectual property protection and enforcement. Compulsory licensing should be interpreted in light of the objectives and principles as prescribed under the TRIPS Agreement. Compulsory licensing encourages locally foreign patent holders to work their patents. Concomitant to this, it discourages patent holders from employing their intellectual property rights in a manner as would abuse these rights to the effect of defeating an essential objective which is transfer of technology.

I. Compulsory Licensing in Light of TRIPS Objectives and Principles.

Compulsory licensing or other use without authorization of the right holder, as provided for in article 31 of the TRIPS, is a right conferred on a member state, where the law of that state allows for that other use. Perhaps it is of prime importance, to indicate that the provisions of Article 31, did not lay a complete catalogue of grounds or events under which the Article is to apply. It only contains an array of procedure to be observed by member states. Each member state had to consider each case on its own merits, subject to exerting an effort to obtain a voluntary license on reasonable commercial terms¹¹. If an authorization is obtained, it must include adequate compensation, commensurate with the economic value of the authorization. Paragraph 31(f) provides in pertinent part that the device of compulsory licensing shall be employed “predominately for the supply of the domestic market.” Again, paragraph 31(b) provides that the requirement of authorization may be waived by a member state, “in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” Nonetheless, the right holder shall be notified as soon as reasonably practical. Paragraph (c) prescribes a caveat that the “scope and duration of such use shall be limited to the purpose for which it was authorized.” In connection with a case of semi-conductor technology the caveat goes further, that the authorizations shall only be “for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive. On the other hand, paragraph (k) provides that the limitation stipulated in paragraph 31(b) dealing with prior authorization and the limitation prescribed in paragraph (f) prohibiting export may not be applied where the use is “permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.”

In sum Article 31 left open the grounds on which compulsory license may be invoked by a member state, however, the conditions for compulsory licensing are clearly spelled out. Accordingly, members were allowed wide latitude to ascertain the grounds for granting compulsory licensing. Against this background, the first question which falls to be determined is whether developing and LDCs are entitled to implement the flexibility as contained in the TRIPS Agreement and to what extent?¹² The provisions

¹¹ Cf. Frederick. M.Abbott, ‘Compulsory Licensing For Public Health Needs: the Trips Agenda at the WTO after the Doha Declaration on Public Health, Quaker UN Office at p.24, see also generally J.H Reichman, *Compliance with the TRIPS Agreement: Introduction to a Scholarly Debate*, Vanderbilt .J. Transnational. L Vol.29 May at p.377 (1996)

¹² Frederick. M.Abbott, *Supra note 11 at p.56, see generally, Adrian Otten ‘Compliance with the TRIPS. The Emerging World View’* 29 VAND.J.TRANSNA’L.L 391(1996), see generally Ruth L.Gana, ‘Prospects for Developing Countries under the TRIPS Agreement’ 4 VAND. J.TRANSNA’L.L 735(1996)

dealing with objectives and principles in the TRIPS Agreement provide flexibility as a matter of consensus. To ascertain this point one must first dispose of certain questions of construction. Article 7 entitled objectives reads: “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.” The nub is: does IPR protection result as a foregone conclusion in technology transfer? I see considerable force in the contention that TRIPS negotiators were aware that intellectual property protection would not automatically lead to technology transfer. They were not oblivious to the balance that would further the objectives of social and economic welfare.¹³

The word “should” in Article 7 lends support to the view that technology transfer is not intrinsically linked to the machinery of IPR protection. If a country pursuant to the mandate as prescribed in the TRIPS designed IPR legislation ensuring for adequate IPR protection, and worked hard to ensure the requisite enforcement, that country could not make certain that technology transfer shall ensue. It is in these circumstances, difficult, to say the least, to find in Article 7 valid grounds to hamper a WTO member from employing this provision to address public interest concerns. On the contrary, in reliance on this provision an interpretation may be offered, that IPR protection can not be maintained, if the international community does not objectively address public interest concerns for WTO member states. Societal interests must be assimilated into the IP regime, to the effect that implementation of the TRIPS Agreement, must not contravene with the attainment of societal interests, economic and social related concerns.¹⁴ This may be the reason why WHO offered interpretation of the relevant TRIPS provisions permitting compulsory licensing and parallel imports as devices prone to reduce prices.¹⁵ It seems to me that the balance to which a WTO member must have regard to is that, the necessity to protect human life or health, must take precedence over TRIPS Agreement general rules, subject to the principle of non-discrimination. It is submitted that it is highly difficult to challenge a state’s discretion as regards public interest matters, unless a glaring abuse could be established.¹⁶ It may be argued that Article 7 encourages WTO members to take the appropriate measures conducive to enhance public interest in areas of prime importance to their socio-economic and technological advancement.

Article 8.1 reads: members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and

¹³ Cf. *UN Conference on Trade & Development (UNCTAD), the TRIPS Agreement and Developing Countries*, at p15 U.N.Doc.96 11/ D/10 (1996), see generally, Robert M. Sherwood, ‘Promotion of Inventiveness in Developing Countries Through a more Advanced Patent Administration’ 39 *IDEA J.L&T* (1999)

¹⁴ Cf. Frederick. M.Abbott, *supra* note 11 at p.16

¹⁵ Cf. Allyn Lise Taylor, *Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions of Health*, 18 *AM.J.L &MED.*301 (1992)

¹⁶ Cf. *Globalization and Access to Drugs, Perspective on the WTO/TRIPS Agreement*, World Health Organization, DAP Series No. 7, WHO/DAP/98.9 Rev. (1999) see generally Elizabeth A. Taylor, “The Dudley street neighborhood initiative and power of eminent domain,” 36 *B.C.L .Rev.*1061 (1995), see also Courtenay C. Brinckerhoff, “Medical Patents and the Fifth Amendment: Do the New Limits on Enforceability Effect a Taking? 4 *UBalt. Intell. Property.L.J* 147(1996)

technological development, provided that such measures are consistent with the provisions of this agreement.” Article 8.2 reads: “appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.” The mechanism of compulsory licensing could be used to address the abuse of intellectual property rights by rights holders in sectors of vital importance to socio-economic and technological development of a member state. This abuse includes anti-competitive practices by right holders.

In the briefest possible compass, one can state that Article 8 maintains that one of the crucial objectives of TRIPS Agreement is a balance between intellectual property rights and other important socio-economic policies of WTO members. It is germane to this point, to state that Article 8 expands the socio-economic policies, with specific consideration to health and nutritional policies. In my view, it represents a sweeping provision. It may be interpreted to engulf the historical former principles and reasons for which compulsory licensing was originally coined out. However, the caveat embraced in the phrase, “provided that such measures are consistent with the provisions of this agreement” is a bit wide and open to divergent interpretations and begs the questions: does the phrase imply strict compliance? Does the flexibility contained under Article 8 as regards the said measures, sufficient as to allow WTO members, with a latitude of public policy autonomy in the field of intellectual property protection, even if, that public policy impairs the rights of patent holders? Can a WTO member on the pretext of Article 8 actuate a balance of rights and obligations resulting from the commitment to provide intellectual property protection? Would the negotiated balance of concessions between developed and least developed countries be defeated by the utilization of public health measures to ensure access to HIV/AIDS medication in least developed countries?¹⁷

To provide efficacy to the provisions of Article 7 and 8, the three conditions as stated in Article 30 of the TRIPS, must be accorded an interpretation to avoid a paradoxical outcome. Article 30 reads: “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent holder, taking into account the legitimate interests of third parties.” It should be noted that providing a member state with a flexible latitude to address public policy concerns, does not contravene the basic purport of the TRIPS as laid down in the preamble and Article 1.1 which prescribes the minimum requirements for the protection and enforcement of intellectual property rights.¹⁸ However, these minimum requirements were considered by LDCs which came to the mill when the detailed work was more or less finished as maximum requirement. TRIPS Agreement is criticized as an international agreement structured on the basis of “one size fits all” as

¹⁷ See generally, Sara M.Ford, “Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills & Patents,” *Am.U.Int’l L. Rev.* 941(2000), see also John H.Harrelson, “TRIPS, Pharmaceutical patents, and HIV/AIDS Crisis; Finding a Proper Balance Between Intellectual Property Rights and Compassion,” *7Widener L.Sym.j* 175(2001), see also, Allyn Lise Taylor, “making the world health organization work: a legal framework for universal access to the conditions for health,” *18 Am.J.L&MED* 301(1992)

¹⁸ Cf. J.H.Reichman, “Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of WTO Agreement,” *The International Lawyer* Vol.29, No.2 at p.345 (1995)

regards the minimum rules for intellectual property protection. The position taken by developed countries is structured on the hard realities of the contemporary economic order where each nation state is regarded responsible for its achievements and failures akin to an entity in a market economy. For myself, I confess to feeling some difficulty in understanding how such standards be required from a small country such as Eritrea which had come recently into existence and had to cope with its teething troubles. As accurately observed by one commentator, “ the first question that comes to mind is how a young and still untested international organization like WTO can hope to manage the complexities of the TRIPS Agreement(and the pitfalls it contains) when so many of its constituent members lack the legal infrastructure, technical skills, and philosophical commitment to make it work.”¹⁹

The general agreement on Tariff and Trade (GATT) and the World Trade Organization (WTO) recognize that developing and least developed countries are disadvantaged in international trade, to the effect that the Special and Differential Treatment (SDT) arrangement as incorporated in the aforesaid agreements, stands as a fundamental principle of the said two organizations.²⁰ The Covenant on Economic, Social and Cultural Rights (ICESCR) recognizes that implementation of the Covenant is to be progressively undertaken according to the state’s resources and ability. The Covenant as provided for under Article 2(1) urges states to implement the Covenant “To the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present covenant by all appropriate means.” Again, under the earlier Paris Convention each country is obliged to provide intellectual property protection no worse than its own to other members of the Convention. By demanding a similar level of protection for all countries, the TRIPS Agreement no longer permits countries to elect the level of intellectual property protection in line with the level of each country economic development. The Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement does not incorporate similar provisions. It is devoid of significant differences in the rules applicable to developing and least developed countries in contrast to developed countries.²¹

Article xx of the GATT dealing with safeguard measures was invoked to prevent fleets of fishing vessels from operating in a way injurious to dolphins and sea turtles. If this was the case, it should be axiomatic that a member state is entitled to suspend IPR protection or impose compulsory licensing to address the vital needs of medicine and nutrition to save human lives.²² There is no official institutional association between human rights and WTO. This may be the reason why representatives of international human rights institutions are not strongly involved in WTO negotiations. However, WTO requires compliance with human rights obligations as a condition precedent to market access. It is pertinent to indicate, that the UN High Commissioner on Human Rights has issued a resolution to the effect that access to medication in the context of pandemics such as HIV/AIDS, Tuberculosis and Malaria is a human right. His report recommends

¹⁹ See J.H.Reichman, *supra* note 11 at p.367, see generally A. Weston, “ The Uruguay Round-Costs and Compensation for Developing Countries,” (UNCTAD) Geneva (1995)

²⁰ Cf. Constantine Michalopoulos, “ Special And Differential Treatment of Developing Countries in TRIPS,” Quaker United Nations Office(QUNO) Geneva, Quaker International Affairs Programme(QIAP), Ottawa at p.4

²¹ Cf. J.H.Reichman, *supra* note 11 at p.371

²² Cf. *Resource Book on TRIPS And Development-UNCTAD-ISTSD*, Cambridge University Press

taking into account human rights instruments and other relevant treaties as a weighty backdrop in the process of interpreting the TRIPS Agreement and other relevant WTO rules.²³ The Universal Declaration of Human Rights prescribes in Article 25 (1) that "everyone has a right to a standard of living adequate for health and well-being of himself and of his family." However, such an ideal concept requires positive cooperation on the basis of a shared obligation to ensure that basic human needs are maintained. The question naturally arises as whether it would be imperative that WTO rules including TRIPS Agreement shall conform to normative areas of public international law such as legitimacy.²⁴

Perhaps it is in order to indicate that drafters of Article 31, omitted any reference to the application of compulsory licensing, on the ground of failure to work or insufficient working, after expiry 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. The obligation of the patentee to work his patent in the country where the patent was granted appeared in the original text of the Paris Convention as adopted in 1883. The text of Article 5A of the Paris Convention which obliges the patentee to put his patent into operation witnessed a number of revisions.²⁵ In all these revisions the basic purport was kept intact. The original text and all subsequent revisions, clearly provide that 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. Importation of articles manufactured in any of the countries of the union would operate against the possibility of forfeiture. Forfeiture under such a circumstance would be deemed illegal, though failure to work is deemed an abusive act. However, even forfeiture is not an unfettered right, under the Paris Convention, even if an abusive act had been recorded. Forfeiture of the patent shall not be invoked, except in cases where the grant of compulsory license would not have been sufficient to prevent the established abuse, and after expiry of two years from the grant of the first compulsory license.

Compulsory license shall not be granted if the patent owner is in a position to adduce a cogent justification for his inaction by legitimate reasons. With a view to preserving any residual right that may accrue for the patent holder, a compulsory license shall be non-exclusive. Again, it shall not be transferable in any form including the form of a sub-license except with that part of the enterprise or goodwill which exploits such license. It appears to me that Paris Convention, in connection with compulsory licensing, was structured on the basis of established property rights. Property rights are not absolute. A property owner must give up to the state a portion of his property rights when public interest needs arise. Many restrictions on private property rights can be justified on

²³ Cf. UN.Doc.E/CN.4/sub.2/2001/13, "Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria," see generally H. Lim, "Human Rights: What is at Issue?" 35:2 *Journal of World Trade* 275 (2001), see also, F. Garcia, "the Global Market And Human Rights: Trading away Human Rights Principle," 25 *Brooklyn J.Int'l* 39 (1999)

²⁴ See generally, "publications of the American society of international law interest group on the theory of international law," volume 111(1) 1977

²⁵ First, in Washington in 1911. Second, in The Hague in 1925. Third, in London in 1934. Fourth, in Lisbon in 1958. Fifth, in Stockholm in 1967.

the basis of societal concerns such as public health. The state is representative of the public and it must act to maintain public confidence.²⁶

It is respectfully submitted that compulsory licensing does not stand for an expropriation or a taking. In recognized major legal systems, the state had to compensate a proprietor, in the event; property is taken on the premise of a public interest. The state's interference with private ownership is considered a taking only in two instances. First, when the interference with private ownership constitutes a physical invasion. Second, when the state's interference eliminates the entire economic value in the property.²⁷ This does not apply in the case of a non-exclusive compulsory license. In a non-exclusive compulsory license, the patent holder still retains possession of his property in the patent to the effect of being able to make use of his patent rights. From the preceding discussion, it may seem that compulsory licensing is a legal limitation on property rights, reserved to the state, which may be invoked by it for public interest considerations. Paragraph 31(h) provides that "the right holder shall be paid adequate compensation in the circumstances of each case, taking into account the economic value of the authorization." Considerable support can be mustered for the view that a state's underlying policy considerations, can determine on the basis of definite pragmatic settings, whether compensation may be paid in any event or interference. The state is in a position to decide on the basis of definite realistic settings whether something, has acquired under the prevailing law, the property status or not.²⁸

The question now is: why, when a public interest concern materializes, a patent holder under the TRIPS Agreement shall not remain bound to work the patent in conformity with the law of the country which granted the patent or into which he introduces the patented objects? Does the non-discrimination principle as contained in Article 27 (1) provide an answer? The non-discrimination covenant is clearly confined to the question of national treatment which is addressed by Article 3 of the TRIPS Agreement. It provides in pertinent part that "each member shall accord to the nationals of other members treatment not less favorable than that it accords to its own nationals with regard to the protection of intellectual property? Again, Article 4 in connection with the principle of most-favoured-nation treatment provides in pertinent part "with regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other members."

Article 27 (1) states in pertinent part "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced". This provision provides for non-discrimination as to the location of invention, the discipline of technology and whether products are locally produced or imported. Again, this provision provides an extension of

²⁶ A proprietor of intellectual property is not entitled to an absolute right to use intellectual property in any manner without restriction. *U.S. v Microsoft Corp*, 253 F.3d 34, 63 (D.C. Cir.2001) is a good example.

²⁷ All major legal systems have provisions supporting this stand. The same position holds in the context of U.S Fifth Amendment. See also generally Michael Boldrin & David Levine, "the case against intellectual property," 29 *Am.Econ.Rev* 209 (2002)

²⁸ See generally Roger .E.Meiners & Robert .J. Staaf, "Patents, Copyright and Trademarks: property or monopoly?" 13 *Harvard L.J& Pub. Policy* 911 (1990) see also generally Kenneth W.Dam, "the economic underpinnings of patent law," 23 *J.Legal Stud.* 247 (1994)

the range of protection to all kinds of technologies. It embraces within its scope technological fields such as pharmaceutical products.

Article 40 of the TRIPS Agreement authorizes application of competitive rules to address unfair business practices. Compulsory licensing is a device which enables a member state to address problems arising from competition law. The chief task of competition law is to uphold the incentive and reward justifications of intellectual property protection, without being oblivious to the risk of an undue extension of legal exclusivity. A member state may need to take elaborate measures, to defeat unfair practices, conducive to restrict or distort competition, such as practices amounting to monopoly pricing or any other adverse trading condition.²⁹ An anti-competitive practice may amount to limit or control production or capital investment or technology transfer of technical development. Again, a member state may need to curtail practices that discriminate between customers in trade, as would place other customers at a competitive disadvantage, or restrain an unfair practice, where supplementary obligations irrelevant to the transactions, are stipulated as contract conditions. If harmonization of intellectual property rights, would restrain a member state from addressing competition law matters, then such an approach, would definitely hold back a member's efforts, to enhance its economy and hence improve its technological base.

A conflict between intellectual property and competition law arises, in instances where a member state, takes cognizance that intellectual property owners, have used their market power to extend their rights, beyond the parameters as prescribed under the law, or to achieve anti-competitive targets, incompatible with the rights conferred under the law. When intellectual property owners, abuse or misuse conferred IPR rights, the remedy resides in compulsory licensing, as a public policy option, and even forfeiture if a situation so warrants. Competition laws fall within the ambit of the remaining territorial jurisdiction a member state may entertain. The exigencies of infant industries in developing and LDCs may require prompt actions in the area of competition law.

II. Extension of the Patent Regime

It is submitted that developing countries worked hard, to exclude from the ambit of the patent regime, inventions relating to animals and plant life. Again, they resisted inclusion of pharmaceutical products; and processes on the premise of public interest concerns. However, the U.S.A espoused an opposing view, calling for a broad ambit of patent protection. Due to the leverage exercised by the U.S.A employing trade sanctions, pharmaceutical products were brought within the ambit of patent protection.³⁰ This great

²⁹ See generally Michael J. Madinowski, "capitation, advances in medical technology, and the advent of new era in medical ethics," 22 *Am.J.L& MED* 331(1996), see also Gathii, James Thuo, "constructing intellectual property rights and competition policy consistently with facilitating access to affordable Aids drugs to low-end consumer," *Florida L.Rev.* Vol.53 727 (2001) see also generally working paper by Andrew Greese & Jonathan Quick, "Differential Pricing Arrangement and Feasibility: Context Setting Paper World Health Organization 21 January 2001

³⁰ See generally Bhala, "Mrs.Watu: Seven Steps on Trade Sanctions Analysis." 20 *Mich.J.Int'l. L.* 565 (1999). Special 301 provisions serve the purpose of imposing, "pressure on countries to change their negotiations positions," see MTN.GNG.TRIPS, dated July 25th, 1991, Meeting of Negotiating Group dated 27-28 June 1991. It may be argued that extension of patent to pharmaceutical products is a violation of the non-discrimination principle as contained in Article 27.1 of the TRIPS. In this respect see, Daya Shanker, "legitimacy and the TRIPS Agreement," University of Wollongong, Report of Economics Working Paper Series 2002 at pp 32-34

pressure culminated in extension to the patent regime to include chemical and pharmaceutical products per se. In connection with compulsory licensing, as already noted, the TRIPS Agreement fails to enumerate, the events or situations where compulsory licensing may be justifiably invoked, by a member state without the patentee's consent. However, the TRIPS Agreement specifies a series of conditions, in addition to the procedural requirements for granting a compulsory license, on the basis of each individual case. The TRIPS Agreement provides that a license when granted must be non-exclusive, non-assignable, and subject to judicial review.³¹ Again The TRIPS Agreement stipulates that adequate compensation must be paid.³² The TRIPS Agreement does not specify the substantive rules governing compulsory licensing. Again, the substantive rules governing patentability are not clearly spelled out.³³ In contrast the Paris Convention required states to bring their substantive law in conformity to the standards of compulsory licensing requirements.

It is pertinent to indicate that pharmaceutical products were excluded from patentability before the advent of TRIPS by many countries. France initiated pharmaceutical patent protection in 1960.³⁴ Germany introduced the same in 1968³⁵. Japan brought in pharmaceutical patent laws in 1976.³⁶ However, Switzerland followed suit in 1977.³⁷ This may explain the underlying reason why the first controversy as regards enforcement of the TRIPS relates to pharmaceutical products.³⁸ On the other hand, paragraph 2.2 of the Trade Related Aspects of Intellectual Property Rights (TRIPS Agreements) provides "Nothing in Parts 1 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." The TRIPS Agreement does not define the type of the said pre-TRIPS existing obligations. However, the U.S.A government and TNC pharmaceutical companies have labored hard to secure a retroactive recognition of protections for pharmaceuticals already patented under the rubric of what is termed "pipeline" protection. Such an attempt diametrically opposes the legal concept of novelty as contained under the TRIPS Agreement

In connection with pharmaceutical and agricultural chemical products Article 8 provides in pertinent part " where a Member does not make available as of the date of entry into force of the Agreement establishing the WTO patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that member shall (iii) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term,

³¹ Paragraphs 31(d), 31(e) and 31(I) of the TRIPS

³² Paragraph 31(h)

³³ Article 27 of the TRIPS. It is pertinent to note that harmonization of the substantive rules is required on all-embracing basis as to include a detailed definition of prior art, novelty, on-obviousness and an inventive step. The envisaged harmonization should address public interest concerns to the effect of achieving a balance between private interests of patent applications and the general public interest.

³⁴ Cf. Juma, C (1999), *Intellectual Property Rights and Globalization: Implications for Developing Countries. Science, Technology and Innovation Discussion paper No. 4, Centre for International Development, Harvard university, Cambridge, MA, USA at p.18 footnote 13*

³⁵ *Ibid*

³⁶ *ibid*

³⁷ *ibid*

³⁸ *Supra note 34 at p. 7*

counted from the filing date in accordance with Article 33 of this Agreement, for those applications that meet the criteria for protection referred to in sub-paragraph (ii) above.” Again paragraph 70 (9) provides that exclusive marketing rights shall be granted for a period of five years after obtaining market approval in a member not obliged to make available patent protection as of entry into force the TRIPS Agreement. These provisions are equivalent to proper patent protection, though a member is not bound to make available patent protection. The question to be posed under the circumstances is this: what would be the position, if a member on the basis of public non-commercial use, elected to use the mail-box patent, would that fall within the ambit of compulsory licensing? The mail-box situation would not confer an exclusive right as it lacks a proper registration. For, myself, I confess to feeling some difficulty in understanding how this issue could be resolved on an appropriate legal categorization.

The TRIPS Agreement incorporates by reference Article 5A(2) of the Paris Convention, which expressly provides that compulsory license shall be invoked, on the ground of failure to work or insufficient working of the invention, within the period as prescribed under the Convention. It is submitted that for developing countries the basic matter is access to technology.³⁹ The question of bringing their legislation in line with the TRIPS provision, and hence enforcement of IPR rights, would logically follow if the first concern is answered. The position as now stands is this: the developed countries that create technology, labor hard to protect it. On the other hand, developing countries which import such technologies exert an effort to find ways to enlarge access to the existing technology.⁴⁰ As a matter of fact, countries in search of technologies have on a regular basis imitated and gained knowledge from those already in control of the knowledge. When the United States was yet a comparatively new and a developing country, it declined to abide by international intellectual property rights on the pretext that it was utterly free to exploit foreign works to promote its social and economic growth.⁴¹

III. The Legal Controversy Surrounding Article 30 and Paragraph 31(f)

Compulsory licensing as a public policy device depends on the economic strength of a country. Industrialized countries with sound economies resort to compulsory licensing in rare cases to address an anti-competitive practice.⁴² On the other hand, developing and LDCs lacking an industrial production base coupled with low per capita income, resort to compulsory licensing to secure low prices.⁴³ However, the main difficulty resides in the manufacturing capacity of developing and LDCs members of the WTO. These countries lack adequate economic resources to purchase the required technology. The current

³⁹ Cf. Luc Soete, “Opportunities for and limitations to technological leapfrogging, in technology trade policy and the Uruguay Round,” *UN Conference on Trade & Development UNCTAD/ITP/23* at pp. 5-25, see also J.H Reichmann, “Intellectual Property and the Dissemination of Technological Knowledge: A Pro-Competitive Strategy for Compliance with the TRIPS Agreement (Nov.22 (1995), Paper presented to the experts meeting in connection with intellectual property rights and technology transfer.

⁴⁰ Cf. Frank J. Gracia, “Protection of Intellectual Property Rights in the North American Free Trade Agreement. A Successful Case of Regional Trade Regulations,” *AM.U.L.Int’l.L.&Pol’y* 817 (1993)

⁴¹ Cf. juma, C, *supra* note 34 at p.4, and see also Office of Technology Assessment 1986, “Intellectual Property Rights in an Age of Electronics Information. US Printing Office, Washington, DC at p.228

⁴² Cf. Carlos. M. Correa, “Intellectual Property Rights and the use of compulsory licenses: options for developing countries,” *South Centre, Trade Related Agenda, Development & Equity, working paper.*

⁴³ Cf. Arvind Subromanian, “The Aid Crisis, Differential Pricing of Drugs, And the TRIPS Agreement-Two Proposals,” *4 Journal of World Intellectual Property*,” (2001)

patent regime aggravates the dilemma, as it gets involved with the market process; and increases the cost of technology expenditure. The patent proprietor due to lack of ample competition capable to create a substitute, utilizes the patent regime to achieve market hegemony.⁴⁴ The problem is further exacerbated by the fact that most of the patent holders are TCN companies owned by nationals of the developed countries.

The industrialized countries hold 99% per cent of all patents worldwide.⁴⁵ In 1995 more than half of the global royalties and licensing fees were paid to U.S.A companies. Unauthorized copies of patented drugs were prohibited in all countries where the agreement came into force. These TCN are reluctant to offer technology licenses on reasonable terms. TCN companies fix high prices to offset R& D expenditure which in most cases highly surpass product marginal cost. Thus compulsory licensing remains an important public policy tool to address the adverse effects of patents monopoly on prices. Again, compulsory licensing ensures availability of indispensable products and in particular essential drugs.⁴⁶

On account of the fact that developing and LDCs lack the requisite technical and financial capacity, these countries normally opt for seeking a compromise with foreign patent holders, rather than resort to compulsory licensing as a public policy device. The point at issue is this: does paragraph 31(f) represent an impediment to invoking compulsory licensing?⁴⁷ Paragraph 31(f) addresses the situation as and when compulsory licensing is made without authorization of the right holder. Paragraph 31(f) reads: any such use shall be authorized predominately for the supply of domestic market of the Member authorizing such use” One must first dispose of certain points of construction. What does the phrase, “authorized predominately” mean? The adjective predominately as shown in Roget's International Thesaurus means chiefly, in the main, for the most part, principally, on balance, generally, in the long run. Again, does the use of the word predominately connote any percentage such as fifty percent for domestic supply? If the interpretation of the said provision is to imply stipulating of a percentage, then such a construction if correct is capricious, erratic or irregular. The contention of developing countries on local working of a patent was made on the basis of an economic benefit, dedicated by public interest concerns, and in appropriate cases, to circumvent having patents as a mask for protecting importation of foreign goods.

From the perspective of industrialized countries, it appears that the underlying motive behind paragraph 31(f) is to avoid an economic backlash on the value of the patent, insofar, as the compulsory licensee's costs would be less than the cost of the patent owner, as R&D costs and marketing costs would not be included in the price of the product. Such an economic advantage may enable the compulsory licensee to resell a portion of the output outside the domestic market.⁴⁸ A patent owner may consider the

⁴⁴ Cf generally Harold C. Wegner, “TRIPS Boomerage,” 29VAND.J.TRANSN'L.Law 535 (1996)

⁴⁵ Cf. *Communications from India, Standards and Principles Concerning the Availability, Scope and Use of Trade-Related Intellectual Property Rights*, MTN, GNG11/W/37, 10 July 1989.

⁴⁶ Cf. Tshimango Kongolo, “Public Interest Versus Pharmaceutical Industry Monopoly in South Africa,” *The Journal of World Intellectual Property*,” at p 626 (2001)

⁴⁷ Cf. Frederick. M.Abbott, ‘Compulsory Licensing For Public Health Needs: the Trips Agenda at the WTO after the Doha Declaration on Public Health,’ *supra* note 11 at pp. 28-33

⁴⁸ Cf. Calestous Juma *supra* note 34 at p.7 see generally W.Lesser, “The Effects of TRIPS-Mandated Intellectual Property Rights on Economic Activities in Developing Countries,” *WIPO Research Paper 2001*

profits generated by the compulsory licensee as a windfall. The better view is that, the compulsory licensee, acts in response to a public concern. Accordingly, such acts must be encouraged and must not be defeated or equated with free riding.⁴⁹ It appears to me that Article 31 totally negates conventional situations, where compulsory licensing may be invoked, without authorization of the right holder, other than the emergency situations provided for under paragraph 31(b).⁵⁰ On principle, prior authorization must be obtained in conventional situations, however paragraph 31(b) provides in pertinent part that obtaining prior authorization from the right holder “ May be waived by a member in the case of a national emergency or other circumstances of extreme urgency or in the case of public non-commercial use”

The question to be raised is this: is there any direct provision in the TRIPS Agreement, which disallows employing compulsory licensing, to import or export a product or a process, for which the right holder enjoys a fully fledged protection? Paragraph 31(k) of the TRIPS Agreement reads” Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) above where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur” It is evident from the wording of paragraph 31(k) that in applying compulsory licensing to combat anti-competitive practices, the condition of prior authorization from the right holder; and the restriction that the use “ shall be authorized predominately for the supply of the domestic market of the Member authorizing such use” are inapplicable.

It is submitted that the rights conferred on a patent holder, pursuant to article 28 of the TRIPS Agreement, are subject to limited exceptions, necessary to address public interest considerations, as provided for under Article 30 of the same. Article 30 reads “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent owner, taking account of the legitimate interests of third parties” On principle, exceptions or limitations on property may be imposed with compensation, even if such compensation would have an impact on the value of property. Nonetheless, a limitation on patent rights may not be compensable, as regards cases of anti-competitive practices, on the ground that such an action does not amount to expropriation or a taking, insofar, as the proprietor still maintains a considerable economic value.⁵¹

⁴⁹ Cf. J.H. Reichman, “From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement,” 29 *N.Y.U.J.Int’ L. & Policy* pp.15-20 (1997). The Article suggest that the new enforcement rules and regulations that are envisaged to be implemented by the European Union and U.S would assist in moving developing countries to structure legislation in compliance with the enforcement measures called for under the TRIPS.

⁵⁰ Cf. W.R Cornish, “Intellectual Property,” 4th edition, Sweet & Maxwell at P.116

⁵¹ Cf. *U.S v Microsoft Corporation*, 253 F.3d 34, 63 (D.C.Cir.2001) see also generally John .H. Leavitt, “*Hodel v Irving: The Supreme Court’s Emerging Taking Analysis-A Question of How Many Pumpkin Seeds per Acre*,” 18 *ENVTL.L.* 597 (1988)

Compensation may be imperative in cases, where an expropriation, eradicates all or most of the economic value of property.⁵² Accordingly, interpretation of Article 30 may imply the right of a member state, to employ compulsory licensing to meet a full or partial demand for a product, in the domestic market. One may ask how failure to meet a demand can be ascertained. It could be ascertained in two instances. First, when the demand for the product is not being met on reasonable terms. Second, when the demand is being met to a substantial extent by importation, or the working of the patent, is being defeated in any manner by the importation mechanism from outside.⁵³ It is pertinent to indicate that it is not sufficient to meet the demand in terms of quantity, but it must also be met in terms of reasonable prices. The question of prices is of prime importance because the main problems as regards any least developed country (LDC) reside in the distribution of meager resources towards production requirements. In contrast, the main problems as regards any developed country reside in managing the nation's resources into a constantly changing output or production to match up a dynamic market

Given the fact that the TRIPS Agreement lacks the substantive objective test as to the events or grounds for invoking compulsory licensing, it seems to me that the key to the riddle exists in the following. First, Article 30 should be interpreted in light of the objectives and principles as contained in the TRIPS Agreement. Second, account must be taken of the principles as contained in the major preexisting international conventions on intellectual property incorporated into the TRIPS Agreement. Third, substantive compulsory licensing rules must be sought in the law of WTO members pre-dating the Uruguay Round negotiations. Fourth, paragraph 4 of the Doha Declaration on the TRIPS Agreement and Public Health must be given weight in the process of interpretation.⁵⁴ The said Declaration clearly affirms that "The TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Member's right to protect public health, and, in particular to promote access to medicine for all".

It should be noted that the crucial problem is not only a restrictive interpretation of the TRIPS Agreement. The Doha Declaration aptly noted that due to lack of manufacturing capacities, developing countries would not be in a position to employ compulsory licensing, to adapt technologies to produce cheaper local equivalents. Paragraph 6 of the Doha Declaration⁵⁵ reads as follows: we recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and report to the General Council before the end of 2002"

It is in order to indicate that U.K Patent Act of 1977 as contained in ss.48, 50 provides that compulsory licensing may be granted for the supply of the export market, if, the right holder of the patent refuses to grant a license on reasonable terms in the

⁵² See *U.S Fifth Amendment*

⁵³ Cf. *Cf. W.R Cornish supra note 50 at p.116*

⁵⁴ *Ministerial Conference, Fourth Session, Doha, 9-14 November.2001, WT/MIN(01)DEC/2, 20 Nov.2001*

⁵⁵ *Ibid*

following instances⁵⁶. First, if a market for the export of any patented product is made in the country is not being supplied. Second, the working or efficient working in the country of any other patented invention which makes a substantial contribution to the art is prevented or hindered.⁵⁷ Third, the establishment or development of commercial or industrial activities in the country is unfairly prejudiced.⁵⁸ Fourth, to address unfair competitive practices.⁵⁹ In addition to that, any government department or any person authorized by the government may issue a compulsory license without the consent of the right holder, where the invention is a product or a process for the production or supply of specified drugs and medicines.⁶⁰ Article 28(4) of Community Patent Convention provides that “for the purposes of this Convention, the term “compulsory license” shall be construed as including official licenses and the right to use patented inventions for the public interest”⁶¹

IV. Compulsory Licensing Reduces Parallel Importation.

Pursuant to Article 6 of the TRIPS Agreement any WTO member has an incontrovertible right to allow parallel imports on the ground of the doctrine of exhaustion of rights. Article 6 of the TRIPS Agreement reads: “for the purpose of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.” On the basis of this provision, any member state has an unfettered right, to develop its own policies in connection with the question of exhaustion, subject to the covenants as provided for under Articles (3) and (4) which deal with national and most favored nation treatment. Paragraph 5(d) of the Doha Declaration⁶² confirmed the purport as contained in Article 6. It reads as follows: “ the effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish it own regime for such exhaustion without challenge, subject to MFN and national treatment provisions of Articles 3 and 4.”

It is pertinent to indicate that Article 28 of the TRIPS Agreement has specified the exclusive rights conferred by patents; however, it does not address the exhaustion of patent rights as the question of exhaustion is set aside to national laws.⁶³ Again such an approach accords with WTO objectives in removing the entire sorts of trade restrictions.

⁵⁶ Cf. *W.R Cornish supra note 50 at p.116. In Extrude Honev Heathway Machine Sales. [1981] 3CMLR 379 at p.404 the High Court (Chancery Division-Patent Court) in support of a compulsory license the court said. “The grant of a compulsory license is plainly not in terms of a qualitative restriction. Nor is it, in my view, a measure having equivalent effect. It is, however, calculated to encourage competition and is entirely in accord with the general concept of the treaty (Treaty of Rome) see Daya Shanker, “ legitimacy and the TRIPS Agreement,” University of Wollongong, Report of Economics Working Paper Series 2002 supra note 30at p. 15*

⁵⁷ *ibid*

⁵⁸ *ibid*

⁵⁹ *ibid*

⁶⁰ *ibid*

⁶¹ *Community Patent Convention (1975)*

⁶² *Ministerial Conference, Fourth Session, Doha, supra note 54*

⁶³ Cf. *Harvey .E.Bale, “the conflicts between parallel trade and product access and innovations. The case of pharmaceuticals,” J.Int’l Econ.L 650 (1998), see generally Frederick M. Abbott, “ First Report to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation,” J.Int’L.Econ.L 607 (1998)*

In the same vein, the approach accords with the alleged TRIPS Agreement objectives in striking a balance between the requirement for a free movement of goods and an appropriate protection of intellectual property rights. Though the rule of exhaustion works to enhance competition as would eventually benefit consumers, however, supporters of a limitation to the rule of exhaustion entertain the view that, market division by IPR owners, facilitates imposing different prices to recoup R&D expenditure which would ultimately direct reinvestment in new useful products to consumers.

The rule of exhaustion recognizes that a patent owner has the right to use and alienate his property right in the patented goods by way of sale, transfer or importation, that is to say, he is fully entitled to the exclusive intellectual property rights as prescribed under Article 28 of the TRIPS Agreement, however, once the patented goods are placed lawfully on the market the property status ends.⁶⁴ This is because access to the property in patented goods can not be controlled. First sale doctrine or domestic exhaustion takes place when the sale occurs in the domestic market. International exhaustion takes place when the sale of the products occurs anywhere in the world. The legal categorization for this legal position can be found in the doctrine against perpetuities which is a concept recognized by the common law system and other major legal systems. The doctrine of international exhaustion is premised on the said doctrine. The doctrine of international exhaustion mandates that property rights in the patented goods, shall exhaust upon first sale or once the goods have been put on the market of one country.⁶⁵ Under the circumstances, the goods can be shipped for sale in another country where the right holder has equivalent patent rights; and can be disposed there with exemption from any claim of patent infringement. The U.S Supreme Court ruled in *Quality King Distributors Inc V L'anza Research Int'l* that a copyright owner loses control over a product once it enters the stream of commerce. Accordingly, the doctrine of international exhaustion may be used in lieu of compulsory licensing and thus divest a patentee or licensor of his right to claim legal compensation for utilizing his patent rights in a specific state.

The only instance where an exhaustion of rights may take place without the consent of the patent owner is the case of compulsory licensing. However, in normal situations consent of the right holder is the basis for an international exhaustion policy. Consent materializes once a lawful or legitimate placing of IPR protected goods or services have been made anywhere in the world to the effect of permitting the right of importation. The doctrine of international exhaustion operates as a mechanism to restrain the grip of the patent regime, in the sense of promoting competition. It operates to answer a country's needs, when compulsory licensing may not be invoked for any reason. By virtue of the doctrine of international exhaustion, a country may resort to parallel import, whereby goods protected under a domestic patent, may be imported.

Gray goods are legitimate patented products or products made by patented processes, sold through unauthorized channels, in open competition with authorized distributors. These goods are manufactured legally under the laws of the country where they were made. The products may be manufactured by a domestic patent or may be

⁶⁴ Cf. generally Margreth Barret, "the United States Doctrine of exhaustion: Parallel Imports of Patented Goods," 27*N.Y.L.Rev.* 911(2000)

⁶⁵ Cf. generally Lisa Harlander, "Exhaustion of Trademark Rights. Beyond the European Union in Light of *Silhouette International Schmied v Hartlauer Handelsgesellschaft: Towards Stronger Protection of Trademark Right and Eliminating the Gray Market*," *J.Int'l & Comp.L.* 267 (2000)

manufactured abroad by a foreign patent. Gray goods include products exported abroad and re-imported in the country where they were made. Gray goods survive because manufacturers in industrialized countries, with a view to marketing their products in foreign market, sell consumers goods to foreign distributors at substantial discounts. The discounts offered represent conspicuous price differential. Distributors with the motive of earning high profits re-import the goods at a price less than the domestic market. Manufacturers contend that gray markets adversely affect quality control. Accordingly, Gray goods manufactured under a license agreement, in any country, may be imported in another country where the same goods are protected by a domestic license. Comparable to the device of compulsory licensing, the mechanism of parallel imports may provide consumers with competitive low prices, in addition to, brand range. Again, equal to the device of compulsory licensing, manufacturing costs for parallel imports are substantially less, insofar, as costs of R&D, and marketing are not included.

Due to the fact that parallel imports raise difficult problems not amenable to happy solutions, some countries attempted to find solutions in bilateral free trade arrangements, where territorial limitation provisions, were incorporated prohibiting resale in other countries. However, the use of territorial limitations as a strategy, may not work to resist the doctrine of international exhaustion, in countries where territorially limited licenses are not acknowledged. In effect, compulsory licensing may operate to reduce resort to parallel imports. The doctrine of international exhaustion if invoked may result in a significant loss of revenue to the patentee as it deprives him of his legitimate right to compensation for use of his patented rights.

V. Compulsory Licensing and TRIPS Enforcement Measures.

Part 111 of the TRIPS Agreement contains Articles 41-61 which deal with enforcement of intellectual property rights. Article 41 as far as it is material provides that, “members shall ensure that enforcement procedures as specified in this part are available under their national laws so as to permit effective action against any act of infringement on intellectual property rights covered by this agreement.” These provisions as contained in part 111 embrace administrative and civil judicial procedures for the enforcement of intellectual property rights. The judicial measures include indemnification in the form of payment of adequate damages and expenses. The enforcement measures provide for other remedies which include injunctions, disposal or destructure of the goods. Again, tight border measures as contained in Article 51 including an obligation to give an account as regards trademarked goods and pirated copyright goods. In addition to that, the TRIPS Agreement embodies inflexible dispute settlement machinery within WTO structure which may culminate in imposing trade sanctions for non-compliance with the minimum standards called for under the TRIPS Agreement⁶⁶. With a view to maintaining effective dispute settlement machinery, the TRIPS Agreement mandates WTO members to abide by the requirement of transparency to the effect of making publicly available any information in respect of laws, regulations, final decisions, administrative rulings, and enforcement and prevention measures.⁶⁷ The said Article further obligates members to notify the Council for TRIPS Agreement of all the laws and regulations.

⁶⁶ Cf. J.H.Reichman, “*Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Agreement of WTO Agreement*,” 29.2 Vol. *the international lawyer* 345 (1995)

⁶⁷ See J.H Reichmann, *Compliance with the TRIPS Agreement: Introduction to a Scholarly Debate*, *supra* note 11 at p.368

The measures proposed by developing countries at Doha Ministerial Conference may contravene the provisions relating to compulsory licensing as contained in Article 31 of the TRIPS Agreement.⁶⁸ The developing countries suggested that a member state may under Article 30 of the TRIPS Agreement, grant a compulsory license without authorization of the patent holder, to be implemented by a duly authorized supplier in another country, though the said supplier is not a patent holder, of the product required to be supplied. It may be argued that the doctrine of public interest may be used to address practical issues such as public health concerns, albeit, such an act contradicts with the TRIPS Agreement, provided that the public interest tool must be used in a legitimate, reasonable manner and devoid of any arbitrariness.⁶⁹

In addressing this issue, the European Commission, suggested that the qualification as contained under paragraph 31(f) may be dismantled, in the event the imported goods, have been produced in a country where no patent protection exists or the term of the patent expired. The European Commission also suggested that a compulsory license may be granted to a third person in another country, provided however, that the other country recognizes the license, on the understanding, that all the manufactured goods shall be directed to the country granting the compulsory license.⁷⁰ On the other hand, the United States of America entertains the view that, if the compulsory licensee elects to manufacture the products in his own country, for ultimate purpose of export to the country that authorized the license, then such an action would amount to an infringement.⁷¹ The patentee is entitled to sue the producer in the other country. The envisaged outcome of a successful case, is that the compulsory license initially authorized, shall be ineffective in supplying the needed products whether drugs or otherwise. To avoid the limitations set by Article 31, the non-national supplier must ensure either of the following. First, no protected patent exists in his home country. Second, he had obtained a voluntary license from the patent holder in his home country for the purpose of export to the other country. Third, production shall be made in the country authorizing the compulsory license.

Paragraph 44(2) provides that if the provisions of part 11 specifically addressing use by a government or a third person authorized by the government in connection with compulsory licensing are not complied with, then the remedies as contained in the enforcement measures shall apply, or where these remedies are inconsistent with domestic legislation, declaratory judgments and adequate compensation shall be available.

⁶⁸ Ministerial Conference, Fourth Session, Doha, *Supra* Note 54

⁶⁹ Cf. J.H.Reichman & David Lange, "Bargaining Around the TRIPS: The Case for Ongoing Public-Private Initiative to Facilitate Worldwide Intellectual Property Transactions," 9 *Duke J. of Comparative Int'L. at p.18*(1998), see generally Michael J.Madinowski, "Capitulation, Advances in Medical Technology, And the Advent of a New Era in Medical Ethics," 22 *AM.J.L&MED* 331(1996)

⁷⁰ Cf. European Commission, *Compulsory Licensing and Data Protection, Legal Issues Related to Compulsory Licensing Under the TRIPS Agreement, An Eu Contribution*, available at www.europa.eu.int/comm/trade/pdf/med, See also *Communication from the European Commission and their Member States, "the relationship between the provisions of the TRIPS Agreement and access to medicine, IP/C/W280, 12th June 2001*

⁷¹ U.S, *Submission under item N entitled, "Intellectual Property and Access to Medicine,"-Agenda of the TRIPS Council's meeting dated 18-22 June 2001, JOB(01) 97/Add.5 TRIPS Council 28th June 2001*

It appears to me that the enforcement measures of the TRIPS Agreement are built to play the role of pointers indicating the legal route through which Intellectual Property protection may be achieved. However, the same enforcement measures operate as a ground on the basis of which economic sanctions may be justified. The TRIPS Agreement lays down enforcement procedures, but it lacks the flesh of substance as would obtain consistency. This state of ambiguity as regards the distinction between positive law and international law norms is the main reason of divergent opinions among international law jurists as regards the basis of compliance with international instruments. Some commentators⁷² espouse a line of thought that sanctions as an enforcement pattern may be unsuccessful as they entail high cost and lack of legitimacy. They contend that international treaty norms may provide an authoritative groundwork in persuading compliance. The offered alternative is a management strategy. They maintain that the managerial strategy is apt to succeed if the required components are satisfied such as, inter alia, transparency, strategic interaction, coupled with active management such as capacity building, technical assistance and a proper dispute settlement mechanism. Another commentator⁷³ argues that the realities of compliance indicate that compliance strategies must adjust to varying conditions, in each agreement, and must be tailored to suit the stage of development in respect of each nation-state. One commentator⁷⁴ takes the view that compliance could be maintained if the criterion of fairness is observed.

Another⁷⁵ entertains the view that compliance with an international instrument can be achieved, provided however, that voluntary obedience and internalized compliance are ensured. He contends that normal internalization is a prerequisite to compliance which emanates from obedience. In explaining his view one can not do better than to quote his words. He said "when I was in the government, I learned the tragedy that those with ideas have no influence and those with influence have no ideas. There is a tragic triangle: Decision makers promote policy without theory, activists implement tactics without strategy, and scholars generate ideas without influence. I try to overcome this tragedy through the concept of transnational legal process. I do not believe that international law is self-executing, but by promoting norm internalization, lawyers, policymakers, and scholars can promote greater compliance with international law."⁷⁶ One commentator expressed a different view. He said "A better conception of international law rules sees it as serving the people on this globe, not their governments. Legal rules and processes should be interpreted in the light of human values, not state values."⁷⁷ The author said these words in an attempt to provide a conceptualization, in terms of a general

⁷² Cf. Abram Chayes & Anonia Handler Chayes, "The New Sovereignty: Compliance with International Regulatory Agreements" (Harvard University Press, London, 1995). The required components, in addition to active management are: transparency, strategic interaction, reporting and data collection, policy review and assessment, non-governmental organizations.

⁷³ Edith Brown Weiss, "Understanding Compliance with International Environmental Agreements: The Baker's Dozen Myth," 32 U.Rich. L.Rev. (1999)

⁷⁴ Cf. Thomas Frank, "Fairness in International Law and Institutions: Oxford University Press. New York, (1995)

⁷⁵ Cf. Harold Hongju Koh, "Why do Nations Obey International Law?" 106 Yale Law Journal 2599 (1999) Internalized compliance takes place when the "rule is interpreted through the interaction of transnational actors in a variety of law declaring fora, then internalized into a nation's domestic legal system."

⁷⁶ Cf Harold Koh, "The Value of Process," available at <http://law.ubaut.edu/asil/koh.html> at p.2

⁷⁷ Cf. Fernando Teson, "Defending International Law" available at <http://law.ubaut.edu/asil/koh.html> at p.2

justification, as to why war was launched against Iraq, irrespective of international law norms. The author, paradoxically admits, that it was certainly unlawful.

This argument can be seen to be flawed as one realizes that the position of the factual reality does not support such a view⁷⁸. The relevant and crucial questions are: do the economic retaliation measures or sanctions, imposed by the U.S.A on some LDCs to ensure enforcement mechanism, under the TRIPS Agreement, can serve the people on the globe; and can be interpreted in light of human values, even when such retaliation measures touch on public health concerns?⁷⁹ Does any evidence exist, on the basis of the alleged human values concept, that developed countries place the right of LDCs to development at the top of their priorities? Or to put it in another way: does any evidence exist that developed countries place global human dignity and human values above their own interests? The concern of developed countries in technology transfer ends where such concerns clash with corporate profits: does such an approach serve the people on the globe? However, the issue that remains difficult to dispose of is this: which legal perspective, ideology or doctrine shall play the major role in the process of internalization. It is axiomatic that liberal democracy and its associated political economy theory of enforcement may be a compelling option having active players, however can other legal perspectives, doctrines or ideologies be interacted, given the widening gap between developed and developing countries? Developing and least developed countries are, as a matter of fact, unable to counterbalance and thus are forced to submit to developed countries hegemonic control of the global system.

VI. Compulsory Licensing was a product of Western Heritage.

The provision obliging a foreign patent owner to work his patent locally, in conformity with the law of the country into which he introduces the patent objects, as prescribed under the Paris convention, was a western heritage which could be traced in the history of modern Europe. Most of the intellectual, political, economic and social characteristics associated with modern Europe came into being during the Enlightenment era⁸⁰. During this period Europe became the larger exporter of ideas and technologies. The stipulation of local working of patents was a reflection of the concept of territoriality. The nation-state was based on the concept of territoriality which was first launched in Europe following the treaty of Westphalia,⁸¹ though its actual vigor appeared during the Enlightenment era.

The main question for a nation-state was to carry out its affairs exclusive of exterior pressure in the governance of its internal affairs as to ensure state autonomy and

⁷⁸ Cf. Elias Davidson, "comment on Fernando Teson's article "defending international law" available at <http://law.ubaut.edu/asil/koh.html> pp.2-4

⁷⁹ South Africa initiated the Medicine & Related Substance Control Amendment Act which took effect in May 2003 to address the incidence of HIV/AIDS epidemic and ensure availability of Antiretroviral (ARV) treatment by invoking parallel importing and compulsory licensing. The U.S.A reacted to the amendment by intimidating South African Government with economic sanctions.

⁸⁰ Cf. Donald Kagan, "the western Heritage," vol111 (1995) Prentice Hall, Inc at p. 647, see also Chodorow, Knox, Schirokaues, Strayer, Gatzke, "the mainstream of civilization since 1500, six edition, the Harcourt Press at pp.619-625, see also D. Landes, "the unbound Prometheus (1992), see also T.Kemp, "industrialization in the nineteenth Century Europe" (1969)

⁸¹ The treaty of Westphalia of 1648 paved the way for the formation of a confederation of independent states including France, Germany, and Sweden following the thirty years war. The treaty of Westphalia introduced the concept of territory, state autonomy and sovereignty.

sovereignty. During the late nineteenth century democratic concepts prevailed which ultimately changed the political legitimacy of the state from the king to the people. The democratic revolutions that occurred were inspired mostly by the English constitutional system to the effect that the concept of state sovereignty representing the general populace was firmly embedded in English constitutional law. Consequently, regulations of industry and businesses connected with public interest were considered as the key elements to determine state governance ability.⁸² It may be in order to indicate that the community patent convention of 1975 maintained the territoriality concept where Article 45(1) provides that “any provision in the law of a Contracting State or the grant of compulsory licenses in respect of national patents shall be applicable to community patents. The extent and effect of compulsory licenses granted in respect of community patents shall be restricted to the territory of the state concerned.” Insofar as the underlying policy behind EC is to eliminate boundaries between member states, it seems appropriate, to bestow on the patent holder an unfettered discretion to elect where to locate the factory for working out the patent. However, the territoriality concept prevailed.

Perhaps it is of prime importance to point out that the changes followed the Industrial Revolution may be attributed to a state insistence on local working of patents. During the European Enlightenment between 1750 and 1850 Europe turned out to be the sole exporter of manufactured commodities.⁸³ However, during the third quarter of the nineteenth century, heavy industries experienced considerable development, to the effect of witnessing heavy new industries.⁸⁴ This was the period named by historians as the second industrial revolution, in contrast to the first industrial revolution which was correlated with the textile industry, steam and iron.⁸⁵ The second industrial revolution was associated with steel, chemicals, electricity and oil.⁸⁶ The Europeans productive capacity attained during this period, coupled with their naval power, paved the way for major European countries to control the markets of the world. As a result, acquiring industrialization was a prerequisite to be strong, independent and modern. In the same vein, imitation of the manufacturing techniques available at that time was of paramount importance.⁸⁷

With a view to maintaining a sustained economic growth in such an environment where rivalry was the norm, it was quite normal to oblige the patentee to work his patent locally. Article 5 A of the Paris Convention version 1883 reads as follows:” the introduction by the patentee into the country where the patent has been granted of objects manufactured in any of the states of the Union shall not entail forfeiture. Nevertheless, the patentee shall remain bound to work his patent in conformity with the laws of the country into which he introduces the patented objects” failure to work a patent was a

⁸² Cf. Miguel De La Madrid H. “ National Sovereignty and Globalization,” 19 *HOU.S.J.Int’L.L* (1997)

⁸³ *Supra* note 76at p. 647

⁸⁴ *ibid*

⁸⁵ *ibid*

⁸⁶ *Ibid* It should be noted that during the second industrial revolution key technologies were discovered such as Henry Bessemer & Siemens-Martin breakthroughs in connection with combustions gases utilized in the steel industry. Alfred Nobel invention of the stabilized nitroglycerine in the area of chemicals is another significant breakthrough. Again, in the area of electricity the inventions of Alexander Graham Bell of the telephone and of Guglielmo Marco of Radio revolutionized the communication industry.

⁸⁷ *ibid*

justification for forfeiture. The question of compulsory licensing was not envisaged at the time the Convention was drafted. The only option for failure to work the patent was forfeiture. This shows how the approach had been very strict. Compulsory licensing was introduced in the 1925 revision as a measure to ensure working of the patent. If this measure failed then forfeiture would be imposed as a foregone conclusion. .

The first major public power plant was constructed in Britain in 1881, just two years before the Paris Convention was promulgated or put into operation.⁸⁸ The internal combustion engine giving birth to the automobile industry was invented in 1886 by the German engineer Gottlieb Daimler who obtained a French patent in 1887. It is in order to indicate that the middle of the eighteenth century witnessed wars between European countries for dominance in Western Europe. In this connection one can cite the wars between Austria and Prussia. In connection of commercial and colonial dominance one could cite the wars between Britain and France. Perhaps of prime importance to mention that the wars of the French revolution and of Napoleon stretching from 1792 to 1815 stimulated the political vigor of nationalism which has provided evidence to be the main influential ideology of the modern world.⁸⁹ As a matter of fact, nationalism as political ideology was employed in Europe at that time as a justification of wars of aggression. On other hand, it was employed to liberate people from domination of another nation.

As regards recent history, it is submitted that most of the industrialized countries have experienced the use of compulsory licensing. In the U.S.A Federal Courts have passed decrees authorizing the Use of compulsory licensing to regulate misuse of patents including antitrust violations. However, since 1988 the U.S.A Federal Courts have passed comparatively little compulsory licensing decrees.⁹⁰ Again, the Federal Trade Commission has made a wide-ranging use of compulsory licensing in the process of corporate merger and acquisition.⁹¹ The U.S.A has made a wide use of compulsory licensing on the ground of non-commercial public interest to reduce the cost of certain medicines.⁹² It has also employed compulsory licensing to enhance environmental and economic development goals including major power generation projects.⁹³

The United Kingdom has amended the provisions of its Patent Act in connection with compulsory licensing as of July 29, 1999 in response to an adverse comment contained in the ruling of the European Court of Justice in *Smith-Kline and French Laboratories V Generics*.⁹⁴ However, the U K Patent Act of 1977 provides for compulsory licenses in ss.48, 50. Grounds on the basis of which compulsory licenses may be sought are clearly spelled out in the said provisions. Compulsory licensing may be invoked where the patented invention is capable of being commercially worked out in the UK, however, it is not so worked, or is not worked to the fullest extent. Another ground where the patent invention is a product and the demand for that product in the UK is not being met on reasonable terms or it is being met to a substantial extent by importation.⁹⁵

⁸⁸ *ibid*

⁸⁹ *ibid*

⁹⁰ Cf. Jerome H.Reichman, “ Non-Voluntary Licensing of Patented Inventions,” UNCTAC-ICTSD, Issue Paper No.5 at p.4

⁹¹ *Ibid* at p.5

⁹² *Ibid*

⁹³ *ibid*

⁹⁴ *Smith-Kline and French Laboratories v Generics* [1990] 1CMLR 416

⁹⁵ Cf. W.R Cornish *supra* note 50 at p.116

Again, compulsory licenses may be invoked where the patent product is capable of being commercially worked out in the UK, however, it is hindered or prevented from being so worked by importation of the product or where the invention is a process by importation of a product obtained directly by means of the process or to which the process has been applied.⁹⁶ Again, compulsory licenses may be triggered, in the event the patent owner refused to grant a license on reasonable grounds, to the effect that a market for the export of any patented product made in the UK, is not being supplied or the working or efficient working in UK of any other patented invention which makes a substantial contribution to the art is prevented or hindered or the establishment or development of commercial or industrial activities in UK is unfairly prejudiced.⁹⁷ Once more, compulsory licenses may be granted where the patent owner abused his rights under the grant.⁹⁸

In February 1993 Canada made an amendment to its Patent Act to the effect of utterly abolishing the compulsory licensing regime. The machinery of compulsory licensing as used in Canada prior to elimination of the compulsory licensing regime was explained by the Court of Appeal in *Eli Lilly & Co v Novopham Ltd*⁹⁹. Canada has made extensive use of compulsory licensing particularly as regards pharmaceuticals and food patents. Parliament has deliberately provided for restriction to the right of a patentee. Article 41(4) as amended in 1969 reads as follows”:

(4) Where, in the case of any patent for an invention intended or capable of being used for medicine or for the preparation or production of medicine, an application is made by any person for a license to do one or more of the following things as specified in application namely:

(a) where the invention is a process, to use the invention for the preparation or production of medicine, import any medicine in the preparation or production of which the invention has been used or sell any medicine in preparation or production of which the invention has been used, or

(b) Where the invention is other than a process, to import, make, use or sell the invention for medicine or for the preparation or production of medicine.

The Commissioner shall grant to the applicant a license to do the things specified in the application except such, if any, of those things in respect of which he sees good reason not to grant such a license; and, in setting the terms of the license and fixing the amount of royalty or other consideration payable, the commissioner shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention and for such other factors as may be prescribed.

Compulsory licensing, in Canada, was the main device contributing to a huge generic medicine industry.¹⁰⁰ Utilization of the compulsory licensing device enabled generic pharmaceuticals to reach high production levels. As a consequence, Canada experienced low drug price compared to other industrialized nations. It is pertinent to

⁹⁶ *Ibid*

⁹⁷ *ibid*

⁹⁸ *ibid*

⁹⁹ *Eli Lilly & Co.v Novopharm Ltd.*, [1998] 2 S.C.R.129, 1998 CanLII 791(S,CC.), *Parallel Citations*: [1998], 161D.L.R(4TH) 1; [1998],80C.P.R(3d) 321; [1998];[1999]

¹⁰⁰ Cf. Jerome H.Reichman, “ Non-Voluntary Licensing of Patented Inventions” *Supra Note 82 at p.4*

indicate that prior to February 1993 failure to work patents locally was deemed an abuse of patent rights which justifies compulsory licensing. On the other hand, compulsory licensing as regards medicines and food used to be imposed under the public interest justification. In *Parke, Davis & Co v Fine Chemicals of Canada Ltd*¹⁰¹ Rand J., in stating the policy underlying a compulsory license in connection with new medicines prepared for patented process was reported to have said that compulsory licenses “are in the public interest, to be free from legalized monopoly.”¹⁰² The same underling policy was concisely stated in *Hoffman-la Roche Ltd v Delmar Chemicals Ltd*¹⁰³ where Thurlow J., said “I would carry the matter a stage further and say that the subsection also aims at freeing the new process from the absolute control of the patentee by denying him both the exclusive right to refuse licenses and this to prevent the use of the process by others and the right to dictate the terms of a license.”¹⁰⁴

Again, in *Hoffman-La Roche Ltd v. L.D Graig ltd, Bell Graig Pharmaceuticals Division*¹⁰⁵ Jackett J., was reported to have said, “In my view, the objective of the provision is to bring about competition. On balance, in most fields, competition is regarded by Parliament as being in the public interest and also because competition tends to bring about greater efficiency, better service, and further research. The monopoly granted by an invention is an exception to this general principle in our law. Section 41 (3) was passed because in the field to which it applies the specific public interest in free competition was deemed to be more important than maintenance of patentee monopoly rights”¹⁰⁶

On appeal¹⁰⁷ the court speaking through Abbot J., said, “In my view the purpose of s. 41(3) is clear. Shortly stated it is this: no absolute monopoly can be obtained in a process for production of food or medicine. On the contrary Parliament intended that, in the public interest, there should be competition in the production and marketing of such products produced by a patented process, in order that as the section states they may be available to the public at lowest possible price consistent with giving to the inventors due reward for the research leading to the invention.”¹⁰⁸ The question of compulsory licensing was squarely placed before the Supreme Court of Canada in *Frank v. Horner Ltd v Hoffman-La Roche Ltd*,¹⁰⁹ a case decided after s. 41(3) was amended to read as s. 41(4); however the basic purport was kept intact. In that case A.M. Laidlaw J was reported to have said, “In short, compulsory licenses applied under s.41 of the Patent Act leave little discretion to the Commissioner of Patents. These licenses, in fact, amount to licenses of right. What the Commissioner of Patents is required to do is mandatory unless he sees good reason not to grant the license applied for.”¹¹⁰

VII. Compulsory Licensing and Strategic Patent Protection.

¹⁰¹ 30 C.P.R 59

¹⁰² *Ibid* at p.62

¹⁰³ 43 C.P.R 93, 64 D.L.R (2d) 140(1965) Ex C.R 611

¹⁰⁴ *Ibid* at pp.97-98

¹⁰⁵ 46 C.P.R 32(1965) 2 EXC.R266

¹⁰⁶ *Ibid* at p.50

¹⁰⁷ 48 C,PR 137 56D.LR (2d) 97 (1966) S.C.R 313

¹⁰⁸ *Ibid*

¹⁰⁹ 61C.P.R 243 January 20, (1970)

¹¹⁰ *Ibid*

By virtue of Article 31 of the TRIPS Agreement, a member may determine the grounds for granting a compulsory license on the basis of “individual merits”¹¹¹. However, the conditions are identified in circumstances such as national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use, anti-competitive practices, semi-conductor technology and dependent patents.¹¹² Compulsory licensing operates to trim down the power of the exclusive rights conferred by a patent. Its application arises where a patent protection exists in countries where an inventor has received a valid patent. Good patents are expensive and should be filed in each country in which protection is sought.¹¹³ It is now firmly embedded in law that if an inventor elects not to secure protection in a particular country or a market, any interested person may make use, offer for sale or sell the product in that market or use the process or produce the product for export. In historical fact, the underlying justification for compulsory licensing was to maintain a state's national security and public interest. Compulsory licensing is a device utilized to meet domestic needs by limiting importation of a patented product and ensuring that lack of exploitation by the patentee will not impede the export market being supplied with the patented product.¹¹⁴ The state's ability to surpass the patentee's non-authorization after being consulted is a crucial counterbalance to absolute monopoly power.

As a matter of fact, the great majority of patents are owned by larger corporations or multinational companies having the financial capacity to undertake the required research. Accordingly, it is a pre-condition to funding that ownership of all patents rights shall bestow on these corporations. The financial capacity of larger corporations provides them with the power to utilize the regime of patent protection in a manner conducive to claim ownership in many inventions.¹¹⁵

The prime goal of an offensive patent strategy is to set up an extensive patent protection to the extent of controlling a particular business area in the territories covered by the patent.¹¹⁶ On the other hand, the main purpose of the defensive patent strategy is to utilize well calculated measures to preclude others from patenting in a specific field. Larger corporations prefer to employ their patents defensively with a view to protecting strategic technologies more willingly than to license them to non-competing companies.¹¹⁷ Immediate competitors would be perfectly debarred. Patents are considered strategic assets which deserve to be defended to boost up the company's

¹¹¹ Paragraph 31(a) of the TRIPS

¹¹² Paragraphs 31(b) and (c)

¹¹³ Article 28 of the TRIPS

¹¹⁴ Cf. W.R Cornish *supra* note 50 at p.116

¹¹⁵ See generally Marc A. Hamilton, “the TRIPS Agreement: Imperialistic, Outdated, And Overprotective,” 29 *VAND.J.TRANSNATIONAL LAW* 613 (1996), see also S.Musungu & G.Dulfield, “Multilateral Agreements and a TRIPS-Plus World: The World Intellectual Property Organization (WIPO), TRIPS Issue Paper 3, Quaker United Nations-Office Geneva 2003, available at www.Geneva.Guno.Info/pdf/WIPO.

¹¹⁶ See generally Jean O. Larjoue & Mark Schrkerman, “Enforcing Intellectual Property Rights,” Working Paper 8656 available at <http://www.nber.org/papers/w8656> at p. 3

¹¹⁷ Cf. Merz J. “Disease Gene Patents: overcoming Unethical Constraints on Clinical Laboratory Medicine,” *Vol.45 Clinical Chemistry* at p.224

competitive edge and earning capacity.¹¹⁸ It is pertinent to indicate that some of these inventions may not be put into operation and others may be filed to perplex competitors. Again, patent monopolies lead to keeping research findings under wraps in a manner that would ultimately restrict the dissemination of research findings and hence slow down the advancement of research. Such a state of affairs will provide transnational companies the chance to deal with the entire world as their untreated field of open wealth, workforce and consumer market.¹¹⁹ On account of this, patent monopolies result in economic distortions in the like manner that trade tariffs or quoted quotas steer economic distortions,¹²⁰ however, the extent of distortions in the former case is excessive. Consequently, the earliest notion of the patent as an individual or an entrepreneurial right does no longer survive.

At present an inventor may be one who has put in a significant part to an invention, as a minimum, one of the claims scheduled in the patent is attributable to that inventor. The argument that diminutive protection usurps innovators from the fruit of their creativity i.e. the predictable reimbursement in substitute of making a full and complete disclosure can no longer be convincingly upheld. The general view even in major industrialized countries such as the U.S.A is that the direct reason of elevated drug prices is government approval of patents monopolies, which permits drug companies to charge prices commonly 400 percent or extra on top of competitive market prices. Lack of competition in some industries entails high profits. This is due to the fact that rival companies have no access to critical inputs such as skilled labor and entrepreneurship.¹²¹

This signifies a vital resource limitation and hence the likelihood of unusual profits. Given these facts, the likelihood of some of the developing countries being entirely competitive is highly remote in the near future. In addition to that lack of specialist knowledge in appraising investment in innovative pursuits may add to the technological gap. Again, Research and Development (R&D) requires a science-base sector which is

¹¹⁸ See generally Frederick M. Abbott, "First World Assets in the Third World: intellectual Property Negotiations in the GATT Multilateral Framework," 22 *VAND. J. TRANSNAT'L. LAW* 689 (1989), see also Frederick M. Abbott, "The Future of the Multilateral Trading System in the Context of TRIPS," 20 *Hasting Int'l & Comp. L. Rev.* 661 (1997)

¹¹⁹ See generally James Boyle, "A Politics of Intellectual Property Environmentalism for the Net," available <http://www.law.duke.edu/journal/dli/downloads/dlj47p87.pdf>, where the write states at p.9, There are structured tendencies in our pattern of thinking and discourse about intellectual property that lead us generally to "over" rather under protect and that partly as a result we are currently in the midst of an intellectual land-grab, and unprecedented privatization of the public domain."

¹²⁰ *The Ministerial Declaration on the Uruguay Round: Declaration of 20th September 1986 in GATT Basic Instruments and Selected Documents (BISD) reprinted in 25 ILM 1623-1626 (1986) the negotiators were not oblivious to the question of distortion where it was stated in the said declaration that, "in order to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedure to enforce intellectual property rights don't themselves become barriers to legitimate trade, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines,"*

¹²¹ See generally Keith E. Maskas, "the role of intellectual property rights in encouraging foreign direct investment and technology transfer," *Duke. J. C. Int'l. Law* 109 (1998), see generally Ruth L. Gana, "prospects for developing countries under the TRIPS Agreement," 29 *VAND. J. TRANSNATIONAL L.* 735 (1996)

weak or not sufficiently available in developing countries¹²². In the industrialized countries such as the U.S.A public and the private sector engage to perform R&D utilizing specialized governmental facilities regularly having exceptional potentialities not available to the private sector such as equipment, expertise and information. In cases where the information is of high interest to the scientific community at large a Cooperative Research & Development Agreement (CROA) will be structured. This entails sharing information, exchanging personnel, finding technical assistance, utilizing distinctive government laboratory facilities and potentialities, licensing patent and technical know-how, forming consortia and using technology built-up by virtue of government contracts.

Some commentators espouse the view of establishing publicly aided research centers through purchase of patents by governments and set them in public domain.¹²³ A host of other suggestions are offered such as zero-cost compulsory licensing founded on value and extent of use, a mandatory employer developed research fee to be distributed to researchers, curtailing expenses squandered on excessive marketing, and duplicate research. Moreover, it is suggested that research and development of copycat drugs may militate against the present crisis. This suggestion is structured on the ground that developing countries in reliance on paragraph 39.3 of the TRIPS¹²⁴ are entitled to undertake testing to establish the bioequivalence of generic products before expiration of the relevant patent on the premise that protection as regards test data is confined to chemical entities to the effect that usage for second and further applications is permissible.

The conflict between the yearning of the industrialized countries to control the justifications of compulsory licensing and the developing countries to ease and make things easier as regards compulsory licensing typified the TRIPS negotiations.¹²⁵ As a compromise article 31 of the TRIPS provides in pertinent part for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, subject to certain conditions such as assessment of the other use on its individual merits, securing prior authorization from the right holder. However such authorization may be waived in the case of national emergency or other circumstances of extreme urgency or in case of public non-

¹²² See generally Robert M. Sherwood, "Promotion of Inventiveness in Developing Countries Through a more Advanced Patent Administration," 39 IDEA J.L&T (1999)

¹²³ Cf. Establishing a "Development Agenda" for the World Intellectual Property Organization, Submitted by Brazil and Argentina to 40th Series of Meetings of the Assemblies of the Member States of WIPO and to the 31st Session of the WIPO General Assembly 27 September-5 October 2004 at p.5

¹²⁴ Paragraph 39(3) reads, "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involve a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.

¹²⁵ See Michael Blakeney *supra* note 3 at pp. 2-9.

commercial use or in the event that prior to use the right holder declined to provide authorization though reasonable commercial terms were offered.¹²⁶

In a case of anti-competitive practice, prior consultation is not required, and the amount of remuneration will be assessed on the need to correct the said anti-competitive practice. In the case of semi-conductor technology, compulsory licensing shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive.¹²⁷ The said use shall be non-exclusive, non-assignable, authorized predominately for the supply of the domestic market subject to payment of adequate remuneration to the right holder and adequate protection of the legitimate interests of the authorized person. As a safeguard, the right for judicial review to assess legal validity of the authorization and adequacy of the compensation is provided for. Article 7 entitled objectives sets down a subtle weighing scale between the requirement to recompense inventors and the demand for technological dissemination. It aims at striking a balance that protection and enforcement of intellectual property rights may eventually lead to the promotion of technological innovation and the transfer of technology.¹²⁸ Again, article 8 provides that members may adopt the necessary required measures to protect public health and nutrition, insofar; as such measures are not contravening the provisions as contained in Article 31 of the TRIPS which deal with compulsory licensing.

It is obvious that the TRIPS Agreement does not thoroughly itemize the basis for granting of a compulsory license without prior authorization of the right holder. However, as hereinbefore stated a number of conditions were indicated such as national emergency or other extreme urgency, public non-commercial use, to remedy an adverse anti-competitive practice as determined by a competent judicial and administrative authority. In other instances, such as the case of a dependent patent, prior consultation with the patentee is required unless an unsuccessful effort has been exercised and proved to be futile¹²⁹. The effort must be in line with normal commercial practices. Overriding public interest furnishes the ground for exploitation by the government or any other authorized third party. Failure to supply necessary products such as drugs at affordable prices justifies compulsory licensing within the ambit of public non-commercial use.¹³⁰

Access to drugs at reasonable prices may be difficult to achieve in a country facing financial hurdles, physical and infrastructure barriers, in addition to the information gap. In the same vein, compulsory licensing may be executed by means of parallel importation from compulsory licensees of patent products where the size of the market does not justify local manufacturing. Concomitant to this, a compulsory licensee can export the products to other markets. The said measures are considered to be effective

¹²⁶ Paragraph 31(b) of the TRIPS

¹²⁷ Paragraph 31 (c) of the TRIPS

¹²⁸ See generally G. Rodriguez Stevenson, "Trade Secrets: The Secrets to Protecting Indigenous Ethno biological (Medical Knowledge) 32 *N.Y.U.J.Int'l & Policy* (2000), see also Carlos M. Correa, "Trends in Technology Transfer: Implications for Developing Countries," 21 *SCI& Pol'y* 369 (1994) (U.K)

¹²⁹ See paragraph 31 (L)

¹³⁰ Paragraph 31 (a) of the TRIPS Agreement.

machinery apt to force intellectual property rights holders to sell their protected products of high need at reasonable affordable prices.

In connection with access to essential medicine, developing countries have argued that the TRIPS Agreement does not limit their sovereignty to address epidemics such as HIV/AIDS, tuberculosis, and malaria. They entertain the view that compulsory licensing; and parallel importation are permissible objectives that do not violate the TRIPS Agreement. They contend that the Ministry of Health in any developing country may on the basis of national security and the public interest, authorize an importer to procure essential drugs not manufactured by the patentee to meet national health requirements¹³¹. Developed countries, particularly the U.S.A and Switzerland have argued that the only flexibility in the TRIPS Agreement is the deferred implementation periods developing countries can enjoy under the agreement. One would hope that Article 31 is to be given its ordinary sense and is not to be watered down. Any effort to whittle away the privilege conferred by the said article may have a negative impact. Access to essential medicine represents the first dispute between developing and developed countries as regards the TRIPS Agreement. Developed countries adopt the view that high level of intellectual property protection, furnishes the needed incentive for investment in research and development, which is the paramount guarantee to access to indispensable medicine for all countries.¹³² In contrast, developing countries advocate the view that strict construction of the TRIPS Agreement fails to recognize the legitimate interest of these countries.¹³³

The ministerial Declaration on TRIPS and Public health adopted by WTO ministers in the Doha Round in December 14, 2001 entitled "Doha Ministerial Declaration" clearly delineates the grounds and conditions under which compulsory licensing may be given and at the same time keeping the TRIPS provisions intact. The yardstick in employing compulsory licensing is an exercise of an assessment of the public interest of working the patent against the public interest in the protection and enforcement of intellectual property rights. The relevant country is obligated to weigh up the competing interests. In light of the predictability needed in the intellectual property regime, the public interest of working the patent must outweigh the public interest in the protection and enforcement of intellectual property. However, such a decision as stipulated in paragraph 27.1 of the TRIPS must be made without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

VIII. Compulsory license is a device to obtain technology transfer.

Pursuant to the Doha mandate on trade and technology transfer, developing and LDCs countries may avail themselves of the flexibility built in of the TRIPS Agreement to revive the requirement of patent local working, insofar, as the mechanism to ensure transfer of technology is not sufficient. Joint ventures agreements may incorporate

¹³¹ See Frederick. M. Abbott, *supra* note 47 at p 28, see also T. Kongolo *supra* note 46 at p. 629.

¹³² See Keith E. Maskas, "The role of Intellectual Property Rights in Encouraging Foreign Direct Investment," *supra* note 110

¹³³ Cf. Frederick M. Abbott, "The New Global Technology Regime: The WTO TRIPS Agreement and Global Economic Development," 72 *CH-Kent. L.Rev.* 385 (1996)

conditions to promote technology transfer. It is submitted that one of the most important channels of international technology transfer is direct transfer of technology through international licensing agreements. Yet again, importation of intermediate products and capital equipment which is an international trade facet represents a crucial channel of international technology transfer. Concomitant to this, the process of exporting into industrial countries provides knowledge spillovers as the mechanism of exporting itself operates to import learning. Nonetheless, transfer from a TNC to its local affiliates remains an important channel of international R&D spillovers. Foreign ownership normally imparts local firms with well-organized corporate governance apt to raise the level of technological capabilities and managerial skills.¹³⁴ Yet, public-private partnerships may incorporate similar provisions to meet practical technological challenges.

Cooperative technology ventures may be employed to generate practical positive results. Needless to say foreign direct investment should be encouraged with the requisite safeguards prone to promote technology transfer. It is germane to this point to state that what matters in technology transfer is the domestic absorptive capability of the developing or LDC country rather than the transactional structure. The aptitude to ascertain, absorb and exploit knowledge spillovers would ultimately determine the effect of technology transfer. A well structured contract without adequate implementation is a paper work. Again, the relationship between technology transfer and IPR protection is not an exercise of a mechanical process. Technology transfer is a specialized process importing diversified disciplines. It comprises public and competition policies, intellectual property rights, know how, trade, technology and a host of other matters.¹³⁵

Developed countries stressed the alleged positive economic returns that would accrue to developing countries through stronger IPR protection such as increased technology transfer, greater inflows of foreign investment, economic growth and higher standards of living. Now the question is: how can intellectual property protection pave the way for technology transfer in countries lacking the requisite capacity to absorb technology?¹³⁶ Articles 66, 67, 69 portray the extent of developed countries commitment as regards technology transfer. It seems difficult to find a link that enhanced protection of IPR protection in developing countries would actually result in increased technology transfer to these countries, insofar, as the called for technology transfer shall be provided on request. It appears from the above indicated articles, that for the developed countries, combating trade in counterfeit goods and pirated copyright goods is a condition precedent

¹³⁴ cf. Michael Blakeney, "legal aspects of the transfer of technology to developing countries," Oxford 1989 ESC Publishing.

¹³⁵ Cf. Branscomb, L. & Auerswald, P, " Taking Technical Risks: How Innovators, Executives, and Investors Manage High-Tech Risks, MIT Press, Cambridge, MA

¹³⁶ Cf. Forging Ahead, Technological Innovation and the Millennium Development Goals. Final Report of the Task Force On Science, Technology and Innovation, United Nations Millennium Project Commissioned by the Secretary-General Kofi Annan, November, 2004-13TF10 Report. In p.13 it was stated, "Technological innovation is therefore not simply a matter of installing of devices, but a transformation of society and its values systems. It defines "new technologies" in two ways. First, new technologies include applications in new areas, irrespective of whether the technologies have been used in other parts of the world. Second, the concept of new technologies is used to denote the use of emerging technologies, including information and communications technologies (ICTS) biotechnology, nanotechnology, and new materials."

to considering technology transfer to developing and least developed countries. If the developing and least developed countries labored hard through their contact points, and eventually succeeded to substantially curtail the illegal practice, then technical cooperation and technology transfer would be considered on request, but would not ensue as a logical inference with a clear cut obligation.

In connection with LDCs there exists a commitment carried in the phrase "shall provide incentives to enterprise and institutions" Here again, the commitment does not relate to technology transfer but to recommendations in the form of incentives to encourage enterprises and institution in their territories to provide the core bargain underlying the TRIPS Agreement. It is evident that technical assistance, envisaged under the TRIPS Agreement, to emanate from developed countries to developing and LDCs countries is not couched in terms implying an obligation. Nor does Article 67 embrace mandatory machinery for cooperation. The TRIPS Agreement embraces novel great measures embodying developed countries commitment to assist developing countries. Nevertheless, the said commitment, as it appears to me did take the form as to be considered legally binding. Placed in this context, one may ask what is the difference in the context of a nation-state's reputation between a legally binding stance or a declaratory pronouncement and a moral stance. Does the wording as contained in articles 66, 67, and 69 could be interpreted to a have legal effects or quasi-legal effects or just a moral recommendatory effect? Again, does the failure of transfer technology by developed countries to developing countries warrant a negative sanction in the sense of providing developing countries with a moral force to slacken intellectual property protection? As aptly observed by one commentator, "International law becomes a purposeful law, no longer merely reflecting international conduct, but instead a tool to achieve certain goals."¹³⁷

Pursuant to WTO Ministerial Decision taken at Doha Conference in November 2001, relating to implementation of Article 66.2, it is incumbent upon developed countries to submit reports on actions taken or envisaged to be taken to provide incentives to TNCs and institutions in the developed countries for the promotion of technology transfer to LDCs. Paragraph 37 of the Doha Ministerial Declaration provides for creation of a Working Group on trade and technology transfer. The main mission of the said Group is to examine the relationship between trade and transfer of technology with a view to suggesting recommendations on the requisite steps that might be taken within the WTO mandate to increase the flow of technology to LDCs.

Transnational Companies (TNC) in the industrialized world hold just over 97% of all registered patents.¹³⁸ Local working of a patent is governed by commercial considerations such as the size of the local market and the available technological infrastructure. A weak technological capacity of the recipient country hampers the transfer and dissemination of technology. Technological capacity entails both the ability to create new technology and to adapt and modify technology available in another place. Most Research and Development (R&D) undertaken by multinational companies was

¹³⁷ Cf. R.Rich, "The Right to Development as an Emerging Human Right," 23Vol. Virginia J. of. Int'L.Law. at p.287 (1983)

¹³⁸ Cf. The Agreement On Trade Related Aspects of Intellectual Property (TRIPS)-Globalization and The Impact on Health-A third World View-Issue Papers at p3, available at <http://www.phmovement>, see also UNDP 1999:68

done within the industrialized nations.¹³⁹ Developing countries depend on TNC for technology transfer, however, Article 27(1) of the TRIPS Agreement, under the pretext of non-discrimination permits importation of patented products. This provision equates actual working of the invention in the country with importation. Such an approach would deprive the local cadre or innovators of the opportunity to have access to technological information.

The only avenue open, under the circumstances, is to resort to the process of reverse engineering which is a categorical violation of the TRIPS mandate.¹⁴⁰ Again, at present the greater part of technology transfer stands for cross-border merges and acquisitions. As has been shown by UNCTAD 70% of the global payments of royalties and fees represent business deals between parent companies and their foreign affiliates. In 1996 the level of TCN investment in foreign affiliates amounted to US\$ 1.4 trillion. Only a quarter of this amount represents Foreign Direct Investment flows. The developing and least developed world are in dire need for genuine technology transfer to be harnessed in the process of economic development.

Technology transfer is a process of transferring intellectual property, employing the appropriate legal vehicle, from one technology developer organization to another innovation-seeking organization, to the effect of attaining scientific and technical progress in a specific industry open to the user. The user of the technology may be in a position to enhance the technology further into new products, processes, materials or services as would upgrade the user's industrial capabilities. The process would ultimately raise the standard of living in a nation, improve quality of life and hence boost up economic growth. Technology transfer is the bedrock of industrial countries economic success. A highly related matter is commercialization, which is the mechanism employed to transform an invention into a valuable application in industry or introducing a new product to the market. Technology transfer embraces an array of official and unofficial cooperation between technology producers and technology users. It is not only confined to the transfer of knowledge and technical know-how but it also includes physical devices and equipment. The means employed to obtain technology transfer encompass licensing, information dissemination, technical meetings, joint research, cooperative agreements, cooperative and research development agreements.

The most utilized device to transfer technology is the license contract. A license is a contractual arrangement between the licensor and the licensee by virtue of which the licensor grants the licensee the right to use or develop the technology for a prescribed fee normally termed as a royalty. Licenses fall into three categories, exclusive, partially exclusive and non-exclusive. Technology transfer may be defined as the route of moving research into the commercial arena. American universities¹⁴¹ earn approximately a

¹³⁹ Cf. Loo & Soete L., *"The Impact of technology on economic growth: some new ideas and empirical observation"* Maastricht Economic Research Institute on Innovation and Technology, Maastricht, Netherlands," (1999). The article maintains that R&D may contribute to creating new brands; however it may not imply economic growth.

¹⁴⁰ Cf. Kim.L., *"Imitation to Innovation. The Dynamic of Korea's Technology Learning,"* Harvard Business School Press, Cambridge, U.S.A

¹⁴¹ Cf. Etzkowitz., H., Webster A & Healey P. *"Capitalizing Knowledge: New Intersection of Industry and Academia,"* (1998) state University Of New York Press.

billion dollars in royalties from science and technology which is thus far only a little bit of the royalties ascribed to gigantic patent licensors such as IBM and Qualcomm. Qualcomm Research and Development (R&D) expenses were \$ 252 million in the second fiscal quarter of 2005. The U.S.A has over seven hundred Federal Laboratories which are annually funded at over \$24 billions. The U.S.A government finances approximately fifty percent or thereabouts of all R&D in the U.S.A and employs one sixth of U.S.A scientists.¹⁴²

The utilization of computers extended from Federal Laboratories to corporate America. The U.S.A government expenditure on R&D surpasses Japan, Germany, France and England collectively. A substantial portion of on-the-shelf government inventions are not yet licensed for commercial operations. On account of the above it is obvious that the process of technology transfer requires a great effort including the compulsory licensing option. In terms of magnitude technology transfer is still at the stage of a code conduct. Technology transfer was a major concern of developing and LDCs which were former colonies.¹⁴³ The draft UN code on the transfer of technology embraced provisions urging industrialized countries to put into operation policies aimed at furthering technology transfer to developing and LDCs. Again, the OECD Guidelines of 1967 for transnational companies urged TNC to assist in the field of technology transfer to developing countries.

TRIPS had been accepted by developing and least developed countries against the transfer of technology and the opening of agricultural markets. As a matter of fact, supported by empirical historical evidence, countries adopted stronger patent protection once they have developed strong technology. However, the ability of a country to choose a level of patent protection that corresponds to its level of technology had disappeared with the TRIPS. Again, technology transfer is a long term process, and in the meantime large sums of money will be transferred from developing to developed countries. It is in the interest of all industrialized countries to reinforce their dominant position in research, technological innovation and industrial protection by strengthening intellectual property rights and pressing for worldwide system.

A stronger and enforceable global system of IPRs, would provide principal countries in manufacturing and technology, with unfettered authority to determine how innovative products where to be used and by whom. In this respect, it would be difficult to challenge the dominant position of the industrialized countries in research, technological innovation and industrial production. Technology is the main competitive factor. An intellectual property regime characterized by being too open, as regards technological and scientific achievements, would probably permit developing countries to imitate innovations worked in the industrial world.¹⁴⁴ The competition shown by the NIC countries is considered by countries such as the U.S.A, as an unintended transfer of

¹⁴² See generally Etzkowitz., H & Leydesdorff., L “ Universities and the Global Knowledge Economy: Tripe Helix – University - Government Relations,” Printer Publications, London, UK (1997)

¹⁴³ Cf. Communication from India, World Trade Organization, “Transfer of Technology” WTO (1999) see also Communication from Kenya on behalf of the African Group, WTO (1999) Geneva.

¹⁴⁴ Cf. Kim L., “ Imitation to innovation: the Dynamic of Korea Technology Learning supra note 129

wealth,¹⁴⁵ due to lack of strong intellectual property enforcement machinery, which gave rise to proliferation of counterfeiting and piracy. It is submitted that a strong IP protection, would promote domestic and economic growth, by encouraging the inflow of foreign technology and eventually result in an increase of local innovation. However, NIC countries continue to maintain weak IP protection, due to the strong monopoly power of giant multinational companies. The approach followed by NIC countries does not appear to be a strategic option residing on a trade-off between innovation and imitation. The slow tempo of the dissemination of knowledge due to the monopoly power grip underlies the said approach. The inference is well-nigh irresistible. In the end, the industrialized countries would opt for trade rather than to diffuse their technology. Under the circumstances, imitation may be sought as a vehicle to increase dissemination of knowledge to the effect of furnishing the consumer with cheaper cost varieties.

A strong intellectual property regime would ultimately lead to a technological and scientific monopoly, prone to maintain the status quo, or even reverse the situation, and hence pave the way for industrialized countries' products to dominate the global market. This is made easier by elimination of the obligation to exploit patents locally. Such a change would support multinational companies to recoup R& D expenditure. Under the TRIPS regime patents are an instrument for retaining and increasing industrial capabilities in developed countries, while also controlling commercialization of protected goods and services in the rest of the world. If the new intellectual property regime would ultimately lead to market control, the justification for overseas investment may be substantially weakened. On the other hand, the motive to transfer technology or establish productive facilities in the developing world may substantially slacken or disappear. The TRIPS Agreement provides world protection which developed countries have been seeking. It narrows access to technology, and slows down the expected rapid diffusion of new technology to developing countries. The new notion carried in the TRIPS Agreement requires changes in many of the basic principles of the legal systems as developed by international conventions and national legislation. It includes the expansion of new areas such as biotechnology, integrated circuits, computer programs, the universalization of standards of protection and the strengthening of enforcement mechanism.

Conclusion.

This article maintains that an all-embracing harmonization of substantive patent law is required to address inter alia, public interest concerns by dismantling the limitations imposed by the TRIPS Agreement in this regard. Compulsory licensing is a public policy tool devised to respond to public interest concerns in a process of rebalancing rights and obligations. Public interest encompasses promotion of industrialization, development and societal interests including Public Health and Nutrition. The envisaged harmonization should address the question of WTO members as proposed public users. The word user as contained in paragraph 31(b) of the TRIPS Agreement must embrace the public at

¹⁴⁵ Cf. Daniel Tully, "Prospects for Progress. The TRIPS Agreement and Developing Countries after the Doha Conference" at p.2 available at <http://www.be.edu/schools/law/lawyerview/meto-elements/journal/cciclr/26-1/06-t>

large on the pretext that WTO & WIPO members signatories of Treaties are obliged to observe the measures calling for compliance and enforcement.

This article contends that Article 31 of the TRIPS Agreement is less than satisfactory to address compulsory licensing as a practical public policy tool for developing and least developed countries. It does not lay down a complete catalogue of events under which compulsory licensing may be triggered. It is conspicuously narrow compared with conventional compulsory licensing provisions as contained in the Patent Acts of most industrialized countries prior to advent of the TRIPS Agreement. Again, Article 27 represents an unprecedented extension of patent rights without a concise definition of prior art, novelty, non-obviousness and an inventive step. It excludes from patentability as provided for in paragraph 27.3 (a) diagnostic; therapeutic and surgical methods for the treatment of humans or animals though it includes pharmaceutical products and processes. Paragraph 27.3(b) excludes from patentable subject matter “plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes.” This signifies that any pharmaceutical products that are extracted or produced utilizing animals and plants shall not be patentable. The TRIPS lacks a definition of the phrase, “micro-organism” and why it is not considered a living organism when it reaches the stage of microscopical life form such as viruses and bacteria.

An unfavorable extension of the scope of patent protection can be discerned in the American case *State Street Bank & Trust Co.v. Signature Financial Group*¹⁴⁶, where the court decided that business methods fall within the ambit of patentability, insofar, as the inventions met the criteria of patentability as regards prior art. Such an interpretation would defy the recognized criteria of patentability, and in effect it is an exercise to avoid conventional patentability rules without cogent justification so to warrant. It may be relevant to indicate that Section 102(a) of the US Uruguay Round Agreement Act of 1994 provides as far as it is material, “no provision in any of the Uruguay Round Agreements, nor the application of any such provision to any person or circumstance, that is inconsistent with the law of the United States shall have effect.” This lends support for the need to harmonize substantive patent law so as to eliminate the differences in substantive law and practice of all WTO members.

Developing and least developed countries invoke compulsory licensing, in much greater number of events, to address public policy concerns such as combating the AIDS crisis and other epidemic diseases. Such a public tool policy must be endorsed by developed countries rather than be defeated or equated with free riding. Article 31 is couched in general terms, but in terms sufficient to embrace the question of compulsory licensing. However, it embraces definite subjects including paragraph 31(f) dealing with supply of the domestic market. From the legal point of view, where you get two opposing provisions, one in general terms, nonetheless, broad enough to cover a definite subject, and one dealing exclusively with it, the definite provision shall prevail.

It submitted that that paragraph 27.3 (a) and paragraph 31(f) constrain the autonomy of national legislatures to shape intellectual property law to serve public interest concerns. The suffering and troubles in South Africa of HIV/AIDS crisis is glaring evidence. Lack of common access to Antiretroviral (ARV) treatment was due to

¹⁴⁶ 149 F.3d 1368 [Fed.Cir., 1998]

patent protection. The practical approach is to dismantle the obstacles created by these provisions via amendment. As a matter of fact, a substantial portion of patent applications are associated with processes and formulations of already recognized effective ingredients introducing only new or second applications of accessible medicine which do not entail an important addition to the state of art. It may be relevant to indicate that the WTO panel in respect of the dispute raised by EC against Canada¹⁴⁷ permitted testing to establish the bio-equivalency of generic products before expiration of the term of protection. Pursuant to Article 27(1) patent protection in the pharmaceuticals field should be confined to applications relating to new chemical entities. A broad patent protection in the pharmaceutical field, as to encompass processes would unduly encroach on the public domain doctrine. The ultimate result would lead to monopoly. Accordingly, paragraph 27(1) should be amended as to exclude pharmaceutical products which do not satisfy the test of being new chemical entities.

Exceptions conducive to ensure public health protection should not be resisted in substance or procedure. Any mechanism employed by developing and least developed countries to enhance public interest concerns should not be played down. Accordingly, the restriction as contained in paragraph 31(f) should be removed as would enable supply of export market as when cogent grounds so warrant. In countries lacking manufacturing capacity, compulsory licensing for the supply of the domestic market, would not be feasible. The small size of most African countries may imply difficulties in developing the infrastructure necessary for competition markets.

The doctrine of exhaustion must be interpreted in favour of importing countries as and when the legal conditions for its application are maintained. Under the doctrine of exhaustion the patent holder would not be in a position to trigger paragraph 44(2) as to claim payment of compensation pursuant to paragraph 31(h) of the TRIP Agreement.

¹⁴⁷ (WT/D114/R of March 17, 2000)