THE INDIAN JOURNAL OF LAW AND TECHNOLOGY
Volume 2, 2006

PATENTABILITY UNDER TRIPS: THE NEED FOR UNIFORMITY

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ABSTRACT

International intellectual property law has never been uncontroversial, and patent law in particular has been the subject of heated debate. The advent of TRIPS seems to have fuelled rather than ended these discussions, as arguments continue to rage on in developing countries about the subject-matter and patent term provisions of TRIPS and the ways in which developed countries have purportedly used TRIPS to impose their own laws on the world. However, such an approach misses the point of TRIPS altogether: the need for international harmonisation. By examining two recent examples from US case law, it becomes apparent that the developed nations need harmonisation as much as the developing nations do, and thus the focus should be on facilitating full harmonisation rather than impeding it through challenging specific provisions.

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I. THE GENESIS OF THE TRIPS AGREEMENT

The adoption of the TRIPS Agreement[1] in 1995 was a unique development in international intellectual property law. The agreement mandated minimum standards that must be met by all nations with regard to the protection of intellectual property. "All nations" meant all nations that participate in the World Trade Organisation (WTO) and, from a practical perspective of trade policy and economics that meant, truly, *all* nations. The TRIPS Agreement became the global Constitution of intellectual property law. Under it, *all* nations must ensure that their domestic laws conform to the TRIPS standards, or risk sanctions under the WTO system.

No area of intellectual property law has been quite as controversial as patent law. The TRIPS Agreement contains two specific provisions directed towards raising standards for countries that were deemed by developed countries to fall short of a "minimum" level. The countries advocating these two provisions were primarily the United States and, secondarily, Japan and countries in Europe. The two specific provisions concerned the scope of patentable subject matter and the term (i.e. length) of patent protection. Thus, Article 27(1) provides that "patents shall be available... without discrimination as to...the field of technology..."[2] and Article 33 states, "The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date."[3] These two provisions were of great interest to developed countries, which advocated minimum standards, and of great concern to countries such as India and Brazil, which viewed such standards as improper interference in domestic policy.

II. IS THERE A DEBATE ON PATENTABILITY?

Lost in the debate over these two provisions – subject-matter coverage and patent terms – was a serious consideration of other important aspects of patent law. Article 27 of TRIPS effectively codified the alternative substantive standards of patentability derived from United States patent law and the European Patent Convention. The standards of patentability in the European Patent Convention reflect Japanese law. Thus, Article 27(1) provides that inventions are patentable if they are "new, involve an inventive step and are capable of industrial application."[4] The phrases "inventive

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[1] Agreement on Trade-Related Aspects of International Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

[2] *Id.* at art. 27(1).

[3] *Id.* at art. 33.

[4] *Id.* at art. 27(1).

step" and "capable of industrial application" track the European Patent Convention standards. To accommodate the United States' "non-obviousness" and "utility" requirements, the footnote to Article 27(1) states: "For the purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non obvious' and 'useful' respectively." Similarly, to accommodate United States law on disclosure requirements, Article 29(1) provides that "[m]embers shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art."[5] Giving leeway to the unique United States "best mode" requirement, Article 29(1) goes on to provide, generously, that a member (that is, a WTO country) "may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application."[6]

The TRIPS Agreement thus incorporates standards of patentability as applied in the United States and Europe internally for the purposes of their own laws. Notwithstanding this bias, and an ostensible disregard for the patent laws of any other countries, the requirements of patentability, subject matter coverage including coverage of pharmaceutical products, and the term of protection (twenty years from patent filing) have received universal acceptance. I believe that discussions about those fundamental issues should be deemed closed and all WTO members should comply, fully and in good faith, with these standards.

III. PATENTABILITY AND THE INTERPRETATION OF CLAIMS: A STORY OF INCONSISTENT STANDARDS

However, other important questions about patent protection standards can and should be considered open and subject to debate at the national level and also, perhaps, at a transnational level. These issues include basic questions on patentability, such as what constitutes an unobvious advance over the prior art, and what constitutes a sufficient disclosure of a broadly claimed invention. There are conflicting approaches to treating patent claims in different jurisdictions; some states may allow a broadly claimed invention as an enabling disclosure, while other states have disclosure requirements that place a more onerous burden upon the inventor. Similarly, there are no uniform rules that are applied to the interpretation of patent claims and their scope.

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[5] *Id.* at art. 29(1).

[6] *Id.*

Below, I will give specific examples derived from case law in the United States illustrating the importance of having consistency in these standards. But consider in the abstract the following:

Pharmaceutical company X files an application claiming a therapeutically valuable new chemical entity (NCE). It obtains a patent (let us assume patents in all significant markets) claiming the chemical entity. The company X does further research and determines that a compositional structure makes the administration of the NCE better, on a weekly dosage rather than a twice daily dosage. It files subsequent applications for the improved usage of the NCE. Company X launches its commercial drug, using both the new chemical entity and the improved compositional structure. Upon expiration of the primary patent, which claims the new chemical entity, questions arise as to the secondary patent, which may be described as an "improvement" or "derivative". The second patent, if upheld, effectively extends Company X's exclusive rights over its commercial product, thereby precluding generic equivalents. Is the new compositional structure patentable? Is it new and "non-obvious" in view of the prior art, which includes the new chemical entity? Does it meet the TRIPS "inventive step" standard? Further, assume that a potential generic competitor proposes to market a composition that is not identical to that claimed in the second patent but that is, arguably, "equivalent". Does the composition infringe the second patent? These are difficult issues, ones with significant economic implications, and the TRIPS Agreement provides no guidance on these.

If one looks to jurisprudence in the United States, Europe and Japan, the primary sources of the TRIPS patentability standards, one will find a variety of opinion. Indeed, the standard of patentability has ebbed and flowed over time. TRIPS took the enormously important step of creating global standards for patent protection. It should follow that all members of the global community may participate in the articulation and refinement of the standards, including, most particularly, the "inventive step" standard for patentability. Legislative bodies, patent granting agencies, courts, scholars, and commentators in all member countries may address, in good faith, what the core standards of patent law mean. Evolution of uniform standards on patents will confer a practical advantage; inventors and innovators around the world may obtain a property right of consistent scope in all countries, that is, in the global economy.

The essential point is that the details of articulating and applying patent law standards are as important as the postulation of standards in the abstract. I set forth below two specific case law examples.

A. Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.

An exemplary recent decision pertaining to pharmaceutical patent protection is *Teva Pharmaceuticals USA, Inc.* v. *Pfizer, Inc.*,[7] in which the Court of Appeals for the Federal Circuit affirmed a district court's preliminary injunction that removed from the market a generic competitor's product. The patent owner was the large pharmaceutical firm Pfizer; the generic competitor was Ranbaxy, a large Indian drug manufacturer. The drug was an "angiotensin converting enzyme (ACE) inhibitor". The patent claimed a particular metal stabilizer and a "saccharide" added to the primary ACE inhibitor to minimise cyclisation, hydrolysis and discolouration. To gain a sense of the economic dimensions of such cases, one should consider first that this particular case only deals with a preliminary injunction (a court order pending a complete trial) and that, to meet the legal requirement for obtaining such an extraordinary order, the plaintiff (the patent owner Pfizer) was required to post a cash bond to the tune of US $200,000,000.

A key issue in the case, as in so many patent cases, was the proper interpretation of the patent's claim language. The claim required a "saccharide". The accused infringer's drug included a microcrystalline cellulose, which is a polysaccharide but not a sugar. The accused infringer argued that "saccharide" was limited to "sugars" and, therefore, it did not infringe the patent's claims. The Federal Circuit affirmed the district court's tentative decision that "saccharide" was not limited to sugar. It did so despite significant support in the patent itself for a contrary conclusion. The patent referred to "saccharides (i.e., sugars)". In common English language usage, the phrase "i.e." constitutes a definition, meaning "in other words. . ." and is derived from the Latin phrase "id est". However, the court relied on other language in the patent to reach a contrary conclusion. This may seem to some a rather particular point of linguistic technicality, but consider how much was at stake, not only for the generic manufacturer (Ranbaxy) but also for consumers who must continue to pay a high price for the patented drug.

Implicit in the court's decision are standards regarding how to interpret patent claim language and assess patent claim scope. These are important standards that any patent system must evaluate and assimilate. At stake are policies, such as the need for clarity and clear notice to potential competitors and the need to provide an appropriate scope of protection for innovators. How to balance these policies should be the subject of rigorous discussion and, hopefully, consensus among members of a globalised patent law regime.

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[7] 395 F.3d 1324 (Fed. cir. 2005).

B. Merck & Co. v. Teva Pharmaceuticals USA, Inc.

A second example, again a recent case dealing with pharmaceuticals, will, probably, perplex a reader not familiar with the vagaries of case law on patents in the United States, because it seems so inconsistent in tone with the prior example.

At issue in this case, *Merck & Co,* v. *Teva Pharmaceuticals USA, Inc*.,[8] was a patent that claimed a method of treating and preventing osteoporosis through less than daily administration of bisphosphonate compounds, specifically alendronate monosodium trihydrate. The basic (new) chemical entity, that is, part of the prior art, was known and its administration on a daily dosage basis was also known. Hence, the patent was based on a change from daily administration (with a small dosage) to a weekly dosage (with a larger dosage, "about 70 mg" and "about 35 mg"). Common sense would suggest that such a change would have been "obvious". Yet the patent owner relied on evidence that a larger dosage would cause adverse effects in patients. To counter that showing, an accused infringer relied on two newsletter publications that suggested weekly dosages (40 mg and 80 mg). The Federal Circuit found the patent not valid on grounds of obviousness.

First, the Federal Circuit addressed an issue of claim interpretation. The issue should be as perplexing as that of the prior case on "i.e". In this case, the key word was "about", a word that patent professionals commonly use to give added scope to a limiting word or phrase. To reiterate, in this patent, the claims required, *inter alia*, administering once weekly "about 70 mg" and "about 35 mg". Typically, patent owners urge a broad construction to disputed claim language, the purpose being to establish infringement. Here, however, the patent owner argued for a very limited construction, the purpose being to distinguish the prior art newsletters' disclosure of 40 mg and 70 mg. In what must seem an odd argument, the patent owner argued that the claims meant *exactly* 70 mg and 35 mg despite the word "about". The trial court agreed, based on the language in the patent. The Federal Circuit, however, disagreed, interpreting "about" in its ordinary parlance, and construing that it should mean *approximately* 70 mg or 35 mg. Secondly, the Federal Circuit addressed the basic patentability standard of obviousness, and held that the claims were invalid because their subject matter would have been obvious to a person of ordinary skill in the art in view of the two prior art newsletters.

However, what is important for our consideration is the manner in which, in both these cases, the interpretation of claims was addressed. In *Pfizer*, the attempt of the patent holder was to interpret "saccharide" in the broadest possible manner,

[8] 395 F.3d 1364 (Fed. Cir. 2005).

despite the presence of the term "i.e." in the claim itself, qualifying the former term to mean "sugar". In the *Merck* judgment, the term "about" was given a strict interpretation, thus rendering a commercially successful patent void. What needs to be underscored here is that these two cases demonstrate that there exist no uniform standards to interpret patent claims. This is the need of the hour, for in the absence of any such uniform standards, the patentability requirements of TRIPS, as well as its attempt to globalise standards, may be rendered nugatory.

IV. CONCLUSION

Therefore, while prior discussions on patent law have focused on a limited set of issues, such as subject matter coverage and patent term, these issues are effectively settled by TRIPS, and the nature of the origin of these standards should no longer be considered relevant to current TRIPS-related discussions. It is time to focus on more pressing and current issues, such as the interpretation of patent claim scope. However, as long as inconsistencies persist between courts in matters such as the interpretation of patent claims, it is difficult to claim that *any* sort of "minimum standard" can be said to exist on a global scale, and the cases above illustrate how such inconsistencies may occur even *within* a country, thus impeding the evolution of a consistent patent jurisprudence upon which one can rely when filing claims. In theory and in practice, it is thus imperative that, for TRIPS to be truly effective, there must be a uniformly accepted set of principles for the interpretation of claims and patent scope.

THE INDIAN JOURNAL OF LAW AND TECHNOLOGY
Volume 2, 2006

ACCESS TO MEDICINES, PARAGRAPH 6 OF THE DOHA DECLARATION ON PUBLIC HEALTH, AND DEVELOPING COUNTRIES IN INTERNATIONAL TREATY NEGOTIATIONS

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ABSTRACT

Paragraph 6 of the Doha Declaration on Public Health, dealing with access to medicines for countries lacking the manufacturing capacity for them, became an important issue because its solution on 30th August 2003 on the basis of the Note of the Chairman of the TRIPS Council was perceived as changing the basic features of the TRIPS Agreement. This was the subject of much debate, and a number of proposals from different countries were submitted either individually or collectively. However, the proposals from developing countries did not find their way into Paragraph 6, and the problem of developing countries not being able to make their voices heard in international negotiations is the focus of this article. By discussing the circumstances of the Paragraph Solution and the ways in which the interests of the developed countries were prioritised over the interests of developing countries, this article attempts to find ways in which the negotiating process may be made more transparent in future so as to accommodate all interests more fairly.

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I. INTRODUCTION

Access to medicines for underdeveloped countries has always been a crucial issue, and it became especially controversial after the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[1] was finalised in 1995. The controversy has acquired particular significance in the wake of the HIV/AIDS pandemic, particularly given its prevalence in many parts of the world which are not in a position to manufacture the required drugs to treat the disease.[2] The issue of access to medicines for such nations came to the fore during the Doha Ministerial Meet, where the developing countries present moved a resolution for an authoritative interpretation of Article 30 of the TRIPS Agreement for the purpose of clarification so as to avoid unnecessary litigation in situations where countries permit manufacture and export of drugs to countries which lack the requisite capacity, especially to those countries which were in the grip of the HIV/AIDS pandemic. However, this simple and TRIPS-compatible approach was not accepted, and a strict regulatory regime was imposed through various means, the failure of which becomes evident when one finds that no medicines at all have been exported since August 30, 2003 under this solution.[3] In fact, countries such as Canada have even tried to undermine it through first permitting the patent-holder to take over export after the completion of the negotiation between the country in need and the third-party supplier, and then limiting the scope of diseases, another bone of contention.[4]

An issue of crucial importance to the lack of access to medicines for developing countries is thus their marginalisation in international treaty negotiations, which is evident from the introduction of industrial and other monopolies as a part of the

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[1] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, Legal Instruments—Results of the Uruguay Round vol. 31 (1994), 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

[2] WTO Secretariat, *Available Information on Manufacturing Capacity for Medicines*, IP/C/W/345 (May 24, 2002), http://www.wtocenter.org.tw/SmartKMS/fileviewer?id=33236.

[3] According to certain WHO officials, no country has yet issued a demand for compulsory licences as authorised by the paragraph 6 solution of August 30, 2003. It has also been reported that the complexity of the Solution, along with the pressure on the needy countries not to take advantage of it, are the factors responsible for its non-use. UNI, Poor Nations Fail to Import HIV Generics, *available at* http://www.union-network.org/uniafrican.nsf/574a89c88160dd42c125682c0046d1c8/55c62506e7488140c1256e510040819f?OpenDocument.

[4] *See* Bill C-56, An Act to Amend the Patent Act and the Food and Drugs Act, S.C. 2004, c. 23, *available at* http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend/BillC-9passed40504.pdf.

WTO through TRIPS,[5] restrictive interpretations of the flexibility of this Agreement[6] and its rewriting on August 30, 2003[7] in the form of the solution of Paragraph 6 of the Doha Declaration on Public Health,[8] which added exports as one of the patenting rights in the TRIPS Agreement. The solution has drastically curtailed the possibilities of access to drugs being given to countries which lack the manufacturing capacity for them.[9] This inability of developing countries to participate effectively in international treaty negotiations is reflected in a number of proposals from developing countries requesting developed countries, primarily the USA, not to resort to threats and

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5 *See generally* Frederick M. Abbott, *Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework*, 22 VAND. J. TRANSNAT'L L. 689 (1989) (discussing two relevant documents: General Agreement on Tariffs and Trade: Decisions on Negotiating Structure and Plans for the Uruguay Round, 26 I.L.M. 850 (1987), and General Agreement on Tariffs and Trade: Decisions Adopted at the Mid-Term Review of the Uruguay Round, 28 I.L.M. 1025 (1989)).

6 WTO Dispute Panel Report on Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R (Mar. 17, 2000), *available at* http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf [hereinafter Canada Patent Protection].

7 WTO, Decision of 30 August 2003, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (30.8.2003), *available at* http://www.wto.org/english/tratop_e/implem_para6_e.htm. [hereinafter Decision of August 30, 2003]. *See also* The General Council Chairperson's Statement, Aug. 8, 2003, *available at* http://www.wto.org/english/news_e/TRIPS_stat_28aug03_e.htm [hereinafter the Chairperson's Statement].

8 Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/Dec/2 [hereinafter Doha Declaration], *available at* http://www.wto.org/english/thewto_e/minist_e/mindecl_TRIPS_e.pdf (Nov. 14, 2001).

9 The inability of WTO Members to use the Decision of August 30, 2003 to access requisite medicines becomes evident in the new proposal from the African Group submitted to the TRIPS Council. The African Group has argued that the Chairman's Statement does not provide any legal value and should be removed completely from the Decision of August 30, 2003. They also argued that the conditions imposed through the Decision of August 30, 2003 are neither practical nor required and that article 31 conditions are sufficient to cover any question of quantity of medicines to be produced and its diversion to wrong countries. However, the amendment protocol arrived at on December 6, 2005 does not appear to take into account any of the concerns raised by the African countries. WTO, The TRIPS Agreement and Public Health, Communication from Rwanda on Behalf of the African Group (IP/C/W/2005 dated Apr. 6, 2005) and Legal Arguments to Support the African Group Proposal on the Implementation of Paragraph 11 of the 30th August Decision, Communication from Rwanda on behalf of the African Group (IP/C/W/440 dated Mar. 1, 2005); Proposal for a Decision on an Amendment to the TRIPS Agreement, Implementation of paragraph 11 of the General Council Decision of 30th August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Proposal for a Decision on an Amendment to the TRIPS Agreement, IP/C/41 dated Dec. 6, 2005).

sanctions in international transactions.[10] The problem has been discussed by a number of scholars with widely differing viewpoints, sometimes influenced by their own nationalities.[11] While Gathii tries to explain it as the use of structural power by developed countries,[12] Drahos is more inclined to attribute the limitation of developing countries to participate effectively in international negotiations to their inability to form a coherent group.[13]

This article concentrates on the Paragraph 6 Solution of the Doha Declaration on Public Health and the position of developing countries in international negotiations in the context of the effects of the HIV pandemic. In the course of this article, I will touch upon a number of factors relevant to this issue, such as the concept of enablement, the relevance of Articles 30 and 31 of the TRIPS Agreement in relation to export of the patented products, the legality of the Paragraph 6 Solution, and the issue of repression, exclusion and disorganisation of the developing countries at international negotiations. I will also attempt to analyse the actual process of domination, and thus arrive at possible ways to improve international negotiations involving developing countries.

II. THE HIV PANDEMIC AND ITS SOCIO-ECONOMIC CONSEQUENCES

The extent of the problem caused by diseases like AIDS can be gauged from some of the reports providing the relevant data. The UNAIDS Report says that there have been 20 million deaths from AIDS in the twenty years since the first diagnosis of AIDS in 1981, with young people in the age group of 15-24 accounting for nearly half

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[10] TRIPS: Proposal-Draft Ministerial Declaration: Proposal from a Group of Developing Countries, IP/C/W/312 dated Oct. 4, 2001, addressed to General Council and Council for Trade-Related Aspects of Intellectual Property Rights: Proposals by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, [hereinafter Developing Countries' Proposal, Oct. 4, 2001) *available at* http://www.wto.org/english/tratop_e/TRIPS_e/mindecdraft_w312_e.htm, 10.

[11] *See generally* James T. Gathii, *The Structured Power of Strong Pharmaceutical Patent Protection in US Foreign Policy*, 7 J. Gender, Race & Just. 267 (2003); Peter Drahos, *When the Weak Bargain with the Strong: Negotiations in the WTO*, 8 Int'l Negotiation 79 (2003); A. Samuel Oddi, *TRIPS – Natural Rights and a "Polite Form of Economic Imperialism*," 29 Vand. J. Transnat'l L. 415 (1996).

[12] *See* Gathii, *supra* note 11.

[13] *See* Drahos, *supra* note 11.

of all new infections worldwide, and almost 38 million people are living with AIDS.[14] Sub-Saharan Africa accounts for 25 million of these 38 million – approximately 68% of world's AIDS sufferers – whereas it is home to only 10% of the world's population, although there is a diversity across the African continent in the levels and trends of HIV infection.[15] Among Asian countries, China, Indonesia and Vietnam account for another 7.4 million HIV sufferers, followed by India with nearly 5 million infected people.[16] The AIDS/HIV pandemic has reversed the gradual growth in life expectancy in sub-Saharan Africa.[17] According to the WHO, nearly 6 million people are expected to die because of this disease in the near future if they do not receive treatment—a staggering number by any account.[18] According to the WHO's estimates, only 400,000 people were able to receive treatment by the end of 2003.[19] Out of this 400,000, access to medicines for HIV in the African region is the lowest with only an estimated 100,000 people receiving treatment, a coverage of just 2%.[20]

The World Health Report paints a bleak picture of the economic and social consequences of the HIV/AIDS pandemic.[21] The economic effect of such devastation is already visible; even the economy of Nigeria, a relatively prosperous country with petroleum wealth, is shrinking rather than expanding,[22] and Prof. Clive Bell and others, on the basis of significant importance given to human capital and transmission

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[14] UNAIDS, Report on the Global AIDS Epidemic 3, *available at* http://www.unaids.org/bangkok2004/GAR2004_html?GAR2004_00_en.htm. With the margin of error provided, the figure could be anything between 34.6 million and 42.3 million.

[15] *See id.*

[16] *See id.*

[17] World Health Organisation, World Health Report, 2004 at 2 (2004), *available at* http://www.who.inv/whr/2004 [hereinafter World Health Report, 2004]. *See also* United Nations, World Population Prospects: The 2002 Revision (2003) (noting that the life expectancy in sub-Saharan region reached a high of 49.2 years during the late 1980s and projecting it to drop to just under 46 years in the period 2004-2005).

[18] *See* World Health Organisation, Unprecedented Opportunity to Fight HIV/AIDS and Change the Course of History (2004), *available at* http://www.who.int/mediacentre/releases/2004/pr33/en/print.html.

[19] *See id.*

[20] *See* World Health Report, 2004.

[21] *See id.* at 8. S*ee also* Simon Dixon et al., *The Impact of HIV and AIDS on Africa's Economic Development*, 324 Brit. Med. J. 232 (2002); Economic Commission for Africa, *Africa: The Socio-Economic Impact of HIV/AIDS*, *available at* http://www.ace.msu.edu/agecon/fs2/adult_death/SOCIO_ECO_IMPACT.pdf; Botswana Institute for Development Policy Analysis, *Impacts of HIV/AIDS on Poverty and Income Inequality in Botswana*, *available at* http://www.iaen.org/coonferences/durbansym/papers/31Green.pdf.

[22] *See* Constance Ndubuisi-Enyali, Nigerian Economy to Shrink by 20% due to HIV/AIDS, at the 4th National Conference on HIV AIDS in Africa (May 7, 2004) *available at* http://www.Nigeria-aids.org/msgRead.cfm?ID=2901.

mechanism across generations, have argued that the long-run economic costs of AIDS are going to be devastating for South Africa.[23] By affecting young people, AIDS reduces family and national resources and exacerbates economic inequality. Economic welfare is therefore necessarily dependent on the health of the population.[24] In the context of the Asia-Pacific religion, the impact of HIV/AIDS on households and businesses is expected to be disastrous, not only because the death and incapacitation of workers

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[23] *See generally* Clive Bell et al., The Long-Run Economic Costs of AIDS: Theory and an Application to South Africa 5 (2003), *available at* http://econ.worldbank.org/files/30343_wps3152.pdf; C. Arndt & J. D. Lewis, *The Macro Implications of HIV/AIDS in South Africa: A Preliminary Assessment*, 68 South Africa J. Eco. 856, 887 (2000); R. Dorrington et al., *The Current State and Future Projections of the HIV/AIDS Epidemic in South Africa*, 57 South African Dental J. 408, 409 (2002); and R. Dorrington et al., *Some Impacts of HIV/AIDS on Adult Mortality in South Africa*, 15 (Supp 2) South African J. Clinical Nutrition S3 (2002); South African Institute of Race Relations, *The Economic Impact of HIV/AIDS*, *available at* http://www.sairr.org.za; John S. Nabila et al., *A Preliminary Review of the Economic Impact of AIDS on Firms and Business in Ghana available at* http://www.policyproject.com/pubs/country reports/GHeconimp.pdf (Oct. 1, 2000); Unaids, The Social And Economic Impacts Of HIV/AIDS In Poor Countries: A Review Of Studies And Lessons (T. Barnett et al., eds., 2000); M. Bechara & O. Weeks, *Aids: An Economic Catastrophe?* (2000); L. Bollinger & J. Stover, The Economic Impact of AIDS, (1999) (Bollinger and Stover have done systematic analysis of the economic impact on a number of African countries) *available at* http://www.policyproject.com/pubs/SEImpact/angola.pdf; M. Butler et al., *The Socioeconomic Impact of HIV/AIDS in the Dominican Republic, 1991-2005*, at the 13th International AIDS Conference, Durban (2000); ING Barings, *Economic Impacts of AIDS in South Africa: A Dark Cloud on the Horizon,* (ING Barings, Johannesburg), 2000; P. Wehrwein, *The Economic Impact of AIDS in Africa*, Harv. Aids Rev., Fall Winter 1999, at 4 *available at* http://www.aids.harvard.edu/news_publications/har/fall_win_1999-4.html; Edoardo Gaffeo, *The Economics of HIV/AIDS: A Survey*, 21 Dev. Pol. Rev. 27 (2003) (The extent of the negative effect of AIDS varies between the studies as the forecastings depend significantly on the assumptions but even the most optimistic assumptions such as those in the ING Barings' study confirm a significant negative impact of HIV pandemic on the countries concerned particularly those in Africa).

[24] *See* D. Bloom & D. Canning, *Health and the Wealth of Nations*, 287 Science 1207 (2000). *Also see* D. Bloom & D. Canning, *The Effect of Health on Economic Growth: Theory and Evidence*, NBER Working Paper No. 8357 *available at* http://www.nber.org/papers/w8357.pdf; D. Bloom & D. Canning, *Health as Human Capital and its Impact on Economic performance*, 28 Geneva Papers 304, 315 (2003); WHO, Report of the Commission on Macroeconomics and Health (2002) *available at* http://www.who.int/gb/ebwha/pdf_files/WHA55/ea555.pdf. (the WHO Report on Macroeconomics and Health headed by Jeffrey Sachs estimated that in Sub-Saharan Africa, the loss due to HIV/AIDS is more than 12% of GNP annually and that in malaria-free regions, the growth is more by 1% compared to malaria-ridden regions); WHO CMH, *Macroeconomics and Health: Investing in Health for Economic Development, available at* http://www.cid.harvard.edu/cidcmh/CMHReport.PDF.

would reduce household income, but because the reduced income and resulting decreases in demand would inhibit economic growth as a whole.[25]

The response of countries in a position to contribute substantially towards dealing with such a potential catastrophe has either been negative or negligible. Some of them, such as the USA, Japan and the members of the European Community, contributed to the global fund,[26] but have then nullified its effect by restricting access to medicines through the exclusion of a number of sources of supply on the plea that such access would undermine the patenting monopoly and thus future R&D.[27]

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[25] Symposium, *The Potential Economic Impact of AIDS in Asia and the Pacific* at Asia-Pacific Ministerial Meeting in Melbourne, (Oct. 9, 2001) *available at* http://www.ausaid.gov.au/pupblications/pdf/patential_impact.pdf.

[26] The Global Fund to Fight AIDS, Tuberculosis and Malaria [hereinafter 'Global Fund'] was created to increase resources to fight three of the world's most devastating diseases. It is partnership between government, civil society, the private sector and affected communities and operates on a set of principles such as

a. Operate as financial instrument, not an implementing entity

b. Make available and leverage additional financial resources

c. Support programs that reflect national ownership

d. Pursue an integrated and balanced approach to prevention and treatment

available at http://www.theglobalfund.org/en/about/how/.

[27] *See, Testimony of the US Senate Committee on Health Education, Labor and Pensions*, June 13, 2000 (statement of Patricia Danzen), *available at* http://www.senate.gov/~labor/hearings. The assertion of Patricia Danzon and the pharmaceutical industry association has been questioned by a number of scholars such as Deborah Socolar and Alan Sager (Deborah Socolar & Alan Sager, *Pharmaceutical Marketing and Research Spending: The Evidence Does Not Support PhRMA's claims*, (Oct 21, 2001) *available at* http://dosc2.bumc.bu.edu/hs/ushealthreform.htm. Socolar and Sager, after analysing the annual reports of these firms concluded that 16 percent of the six major pharmaceutical firms had been taken as profit and 31 percent went for marketing and administration which was nearly three times as much as their R&D spending. Similar findings were noted by - Kaiser Foundation (Kaiser Family Foundation, *Prescription Drug Trends: A Chartbook*, 65 Figures 4.5 and 4.6 (July 2000), *at* http://www.kff.org/content/2000/3019/PharmFinal.pdf); Families USA, *Off the Charts: Pay, Profits and Spending in Drug Companies*, (July 10, 2001) *available at* http://www.familiesusa.org/media/press/2001/drugceos.htm; Public Citizen's Congress Watch, *Drug Industry Most Profitable Again*, Public Citizen, (April 11, 2001) *available at* http://www.citizen.org/congress/reform/drug_inidustry/profits/articles.cfm?ID=838. *Also see* T. Lynn Riggs, *Research and Development Costs for Drugs*, 363 Lancet 184 (2004) (who argued that 34% tax benefits should have been taken into account while calculating the R&D expenditure). *Also see* Donald W. Light & Joel Lexchin, *Will Lower Drug Prices Jeopardize Drug Research? A Policy Fact Sheet*, 4 Am. J. Bioethics 3 (2004).

III. TRIPS AND THE PARAGRAPH 6 SOLUTION

A. History of the TRIPS Agreement

The Paris Convention[28] and the Berne Convention[29] dealing with the patenting monopoly and copyright protection were controlled by the Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle (BIRPI).[30] The original treaties provided for little more than national treatment among signatory countries, and a major part of the present developing world was not involved at all. The USA accepted the Berne Convention only in 1989, more than 100 years after it entered into force.[31] From 1971 to 1986, the USA mostly entered into bilateral agreements with developing countries introducing higher levels of industrial property monopoly.[32] Some of the provisions of the General Agreement on Tariffs and Trade (GATT)[33] also had intellectual property implications, namely Article IX(6) and Article XX(d). While Article IX(6) dealt with the issues of trademarks and geographical indications, Article XX(d) permitted contracting parties to "adopt or enforce measures necessary to secure compliance with laws or regulations which are not inconsistent with the provisions

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[28] Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, as revised at Stockholm on July 14, 1967, 21 UST. 1630, 828 U.N.T.S. 305 [hereinafter Paris Convention].

[29] Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, as revised at Paris on July 24, 1971, 25 UST. 1341, 828 U.N.T.S. 221 [hereinafter Berne Convention].

[30] World Intellectual Property Organisation, The First Twenty five Years of the World Intellectual Property Organisation, from 1967 to 1992 at 31-40 (1992).

[31] *See* Orrin G. Hatch, *Better Late than Never: Implementation of the 1886 Berne Convention*, 22 Cornell Int'l L. J. 171, 180-81 (1989).

[32] Bilateral agreements the USA entered into with Nicaragua and Sri Lanka are some of the examples. Agreement on the Protection and Enforcement of Intellectual Property Rights, Sept 20, 1991, US- Sri Lanka *available at* http://www.cptech.org/ip/health/c/agreements/srilanka-1991-ip.html.

Agreement Concerning Protection of Intellectual Property Rights, 1998, US–Nicar. *available at* http://www.cptech.org/ip/health/c/agreements/nicargua-1998-ip.html. Abbott, *supra* note 5, at 711 n 71 (Abbott has described a number of bilateral strategies the USA resorted to, to achieve enhanced intellectual property protection).

[33] General Agreement on Tariffs and Trade, Oct. 30, 1947, 24 UST. 146, 55 U.N.T.S. 194 [hereinafter GATT]. This agreement was supposed to be the part of the Havana Treaty establishing the International Trade Organisation (the ITO) but US Congress did not permit the USA to accede to this treaty. It was replaced in 1995 by the GATT 1994.

of this Agreement, including those relating to the protection of patents, trademarks, copyrights and prevention of deceptive practices."[34]

At the Uruguay Round Negotiations, TRIPS was introduced without much clarity as to its *raison d'être*, as the Ministerial Declaration at Punta del Este only stated the need to "...clarify provisions and elaborate as appropriate new rules and disciplines" with an aim to "...develop a multilateral frame work of principles, rules and disciplines dealing with international trade in counterfeit goods, taking into account work already undertaken in GATT."[35] However, in 1990, the EC,[36] the USA,[37] Japan,[38] and Switzerland[39] tabled exceptionally far-reaching proposals on similar lines to the GATT Negotiating Group dealing with intellectual property. These proposals contained detailed rules on the application of intellectual property, including its interpretations before national courts, and the draft legal texts also contained proposals for the application of the dispute-settlement system which was to be

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[34] Article XX(d) of GATT 1947 as incorporated in GATT 1994 reads as follows:

"Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption of enforcement by any contracting party of measures:

(d) necessary to secure compliance with laws or regulations which are not inconsistent with provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trademarks and copyrights, and the prevention of deceptive practices."

[35] General Agreement on Tariffs and Trade (GATT) Punta Del Este Declaration, (Sept. 20, 1986) *available at* http://www.sice.oad.org/trae/Punta_e.asp. *See also* Ministerial Declaration of the Thirty-Eight Session at Ministerial Level, Nov. 29, 1982, GATT B.I.S.D. (29th Supp.) 19 (1983) (this had discussed the issue of counterfeit goods); Daniel Gervais, The TRIPS Agreement: Drafting History And Analysis, 11 (1998).

[36] GATT. Draft Agreement on the TRIPS, Communication from the EC., GATT Doc. No. MTN.GNG/NG11/W/68, Mar. 29, 1990, *available at* http://www.wto.org/english/tratop_e/TRIPS_e/ur_rft.exe.

[37] GATT. Draft Agreement on the TRIPS, Communication from the United States, GATT Doc. No. MTN.GNG/NG11/W/70, May 11, 1990 *available at* http://www.wto.org/ english/tratop_e/TRIPS_e/ur_rft.exe.

[38] GATT. Draft Agreement on the TRIPS, *Communication from Japan,* GATT Doc. No. MTN.GNG/NG11/W/74 dated May 15, 1990, *available at* http://www.wto.org/english/tratop_e/TRIPS_e/ur_rft.exe.

[39] GATT. Draft Agreement on the TRIPS, *Communication from Switzerland*, GATT Doc.No. MTN.GNG/NG11/W/73 dated May 14, 1990, *available at* http://www.wto.org/english/tratop_e/TRIPS_e/ur_rft.exe.

established at the end of the Uruguay Round. Developing countries also managed to submit their draft legal texts,[40] which were bundled together with the other draft legal texts by Lars Anell, then Chairman of the TRIPS negotiating group.[41] However, practically all the proposals from developing countries were removed by Arthur Dunkel, the then Director-General of the GATT and the Chairman of the Trade Negotiating Committee, in collusion with Lars Anell.[42] Braithwaite and Drahos have discussed the role of mechanisms, principles and actors in the developments leading to the TRIPS Agreement and observed that it was mainly coercion by the USA and a very close cooperation between the USA, the EC and major Western firms which led to the successful introduction of the TRIPS Agreement in the Uruguay Round.[43] The TRIPS Agreement did not stabilise even after the establishment of the WTO,

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[40] GATT. Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria,, Peru, Tanzania and Uruguay, GATT Doc. No. MTN.GNG/NG11/W/71 May 14 1990 *available at* http://www.wto.org/english/tratop_e/TRIPS_e/ur_rft.exe.

[41] GATT, *Chairman's Report to the GNG: Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods*, Doc. No. MTN.GNG/NG11/W/76 July 23 1990.

[42] The Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT doc. No. MTN.TNC/W/35/Rev.1 Dec. 3, 1990. This still contained developing countries' points. *See* Daya Shanker, *The Vienna Convention on the Law of Treaties, the Dispute Settlement System of the WTO and the Doha Declaration in the TRIPS Agreement*, 36 J. World Trade 721, 758. *See also* Paul Champs & Ameer Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the US-Brazil Patent Dispute*, 27 Yale J. Int'l L. 365, 378-379. *See* John Braithwaite & Peter Drahos, Global Business Regulation (2000) ("The considerable power of the Director General is symbiotically linked to the power of the US and EC. One senior US Trade Official pointed out , for example, in the later stages of the Uruguay Round the Director General (Sutherland) 'conspiring with us' made it almost impossible to change texts.").

[43] *See* John Braithwaite & Peter Drahos, Global Business Regulation, 73 (2000); *See* Duncan N. Matthews, Globalising Intellectual Property Rights: The TRIPS Agreement (2002); S.K. Sell, Power And Ideas: The North-South Politics Of Intellectual Property And Antitrust 138 (1998); M. P. Ryan, Knowledge Diplomacy: Global Competition And The Politics Of Intellectual Property, 100 (1998); R.Weissmann, *A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonise Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. Pa. J. Int'l Eco. L. 1069, 1084 (1996).

with constantly-changing interpretations of its provisions by the USA[44] or the EC, and conveniently-generated disputes such as *Canada Patent Protection*.[45]

B. The Paragraph 6 Solution of August 30, 2003

The Paragraph 6 Solution of August 30, 2003 has its genesis in a proposal submitted by developing countries requesting an authoritative interpretation of Article 30 of the TRIPS Agreement to permit manufacture and export of patented medicines by third parties to countries lacking the capacity to manufacture such products.[46] No decision was taken on this proposal, as it was postponed under paragraph 6 of the Doha Declaration on Public Health. Subsequently, the developing countries' proposal of a solution to this problem based on Article 30 of TRIPS was totally removed by the TRIPS Council Chairman, Eduardo Perez Motta, and an Article 31-centric solution based on a combination of the US and EC proposals was adopted on August 30, 2003 by the General Council, which was not rightfully authorised to take such a decision.

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[44] *See* Daya Shanker, *Brazil, the Pharmaceutical Industry and the WTO*, 5 J. World Intell. Prop. 51 (2002). Daya Shanker has discussed the complaint filed by the United States against Brazil against the presence of the local working requirements in the Brazilian Patent Act. Argentina also appears to have been coerced into changing its compulsory licensing provisions amending the use of competition policy to deal with the abuses of the TRIPS Agreement. *See also* Daya Shanker, *Argentina-US Mutually Agreed Solution, Economic Crisis in Argentina and Failure of the WTO Dispute Settlement System* 44 Idea 565 (2004).

[45] *Canada Patent Protection*, *supra* note 6, is a unique dispute where both parties tried to remove local working from the patent acts of Members of the WTO by insisting that Article 27.1 of the TRIPS Agreement would be applicable to Articles 31 and 30 exceptions. The irony of the dispute becomes clear when one recognises that the German Supreme Court on the basis of the Community Patent Convention had decided that the experimental use exemption would be applicable to the generation of data to be submitted to the regulatory authorities in Klinishe I and Klinische II. This aspect has been discussed in Daya Shanker, *Experimental Use Exceptions and Australian Patent Act: Submission to Advisory Council on Intellectual Property*, *available at* http://www.acip.gov.au/expusesubs.htm. *See also* Braithwaite & Drahos, *supra* note 42, at 87, and Duncan Matthews, *Trade Related Aspects of Intellectual Property Rights: Will the Uruguay Round Consensus Hold?* CSGR Working Paper NO. 99/02, 20 (2002) *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=319545/.

[46] TRIPS, Council Discussion on Access to Medicines – Developing Country Group's Paper, IP/C/W/296, June 20, 2001, (submitted by a group of developing countries to the TRIPS Council, for the special discussion on intellectual property and Access to Medicines, TRIPS and Public Health: Submission by the Africa group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela.).

The result is that it has now become virtually impossible for needy countries to access the requisite medicines.[47]

In the Paragraph 6 Solution, the General Council has waived the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products, prescribing specific conditions for exporting and importing countries. The exporting country can export such drugs only when it has made a notification to the Council for TRIPS:

a. specifying the names and expected quantities of the product(s) needed;

b. confirming that the importing Member does not have the manufacturing capacity or has insufficient manufacturing capacities in the pharmaceutical sector for the product(s), and;

c. confirming that a compulsory licence has been issued in its territory under Article 31 of the TRIPS Agreement.

The compulsory licence by the exporting Member, apart from the conditions mentioned in Article 31, must contain additional conditions that only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence, and the entirety of this production must be exported to the Member(s) which has notified its needs to the Council for TRIPS. The products

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[47] Marrakesh Agreement Establishing the World Trade Organisation (Apr. 15, 1994), Annex 1C1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994) *available at* http://www.wto.org/english/docs_e/legal_e/04-wto_e.htm [hereinafter WTO Agreement]. Art. IV(2) states "There shall be a General Council composed of representatives of all the Members, which shall meet as appropriate. In the intervals between meetings of the Ministerial Conference, its functions shall be conducted by the General Council. The General Council shall also carry out the functions assigned to it by this Agreement…".

Art. IV(1) of the Marrakesh Agreement deals with the authority of the Ministerial Conference. It says "… [T]he Ministerial Conference shall carry out the functions of the WTO and take actions necessary to this effect. The Ministerial Conference shall have the authority to take decisions on all matters under any of the Multilateral Trade Agreements, if so requested by a Member, in accordance with the specific requirements for decision making in this Agreement and in the relevant Multilateral Trade Agreement."

Art. IX(3) of the Marrakesh Agreement states "In exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member of this Agreement or any of eth Multilateral Trade Agreements, provided that any such decision shall be taken by three fourths of the members unless otherwise provided for in this paragraph."

Art. IX(4) of the Marrakesh Agreement discusses the procedures the Ministerial Conference has to follow while granting a waiver and that such waiver is to be reviewed by the Ministerial Conference within one year to verify the existence of such exceptional circumstances.

produced under the licence must be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colourings or shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price. It must be clarified here that the supplier is not the patent holder, as there would not be any need to issue a compulsory licence for export purposes in such cases. A similar provision, i.e., that the patented products should be clearly identified, has been added in the EC for export of medicines by the patent holders to poor developing countries to prevent any diversion of such products.[48]

All of the above would have to be done specifically under the guidance of the TRIPS Council, which would have to be informed of "the name and address of the licensee, the product(s) for which the license has been granted, the quantity(ies) for which it has been granted, the country(ies) the product(s) is (are) to be supplied to and the duration of the licence." Paragraph 3 of the Paragraph 6 Solution, which deals with remuneration, says that the supplier from the exporting countries (generic manufacturers) must pay remuneration to the patent holder whereas the receiver is waived from such payment. As we will see later on, none of the above provisions formed a part of any developing country's proposal, nor are they TRIPS-compatible. There is no requirement of payment of remuneration in the importing member countries if the goods are not manufactured in those countries by the patent-holder, in violation of 'local working' requirements. Such compulsory licensing would be covered by Article 5A(2) of the Paris Convention, which does not provide for any remuneration for abuse of the patent. Similarly, if the manufacture and export of the patented product does not affect the commercial interest of the patent-holder in the territory of the patent (i.e. the geographic area of the country), the question of any payment of remuneration to the patent holder does not arise.[49]

The marginalisation of developing countries was consolidated by the General Council Chairperson's Statement accompanying the Decision of August 30, 2003 sharing the "…understandings of Members regarding the Decision to be taken and the way in which it would be interpreted and implemented" and "to provide comfort

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[48] EC, *Trade and Development: Access to Medicines, available at* http://europa.eu.int/comm/trade/csc/med08qa_en.htm ("q.4. Is there any link between this regulation and the Trade related Aspects of Intellectual Property Rights (TRIPS) discussions on enabling developing countries to use of compulsory licences to manufacture the drugs they need? In principle, no. The discussion on compulsory licensing at the WTO TRIPS Council is a separate exercise. However, in practice it's clear that if poorer countries get the medicines they need under tiered pricing arrangement, they won't need to use compulsory licences.").

[49] *See* Daya Shanker, *The Paragraph 6 Solution of the Doha Public Health Declaration and Export Under the TRIPS Agreement*, 7 J. World Intell. Prop. 365 (2004).

to those who feared that the decision might be abused and undermine patent protection."[50] The Chairman's statement attached the "Best Practices" guidelines apparently prepared by the pharmaceutical multinationals for members to follow. It also provided the names of the members who opted out of using the system as importers.[51] The vacuity of the above solution becomes clear when one realises that not one country has been able to avail of the intended benefit under the Decision of August 30, 2003. In fact, Canada, while trying to amend its patent legislation to permit manufacture and export of patented products, insisted on giving the option to the patent-holder to take over the export of the products after the completion of negotiations between generic manufacturers and the importing countries.[52]

C. The Paragraph 6 Solution of the Doha Declaration

The Doha Declaration on the TRIPS Agreement and Public Health[53] was essentially an outcome of developing countries' proposals to affirm the concept of the basic international customary law in international treaty interpretations to ensure availability of medicines to their citizens because of the distortion introduced by the WTO Panel Report in Canada Patent Protection saying that the objectives and purpose are not to be taken into account while interpreting provisions of TRIPS.[54] However,

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[50] The Chairperson's Statement, *supra* note 7. *See* African Group's recent proposals, *supra* note 9, where they have questioned the legality of the Chairman's Statement and why it was linked at all in the August 30, 2003 Decision. It is still a controversy whether the Chairman's Statement would form part of December 6, 2005 Amendment.

[51] These countries are Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States of America.

[52] However, in an editorial in Canadian Medical Association Journal, the editor discussed the limitation of the Canadian legislation. *See* Editorial, *Patently necessary: improving global access to essential medicines,* 169 Canadian Medical Association Journal 1257, (December 9, 2003) *available at* http://www.cmaj.ca/cgi/content/full/169/12/1257?etoc.

[53] Doha Declaration, *supra* note 8.

[54] Developing countries submitted two proposals to the Council for Trade Related Aspects of Intellectual Property Rights. The first one was submitted on 20th June 2001 (IP/C/W/296) followed by the second one which was submitted on 4th October 2001 (IP/C/W/312). Both the proposals contained paragraphs related to interpretations of the provisions of the TRIPS Agreement, flexibility in issuing compulsory licensing and use of Article 30 to export medicines to countries not having sufficient capacity to manufacture required medicines. In Canada Patent Protection, the Panel led by Professor Robert Hudec agreed with the EC's argument that the objectives and purpose mentioned in Articles 7 and 8 of the TRIPS Agreement are not relevant in interpretation of other provisions such as Articles 30 and 31 of the TRIPS Agreement which led to a narrowing of flexibility present in the TRIPS Agreement.

Paragraph 10 of the Draft Ministerial Declaration from a group of developing countries[55], which states that each member shall refrain from imposing sanctions or threatening to impose sanctions against developing countries which avail themselves of policy options to promote and protect public health, suggests that the present economic and power structure have deteriorated considerably against developing countries.[56] This proposal was not accepted in the Doha Declaration on Public Health. The only thing that developing countries gained at Doha was an affirmation that, when applying the customary rule of interpretation to the provisions of the TRIPS Agreement, it should be done in the light of the object and purpose of the TRIPS Agreement,[57] a fundamental tenet in international treaty interpretation as mentioned in Article 31 of the Vienna Convention and in various decisions of the Appellate Body.[58] This was necessary because the Panel Report in *Canada Patent Protection*[59] had accepted the argument of irrelevance of the object and purpose in interpretations of the provisions of the TRIPS Agreement.[60] However, as stated earlier, the most important issue affecting the majority of the world's population was the matter of access to medicines in countries without manufacturing capacity or with insufficient manufacturing capacity, because such countries have to depend on other countries for the supply of medicines at accessible prices. The developing countries requested in their October 4, 2001 proposal that a compulsory licence issued by a member to supply medicines should be allowed to be given effect by another member under Article 30 of TRIPS (general exceptions).[61]

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55 TRIPS: Proposal-Draft Ministerial Declaration, *supra* note 10.

56 *Id.* 10.

57 TRIPS: Council Discussion on Access to Medicines, *supra* note 46, 17. "Each provision of the TRIPS Agreement should be read in light of the objectives and principles set forth in Articles 7 and 8. Such an interpretation finds support in the Vienna Convention on the Law of Treaties (concluded in Vienna in 23 May 1969), which established, in Article 31, that '[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose…'", *available at,* http://www.wto.org/english/tra_top_e/TRIPS_e/mindecdraft.htm. The Doha Declaration in paragraph 5(a) says "[I]n applying the customary rules of interpretations of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."

58 *See* Shanker, *supra* note 44.

59 *See Canada Patent Protection*, *supra* note 6, 7.92.

60 *See id.* (" . . . to the extent that prohibition of discrimination does limit the ability to target certain products in dealing with certain important national policies referred to in Articles 7 and 8.1, the fact may well constitute a deliberate limitation rather than a frustration of purpose"). *Also see* Shanker, *supra* note 42, at 738-39 and 742.

61 *See* Developing Countries' Proposal Oct. 4, 2001, *supra* note 10.

The most crucial outcome of the Doha Declaration – that TRIPS should be interpreted and implemented in a manner supportive of WTO members' "right to protect public health, and in particular, to promote access to the medicines for all"[62] – was not actually agreed to in the Decision of August 30, 2003. While recognising that a "WTO Member with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement",[63] the developed countries, particularly the USA, did not agree to the proposal regarding Article 30 as mentioned in paragraphs 5 and 9 of the Draft Declaration.[64] However, under paragraph 6 of the Doha Declaration, the Council for TRIPS was instructed to find an expeditious solution to this problem and to report to the General Council before the end of 2002.[65]

D. Non-Local Working and Compulsory Licensing

The concept of non-local working is applied to a situation where a patent-holder, after obtaining the patent, does not start manufacturing the patented goods in the territory of the patent. Although, on the basis of Article 27.1 of the TRIPS Agreement, the USA has tried to push the interpretation that working a patent can be accomplished by importing the said patented product, this interpretation runs contrary to Article 5(A) of the Paris Convention, which deals with the issue of compulsory licences and forfeiture of patents.

The major issue raised by incapacity or insufficient capacity to manufacture the patented product is that, after obtaining a patenting monopoly, a patent-holder would not start manufacture of the patented product in the territory of the patent. The resulting non-manufacturing or non-local working is regarded as an abuse of the patenting monopoly under Article 5(A) of the Paris Convention[66] as incorporated in TRIPS in Article 2.1, and permits such countries to issue compulsory licensing to third partiers to manufacture or import such patented products without payment of any remuneration. There is no provision for remuneration under Article 5(A) of the

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[62] Doha Declaration, *supra* note 8, 4.

[63] *Id.* 6.

[64] *See* Doha Declaration on the TRIPS Agreement and Public Health: Second Communication from the United States, IP/C/W/358, July 9, 2002, 6 [hereinafter 'US Second Communication'].

[65] Doha Declaration, 6 states "[W]e recognise 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 to report to the general council."

[66] See Paris Convention, *supra* note 28.

Paris Convention in cases where a compulsory licence is granted to third parties such as generic manufacturers because the patent-holder did not start manufacturing the patented product. The issue of compulsory licences for public order or public policy or other reasons is covered by other provisions of the TRIPS Agreement.[67] It is clear that Articles 30 and 31 deal with different situations, and not with the abuse of a patent through non-local working or insufficient working. This interpretation has been followed by the House of Lords in *Parke Davis* v. *Comptroller of Patents*[68] and by the German Supreme Court in Zwangslizenz.[69]

The requirement of local working of the patent cannot be satisfied by importing the patented product. This has been clarified by Bodenhausen, former Director of the World Intellectual Property Organisation (WIPO), and by a large number of judicial decisions.[70] Article 27.1 would not be applicable in the case of compulsory licences issued for non-local working, as Article 2.2 of the TRIPS Agreement

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[67] *See generally* Daya Shanker, *India, the Pharmaceutical Industry and the Validity of TRIPS*, 5 J. World Intell. Prop. 315 (2002); *See also* Paul Champs and Ameer Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the US-Brazil Patent Dispute*, 27 Yale J. Int'l L. 365, 378-379; E. Richard Gold and David K. Lam, *Balancing Trade in Patents-Public Non-Commercial Use and Compulsory Licensing,* 6 J. World Intell. Prop. 5 (2003). A number of judgements have clarified the point that the abuse under Art. 5(A) is limited to local working and insufficient working and would not be covered by provisions of compulsory licensing under public policy such as for food or medicines issued under public policy. *See* Parke Davis v. Comptroller-General of Patents [1971] RPC 425, [1970] FSR 443 and Zwangslizenz, GRUR 1996, 190. Other relevant judgments are Fette's Patent [1961] RPC 396; Re Cohmor Holdings, Chancery Division (Patents Court), (Transcript Martin Walsh Cherer), Jan 27, 1997. Ss. 48, 49 and 50 of the un-amended UK Patent Act 1977 were intended to reduce the 'abuse of monopoly' by the patent holder. S. 50(1)(a) of the un-amended UK Patent Act 1977 stated "…that an invention which can be worked on a commercial scale in the United Kingdom and which should in the public interest be so worked shall be worked here without undue delay and the fullest extent that is reasonably practicable."

Section 48(3) of the UK Patent Act till it was partially modified by The Patents and Trademarks (World Trade Organisation) Regulations, 1999, provides for the issue of compulsory licences. It said "Where the patented invention is capable of being commercially worked in the United Kingdom, that it is not being so worked to the fullest extent that it is reasonably practicable; Where the patented invention is a product, that a demand for the product in the United Kingdom… is being met to a substantial extent by importation; Where the patented invention is capable of being commercially worked in the United Kingdom, that it is being prevented or hindered from being so worked."

[68] *See* Parke Davis v. Comptroller-General of Patents [1971] RPC 425, [1970] FSR 443.

[69] Zwangslizenz, GRUR 1996, 190 [Supreme Court](G.D.R.).

[70] *See* G.H.C. Bodenhausen, Guide to the Application of the Paris Convention for the Protection of Industrial Property, (BIRPI, World Intellectual Property Organisation, Geneva, 1968).

specifically prohibits any derogation from the provisions of the Paris Convention by any provision of the TRIPS Agreement and it is a general principle of interpretation that a general provision cannot be applied to a specific stipulation.[71] In the case of compulsory licensing for non-local working or insufficient working, there is no provision for any remuneration, which explains the exceptional hostility of the USA against local working, as revealed in its complaints against Brazil,[72] which forced Brazil to enter into a Mutually Agreed Solution for prior consultation with the United States.[73] The local working provision is present in patent acts of practically all developing countries including that of India. However, the threatening language used by the United States Trade Representative (USTR), implying that countries which issue compulsory licensing for non-local working would be aggressively pursued, have been sufficient to deter developing countries from resorting to such compulsory licenses.

E. Enablement and Voidability of the Patent

The incapacity of a country to manufacture a patented product has a corresponding issue of non-enablement. The concept of enablement while granting a patent requires a clear and precise description of the patent and the manner of making and using such patent for the patent to be valid. A patent is a limited monopoly given to the innovator of the product on the express condition that he or she would provide detailed and accurate information, using which a person familiar with the Art would be able to replicate the product. If, because of the lack of technical qualifications and other resources, it is not possible to duplicate the patented product, then the purpose of granting a monopoly to promote social welfare through dissemination of information would be defeated. The enablement of a patent is one of the most important obligations of a patent-holder, wherein the temporary monopoly is granted on the grounds that the patent can be enabled in the territory of the patent.[74] Two

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[71] *See* Daya Shanker, *Brazil, the Pharmaceutical Industry and the WTO*, 5 J. World Intell. Prop. 51, 62-64.

[72] *See id.*

[73] *See* World Trade Organisation, Brazil-Measures Affecting Patent Protection, Notification of Mutually Agreed Solution, WT/DS199/4, G/L/454, IP/D/23/Add.1, July 19, 2001.

[74] 93 F2d 94 (1937, CA III), *cert. den.* 304 US 570 (1938), 82 L Ed 1535, 58 S Ct 1039, *reh den* (1938) 304 US 590, 82 L Ed 1549, 58 S Ct 1054.

In National Carbon v. Western Shade Cloth Co. 304 US 570 (1938), the Court observed "Specifications of patent including description and claims constituted contract between public and patentee under which public, through government, agreed that in consideration of inventor's disclosure and grant of right to use same after his monopoly expired, he should have been protected in his exclusive use during life of patent; the object was to place patent fully within knowledge of public and defined actual creation which public had undertaken to protect."

important considerations should thus be kept in mind during the patent grant process: firstly, that the description of the patent should be so clear and precise that it is possible for one in the art to replicate the patent, and, secondly, that in a situation where the patent cannot be replicated because of lack of suitably qualified personnel and infrastructure in the territory of the patent, granting of the patenting monopoly should not arise. Enablement cannot be uniform across all countries and will differ depending on each country's human resources and industrial capacity. Where a patent cannot be enabled it would be void, as interpreted in a number of judicial decisions in the USA and UK.[75] The US Supreme Court and other courts observed that, when foreign patent specifications do not sufficiently describe essentials of the invention so that a person skilled in the art cannot put it into practice, such prior art cannot invalidate the patent.[76] The specifications should be so clear that undue experimentation is not required by one skilled in the art to which it appertains to enable him to compound and use it.[77] Sections 5(2)(b), 14.3 and 72.1(c) in the UK Patent Act, Article 83 of the European Patent Convention (EPC), Article 5 in the Patent Cooperation Treaty (PCT)

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[75] Recent decisions dealing with enablement in the US are Hazeltine Research v. Dage Electric Co, 271 F.2d 218, 220 (7th Cir. 1959); Plant Genetic Systems v. Dekalb Genetics, 271 F.2d 218 (Fed. Cir. 2003); Genentech v. Novo Nordisk108 F. 3d 1361, 1365 (Fed. Cir. 1997) (quoting In re: Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993)); Biotechnology General v. Genentech, 267 F. 3d 1325 (Fed. Cir. 2001); Process Control Corporation v. Hydreclaim 190 F. 3d 1350 (Fed. Cir. 1999); University of Rochester v. G.D. Searle, 249 F. Supp. 2d 216 (W.D.N.Y. 2003) *aff'd* 358 F.3d 916, 928 (Fed. Cir. 2004) (The Federal Circuit reiterated its observation in Union Oil Co. v. Atlantic Richfield Co., 208 F. 3d 989 (Fed. Cir. 2000) that ordinarily skilled artisans would have been able to identify any compound based on its vague functional description as "a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product."); Johns Hopkins University v. CellPro, 152 F. 3d 1342, 1360 (Fed. Cir. 1998); Durel Corporation v. Osram Sylvania, 256 F.3d 1298, 1306-1307 (Fed.Cir. 2001); Enzo Biochem v. Calgene 188 F.3d 1362, 1369 (Fed. Cir. 1999), 52 USP.Q.(BNA) at 1134; In re: Vaek, 947 F. 2d 488, 495-96 (Fed. Cir. 1991); In re: Fisher, 57 C.C.P.A. 1099 (C.C.P.A. 1970) (The Federal Circuit reiterated the factors to be taken into consideration while determining enablement. These are: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.).

[76] Cawood Patent 94 US 695 (1877), 24 L Ed 238; Carson v. American Smelting & Refining Co. 4 F2d 463 (1925, CA9 Washington), cert den 269 US 555 (1925), 70 L Ed 441, 57 S Ct 18; Wisconsin Alumni Research Foundation v. George A. Breon & Co. (1936, CAB Mo) 85 F2d 166, cert den 299 US 598 (1936), 81 L Ed 441, 57 S Ct 191; Le Roy v Tatham 55 US 156 (1853), 14 How 156, 14 L Ed 367.

[77] Wood v. Underhill 46 US 1 (1846), 5 How 1, 12 L Ed 223; Expanded Metal Co. v. Bradford 214 US 366 (1909), 53 L Ed 1034, 29 S Ct 652; United States Industrial Chemical Co. v. Theroz Co. (1928, CA4 Md) 25 F2d 387, cert. den (1928) 278 US 608, 73 L Ed 534, 49 S Ct 12

and section 27(3) of the Canadian Patent Act have similar enablement provisions.[78] The concept of enablement can be clearly understood by an analysis of various judicial decisions dealing with § 112 in the US Patent Act.

In *Johns Hopkins*, the Federal Circuit discussed the District Court's observation that "testimony at trial established that a person skilled in the art of making monoclonal antibodies must have a bachelor's degree in the appropriate scientific field and must have made a monoclonal antibody at least once with approval."[79] The reasoning used was that the requirements for enablement were based on the notion that the purpose of granting a patent is to grant a limited monopoly to encourage the further progress of science and art and thus, if a particular product could not be manufactured by a lack of description, wherewithal, equipment, or personnel, it would not be patentable as the whole purpose of patenting it would be defeated. In a developing country, therefore, enablement of a patent of high complexity would be harder than in a technologically advanced country such as the USA. The description of a patent leading to enablement in such situation would be different and, in those countries where the products cannot be manufactured or replicated, patenting rights for such products cannot be granted. The importing of a patented product would not satisfy enablement criteria for granting a patent.[80] In the UK, the disclosure has been regarded as that of the highest degree of good faith for being granted a monopoly and it is required to be clear, precise, honest and open.[81] In *Biogen* v. *Medeva,*[82] the

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[78] S. 14. 3 of the UK Patent Act says that "[t]he specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art."S. 72(1) of the UK Patent Act provides that the absence of enabling disclosure as one of the grounds for the revocation of patent, the paragraph (c) of which states the treason for revocation of a patent when "the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art."

The Canadian Patent Act 27(3) requires the inventor to set forth clearly the steps required to make the "composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make it."

[79] *See* Johns Hopkins University v. CellPro, 152 F.3d 1342, 1360 (Fed. Cir. 1998).

[80] 35 USC. § 112 of the US Patent Act provides that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

[81] British Ore Concentration Syndicate Ltd. v. Minerals Separation Ltd., 27 R.P.C. 47 (1907); Cincinnati Grinders (Inc.) v. BSA Tools Ltd., 48 R.P.C. 33 (1931); Biogen v. Medeva [1997] R.P.C. 1.

[82] Biogen v. Medeva [1997] R.P.C. 1.

question of enablement was discussed by the House of Lords, which held that for the purposes of Sections 14(3) and 72(1)(c), the disclosure must be sufficient to enable the whole width of the invention to be performed. Where the specifications are regarded as addressed to a group of persons with different capabilities, such group of persons is assumed to cooperate for the purpose in view.[83] In *Mentor Corporation* v. *Hollister Inc.*, the Court observed that the hypothetical addressee had to be prepared to display a reasonable degree of skill and common knowledge of art in making trials and to correct obvious errors.[84]

Hence, the TRIPS Agreement covers the issue of exports to countries with no capacity or insufficient capacity to manufacture completely and does not need any addition or subtraction as suggested by the EC, the USA, Japan, Canada and Switzerland for this purpose. The incapacity to manufacture a patented product brings out the relationship between enablement and local working. The concept of local working thus continues to be present in the Paris Convention and has been incorporated into TRIPS.

IV. THE POSITION OF ARTICLES 30 AND 31 OF TRIPS IN THE PARAGRAPH 6 SOLUTION

A. Paragraph 6 at Doha and Proposals from WTO Members

As mentioned earlier, the developing countries' proposal at Doha for an authoritative interpretation of Article 30 of TRIPS regarding the manufacture and export of required medicines to needy countries was not finalised, and participants were pushing for either alternative proposals or non-proposals at the negotiations. The TRIPS Council received a number of proposals about Paragraph 6 of the Doha Declaration. By June 2002 the proposals were compiled together in document IP/C/W/363 dated 11th July 2002.[85]

1. Proposal from the European Community

The EC first asserted that current WTO legislation did not cater to situations in which a nation which issues a compulsory license does not have the capacity to

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[83] Valensi v. British Radio Corporation [1973] R.P.C. 377; Osram Lamp Works v. Pope's Electric Lamp Co. Ltd. 34 R.P.C. 369, 391 (1917).

[84] Mentor Corporation v. Hollister Inc. [1973] RPC 7.

[85] World Trade Organisation, Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation, IP/C/W/363 dated 11 July 2002 [hereinafter Thematic Compilation].

manufacture the said product.[86] The two options suggested by the EC to deal with such situations were:

a. an amendment to Article 31(f) so that the medicines can be produced elsewhere under compulsory licenses and exported to the country in need; or

b. an interpretation of Article 30 of the TRIPS Agreement to allow medicines to be produced elsewhere for export to the country in need.

The EC also introduced the issues of diversion of the medicines manufactured for export to needy countries to other countries and transparency in such transactions "in order to allow other Members to be informed if a Member makes use of this mechanism".[87]

However, the most significant part of the EC's proposal concerned the use of Article 30 to manufacture and export medicines to needy WTO members. The EC without reservation proposed: "WTO members could adopt a declaration stating that a WTO Member may, in accordance with Article 30 of the TRIPS Agreement, provide that the manufacture, on its territory, of a patented product, without the authorisation of the right holder, is lawful when it is meant to supply another country which has granted a compulsory licence for the import and sale of the product concerned in its territory in order to deal with a serious public health problem."[88] The EC reiterated its Article 30 solution in the subsequent document also.[89]

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[86] *EU Tables Proposals on Access to Medicines for Developing Countries with No Drug Production*, Press Release, Brussels, (Mar. 5, 2002), *available at* http://europa.eu.int/comm/trade/csc/pr_050302.htm and Concept Paper Relating to Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Communication from the European Community and its Member States, IP/C/W/339, Council for Trade Related Aspects of Intellectual Property Rights, WTO (Mar. 4, 2002) [hereinafter EC's Concept Paper]. Subsequently on 20th June 2002, the EC submitted another Communication (IP/C/W/352) adding two more solutions based on the US Communication. These additional potential solutions were

   a. a dispute settlement moratorium with regard to the non-respect of the restriction under a compulsory licence, and

   b. a waiver with regard to Article 31(f).

[87] *See id.*, EC's Concept Paper 16, 20.

[88] *See id.* at 24.

[89] World Trade Organisation, Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health (Communication from the European Communities and their member States to the TRIPS Council), IP/C/W/352 dated 20th June 2002, WTO [hereinafter EC's Para 6 Proposal].

2. Proposals from the United States

The US proposal was in line with that of the Pharmaceutical Research and Manufacturers Association (PhRMA), a lobby group of the US pharmaceutical industry, when it stated in paragraph 7 of its Second Communication: "A TRIPS-based solution can also only be expected to be effective where Members have, or are provided, the resources necessary to procure pharmaceuticals under the terms of a TRIPS-consistent compulsory license, which includes the provision of adequate remuneration to the patent holder."[90]

In paragraph 8 of the US Second Communication, the question of import from other countries was introduced. While the USA stated the obvious by saying that there was nothing to prevent import under compulsory licenses from other countries, it also stated that "a compulsory license would also need to be issued in that country before medicines could be exported."[91] There is, in fact, no provision either in Article 28 or any other article of TRIPS to support this.[92]

The right to exclude exports has never been granted to the patent-holder either by the TRIPS Agreement or through national patent acts. Except in Section 2567 of the PVPA[93] and § 271(f) of the US Patent Act,[94] a patenting monopoly has never been extended to export.[95] The patenting monopoly on "making" and "offering for sale"

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[90] *See* US Second Communication, *supra* note 66, at 7.

[91] *See id*. at 8.

[92] *See generally* Daya Shanker, *Para 6 Solution of the Doha Declaration, Article 30 of TRIPS and Non-Prohibition of Exports under the TRIPS Agreement*, Working Paper, University of Wollongong, published in SSRN Working Paper Series, *available at* http://ssrn.com/abstract=377160.

[93] *See* The Plant Variety Protection Act (1970) (PVPA) where the patenting monopoly has specifically been extended to export and from 35 USC. § 271(f). The PVPA reads as follows:

"Except as otherwise provided in this subchapter, it shall be an infringement of the rights of the owner of a novel variety to perform without authority, any of the following acts in the United States, or in commerce which can be regulated by Congress or affecting such commerce, prior to expiration of the right to plant variety protection but after either the issue of the certificate or the distribution of a novel plant variety with the notice under section 2567 of this title:

"(1) sell the novel variety, or offer it or expose it for sale, deliver it, ship it, consign it, exchange it, or solicit an offer to buy it, or any other transfer of title or possession of it;

"(2) import the novel variety into, or export it from, the United States;

[94] 35 USC. § 271(f) (1994).

[95] 35 USC. § 271(f) was introduced in the US Patent Act, 12 years after the judgement of the US Supreme Court in *Deepsouth Packing* to overrule its observation that patenting monopoly did not extend to the individual constituents of the assembled machine of invention.

would not affect export of the patented product or process, given the decisions of the US,[96] Canadian,[97] UK[98] and Japanese courts.[99] National patent acts generally only exclude those types of "making" which affect the commercial exploitation of the patent in the territory of the patent. In a number of judicial decisions in the USA[100] and in the WTO Panel decision in *Canada Patent Protection,*[101] it was confirmed that the making of a patented product even in an unlimited amount would not violate the patenting provision if such making does not lead to the commercial exploitation of

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[96] See Sawin v. Guild, 1 Robb, Pat. Case 47, Fed. Cas. No. 12391, 21 F. Cas. 554 (Cir. Ct D. Mass. 1813); Bonsack Machine v. Underwood 73 F. 206 (Cir. Ct. E. D. N. Car. 1896); Brown v. Duchesne 60 US 183 (1856); Dugan v. Lear Avia, Inc. 55 F. Supp. 223, 229 (S.D.N.Y. 1944) affirmed 156 F.2d 29 (2d Cir. 1946); Roche Products Inc. v. Bolar Pharmaceuticals 572 F. Supp. 255, 258 (E.D.N.Y. 1983), rev. Roche Products v. Bolar Pharmaceuticals 733 F.2d 858 (Fed. Cir. 1084) which in turn was reversed by US Congress by introducing § 271(e) in the US Patent Act; Aakro Agate v. Master Marble Co. v. Master Marble Co. 18 F. Supp. 305 (N.D.W. Va. 1937); Kaz Manufacturing Co. v. Chesebrough-Pond's Inc., 211 F. Supp. 815 (S.D.N.Y. 1962), *aff'd.* 317 F. 2d 679 (2d Circuit, 1963); *Quality Tubing v. Precision Tube Holdings* 75 F. Supp. 2d 613, 623 (S. D. Tex. 1999); Rotec Industries v. Mitsubishi 215 F. 3d 1251 (Fed. Cir. 2000); Cybotronics v. Golden Source Elecs. 130 F. Supp. 2d 1152, 1167-73 (C.DE. Cal. 2001), WL 327826.

[97] Microchem v. SmithKline & French, [1972] S.C.R. 506.

[98] Frearsaono v. Loe, (1878), 9 Ch. D. 48.

[99] *See* Ono Pharmaceuticals Co. v. Kyoto Pharmaceutical Industries, Case No. 1998 (ju) 153 (Apr. 16, 1999) (decided by the Supreme Court of Japan).

[100] See Intermedics v. Ventritex, 775 F. Supp. 1269, 1280 (N. D. Cal. 1991), aff'd, 991 F. 2d 808 (Fed. Cir. 1993)(non-presidential decision) ("We infer that the phrase 'reasonably related' (to development information for the FDA) as used in § 271(e)(1) reflects Congress's acknowledgement that it will not always be clear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it will make to win that agency's approval." The question of quantity was discussed in the context that the defendant had manufactured several hundred Cadences); In *Amgen* (Amgen v. Hoechst Marion Roussel, 3 F. Supp. 2d 104, 108 (D. Mass. 1998) *aff'd* by Amgen v. Hoechst Marion Roussel 314 F. 3d 1313 (Fed. Cir. 2003)) the court discussed the question of commercial production of patented products by a generic manufacturer before the expiry of the patent. The argument was based on Amgen's assertion that Hoechst had planned a total of five batches of commercial scale production of GA-EPO as required by the Japanese and the European regulatory agencies and had produced at least three commercial scale productions apart from batch 07. The court in *Amgen* observed that Hoechst was protected by § 271(e)(1) if the production of three batches of GA-EPO was objectively likely to generate useful information, even if the results were discarded for reasons unrelated to FDA approval. The court specifically observed that retention of the GA-EPO manufactured is not an activity that could constitute infringement under § 271(a) as was observed in Telectronics (Telectronics Pacing Sys., Inc. v. Ventritex Inc., 982 F. 2d 1520, 1523-24, 25 USPQ2D 1196, 1199 (Fed. Cir. 1992).

[101] *See Canada Patent Protection*, *supra* note 6, 7.45.

the patent in the territory of the patent. The assertion of the USA that a compulsory licence would also need to be issued in that country for the export of medicines to be possible is, thus, not based on any valid legal interpretation.

In paragraph 12 of its Second Communication,[102] the USA insisted on identification of the countries not having manufacturing capacity or insufficient capacity on the basis of certain criteria followed by its proposal to limit the countries willing to export only to the members of developing and least developed countries.[103] The proposal pertaining to transfer of technology under Article 31(f) by the group of African countries was probably discussed in this context.[104] The USA introduced the concept of "transparency" in part V, paragraph 20 of its Second Communication requiring developing countries and least developed countries to inform the TRIPS Council of actions taken under the proposed mechanism where Article 31(f) is used to export the patented product to fulfil the requirement of other countries, which will apparently ensure that goods reach the needy countries under the policing of the TRIPS Council.

The most disturbing statement in the United States' proposal pertains to Article 30 of the TRIPS Agreement, wherein the USA insisted that the use of Article 30 to export a patented product would unreasonably conflict with normal exploitation of the patent and prejudice the legitimate interests of the patent owner."[105] The US argument appears to be specious, considering that the US permitted manufacturing of the patented product in unlimited quantities for regulatory approval purposes under the *Bolar* exception embodied in the US in the Hatch-Waxman Act, which was confirmed as compatible with Article 30 exceptions in *Canada Patent Protection*.[106] The reasoning behind this assertion from the USA appears to be based on a discussion of Article 30 by Abbott.[107] The US compounded its position by the inclusion of a one-time waiver along the lines of the *Bolar* exception, in line with PhRMA's suggestions

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[102] *See* US Second Communication, *supra* note 66, 12.

[103] *See id.*, 15.

[104] WTO, Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Joint Communication from the African Group in the WTO, IP/C/W/351 (June 24, 2002) received from the Permanent Mission of Kenya on behalf of the African Group in the WTO [hereinafter African Proposal] at 6(e).

[105] *See* US Second Communication, *supra* note 66, 6.

[106] *See* Canada-Patent Protection, *supra* note 6.

[107] *See* Frederick M. Abbott, *WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries*, Report commissioned by the CIPR as a background paper, Study Paper 2a, Commission on Intellectual Property Rights (Feb. 14, 2002) *available at* http://www.iprcommission.org/papers/pdfs/study_papers/sp2a_abbott_study.pdf.

as enumerated by Amir Attaran.[108] The USA also questioned the legality of the authoritative interpretation of a WTO provision provided under Article IX (2) of the Marrakesh Agreement,[109] despite the fact that this assertion goes against the United States' own argument in the *Alcoholic Beverages* case[110] and against the decision of the Appellate Body[111] (discussed in detail later in this chapter). The USA is not only trying to undermine the flexibility inherent in the TRIPS Agreement as partly retrieved by developing countries in the Doha Declaration on Public Health, but also undermines the Ministerial Conference which has been empowered in terms of Article IX: 1 of the Marrakesh Declaration, to authoritatively interpret the provisions of these agreements.

The USA's assertion does not appear to have legal support, as both the phrases "unreasonably conflict with the normal exploitation of a patent" and "unreasonably prejudice the legitimate interests of the patent owner" mentioned in Article 30 of TRIPS are to be interpreted in terms of the direct economic and commercial effect on the patent in the territory of the patent. When the patented products are exported out of the patented areas, they are not affecting the interests of the patent-holder reasonably or unreasonably at all in the territory of that patent. Even without Article 30, the US Supreme Court has delivered verdicts such as *Deepsouth Packing* v. *Laitram Corporation*[112] to the effect that patented products exported under knocked-down conditions do not violate the US Patent Act and that the patent holder does not have the right to prohibit the export of the patented product.[113]

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[108] *See* Amir Attaran, *Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Options for TRIPS Council*, Working paper No. 87, Center for International Development, Harvard University (2002) at 8 *available at* http://www2.cid.harvard.edu/cidwp/087.pdf. This paper was subsequently published in Fordham Intellectual Property, Media and Entertainment Law Journal (Amir Attaran, *The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L. J. 869 (2002)) (Attaran suggested a concept of non-justiciability which would exempt the manufacture and export of generic versions of patented pharmaceuticals when these are intended for countries lacking pharmaceutical manufacturing capacity.) Amir Attaran's relations with the Harvard University was a little controversial when it was found out that his salary during his stay in the Harvard University was paid by an outside organisation, the Africa Fights Malaria, essentially financed by a group of mining firms in South Africa interested in playing down the extent of AIDS/HIV impacts.

[109] *See* US Second Communication, *supra* note 66, 29.

[110] WTO Report of the Appellate Body, *Japan Taxes on Alcoholic Beverages*, WT/DS58/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (4th October, 1996) adopted 8th November 1999 [hereinafter *Japan Taxes*].

[111] *Id.*

[112] 406 US 518, 532 (1972).

[113] *See* Daya Shanker, *supra* note 42, 764-767.

3. Proposals from Developing Countries and the UAE

The proposal from the developing countries was essentially a continuation of their proposal in the Draft Declaration dated October 4, 2001[114] and maintained that the use of Article 30 should "recognise the right of WTO members to authorise third parties to make, sell and export patented public health-related products without the consent of the patent holder to address public health needs in another country."[115] Using Articles 7 and 8 of the TRIPS Agreement, the developing countries discussed two aspects of the issues raised by the insufficiency or incapacity of certain members of the WTO to manufacture: the first was regarding "local working",[116] which was a continuation of their argument put forth in June 2001,[117] and the second was the authoritative interpretation of Article 30 as set out above.[118] There are two aspects to the developing countries argument. The first aspect appears to be based on the presumption that the patent rights granted cover the export of the patented products to territories outside that of the patent, while the second aspect suggests that it is the responsibility of the countries exporting and importing the patented products to establish appropriate safeguards. In paragraphs 9 and 11 of their document, the developing countries elaborated on the use of Article 30 of the TRIPS Agreement and why it would not "unreasonably conflict with the normal exploitation of the patent or unreasonably prejudice the legitimate interests of the patent owner."[119] The United

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[114] TRIPS: Council Discussion on Access to Medicines, *supra* note 46.

[115] *See* Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health received from the Permanent Mission of Brazil, on behalf of the delegation of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Pakistan, Peru, Sri Lanka, Thailand and Venezuela, IP/C/W/355 (June 24, 2002), TRIPS Council [hereinafter Communication from Developing Countries].

[116] *Id*. at 3 "The development of local manufacturing capacities for public health-related products, whenever economically feasible, is critical to ensuring the development of sustainable health policies and access to affordable medicines, particularly in developing countries".

[117] WTO, TRIPS and Public health – Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, document IP/C/W/296 (June 20, 2001) at 20, *available at* http://www.wto.org/english/tratop_e/TRIPS_e/paper_develop_w296_e.htm

[118] *See id*. at 20.

[119] Communication from Developing Countries, *supra* note 119, 9;

Similarly 11 of the Communication from Developing Countries says

"Clearly, nothing in the letter and spirit of Article 30 of TRIPS prevents members from authorising local producers to make, sell and export public health –related products, without the consent of the patent holder, to address health needs in other countries with insufficient or no manufacturing capacities, as a limited exception under this provision. In light of the

Arab Emirates suggested an interpretation of Article 30 of TRIPS to "engage, sell and export patented public health related products without the consent of the patent holder to address public health needs in another country" and further suggested that the interpretation should not "prejudice other exceptions to the exclusive rights initially available to the members under Article 30 of the TRIPS Agreement."[120] While discussing a possible Article 31(f) solution, the developing countries proposed that Article 31(f) should be eliminated altogether.

4. Proposal from the African Group

Perhaps due to their free trade negotiations with the USA, the African countries preferred to file their own proposal separate from the other developing countries.[121] Their proposal was concerned predominantly with the Common Market approach of the African Nations, which they expanded in the paragraph 6(d) of their proposal. This paragraph says:

> *Members, in respect of licences issued to address practices that restrain trade, other abusive practices, and insufficiency of supplies of pharmaceutical products, may recognise or give effect to the licences at a regional level where a domestic market is part and parcel of a regional market for instance under a free trade area or a custom union or the interim arrangements.*[122]

However, in paragraph 3(5) of this document, the African group recognised the limitation of the Article 31(f) solution and suggested that it should be deleted or a clear authoritative interpretation adopted.[123] It also insisted on flexibility in the

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mandate to find expeditious solutions to the problem recognised in Paragraph 6, an authoritative interpretation of Article 30 confirming this legal solution would be an important step to ensure legal certainty of all WTO Members. Moreover, in light of paragraph 4 of the Ministerial Declaration on the TRIPAS Agreement and Public Health [Doha Declaration], Article 30 of TRIPS '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 medicines for all'."

[120] *See* WTO, Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public health, Communication from the United Arab Emirates, IP/C/W/354 (June 24, 2002), 20-21.

[121] African Proposal, *supra* note 108.

[122] *See id.* at 6(d).

[123] *Id.* at 3(e) "These limitations show how paragraph (f) of Article 31 may be far out of line with the needs of members in the face of the international and national health crises upon us. The paragraph needs to be deleted, or a clear exception introduced, or an authoritative interpretation adopted, bearing in mind the said time frame within which an expeditious solution should be adopted."

grounds for issuing of compulsory licenses.[124] The approach of the African group seems to have been to use the opportunity to push for the industrialisation of Africa, which is supported by their subsequent statement in paragraph 6(e) asking for adoption of measures to build a sound technological base in the developing countries of Africa so as to facilitate the domestic production of pharmaceutical products to meet public health needs.[125]

The most important point raised by the African group was the reiteration of a "comprehensive moratorium on disputes against any Member that takes measures to address the international and national health concerns in countries with insufficient or no manufacturing capacity."[126] Another observation from the African group pertains to the tendency seen in some bilateral and multilateral arrangements between developed and developing countries, wherein developing countries have been asked not only to give up not only the flexibility due to them under the TRIPS Agreement but also to raise their levels of patenting monopoly.[127] Such arrangements have been made in the FTAA (Free Trade Agreement of America) treaty signed between the USA and Chile and are part of the free trade agreements being negotiated between the USA and the African countries such as South Africa, Lesotho, Botswana, Namibia and Swaziland, which are members of the South African Customs Union (SACU).[128] The African group suggested that members "should avoid the fragmentation of the multilateral regime on intellectual property rights provided by the TRIPS Agreement, and should respect and ensure the use to the full flexibility in the TRIPS agreement."[129] Overall, the proposal from the African group was essentially complementary to the proposals from the developing countries and the UAE without diluting them, and additionally incorporates an important point on the transfer of technology.

5. The TRIPS Council and Thematic Compilation

On the basis of these proposals, the TRIPS Council prepared a thematic compilation by the middle of July 2002.[130] Coincidentally, Document MTN.GNG/

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[124] *Id.* at 3(f) "As the declaration points out, for instance, members have the right to determine the grounds on which to issue compulsory licences and such grounds are not set out in the TRIPS Agreement. This flexibility needs to be protected against attempt to restrictively define the scope of the freedom of members to determine grounds for compulsory licences."

[125] *Id.* at 6(I), 5.

[126] *Id.* at 6(g).

[127] *See, e.g.*, Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area, *available at* http://www.ustr.gov/regions/eumed/middleasst/USJordanFTA.shtml.

[128] USTR, The letter sent by Ambassador Robert B. Zoellick to Sen. Byrd on or about 4th November, 2002, www.ustr.gov.

[129] African Proposal, *supra* note 108, at 5.

[130] Thematic Compilation, *supra* note 89.

NG11/W/76 dated July 23, 1990 was prepared in similar circumstances during the TRIPS negotiations, where then-Chairman Anell put the proposals from different countries together and similarly divided it in a number of sections depending upon the origin of the proposals. Subsequently, each and every proposal from developing countries was removed or circumscribed. The TRIPS Council divided the proposals in its thematic compilation in two sections: one which included the elements suggesting facilitation of exports to members with insufficient manufacturing capacities (including proposals from the USA, the EC and developing countries) and one which included proposals mainly from the African group, which discussed the issues of technology transfer and establishment of manufacturing capacity along with the expansion of a unified market.

All this indicated the shape of things to come. The USA suggested the waiver of conditions in Article 31 of TRIPS as if the Article 30 solution did not exist, and made the unethical observation that an authoritative interpretation would lead to more litigation. The EC gave the Article 30 solution a chance to be adopted, but recommended a thick web of conditions to block the so-called diversion of patented products without providing any evidence of diversion.[131] Outterson has discussed the question of diversion in detail and he concludes that the question of diversion to developed countries has never been an issue, since, throughout the period when medicines and chemicals were exempted from patenting in developing countries, there was no diversion of such medicines and chemicals to developed countries. Outterson also points out that parallel trade – where the patented goods, once sold, are supposed to go out of the control of the patent-holder under the first sale exhaustion regime and can be freely imported and exported – did not lead to price convergence, as is evident from the price divergence in the EC. The scare of diversion was created by the monopolistic industries essentially to segregate the international market into different segments to gain maximum revenue, without making any effort to provide access to medicines to developing countries.

Another intriguing development at this stage was the African group's choice to separate itself from the other developing countries. There was a commonality of purpose between the USA and the African group proposals regarding the need for technology transfer and the extension of compulsory licensing to the regional geographical area instead of confining it to a single country. The break-up of the

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[131] *See* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 Yale J. Health Pol'y, L. & Ethics 193 (2004) (discussing the scare of diversion of such medicines generated by the pharmaceutical industry by giving example of the Dowelhurst case (Glaxo Group Ltd v. Dowelhurst Ltd [2004] All E.R. (D) 126 (Mar) where the goods claimed to have been diverted to Europe by Glaxo never left the EC.).

developing country group also perhaps emboldened Edouardo Motta, the Chairman of the TRIPS Council, resulting in the removal of the Article 30 solution completely from his note. It perhaps further resulted in the prime proposal being a combination of the American proposal of the waiver of the conditions of Article 31 solution and the thick web of conditions recommended in the EC's proposal, which in effect incorporated exports as one of the patenting rights in Article 28 of the TRIPS Agreement.

B. Paragraph 6 and the Introduction of Regulatory Provisions

The introduction of a series of regulatory provisions in the area of exports of patented products for the ostensible reason of providing transparency does not appear to be convincing, as provisions dealing with the exports of the patented products were clearly present in the TRIPS Agreement under Articles 31 and 30[132] and there was a clear observation by the Panel in *Canada Patent Protection* that any question of diversion of the patented product is the responsibility of the patent holder and not that of national governments.[133] Articles 31(f) and 31(k) do not have a corresponding free import provision in the territories where a patent is in force, and the only way a patented product can get through in these territories is through trade diversion. Article 31 implies that non-predominant parts of such manufactured goods can be disposed of, and there is no account-maintenance system whereby the TRIPS Council is informed of details such as the amount manufactured. Based on Article 31(k) of the TRIPS Agreement, a large number of countries, including the UK and India, have incorporated provisions in their patent laws saying that patented products manufactured under Article 31(k) can be freely exported.

There is no provision in the TRIPS Agreement for putting into place an elaborate control structure. From the developments so far, the purpose of constructing such a

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[132] There are two provisions in Article 31 of TRIPS dealing with the manufacture and exports of such manufactured products under compulsory licensing. These are:

1. Article 31(f), which the General Council attempted to amend although not empowered to do so as per Article IX of the Marrakesh Agreement and which says:

> any such use [of the products manufactured under Article 31 of TRIPS] shall be predominantly for the supply of the domestic market of the Member authorising such use; and

2. Article 31(k) which says:

> Members are not obliged to apply the conditions set forth in sub-paragraph (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.

[133] *Canada Patent Protection*, *supra* note 6, at 7.46.

structure appears to be not only to frighten manufacturers or the countries concerned but subsequently to extend it throughout all compulsory licensing systems. Chairman Motta's note and its confirmation as an authoritative interpretation by the General Council of the WTO on August 30, 2003[134] is a rewriting of the TRIPS Agreement and, given the developments so far, it is evidently highly skewed towards the wishes of the USA and the EC. There is nothing new in the export of patented products produced under compulsory licensing, and there appears to be no requirement for such an elaborate structure, as the infringement action is the responsibility of the patent-holder through his private action.[135]

The EC tried to justify the introduction of extensive regulations by Chairman Motta in the Decision of August 30, 2003 by insisting that the existing enforcement measures under the TRIPS Agreement mainly address the possibility of patent infringement and not that of trade diversion. According to the EC, the issue of diversion of a patented product is entirely different from that of the infringement of a patent and, whereas existing enforcement measures in the TRIPS Agreement deal with the latter, there are no provisions in the TRIPS Agreement to deal with the issue of the diversion of a patented product. In this context, as per the EC, the norms prescribed in the Decision of August 30, 2003 are for prohibiting trade diversion from their intended destination.[136] This is a unique argument, as the patent-holders have so much of control in the countries where they are producing the goods that no goods manufactured in developing countries where there has been no patenting have been exported to the developed countries so far.[137] This issue of diversion was exactly the argument raised by the EC in its dispute against Canada in *Canada Patent Protection*, to which the Panel did not agree on the ground that it is the responsibility of the private infringement action of the patent holder that the challenged conduct is inconsistent with the basic patent rights created by national laws, not that of the governments.[138]

The elaborate formalisation of rules and regulations in the Decision of August 30, 2003 does not appear to have a legal basis either in the TRIPS Agreement or in the internal domestic law of these countries. What the EC could not gain from the

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[134] *See* Decision of August 30, 2003, *supra* note 7.

[135] *See Canada Patent Protection*, *supra* note 6, at 7.46.

[136] Sustainable Trade: Access to Medicines-Main Elements of the Chair's 16 December 2002 draft compromise decision (Perez Motta text), Brussels (Jan. 9, 2003), *available at* http://europa.eu.int/comm/trade/csc/memo0090103_en.htm.

[137] *See* Michael A. Friedman, Henk den Besten, Amir Attaran, *Out licensing: A Practical Approach for Improvement of Access to Medicines in Poor Countries*, 361 LANCET 341 (2003).

[138] *See Canada Patent Protection*, *supra* note 6, at 7.46.

Panel decision through the dispute mechanism in *Canada Patent Protection*, it gained through Paragraph 6 of the Doha Declaration negotiations. Changes were introduced in the Community Patent Convention to say that the import of a patented product would satisfy the local working requirement on the basis of the Panel's observation that Article 30 would be covered by Article 27.1's non-discrimination provision. This not only ignores other observations of the same Panel but also attempts to violate the decisions of the Panel in *Canada Patent Protection*, which is at least binding on both the EC and Canada. The attempt by the EC to distinguish between infringement and diversion after losing the issue of diversion of patented products in *Canada Patent Protection* suggests that there is little consistency in international treaty interpretations or negotiations over TRIPS.

C. Non-Discrimination under Article 30 and Paragraph 6 at Doha

Another important aspect of the proposals of the US and the EC is their argument that Article 30's authoritative interpretations to permit export would violate the non-discrimination provision of Article 27.1. This fails to understand the basis of the Panel's observation in *Canada Patent Protection*, which extended the applicability of non-discrimination provision in Article 27.1 to Article 30 of the TRIPS Agreement and was in fact based on the acknowledgement from Canada that Article 27.1 would be applicable to an exemption under Article 31 of the TRIPS Agreement.[139] The Panel observed that since Article 27.1 would be applicable to Article 31 of the TRIPS Agreement, it would also be applicable to Article 30 of TRIPS. If Article 27.1 is used to suggest that it would not be permissible under Article 30 of TRIPS, it cannot be permissible under Article 31 of TRIPS either, which effectively amounts to saying that there cannot be any solution at all. No international treaty can be interpreted in this manner. Moreover, the question of import of unauthorised patented products is covered by Article 41 of the TRIPS Agreement which explicitly says:

> *It is understood that this Part does not create any obligations to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of members to enforce their law in general. Nothing in this Part creates any obligations with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.*

In other words, nations can resort to their own judicial system to block any diversion of unauthorised patented products.

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[139] *Id.*

D. Exports Under Article 30 of TRIPS and the Limited Exception

Article 30 of the TRIPS Agreement is an exceptionally important provision in the TRIPS Agreement because it permits a degree of flexibility to reduce monopolistic negative externalities and to keep the social welfare purpose of the monopoly granted through patents on the right track. The Article states:

> *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 interests of the patent owner, taking into account the legitimate interests of third parties.*

One possible argument to eliminate an Article 30 solution to Paragraph 6 of the Doha Declaration is to say that manufacture of the patented products for the purpose of exports would not be covered under the limited exceptions permitted by Article 30 of TRIPS, although this argument was not made either by the EC or the USA. Another argument to exclude the Article 30 TRIPS solution could be to see whether the limited exception in Article 30 affects or prejudices the legitimate interest of the patent holder. The WTO Appellate Body has discussed the interpretation of the term 'exception' in *EC-Measures Containing Meat and Meat Products (Hormones),* [140] in which it observed:

> *Merely categorising a treaty provision as an 'exception' does not by itself justify 'stricter' or narrower interpretation of that provision than would be warranted by examination of the ordinary meaning of the actual treaty words, viewed in context and in the light of the treaty's object and purpose, or, in other words, by applying the normal rules of treaty interpretations.*[141]

In *Canada Patent Protection*, the Panel, led by Robert Hudec, interpreted the term "limited exception" in a very narrow sense, although in terms of the interpretation given by the Appellate Body, its interpretation is incorrect. Even accepting the restrictive interpretation of the term "limited exception" in *Canada Patent Protection* on the basis that the object and purpose of a treaty are irrelevant for treaty interpretation, the manufacture of patented medicine for approval by the regulatory authorities is regarded as within the exception of Article 30 as far as TRIPS is

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[140] WTO, Report of the Appellate Body, *EC-Measures concerning Meat and Meat Products (hormones),* WT/DS26/AB/R, WTO Doc. AB-1997-4, and WT/DS48/AB/R (Jan 16, 1998).

[141] *Id.* at 104.

concerned. The manufacture to fulfil the tests requirement for regulatory approval permitted under the *Bolar* Exception in the USA,[142] by the German Supreme Court in Clinische I[143] and II[144] and by the Japanese Supreme Court[145] in *Ono Pharmaceutical* is regarded as being within the exception permitted under Article 30. Although the Panel in *Canada Patent Protection* observed that additional benefits, such as monopoly for extended period of patents, are within the rights prescribed by Article 28.1 of the TRIPS Agreement without any legal support,[146] it found that manufacture to remove such extended market exclusivity would be covered by the 'limited exception' criteria mentioned in Article 30 of the TRIPS Agreement. What the Panel actually observed was:

> *Even though regulatory approval processes may require substantial amounts for test production to demonstrate reliable manufacturing, the patent owner's rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of the resulting final products.*[147]

The commercial use of the final products in the above observation of the Panel refers to the commercial use in the territory of the patent, not throughout the world. Once a compulsory licence is issued or where the patent cannot be granted for any reason, the export of the patented products would not be affected by the limitation placed by Article 28.1 and would be covered by Article 30 of TRIPS as it does not affect the patent owner's right as "no commercial use is made of resulting final products".

It must be understood that the term "normal exploitation of the patent" is legally valid only for the area for which the patent has been granted in view of the territoriality of the patent and not for the universal exploitation of the patent. If the patented products are exported out of the patented territory, it does not and cannot conflict

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[142] Bolar Exception, 35 USC. § 271(e) (1994).

[143] Clinische Versuche I, Federal Supreme Court of Germany [1997] RPC 623, LEXIS UK Patent Cases 32, BGH, 11th July 1995, GRUR 1996, 109 [Supreme Court] (F.R.G.).

[144] Clinishe Versuche II [1998] RPC 423, LEXIS UK Patent Cases 32 [Supreme Court] (F.R.G.).

[145] Ono Pharmaceutical Companies v. Kyoto Pharmaceutical Industries, Case No. 1998 (ju) 153 (Apr. 16,1999) (Decided by the Supreme Court of Japan).

[146] *See Canada Patent Protection*, *supra* note 6, at 7.35.

[147] *See id.* at 7.45.

with the "normal exploitation of the patent"[148] nor prejudice the legitimate interests of the patent owner in the territory of the patent. The European Parliament even gave "practical embodiment" to Article 30 exceptions to be used to provide access to such medicines.[149] The "limited exception" criteria is not affected by export under Article 30 of TRIPS to the region where either the patent-holder's rights were suspended through issue of a compulsory licence, or the patent-holder has no interest because the products were not patented. The patent owner does not have access to the territory to which the goods are exported under compulsory licensing or non-granting of patents, and the patent owner does not have any legitimate commercial interests therein. This is how TRIPS stands, and this is how it was viewed by the EC in its concept paper.

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[148] Daya Shanker, *supra* note 42, at 769. In John Brown v. Duchesne, 60 US 183, 195 (1886), the US Supreme Court has interpreted the patenting clause of the US Constitution and observed:

"The patent laws are authorised by that article in the Constitution which provides that Congress shall have power to promote the progress of science and useful arts, by securing for limited time to authors and inventors the exclusive right to their respective writings and discoveries. The power thus granted is domestic in its character, and necessarily confined within the limits of the United States. It confers no power on Congress to regulate commerce, or the vehicles of commerce, which belong to a foreign nation, and occasionally visit our ports in their commercial pursuits. That power and treaty-making power of the General Government are separate and distinct powers from the one of which we are now speaking, and are granted by separate and different clauses, and are in no degree connected with it. And when Congress are legislating to protect authors and inventors, their attention is necessarily attracted to the authority under which they are acting, and it ought not lightly to be presumed that they intended to go beyond it, and exercise another distinct power, conferred on then for a different purpose. Nor is there anything in the patent laws that should lead to a different conclusion. They are all manifestly intended to carry into execution this particular power. *They secure to the inventor a just remuneration from those who derive a profit or advantage, within the United States, from his genius and metal labors (emphasis added)".*

[149] The European Parliament adopted proposals for an Article 30 solution during the first reading of the draft Directive to update Directive 2001/83/EC relating to medicinal products for human use. The amendment stated:

"Manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory licence of that product, or where a patent is not in force and if there is a request to that effect from the competent public health authorities of that third country." Available at http://www3.europarl.eu.int/omk/omnsapir.so/calendar?APP=PDF&TYPE=PV2&FILE=p00210223EN.pdf&LANGUE=EN. On 20th September 2002, the WHO in its submission to the TRIPS Council also suggested:

"Among the solutions being proposed, the limited exception under Article 30 is the most consistent with this public health principle. This solution will give WTO Members expeditious authorisation, as requested by the Doha Declaration, to permit third parties to make, sell and export medicines and other health technologies to address public health needs." *Available at* http://who.int/mediacentre/TRIPS/en/.

E. The TRIPS Chairman's Note and Removal of the Article 30 Solution

By the middle of October 2002, the Chairman of the TRIPS Council, Edouardo Motta, put forward his proposal in the form of a note which omitted all the proposals of the developing countries pertaining to Article 30 of TRIPS from the "thematic compilations",[150] documents in which all the proposals from the various countries had been put together. This note was put before WTO Members on December 16, 2002 at the Sydney mini-Ministerial Meet but was not accepted. The attempt to remove the proposals of developing countries completely and to retain those from the USA regarding the amendment of Article 31(f) with extensive regulatory norms as proposed by the EC[151] was similar to the developments which occurred during the finalisation of the TRIPS Agreement.[152]

Daniel Gervais, a former staff member at WIPO and a regular consultant for the OECD, reproduced some of these developments in his book.[153] The arbitrated draft prepared by the GATT Secretariat, Chairman Anell and Director-General Arthur Dunkel was included as part of the Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations.[154] This Draft not only removed all the references to local working, but also practically all the proposals from developing countries compiled in MTN.GNG/NG11/W/76 dated 23rd July 1990 by Anell[155] and carried through the negotiations in the Brussels Draft Text.[156] These developments

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[150] Thematic Compilation, *supra* note 89.

[151] Chairman's Note dated 25. 10. 2002: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Draft legal Language for General Council Decision. It was slightly modified in the form of addition of preamble in the draft circulated by the Chairman of the TRIPS Council on 16th December 2002 Job(02)/217. On 28th August 2003, the Council for TRIPS approved the draft Decision on "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" contained in document JOB()2)/217 and forwarded it along with the text of the statement contained in document JOB(03) /177 to be made by the Chairman of the General Council prior to the adoption of the Decision. On August 30 the General Council d adopted the Decision in the light of statement read out by its Chairman (WT/L/40).

[152] *See* Daya Shanker, *supra* note 41, at 758.

[153] *See* Daniel Gervais, The TRIPS Agreement: Drafting Analysis And Negotiating History 167 (1998); the arbitrated draft (MTN.TNC/W/FA (Dec. 20, 1991) at Annex 10.

[154] *See id*. at 24.

[155] *See id*.

[156] Agreement on Trade Related Aspects of Intellectual Property, including trade in Counterfeit Goods in Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT doc. No. MTN.TNC/W/35/Rev.1, 3 December 1990, reproduced in part in Gervais, *supra* note 157, at 161.

suggest that the system of international negotiations has rarely been equitable, and that developing countries rarely have any genuine participation in international treaty negotiations as sovereign countries.

The current developments also appear to follow a predetermined script. All the proposals related to the Paragraph 6 solution of the Doha Declaration coming from different countries were put together by the TRIPS Council[157] and were discussed by WTO Members on July 18, 2002 (IP/C/M/36). The suggestions from developing countries were either removed or curtailed by Motta before he put the proposals in the Sydney mini-Ministerial Meet through his note, and even more stringent provisions were included than those in the US or the EC patent laws or their proposals.

F. The TRIPS Chairman's Note and the Article 31(f) Solution

The Chairman's Note presented at the Sydney mini-Ministerial Meet[158] and subsequently finalised on August 30, 2003 appears to follow only the proposals from developed countries. Most of the issues raised by developing countries have been either removed or circumscribed. It has also attempted to incorporate a series of regulations on the pretext of diversion and transparency as suggested by the EC and the USA.

The most disturbing aspect of the Chairman's note was that the proposals under Article 30 suggesting authoritative interpretations had been totally removed. The preamble, which was not drafted on November 19, 2002 but which had been included in the December 16 version of the Chairman's Note, says: "Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products." It does not however, mention anything about the Article 30 solution, which was the most suitable and legal solution, and which did not need any amendment to the TRIPS Agreement. Without mentioning the names of countries, Motta's Note further says that "Most of the conditions have been in the context of an Article 31-based solution (whether through a waiver and/or an amendment) and therefore most of what follows relates to this scenario." It is not mentioned who gave the proposals on the basis of Article 31 of the TRIPS Agreement. Except for the USA

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[157] Thematic Compilation, *supra* note 89.

[158] 16 December 2002 Draft, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health: Draft legal Language for General Council Decision dated 19th November 2002 followed by Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Note from the Chairman, JOB(02)/217, Council of TRIPS (December 16, 2002) *available at* http://www.ictsd.org/ministerial/cancun/docs/TRIPS_para6_16-12-02.pdf.

and some of the smaller countries like Switzerland, no country proposed amendment of the Article 31 solution to the exclusion of other solutions. The EC made a proposal of either amending Article 31 or using Article 30 to cover the export to countries with no manufacturing capacity. A large number of countries demanded normal use of Article 30 to fulfil the requirement of access to medicines to countries without the capacity to manufacture the same, as permitted by the TRIPS Agreement. However, the introduction of an overtly restrictive amendment by the WTO General Council in its August 30, 2003 Decision under the pretext of providing easy access of medicines to needy countries essentially amounts to rewriting TRIPS.

Paragraph 2 of the Chairman's Note as incorporated in the Decision of August 30, 2003 proposed the inclusion of restrictive norms neither required by the TRIPS Agreement nor present in any of the existing patent laws of the Member nations. The Note also appears to cover the proposal from the African countries to extend the concept of domestic market to the regional blocks, but given the way it has been drafted and the way it has been subjected to a number of impractical conditions, the Note as incorporated in the Decision effectively nullified the African proposal.

Apart from its Communications,[159] the USA in its attempt to bring finality to Motta's Note sent another document to the TRIPS Council saying that the USA "…will not seek to enforce Article 31(f) of the TRIPS Agreement through the WTO dispute settlement procedure against a WTO member," provided that certain conditions mentioned in the Chairman's Note are followed.[160] The degree of similarity between the Chairman's Note and the conditions stated in the US Moratorium is remarkable.

G. Diversion of Patented Products and Imposition of New Regulations

The Chairman's Note as fully incorporated in the final Paragraph 6 Solution of August 30, 2003[161] is based on Article 31 of the TRIPS Agreement and, by removing

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[159] US Second Communication, *supra* note 66, at 29, which says "While each option suggested by Members has some merit, at this stage we believe an expeditious, workable, transparent, sustainable and legally certain solution may more likely be achieved through either a moratorium for dispute settlement or a waiver of the obligation in TRIPS Article 31(f). A moratorium or waiver of the obligation of TRIPS Article 31(f) may have several advantages over other options suggested by Members."

[160] Moratorium to Address needs of Developing and Least-Developed Countries with No or Insufficient Manufacturing Capacities in the Pharmaceutical Sector: Communication from the United States, IP/C/W/396 (Jan. 14th, 2003).

[161] *See* Decision of August 30, 2003, *supra* note 7.

the Article 30 TRIPS solution completely, it indicates that developing countries do not have much of a voice in international negotiations and their presence is only to provide legitimacy to a treaty. The attempt to restrict the use of Article 30 to facilitate access to medicines was started by a number of scholars including Alan Sykes,[162] Frederick Abbott[163] and Gillespie White.[164] Sykes stated that developing countries did not suggest "…that they may rely on Article 30 to deal with the pharmaceutical issue,"[165] yet the Draft Ministerial Declaration submitted by the developing countries in paragraphs 5 and 9 specifically demanded that "[u]nder Article 30 of the TRIPS Agreement, members may, among others, authorise the production and export of medicines by persons other than holders of patents on those medicines to address public health needs in importing members."[166] On the basis of a misunderstanding that a domestic patent act is applicable internationally, Abbott observed:

> *The authorisation to make and export under certain conditions might unreasonably prejudice the interests of the patent holder. An authorisation to supply a high-income market might under some circumstances prejudice the interests of the patent holder. An authorisation regarding a low –income market might unreasonably prejudice the interests of the patent holder if the exports were systematically diverted to high-income markets, thereby undermining the commercial return on the patent.*[167]

Gillespie White reiterated this position.[168]

The artificial criteria suggested by Abbott of high- and low-income markets appear to ignore a large body of case law on patents as well as Article 30 of the TRIPS Agreement. To make and export under Article 30 to fulfil the obligations of Article 31 of another country does not prejudice the interests of the patent-holder in the country

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[162] See Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "solution"*, CHI. J. INT'L. L. 47 (2002).

[163] *See* Abbott, *supra* note 111. Also see Frederick Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. INT'L. ECON. L. 469, 499 (2002).

[164] *See* L. Gillespie-White, *What Did Doha Accomplish? Doha Declaration on Intellectual Property rights and Access to Medicines: What was really achieved?* (Nov. 19, 2001), *available at* http://mail.iipi.org/db/views/detail.asp?itemID=21.

[165] *See* Sykes, *supra* note 183, at 52.

[166] Developing Countries' Proposal, *supra* note 10, 5 and 9.

[167] *See* Abbott, *supra* note 111.

[168] See L. Gillespie White, *supra* note 168.

of manufacture. The patent-holder in the country of manufacture does not have any interest where there is no patent for the product or where a compulsory licence has been issued for any reason, from non-local working to emergency to the other situations mentioned in Articles 31 and 27.2 of the TRIPS Agreement. Dealing with the illegal diversion of such patented products to third countries is the responsibility of the patent-holder through private action against infringement. It has nothing to do with the exports under Article 30 of TRIPS to the country with no patenting right or a country that has suspended patent rights by issuing compulsory licences.

The likelihood of diversion of the patented products manufactured under compulsory licensing provisions to countries which have patents for the products has always been present. In the UK, the products produced under compulsory licensing are specifically permitted to be exported as an encouragement of export and this is regarded as being a part of the public policy.[169] Does Article 31 of TRIPS require that patented products under compulsory licensing should be of a different colour and size and have different labelling? Is there any requirement in Article 31 of the TRIPS Agreement to inform the WTO or TRIPS Council regarding manufacture and export of such patented products? The answer to both the above questions is no. The situation is no different in the case of the manufacture of patented products for export to fulfil the requirements of countries with no manufacturing capacity, and it does not require this elaborate and cumbersome procedure in the name of information-gathering and generating competition among the suppliers.

V. THE LEGALITY OF THE PARAGRAPH 6 SOLUTION

A. Authoritative Interpretations and Exports under Article 30

Paragraph 29 of the USA's Second Communication questioned the legal merit of an authoritative interpretation by the Ministerial Council of the WTO. The inconsistency of this argument becomes apparent when one examines the decision of the Appellate Body in *Japan Taxes on Alcoholic Beverages,*[170] in which the Appellate

[169] Penn Engineering and Manufacturing Corporation's Patent, [1973] R.P.C. 233. (Justice Graham J. in his observation stated "In my judgement, particularly at the present time, public interest does demand that exports from this country should be on as large scale as possible. At the same time it would not be right to deprive the inventor of such reasonable remuneration as he may be able to get from his own exploitation of his patent. ...If however the patentee is not manufacturing here and does not process foreign patents in countries in which there is not likely to be a market for export from this country, there seems very little, if any, reason to put restrictions on export in a compulsory licence to be granted.").

[170] *Japan Taxes*, *supra* note 110.

Body had accepted the USA's argument that a panel report does not have significance even as a subsequent practice and stated that authoritative interpretations are the sole prerogative of the Ministerial Conference and not of the Panel or the Appellate Body. As observed by the Appellate Body, the adopted Panel report is not even a "definitive interpretation" of the relevant provisions of GATT 1994.[171] The reasoning given by the Appellate Body is: "There is a specific cause for this conclusion in the WTO Agreement. Article IX:2 of the WTO Agreement provides: 'The Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements." Article IX:2 provides further that such decisions "shall be taken by a three-fourths majority of the members". The fact that such an "exclusive authority" in interpreting the treaty has been established so specifically in the WTO Agreement is reason enough to conclude that such authority does not exist by implications or by inadvertence elsewhere."[172] Authoritative interpretations by the Ministerial Conference or the General Council of the WTO thus cannot be questioned by the Dispute Settlement Body.

The EC's attempt to consistently undermine Article 30 of TRIPS is evidenced by its argument of the societal neutrality of Article 30 in *Canada Patent Protection*, which was accepted by the Panel without any contextual support.[173] It was with great difficulty that the developing countries managed to introduce the requisite sensibility in treaty interpretation through the Doha Declaration by incorporating the fact that the TRIPS Agreement is to be interpreted in terms of societal values and not in terms of societal neutrality. By resorting to Article 31(f) solutions for Paragraph 6 in the Doha Declaration, however, the developed countries appear to have nullified the Doha Declaration.

B. Article 30 of TRIPS and Judicial Decisions

The USA's assertion in paragraph 31 of its Second Communication that "[i]nterpreting Article 30 to allow Members to amend their patent laws to permit compulsory licenses to be granted to authorise their manufacturers to produce and export patented pharmaceutical products to other countries"[174] is incorrect, not because there is no provision of issuing compulsory licensing under Article 30 of

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[171] *See id,* at 12, "We do not believe that the contracting parties, in deciding to adopt a panel report intended that their decision would constitute a definitive interpretation of the relevant provisions of GATT 1947. Nor do we believe that this is contemplated under GATT 1994. There is a specific cause for this conclusion in the WTO Agreement."

[172] *Id,* at 12.

[173] *See Canada-Patent Protection*, *supra* note 6, at 4.30(a), indent 2.

[174] *See* US Second Communication, *supra* note 63, at 31.

TRIPS (if the conditions are satisfied, the patented products can be manufactured and sold without any case-by-case analysis as in Article 31) or because it was against Article 4bis of the Paris Convention, but because it is in disregard of its own patent laws as interpreted by the US Supreme Court and other courts in their judgments. The USA's fundamental problem with the Article 30 solution seems to be the non-payment of remuneration to the patent-holder, which limits multinational companies' litigation capacity. The developed countries have supported remuneration not because remuneration is important in itself, but because the question of remuneration would provide unlimited litigation opportunities, which could apparently be used to block any use of compulsory licensing.

The inconsistency in the US Second Communication regarding freedom to export the patented product is reflected in *Deepsouth Packing Co., Inc.* v. *Laitram Corporation*,[175] in which the US Supreme Court observed: "If Laitram has a right to suppress Deepsouth's export trade it must be derived from its patent grant, and thus from the patent statute. We find that 35 USC. 271, the provision of the patent laws on which Laitram relies, does not support its claim."[176] Justice Laddie also observed in the context of copyright, "If the devices (infringing) are to be sold in a country where manufacture of the unlicensed copies is not proscribed and therefore not objectionable, there is no compelling reason why the handling of them here should be proscribed."[177] Neither TRIPS nor internal patent laws explicitly or implicitly prohibit the export of patented products.[178] The non-applicability of the exporting monopoly to the export of patented products would remove the need for reliance on the exceptions permitted under the TRIPS Agreement, and there is no reason why the Article 31 provision should be resorted to for this purpose.

C. Article 30 of TRIPS and Extraterritoriality in US Patent Act

The US's First and Second Communications also appear to be attempts to introduce amendments to the internal patent law of the USA through international negotiations.[179] In 1994, using the TRIPS negotiations framework, through the Uruguay Round Agreements Act,[180] the US Patent Act was made far more restrictive than it was before by including the introduction of the terms "importing", and "offering

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[175] Deepsouth Packing Co., Inc. v. Laitram Corporation, 406 US 518 (1972).

[176] *Id.* at 528.

[177] Kabushiki Kaisha Sony Computer Entertainment v. Ball, [2004] EWHC 1984 (Ch), 21.

[178] *See* Daya Shanker, *Paragraph 6 Solution of the Doha Declaration and Exports under the TRIPS Agreement*, 7 J. WORLD INTELL. PROP. 365 (2004).

[179] *Id.*

[180] Pub. L. No. 103-465, ss. 532, 533, 108 Stat. 4809, 4983-90 (1994).

for sale", and extending the patenting period to twenty years.[181] Barfield and Groombridge asserted that the importation amendment provides "full statutory backing for United States patent holders to block parallel imports",[182] which is rather an incongruous assumption.[183] This use of international negotiations to incorporate expansive restrictions in the patent laws of developing countries appears to be an extraterritorial expansion of the patent laws of developed countries. In spite of the introduction of clauses (f) and (g) in § 271, the extraterritoriality of the US Patent Act has so far been interpreted in a limited manner by US courts, and the US Supreme Court has held that the US Congress is not empowered by the US Constitution to extend its patenting act beyond its borders.[184]

The term "normal exploitation" of a patent pertains to the commercial exploitation in the territory of the patent, and would not cover the situations where the patented products do not affect the commercial marketplace. By insisting that movement of the patented products outside the territory of the patent would affect the normal exploitation of the patent, the USA is suggesting that the effect of the patent extends outside the territory of the patent, a concept not permitted by the territoriality enshrined in the TRIPS Agreement through Article 4bis of the Paris Convention and

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[181] As amended by the Uruguay Round Amendment Act, Patent Act, § 154 (a) (1) says: "Every patent shall contain a short title of the invention and grant to the patentee, his heirs or assignees, the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specifications of the particulars thereof. 35 USC. s. 154(a)(1). § 271(a), as amended, provide: [e]xcept as otherwise provided in this title whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent 35 USC. § 271 (a)."

[182] *See* Claude E. Barfield & Mark A. Groombridge, Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy, 10 FORDHAM INTELL. PROP., MEDIA AND ENT. L. J., 185 (1999) at 198.

[183] *See generally* Margareth Barrett, The United States' Doctrine of Exhaustion: Parallel Imports of Patented Goods, 27 N. KENT. U. L. R. 911 (2000)*;* Daya Shanker, *supra* note 41.

[184] Brown v. Duchesne 60 US 183, 195-196 (1856). "The patent laws are authorised by that article in the Constitution which provides that Congress shall have power to promote the progress of science and useful arts, by securing for limited time to authors and inventors the exclusive right to their respective writings and discoveries. The power thus granted is domestic in its character, and necessarily confined within the limits of the United States. It confers no power on Congress to regulate commerce, or the vehicles of commerce, which belong to a foreign nation, and occasionally visit our ports in their commercial pursuits."

in the USA by its Constitution.[185] A number of decisions by the US Court of Appeals have also followed the principle of the territorial limits of the patents. For example, in *Trustees of Columbia University in the City of New York* v. *Roche Diagnostics*,[186] Columbia University tried to extend the effect of the US Patent Act's extraterritoriality by arguing that Roche was liable under § 271(a) because an American company owned the cell lines used by Roche in Germany, and because Roche imported serum-free EPO, a by-product of the Axel patents, into the USA. The argument was rejected as "suggesting that ownership status transcends geographical boundaries". [187]

So far, § 271(f) of the US Patent Act has been strictly interpreted as applicable only to component parts.[188] § 271(b) appears to extend the US Patent Act to extraterritorial situations, such as inducement to direct infringement within the United States. Although the Federal Appeals Court in *Packard Co.* v. *Bausch & Lomb*[189] decided that such extraterritorial activity to encourage and advance the infringement should be accompanied with actual intent, circumstantial evidence was found to be sufficient to show such intent.[190] From the discussion in *Hauni Werke Koerber & Co.* v. *Molins,*[191] it appears that the observation of the US Supreme Court in *Strassheim* v. *Daily*,[192] a case dealing with two states within the USA, has been interpreted as permitting extraterritorial use of § 271(b) of the US Patent Act dealing with inducement to infringe. Although the Court did not decide the extraterritoriality of § 271(b) in *Hauni Werke Koerber* and its observation can thus at most be regarded as *obiter dicta*, the injunctive relief under § 283 of the US Patent Act has been interpreted as having extraterritorial implications.[193] It is worth noting here that the US Court of Appeals for the Federal Circuit declined to expand the territoriality of the US Patent Act in *Johns Hopkins University* v. *Cell Pro*[194] when it observed that "neither export

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[185] *Id.*

[186] Trustees of Columbia University in the City of New York v. Roche Diagnostics, 150 F. Supp. 2d 191 (D. Mass. 2001).

[187] *Id. at* 203 n. 30.

[188] Standard Havens Products, Inc. v. Gencor Indus., Inc. 953 F.2d 1360, 1374 (Fed. Cir. 1991) (foreign sales of a machine which used a patented asphalt –making process did not implicate s. 271(f) because no components were involved); Aerogroup International Inc,. v. Marlboro Footworks 955 F. Supp. 220, 231 (S.D.N.Y. 1997) (a design patent for a shoe sole had no component parts to assemble, and therefore beyond the scope of s. 271(f)).

[189] Packard Co. v. Bausch & Lomb, 909 F.2d 1464, 15 USP.Q.2d 1525 (Fed. Cir. 1990).

[190] Water Technologies Corp. v. Calco. Ltd. 850 F.d 660, 668 (Fed. Cir. 1988).

[191] Hauni Werke Koerber & Co. v. Molins (1974 US District. Lexis 8152).

[192] 221 US 280, 285 (1911).

[193] Spindelfaabrik Suessen-schurr v. Schubert and Salzer 903 F.2d 1568 (Fed. Cir 1990).

[194] Johns Hopkins University v. CellPro, 152 F.3d 1342 (Fed. Cir. 1998).

from the United States nor use in a foreign country of a product covered by a United States patent constitutes infringement."[195] Thus, apart from limiting the patenting monopoly to the territory concerned, the export of patented products from the USA itself does not violate the US Patent Act. Thus, PhRMA and the USTR appear to be attempting to influence domestic patent legislation by introducing the idea that export would violate patent protection under Articles 28 and 30 of the TRIPS Agreement, and by insisting on introducing a plethora of regulations apparently to control diversion (and thus infringement) through an amendment in TRIPS.

D. The Paragraph 6 Solution and Its Legitimacy

The Paragraph 6 Solution arrived at by the members of the WTO on August 30, 2003 raises a number of important legal questions. Throughout the negotiations, the EC spoke of the amendment of Article 31 as one of the solutions of the Paragraph 6 of the Doha Declaration. In fact, the USA questioned the whole concept of authoritative interpretation by the Ministerial Conference as being of dubious significance,[196] in spite of the fact that the WTO Appellate Body in *Japan Alcohol* had categorically stated that the Ministerial Conference's authoritative interpretation is binding on every WTO Member, unlike a decision of either the Panel or the Appellate Body. [197] On August 30, 2003, eleven days before the Ministerial Conference was to open at Cancun, the General Council decided that the Article 31 solution prepared by the Chairman of the TRIPS Council was the most appropriate option.[198] This solution and the accompanying statement of the Chairman of the General Council prescribing procedures[199] not only waived the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement as per the preamble of the Decision, but also prescribed detailed procedures regarding the manufacture, movement and sale of the goods manufactured or to be manufactured to fulfil the requirements of the countries which do not have sufficient manufacturing capacity for such drugs.

A simple reading of the Marrakesh Agreement makes it abundantly clear that neither the General Council nor the Chairman of the General Council is authorised to waive the conditions or amend the provisions of TRIPS by adding or subtracting any of the provisions. The question of either of these authorities introducing conditions does not arise in any situation. Article IX(2) permits both the Ministerial Conference and the General Council to authoritatively interpret the provisions of the WTO,

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[195] Johns Hopkins University v. CellPro, 152 F.3d 1342, 1366 (Fed. Cir. 1998).

[196] US 2nd Communication, *supra* note 63.

[197] *Japan Taxes*, *supra* note 110 at 9.

[198] *See* Decision of Aug 30, 2003, *supra* note 7.

[199] *See Chairperson's Statement*, *supra* note 7.

whereas paragraphs 1, 3 and 4 of Article IX permit only the Ministerial Conference to waive any of the provisions. Although Article IV(2) of the Marrakesh Agreement says that in "the intervals between meetings of the Ministerial Conference, its functions shall be conducted by the General Council", this authorisation cannot be interpreted to extend to each and every provision of the Marrakesh Agreement containing a reference to the Ministerial Conference, nor is it a correct interpretation to allow the General Council to take over when a Ministerial Conference is only days away. Such an interpretation would render any reference to the Ministerial Conference in Article IX(2) superfluous. There is also no mention at all of powers being given to the Chairman of the General Council to introduce conditions in the decisions taken either by the Ministerial Conference or by the General Council. The authority to conduct routine functions of the Ministerial Conference given to the General Council cannot extend to the decision-making authority of the Ministerial Conference; and, even if the General Council takes such decisions, they have to be confirmed and ratified by the Ministerial Conference. In the August 30, 2003 Decision, the General Council has not only taken a decision it is not authorised to take, it has also eliminated the Ministerial Conference from further monitoring the waiver through Paragraph 8 of the Decision, which says:

> *The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.*[200]

There is no mention at all in the Marrakesh Agreement of any means by which the Chairman of the General Council may be permitted to introduce conditions in the decisions taken either by the Ministerial Conference or by the General Council. The decision to waive the conditions of Articles 31(f) and 31(h) is not legally appropriate. The waiver of Article 31(h) does not apply with respect to countries which do not have manufacturing capacity or which have issued compulsory licensing under Article 5A of the Paris Convention for non-working or insufficient working of the patent. The waiver is, at best, applicable specifically to Article 31(f), which says that the

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[200] On 28th August 2003, the Council for TRIPS approved the Draft Decision on "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" contained in document JOB()2)/217 and forwarded it along with the text of the statement contained in document JOB(03) /177 to be made by the Chairman of the General Council prior to the adoption of the Decision. On August 30 the General Council adopted the Decision in the light of the statement read out by its Chairman (WT/L/40). The Chairperson's Statement, *supra* note 7.

Also see the 30 August 2003 Decision, *supra* note 7, at 8.

patented products manufactured under Article 31 should be "predominantly" for domestic consumption. The term "predominantly" has been defined in various dictionaries as frequently or mostly.[201] The meaning of "predominantly", used by Frederick Abbott to refer to more than fifty percent of production was thus not appropriate, as mentioned by Abbott himself.[202] The principle of effectiveness in interpretation of international treaty demands that the provisions of a treaty must

[201] Abbott selected a definition of the word "predominantly" on the basis of the New Shorter Oxford Dictionary which defined predominantly as "(1) Having supremacy or ascendancy over others, predominating. (2) Constituting the main or strongest element, prevailing. (3) Rising High over." (at 2329) as a major part or majority and insisted the reading of the word "predominantly" as "more than fifty percent of the production by a compulsory licence [which] should be intended for supply of the domestic market of the Member granting the licence." This particular meaning of the word predominant was most non-compatible with the context of the exemption under Article 31. Abbott himself mentioned that "The difficulty with this interpretation is that it potentially reduces the term "predominantly" to a nullity, for example, if there were 80 Members receiving supplies under compulsory licence, perhaps only two percent (2%) might need to be supplied to the market of the member granting the licence to maintain its predominance." In international treaty negotiations such type of interpretations are not permitted. In Indonesia Automobile (WTO, Report of the Panel, Indonesia Certain Measures Affecting the Automobile Industry, WT/DS55/R, WT/DS55/R, WT/DS/59/R and WT/DS64/R, dated 2 July 1998) based on the Vienna Convention, the Panel observed "In this context we recall the principle of effective interpretation pursuant to which all provisions of a treaty (and in the WTO system all agreements) must be given meaning using the ordinary meaning of words" to avoid turning them into nullity.

The ordinary meaning of "predominantly" in Oxford Advanced Learners Dictionary is "mostly" or "mainly." The dictionary meaning of the term "Predominant" in Collier's Dictionary which is also published as Webster's New World Dictionary of American English, Third College Editing (1994) means "1. having ascendancy, authority or dominating influence 2. to be dominant in amount , number, etc. 3, most frequent. Thus the normal meaning of predominantly can be read as mostly or mainly or frequently. The normal meaning given to the word predominantly does not prohibit export of the patented products manufactured under compulsory licensing. It just says such manufacture mainly should be for domestic consumption and does not stipulate that it is to be measured in quantity as suggested by Frederick Abbott.

Using the ordinary meaning of the word predominantly as mainly or mostly, there is no obligation that is to be waived and the waiver just becomes superfluous and has essentially been used to impose obligations where there have been no such obligations.

[202] *See generally* Frederick Abbott, *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WHO after the Doha Declaration on Public Health*, Quaker United Nations Office- Geneva, Occasional Paper 9, February 2002, p. 26 available at http://www.geneva.quno.info/pdf/OP9%20Abbott1.pdf; Duncan Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?* 7 J. INT'L ECO. L., 73, 78 (2004).

have meaning to avoid them turning into a nullity.[203] If the ordinary meaning of the word "predominantly" – mostly – is used, there can be no ban on manufacture and export under a compulsory licence issued under Article 31(f) of more than fifty percent as suggested by Abbott.

VI. INTERNATIONAL NEGOTIATIONS AND RELEVANCE OF DEVELOPING COUNTRIES

A. The Paragraph 6 Solution and Power as Exclusion

Negotiations regarding Paragraph 6 of the Doha Declaration show the presence of tendencies which suggest the use of primitive power in international negotiations as discussed by Prof. Robert Hudec.[204] He observes that "international legal arrangements have relatively more in common with laws of primitive societies studied by anthropologists, in which litigation is still emerging as a rather tenuous alternative to dispute resolution by force."[205]

The absence of meaningful participation by developing countries in the WTO negotiations, particularly TRIPS, has been discussed by a number of scholars. Gathii used Susan Strange's definition of structural power as the ability to set "the rules of

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[203] WTO, Report of the Appellate Body, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS/9, adopted 20th may 1996, p. 23 Principle of Effectiveness- One of the important observations of the Appellate Body in *Alcoholic Beverages* is that of the principle of effectiveness (ut res valeat quam pereat) which was determined as a "fundamental tenet of treaty interpretation" flowing from the general rule of interpretation set out in Article 31 of the Vienna Convention. In *United States – Standards for Reformulated and Conventional Gasoline*, the Appellate Body observed that "one of the corollaries of the 'general rule of interpretation' in the Vienna Convention is that interpretation must give meaning and effect to all the terms of the treaty. An interpreter is not free to adopt a reading that would result in reducing whole classes or paragraphs of a treaty to redundancy or inutility".

[204] *See* Robert Hudec, "*Transcending the Ostensible": Some Reflections on the Nature of Litigations Between Governments*, 72 MINN. L. R. 211, 212 (1987).

[205] *See also* Meinhard Hilf, *Power, Rules and Principles – Which Orientation for WTO/GATT Law?,* J. INT'L. ECO. L. 111 (2001); Karin Mickelson, *Third World Voices in International Discourse*, 16 WIS. INT'L L. J., 353, 413 (1998). Mickelson says, "Third World writers are frequently characterised as having tremendous faith in the ability of law in general, and international law in particular, to institute social justice. Yet these writers are well aware of the ways in which law has been made to serve the interests of the powerful, and there is something quixotic in their attempts to transform what is perceived as an essentially oppressive discourse into a liberatory one."

the game"[206] to argue that, "[t]o the extent that patents are therefore a barrier to access antiretrovirals, the TRIPS Agreement is no more than a form of structural power."[207] This ability to set the rules of the game becomes apparent in the context of TRIPS when one observes that the USA and the EC initiated twenty-one of the twenty-three WTO complaints under TRIPS; the remaining two, by Brazil and Canada, were reaction complaints against the United States and EC, initiated to gain some bargaining power.[208] However, Drahos based his argument regarding the TRIPS Agreement on "unequal power relations and disparities in information and organisational resources."[209] He identified four basic sources of power in the context of international treaty negotiations. These are: (1) the market power of the powerful states such as the USA; (2) commercial intelligence networks, which includes a state's trade bureaucracy, its business organisations and its individual corporations; (3) enrolment power, which Drahos defined as a state's capacity to enrol state and non-state actors in a coalition; and (4) a state's domestic institutions restricting its negotiators within certain norms, which is exemplified by the European Commission, which deals specifically with trade issues.[210]

Drahos is supported by Shaffer, who discussed inequality in international negotiations in the context of reduction in developing countries' "participation in the international trade dispute settlement system in complaints against developed countries" in the WTO, compared to their relative participation under the less legalised GATT.[211] Following Drahos, Shaffer also suggested that developing countries must pool their resources through national, regional and international centres specialising

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[206] *See* Conversation with Susan Strange, available at http://www.geocities.com/jt revino41/ STRANGE.DOC; She also argues that it is "only by looking at the structural power exercised –often unconsciously-over other states, markets, private individuals, and firms by the agencies of the United States can the extent of the asymmetries of state power be appreciated." See Susan Strange, The Defective State, 124 DAEDALUS 55, 64 (1995).

[207] *See* Gathii, *supra* note 11, at 269.

[208] *See* Gregory Shaeffer, *Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection*, 7 J. INT'L ECO. L, 459-482, 472 (2004) ("As for the complaints under the TRIPS Agreement, either the united States or EC initiated 21 of the 23 TRIPS complaints brought through January 2003 (15 by the United States and 6 by the EC). Brazil and Canada each initiated one TRIPS complaint, but these were merely symbolically claims that they filed in response to WTO complaints. . . As regards TRIPS complaints that resulted in an adopted panels or Appellate Body report, the United States was a party in all seven, and the EC in six of the seven, cases.").

[209] *See* Drahos, *supra* note 13, at 80.

[210] *See* Sophie Meunier, *What Single Voice? European Institutions and EU-US Trade Negotiations*, 54 INT'L. ORG. 103-135 (2000).

[211] *See* Shaeffer, *supra* note 213, at 472.

in trade-related intellectual property issues, as well as through developing closer relations with the US and EC domestic institutions to neutralise the clout of large pharmaceutical firms and work with generic pharmaceutical industries in their own countries. However, Shaffer did not appear to be hopeful of the success of such policies in the presence of the "extra-legal coercion" that the United States and, to a lesser extent, the EC could employ.[212] Steinberg also discussed the inequality in the WTO negotiations, attributing it to the lack of market power of developing countries compared to that of the USA and EC, along with the lack of internal transparency.[213]

However, the power structure discussed by Gathii, Drahos, Shaffer and others misses the point that power is not limited to its structural formulations, but also comprehensively affects the relationship between developed and developing countries, and that it is not the inability of the developing countries to form a coherent group which undermines their negotiating capabilities, but rather the fact that power comes with a string of negatives such as exclusion, rejection, barriers, denial and dissimulation, which prohibits the formation of a coherent group capable of resisting the unrestricted use of power by developed countries. [214] This development can be seen during the TRIPS negotiations, where India and Brazil were isolated and pushed into submission through the use of Special 301 by the USA. Similar developments were witnessed during the paragraph 6 negotiations when African countries disassociated themselves from the main group for no apparent reason or benefit.

The developments leading up to the Paragraph 6 solution suggest that developing countries are not in a position to participate effectively and meaningfully in international treaty negotiations. The weakness of developing countries becomes evident when in their Draft Ministerial Declaration, they found themselves forced to protect themselves by requesting that each member "shall refrain from imposing or threatening to impose sanctions and refrain from employing the grant of incentives or other benefits in a manner which could curtail the ability of developing and least developed country Members to avail themselves of every possible policy option to protect and promote public health."[215] This weakness is further illustrated by paragraph

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[212] *See id.* at 476.

[213] *See* Richard H. Steinberg, *Judicial Law-Making, Internal Transparency, and External Transparency: Recent Institutional Developments at the WTO,* 37 INT'L LAWYER, (Spring 2003, *at* http://www.law.berkeley.edu/cenpro/ils/papers/steinbergwtO17.pdf.

[214] Anna Bennett, Recognising Power: A Discourse Analysis of Power Relations, A thesis submitted in fulfillment of the requirement for the degree of Doctor of Philosophy, The University of New South Wales, 2000. Bennett refers specifically to Foucault's understanding of power.

[215] Developing Countries' Proposal, *supra* note 10, at 10.

6(h) in the Proposal from the African Countries,[216] which says that bilateral and multilateral treaties should not be used to remove the flexibilities provided in the TRIPS Agreement.[217] The Revised Bangui Agreement between sixteen of the world's poorest African countries, which included exceptionally strict patenting provisions at the behest of WIPO as its technical consultant, is another example of the way in which these countries' sovereignties have been compromised at such negotiations.[218] The developing countries' proposals in the Doha Round were simply a reaffirmation of TRIPS as interpreted in terms of customary rules of interpretation, along with an attempt to introduce the rule of law and decency in international agreements; yet even this was rejected at the negotiations, despite the fact that no amendment to any of the provisions of the TRIPS Agreement was requested: it was only a question of simple interpretation in terms of Articles 7 and 8 of the TRIPS Agreement. To deal with such a request by attempting to introduce amendments to Article 31 and institutionalising an elaborate and extensive procedure to nullify the flexibilities present in TRIPS practically amounts to rewriting TRIPS.

Both Drahos and Gathii have described the power relationship between developed and developing countries appropriately, but the concept of power has another aspect in terms of Foucaultian perceptions of power. The underlying power not only sets ever-shrinking boundaries for less powerful nations but also significantly affects the group-formation behaviour of weaker nations and eliminates any possible significant resistance from a cohesive, goal-driven group.[219] This aspect of dysfunctional group behaviour became apparent when the African nations left the main group of developing countries during the final phase of submission and made their own submissions. It appears that the African nations made a separate deal with the USA which removed the possibility of an Article 30 solution for the Paragraph 6 of the Doha Declaration from the discussion. The Paragraph 6 solution included a diluted version of the African proposal of treating the regional grouping as a single market, which anyway should not have been a disputable issue even otherwise. The United

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[216] See African Proposal dated 24th June, 2002, *supra* note 108 at 6(h).

[217] Oxfam has also made similar observations. See Oxfam, *US Bullying on Drug Patents: One Year After Doha*, Oxfam Briefing Paper No. 33, Nov. 2002, http://www.oxfam.org.uk/policy/papers/33bullying.html.

[218] See Oxfam, Conference Report: *Implementation of the Doha Declaration on the TRIPS Agreement and Public health: Technical Assistance-How to Get it Right*, 28th March 2002, International Conference Centre of Geneva (CISG).

[219] M. FOUCAULT, THE SUBJECT AND POWER: AN AFTERWORD BY MICHEL FOUCAULT" at 222, MICHEL FOUCAULT: BEYOND STRUCTURALISM AND HERMENEUTICS, H. DREYFUSS AND P. RABINOW (Eds) (1982). Also *See* M. FOUCAULT, THE HISTORY OF SEXUALITY VOL. I: AN INTRODUCTION, TRANS. R. HURLEY (1990), ORIG. 1976, p. 102.

States and the five member countries of the Southern African Customs Union (SACU) – Botswana, Namibia, Lesotho, Swaziland and South Africa – launched a free trade agreement on June 2, 2003 (South Africa also has a free trade agreement with the European Union). If other recent free trade agreements with the USA are any indicator, this free trade agreement will expand the industrial and other monopolies in SACU member countries, some of which are the world's main suppliers of gold and diamonds and are being mostly controlled by Western mining interests. These countries do not appear to have gained any advantage from this free trade agreement, and the USA's motives seem to be clear from Robert Zoellick's letter to Congress in which he stated: "We also see the negotiations (US-SACU Free Trade Agreement) as an opportunity to advance US objectives for the multilateral negotiations currently underway in the World Trade Organisation (WTO)."[220]

B. The Process of Power

Although inequality in international treaty negotiations and in subsequent interpretations of such treaties is clearly evident, what has not been discussed at length is how this power actually gets transformed into concrete unilateral documents. One example of this is the Argentina US Mutually Agreed Solution, which was a result of Argentina agreeing to all of the USA's demands under the auspices of the WTO's Dispute Settlement Understanding because of the pressure of its International Monetary Fund loan, which affected Argentina's financial institutions and caused a considerable amount of economic vulnerability. Once Argentina entered into the Mutually Agreed Solution with the USA pertaining to patenting issues which were not even in the complaint submitted by the USA to the DSU, the repayment was apparently postponed.[221] Similarly, the USA's use of Special 301 played a significant role in Brazil's capitulation during the TRIPS negotiations. However, the factors during the finalisation of the August 30, 2003 decision were quite different. There was no apparent use of Special 301 and no visible sign of IMF or World Bank interference. One possible reason for the capitulation of negotiators from developing countries is their weakness and susceptibilities to various attractions. There is no direct evidence of any outright corruption but the circumstances – the fact that the General Council allowed the Paragraph 6 Solution as prepared by Eduardo Motta on the basis of the US and EC proposals to be passed just eleven days before the Cancun Ministerial Meet, which was the authorised forum for any decision pertaining to the waiver of

[220] Robert B. Zoellick, USTR Notifies Congress Administration Intends to Initiate Free Trade Negotiations with Sub-Saharan Nations, (May 11, 2002) available at http://www.ustr.gov/Document_Library/Letters_to_Congress/2002/USTR_Notifies_Congress_Admini.

[221] See generally, Daya Shanker, Argentina-US Mutually Agreed Solution, Economic Crisis in Argentina and Failure of the WTO Dispute Settlement System, 44 IDEA 565 (2004).

the conditions of Article 31, suggests that the negotiators did not maintain much transparency or rectitude during this negotiation. No reason has been given by any of the major developing countries to date regarding their total abandonment of the Article 30 solution. The use of Article 30 to manufacture and export the patented product does not need any authoritative interpretations at all. Any manufacture which did not affect the commercial market place of the patent holder in the territory of the patent could have easily been brought within the Article 30 exceptions. The total abandonment of any Article 30 solution by the developing countries' negotiators without any explanation points to some amount of corruption and compromise, howsoever small, involving the use of influence by the interested parties, including the Western pharmaceutical industry. The Criminal Law Convention on Corruption adopted in 1999 describes such use of influence as a corrupt act.[222] Former UN Secretary-General Annan argued that corruption undermines the rule of law,[223] but there is also another question that arises: if the rule of law can be undermined in such a manner, is there not a need for a change in the system that permits it?

An important factor to consider is the economic influence of multinational corporations, who were active participants in the Paragraph 6 negotiations and seem to have played a role in the incorporation of exports as one of the patenting rights in the Paragraph 6 solution. Webb, while discussing the United Nations Convention Against Corruption, observed:

> *"...the huge economic influence of multinational corporations (MNCs) and the consequent leverage they have in relation to states, means that they are an actor that cannot be excluded from an international anticorruption strategy... These powerful non-state actors can make deals with developing country governments that represent a sizable share of a state's national income or resource endowments; they often negotiate with top public officials and, if it is a corrupt environment, the MNC must decide whether to participate actively, quietly refuse to deal, or report the corruption."*[224]

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[222] Council of Europe Criminal Law Convention on Corruption (COE Criminal Convention), done at Strasbourg, 27 January, (entered into force 1 July 2002), E.T.S. 173, available at http://conventions.coe.int/Treaty/Html/173.htm.

[223] UN Secretary –General Kofi Annan, 'Message to the Third Global Forum on Fighting Corruption and Safeguarding Integrity,' delivered by Dileep Nair (Under-Secretary –General for Internal Oversight Services), 29-31 May 2003.

[224] Phillip Webb, The United Nations Convention Against Corruption: Global Achievement or Missed Opportunity?, 8 J. OF INT'L ECONOMIC L. 191 (2005). *See also* BRAITHWAITE & DRAHOS, *supra* note 42.

The vulnerabilities and susceptibilities of the negotiators from developing countries can be reduced, if not completely eliminated, by introducing transparency in international negotiations, the lack of which has proved to be its Achilles' heel. Given the absence of any explanation from the Third World negotiators regarding the change of position during the TRIPS and Paragraph 6 negotiations, the explanation that TRIPS was the handiwork of Arthur Dunkel and Lars Anell and that the Paragraph 6 solution was the handiwork of Eduardo Motta and others in the TRIPS Council and the General Council would not cut much ice with the general public. To combat this, there should be a statute similar to the USA's Freedom of Information Act, which provides access to the information relating to such negotiations. For example, through the use of the Freedom of Information Act, the Center for International Environmental Law gained access to the documents leading to the US-Chile Free Trade Agreement.[225] The absence of transparency in such negotiations, particularly on the part of the developing countries' negotiators, is a continued threat to the sovereignty and independence of the developing countries.

VII. SUMMARY AND CONCLUSION

Patenting in the context of access to medicines, particularly with respect to HIV sufferers from Africa, Asia and Latin America, has become a grave issue, which was exacerbated when a number of countries had to introduce strict patenting provisions under TRIPS which resulted in a large section of the world population not being able to access medicines at affordable prices. This resulted in the developing countries' proposal that the manufacture and export of medicines under the Article 30 exemption should cover a situation where a number of countries issuing compulsory licences do not have sufficient manufacturing capacity to produce such medicines. During the Ministerial Conference at Doha, this request was not accepted by the developed countries, and the matter was referred to the TRIPS Council as Paragraph 6 of the Doha Declaration on Public Health. A number of proposals were subsequently submitted to the TRIPS Council by various countries. The proposals from developed countries were based on modifications to Article 31 of the TRIPS Agreement and added a host of extra regulations, whereas the developing countries mostly wanted

[225] Center for International Environment Law v. USTR, Civil Action No. 01-2350, US District Court (D. Col. 2002). Also see Earthjustice, Securing Public Participation in the Development of New Trade Rules, available at http://www.earthjustice.org/urgent/print.html?ID=57 (While the US-Chile trade agreement was finalised last week and now heads to Congress for approval, this decision sets a legal precedent for a more transparent and democratic process that has been sought by public interest and environmental organisations for years but denied by both the Bush and Clinton administrations. This legal precedent will lead to more transparency in future trade negotiations.").

authoritative interpretations of Article 30 to permit such activities. The common elements of the two sets of proposals were that the export of patented products would be restricted under TRIPS.

The major issue, however, is that a patent should not be granted that where the patented goods cannot be manufactured, i.e., enabled, since the limited monopoly extended to patented products is for the advancement of science and is not to be treated as property in itself. The incapacity to manufacture would also invite issue of compulsory licences for failure to work under Article 5A(2) of the Paris Convention. Since patenting is completely territorial under Article 4bis of the Paris Convention and the export of patented products cannot hurt the interests of the patent-holder in a country where the said patent right either does not exist or has been suspended, there is no merit in the USA's assertions that Article 30 of TRIPS would be violated. The exclusion of the developing countries' proposals by the Chairman Motta from his Note and from the final Paragraph 6 solution, echoing the exclusion of their proposals from TRIPS, is condemnable; and its legal basis is questionable. This marginalisation of developing countries' views is a result of the manipulation and coercion of MNCs and developed countries, as well as the vulnerabilities of the negotiators from developing countries. In the wake of the HIV pandemic, the urgent need for drugs in countries that do not have the requisite manufacturing capacity is more than ever before, and developing countries are often put in a position where they are forced to compromise to get some access to medicines rather than none at all, a situation that is clearly unacceptable given the state of the pandemic in developing regions such as sub-Saharan Africa. If international instruments are to be truly "international" in nature, then the voices of developing countries need to be taken note of and not brushed aside when drafting a final document that will be binding on those very countries. Since the voluntary introduction of transparency in international negotiations has not occurred, a freedom of information statute at an international level would help to combat this problem and prevent obligations from being unilaterally imposed on developing countries in the way that the Paragraph 6 solution and TRIPS before it were.

THE INDIAN JOURNAL OF LAW AND TECHNOLOGY
Volume 2, 2006

OUTSOURCING IN INDIA: PRACTICAL APPROACHES TO INTELLECTUAL PROPERTY ISSUES FROM THE INDIAN COMPANY PERSPECTIVE

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ABSTRACT

International outsourcing transactions by their very nature require some understanding of the laws in multiple jurisdictions on a variety of subjects, including contract law and intellectual property rights law. Such an understanding becomes especially difficult if the systems of law are very different from each other, but it is required nonetheless to ensure that both parties are fully aware of the best ways to avoid liability and maximise their own benefits from the transactions. This article takes the familiar example of US companies outsourcing to India and discusses what the Indian company should be aware of in the context of the intellectual property issues involved, as well as the tactics it can use to maximise the market.

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I. INTRODUCTION AND OVERVIEW

Outsourcing has become common in India, and this phenomenon has resulted in overprotection in some countries such as the United States in the form of perceived concerns about intellectual property issues, among other things. The response of the companies outsourcing the development or manufacture of their products to India (the customers) has in many cases included an attempt to control as fully as possible all of the IP involved in the outsourced activity and to shift liability to the company performing the outsourcing service or manufacturing the outsourced good – often a company based in India. This response is often primarily the result of a customer's familiarity and comfort with, or fears regarding, the intellectual property laws of its home country. This article is intended to provide Indian companies with insight into the types of IP issues at stake in outsourcing and the typical negotiating positions that a customer based in the United States is likely to take with respect to such issues, based on US laws and customs, and to provide practical advice and a decision-making roadmap to Indian companies for responding to a customer's positions. Through familiarity with the laws and customs of its customers' home countries, Indian companies will be better equipped to increase their business without alienating customers, while minimising or at least fully understanding and assessing liability risks involved within and outside the contractual relationship between the parties. (Although this article has been written primarily with a focus on issues specific to United States companies as customers, many aspects of the article are equally applicable to outsourcing companies located in countries other than the United States.)

In general, for the Indian company to maximise and protect the value of its own IP, to restrict the ability of the customer to claim rights in what is often properly the

Indian company's IP, and to make best use of appropriate limits on the customer's IP, the Indian company should fully understand and systematically evaluate limitations on IP, risk-shifting and other competitive restrictions in its contracts with customers, and negotiate or limit those provisions prior to entering into the contracts to the extent necessary and possible. The Indian company should have a good understanding, at the time of entering into the contract, of the limits of the customer's IP, what steps the Indian company can take to enhance its IP, and where, throughout the world, the Indian company can take advantage of limits on the IP that it is to protect as well as the limits on the customer's IP.

One can measure the importance to an Indian company of obtaining this information with reference to the Indian company's business intentions. At one extreme, if, for the life of the Indian company, it is likely to have only one customer for the type of good or service which the Indian company will provide, then the Indian company's concerns about IP are likely to be minimal, other than liability concerns for the manufacturing or service activities, if any. At another extreme is an Indian company that performs services or manufactures products for many customers (possibly for competing products for those customers) and/or sells products or performs services on its own behalf, possibly in the countries where its customers are located, as well as possibly in India and other countries.

We shall begin with some basics about IP rights typically at issue, including the limits on such rights and the importance of a full understanding of how ownership and enforcement of such rights may or may not be established and asserted through contracts, especially depending on the law of the country involved.[1] We will then discuss the evaluation of IP for the Indian company and finally suggest practical approaches to maximising the Indian company's use of such information in the context of a worldwide market.

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[1] In this article, as an example, we focus primarily on United States law as it applies to such rights and ownership, and provide some basic information on how this law may vary in other countries, especially where the particular technology involved may affect IP protection. The ability of a customer in the United States to dictate the application of United States law to IP rights is limited by the doctrines of "nationality" or "territoriality" and "[d]efining intellectual property rights, and protecting them, is largely within the control of the jurisdiction in which the rights are asserted and the infringement occurs." Douglas E. Phillips, *Selected Legal Issues in International Software Outsourcing*, LICENSING J., Sept. 2002, *at* http://www.accessmylibrary.com/coms2/summary_0286-26095701_ITM. Nonetheless, in situations where laws conflict or the location for which IP law applies is unclear

II. BACKGROUND ON INTELLECTUAL PROPERTY AND CONTRACTS

A. Types of Intellectual Property Typically at Issue and Other Considerations

When outsourced manufacturing or services are to be performed, savvy customers will try to secure any IP rights involved, both for the product requested for manufacture or service to be performed, and for any new features or variations developed by the Indian company, and associated IP rights.

1. Utility Patents

The most common type of intellectual property involved in most products is a "utility" patent, whose purpose is to protect the functional aspects of a technology, such as the components and composition of the device, manufacturing techniques, and software processes.[2]

2. Utility Models

In some countries, additional or alternative protection of manufacturing designs may be made using a type of IP often called "utility models" or "utility designs". Utility models and designs generally provide weaker protection than utility patents, but are generally more easily and inexpensively obtained.[3]

3. Design Patents

Another type of patent protection that is less expensive, and often less useful, is the design patent. A design patent does not protect any functional aspect of a device, but only its "ornamental appearance".[4] Thus, for example, the unique shape or unique ornamental features of a syringe, as long as they are unrelated to its functionality, may be protected by a design patent.

One drawback from the point of view of the holder of the design patent is its limited scope of protection, not only in terms of lack of protection for the functionality

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(e.g., a jointly developed invention with inventors for two or more companies in two or more countries), the parties may be able to enter into binding contractual provisions, such as mandatory assignment of rights or use limitations, effectively providing the definition and protection of IP rights for which the parties bargain.

[2] 35 USC. § 101.

[3] Uma Suthersanen, *A Brief Tour of "Utility Model" Law,* 20 Eur. Intell. Prop. Rev. 44, 45 (1998).

[4] 35 USC. §§ 171–173.

of the device, but also in terms of the potential difference between the patented description and any potentially infringing product. As a result, in most cases, if utility patent protection is available, design patent protection is used only as a supplement. The most common use for design patents is when others are likely to copy the protected product identically (e.g., from a mould exactly or nearly exactly replicating the product), including the ornamental feature protected. Design protection may sometimes be sought as an aspect of protection of a "look" of a product or product line associated with a company, similar to a trademark. However, even relatively minor changes in the "look" of a product will generally eliminate significant concerns about infringement of a design patent.[5]

4. Trademarks and Branding

Another type of IP protection that is useful for many products is trademark (and service mark) protection. Trademarks and service marks can cover names, slogans, and logos, and, occasionally, other unique features associated with products and services. Trademarks and service marks only provide protection for unauthorised or confusingly similar use of the marks themselves, not the underlying products or services. Unlike patents, some trademark or service mark protection can arise even without obtaining registration, although a registered trademark is almost always of more value.[6]

Like trademark protection, a particular look or style of a product or service may also be protectable in some countries, such as the United States, using "trade dress" protection. Trade dress can be registered at the United States Patent and Trademark Office, similarly to trademarks and service marks. Generally, trade dress protection is much less defined than trademark protection and more limited in its usefulness against an accused infringer. As with trademarks and service marks, trade dress infringement can be avoided by avoiding the use of identical or confusingly similar looks for products or services.

5. Copyrights

Yet another type of IP protection potentially useful to some customers and Indian companies, especially those engaged in producing or otherwise using software in their

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[5] Roger E. Schechter & John R. Thomas, Intellectual Property: The Law of Copyright, Patent and Trademark 310–311 (2003).

[6] Lanham Trademark Act, 15 USC. §§ 1051–1127. The Act guarantees the registrant trademark rights in all parts of the United States, allows the registrant to use the ® symbol, allows the registrant to invoke the assistance of the US Customs service to prevent import of infringing imports from entering the country and registration provides constructive notice to other parties of the registrant's claim of ownership and the registration can be used in litigation as *prima facie* evidence of the registrant's ownership of the trademark.

products, is copyright protection.[7] Copyrights protect against the unauthorised reproduction of "works", such as documents and software code. Copyright protection, however, does not prevent the use of documents or software that is functionally similar or identical to the copyright protected work, so long as copying from the original or development of a "derivative work" has not occurred; for example, having a programmer produce software code to perform a function, without that programmer copying or otherwise having access to code that has already been developed but is to be replaced, would not give rise to copyright infringement, even if the programmer produces identical code to the code to be replaced. The deliberate development of such similar functioning code while avoiding copyright infringement is often referred to as using a "clean room" technique. Copyrights are not required to be registered in the United States; however, in most cases registration is a prerequisite to filing a lawsuit for infringement.[8]

6. Trade Secrets

One other type of IP protection of potentially limited use to some outsourcing and Indian companies is "trade secret" protection.[9] Trade secrets include products and information, such as processes, formulae, or other expertise, that are carefully protected by confidentiality agreements and other strongly enforced limitations on disclosure. Because trade secrets may be destroyed by public disclosure, they are among the weakest of protections. In many cases where use of trade secrets is involved, this information may only be disclosed if strong contractual limitations are in place. Of course, the presence of trade secrets in a contractual relationship does not normally prevent the Indian company from developing and using its own trade secrets relating to the product to be manufactured or service to be performed (e.g., in the absence of contractual limitations).

B. The Basics of IP Enforcement: The US Model

Even if the customer has strong IP ownership and other controls and limitations on the IP covering the product or service, such provisions may be virtually useless to the customer if they cannot be enforced. For example, some software is not patentable in India.[10] Even if a product or service is protectable, the customer may not choose to spend the money to obtain sufficient rights in India, or may be unwilling to spend the time and money to protect rights obtained in India. If the Indian company may not

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7 Copyright Act, 17 USC. §§ 101–810.

8 17 USC. § 411.

9 Uniform Trade Secrets Act, 14 U.L.A. 438. The federal law on trade secrets is contained in the Economic Espionage Act, 18 USC. §§ 1831–1839.

10 Patents Act, section 3(k) (India),

easily determine whether the customer has rights or that the customer is willing to assert these rights, the Indian company's decision on production outside the contract with the customer will involve assessment of risk, which will likely include consideration of the customer's size and assertion history, the technical specifics of the product to be manufactured, in relation to any IP rights protected (and the countries in which such rights are protected), and assessment of the customer's risk tolerance.

In the United States, a company's IP rights and various terms, including any other rights of the parties arising under contracts, may usually be enforced in either state or federal court, depending on the nature of the IP involved. In addition, for some IP issues relating to products manufactured outside the United States and imported into the United States, rights may be enforced through the International Trade Commission (ITC). Understanding the complexities of enforcement of IP rights in the United States can often be important to a proper assessment of risks for an Indian company seeking to produce products outside the scope of the contract, for which the customer may nevertheless attempt to assert IP rights. In many cases, the nature of the United States court involved, as a practical matter, may severely hamper the customer's ability to enforce IP rights and/or contract terms.

IP and contractual issues relating to IP are tried at the federal or state court level, depending on the issue, and in some cases, the location or nature of the parties. The federal courts and the ITC provide exclusive jurisdiction for matters relating to patent infringement. However, contractual issues relating to patents and patent applications, such as ownership issues, are typically tried in state court or in federal courts applying state law.[11]

In federal court, patent cases typically involve assertions of infringement or non-infringement/invalidity by the parties. Damages may be obtained by the patent holder, if successful, and injunctive relief and declaratory judgments are also common remedies. If infringement is found, damages can be measured for the infringement being either "wilful" or not "wilful." One of the most common defences to an assertion of wilful infringement is that the defendant obtained a non-infringement or invalidity opinion from competent counsel. If the infringement is found to have been wilfully committed, triple damages may be obtained, as opposed to actual damages if the infringement is not found to have been wilful. Damages can be measured in many ways, but commonly can include either a reasonable royalty or lost profits. If a patent holder successfully proves infringement, the patent holder can often obtain injunctive

[11] Peter L. Brewer, *Who Owns the Invention?: Addressing Ownership Claims of Employees and Contractors*, 42 TENN. B.J. 22, 24 (2006).

relief in the form of an injunction to prohibit the infringer from selling the product or performing the service or process that is covered by the patent. An accused infringer will typically seek, and be granted if the accused infringer wins, a declaratory judgment that the patent is either invalid or not infringed.[12]

In the ITC, a patent holder can bring suit against any accused infringer that is manufacturing or having manufactured a product outside of the United States for importation into the United States. No damages may be obtained in the ITC. Instead, the patent-holder, if successful, can obtain an order from the ITC instructing the United States Customs Service to prevent the infringing products from being imported into the United States. The products are then seized upon entry into the United States and returned to their country of origin.[13]

Trademarks can be based on common law, state statute, or the Federal Lanham Act.[14] Actions involving trademark infringement under the Lanham Act may be brought in either federal or state court. However, the majority of trademark actions arising under the Lanham Act take place in federal court. While federal registration is not a prerequisite for trademark rights, registration confers key benefits and rights. A federal trademark registrant may bring an action for trademark infringement under the Lanham Act in federal court, while a common-law trademark owner may bring a similar action under the Federal Lanham Act for unfair competition and false designation of origin. Individual states also provide statutory and/or common law grounds for trademark and unfair competition claims.[15]

In general, if a trademark has been infringed, a trademark owner may sue to recover: (1) actual damages, including lost profits; (2) the defendant's profits; and (3) attorneys' fees and costs. Damages may be tripled upon a showing of bad faith.[16] Nevertheless, most plaintiffs are generally awarded an injunction against future acts of infringement of their trademark.

Copyright cases must be filed in federal court, as federal courts have exclusive jurisdiction over actions arising under the Copyright Act. In general, a copyright owner may sue to recover: (1) actual damages and any additional profits of the infringer; or (2) statutory damages. In the case of wilful infringement, statutory damages may be awarded up to US$150,000 per act of infringement. However, it is important to keep

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[12] 35 USC. §§ 283–284.

[13] 19 USC. § 1337.

[14] Lanham Trademark Act, 15 USC. §§ 1051–1126.

[15] Schechter & Thomas, *supra* note 5, at 550.

[16] 15 USC § 1117.

in mind that the copyright owner's copyright must be federally registered before any infringement occurs in order to recover attorneys' fees and statutory damages from the infringer. For owners of unregistered copyrights, statutory damages and attorneys' fees are not available.[17]

C. The Basics of IP Ownership and the Importance of the Contract Terms

IP ownership issues are important to any outsourcing transaction, since they relate to contracts, which are the primary mechanisms by which outsourcing is accomplished. Of key importance with regard to IP ownership in the outsourcing context is understanding how IP may be transferred and the effect of particular language within the contract that is used (or not used) in attempting to transfer ownership.

1. Company-to-Company and Individual-to-Company Assignment Obligations

In the United States, as a general rule, most IP that is created is presumed to be owned by the individual who created the IP, i.e., a person, and not a company or other non-human entity.[18] Often the IP created by an individual is subject to an existing contractual right or other legal right of an entity (such as a customer or employer), and title is transferred to such entity (often immediately) either by terms of the applicable contract or operation of law. Depending on the specific IP involved and the circumstances of the relationship among the parties, presumptions as to ownership can vary.

For example, with regard to patent rights under United States law, an individual at a company who conceives of a new invention, absent any other obligations, would be the rightful owner of that invention.[19] For the company to obtain these rights, a written agreement, such as an employment agreement or an intellectual property agreement must be in place between the company and the inventor, or the company must obtain a later assignment in writing from the individual to the company. An exception to this written assignment requirement applies to individuals who are explicitly "hired to invent" and to those who are officers of the company, thereby being under a fiduciary duty to assign such rights to the company. In the absence of such written agreement or later assignment by the individual to the company, the company will gain only a "shop right" to use the technology for the company's internal purposes.[20]

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[17] 17 USC. § 412.

[18] Brewer, *supra* note 11, at 23.

[19] *See* RONALD B. HILDRETH, PATENT LAW: A PRACTITIONER'S GUIDE 8-9 (1988).

[20] *Id.* at 10–11.

Similarly, assuming United States law applies, when a customer engages an Indian company to perform work on behalf of the customer, individuals at the Indian company are the owners of the technology they develop, absent their assignment to either the Indian company (e.g., through their written employment agreement with the Indian company) or to the customer, if required by contract or other obligation (e.g., the Indian company's employment agreement requires assignment to any entity designated by the Indian company). The assignment obligation can likewise be extended further, such as to consultants and contractors of the Indian company.[21]

In each case, for the customer to ensure that it has all the rights it needs, a chain of assignment obligations must extend by *written* contract terms, assigning all rights in advance and requiring each employed individual to make assignments and each company to make corresponding assignments so that the customer is ultimately the exclusive owner of all rights. To accomplish this properly, the customer's contract with the Indian company may include obligations on the Indian company to ensure that each individual and contractor or other party working on behalf of the Indian company is under an obligation and has correctly assigned rights to the Indian company or will be otherwise obligated to assign the rights directly to the customer. If the customer has failed to ensure this assignment chain, or, in some cases, if the proper assignment language is not used, the customer may be unable to obtain the patent rights under the contract.[22]

Under United States law, other types of IP besides patents are also owned by the individual creator of the work, absent obligation to assign these rights or an employment or special contractual relationship under which a contracting or commissioning party is considered the author of the work. For example, under copyright law, a copyrightable work is automatically owned by its author. Works by an employee of a company created within the scope of the employee's duties are considered to be authored by the employer, and thus are owned by the employer upon creation, unless the parties agree otherwise in a signed instrument.[23] Copyrightable works created by a non-employee, such as a contractor, are not automatically considered owned and authored by a contracting or commissioning party, unless the following three conditions are met: (i) the work falls within any of

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[21] *See* Jerry C. Liu, *Overview of Patent Ownership Considerations in Joint Technology Development*, Syracuse Sci. & Tech. L. Rep. 1, 4, 7 (2005). Of course, under Indian law, such assignment terms may be superfluous. *See* Patents Act, section 3(k) (India).

[22] *See* Hildreth, *supra* note 19.

[23] 17 USC. §§ 101, 201.

nine specific categories,[24] (ii) the work was specifically "commissioned" or "specially ordered" (i.e., the creator was paid to specifically create the work), and (iii) there is written instrument signed by the creator prior to the works creation that specifically indicates that the works created under the contract are "works made for hire".[25] Absent the satisfaction of these three conditions, the creator of the work is considered its author, and to transfer ownership to the party for whom the work was prepared, the creator must execute a written document of conveyance.[26]

2. Ownership of Developments and Limits on the Definition of Developments

Particular issues that are often of importance for ownership and limits on the customer's options include whether and how the contract defines the IP that is owned or to be owned and how the contract addresses the issue of ownership of "developments", "improvements" and other "related" IP that arises and to which the contract is applicable. As with the actual language of the assignment terms discussed above, a careful analysis of the words actually used in the contract is key.

For example, in many cases, the customer may not contemplate that intellectual property will be developed by the manufacturer, and therefore will fail to address these issues. Similarly, the contract may simply specify that listed patents and other IP are owned by the customer, and any IP that is developed under the contract would therefore be owned by the company at which the individuals are located who conceive of these developments. Further, even if this second type of provision is included, the product produced may differ, if only subtly, from the original product, due to production requirements or cost issues, for example, and these differences may be

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[24] The following types of works may fall under the "work for hire" doctrine and may be considered authored by a commissioning party if other conditions are met:

> a work specially ordered or commissioned for use as a contribution to a collective work, as a part of a motion picture or other audiovisual work, as a translation, as a supplementary work, as a compilation, as an instructional text, as a test, as answer material for a test, or as an atlas, if the parties expressly agree in a written instrument signed by them that the work shall be considered a work made for hire. For the purpose of the foregoing sentence, a 'supplementary work' is a work prepared for publication as a secondary adjunct to a work by another author for the purpose of introducing, concluding, illustrating, explaining, revising, commenting upon, or assisting in the use of the other work, such as forewords, afterwords, pictorial illustrations, maps, charts, tables, editorial notes, musical arrangements, answer material for tests, bibliographies, appendixes, and indexes, and an 'instructional text' is a literary, pictorial, or graphic work prepared for publication and with the purpose of use in systematic instructional activities. 17 USC. § 101.

[25] *Id.*

[26] 17 USC. § 204.

patentable or constitute trade secrets or other IP that may become the property of the Indian company. It is also possible that production techniques may develop that are patentable and not envisioned by the customer. Finally, the customer may intentionally use the Indian company to develop the technology, either from the beginning of product development or based on an initial concept or prototype provided by the customer.

Sometimes the contract will specify that the patents and other IP, as well as "improvements" to these patents and IP are owned by the customer. However, if a patent only covers a product produced by the Indian company for the customer, this language may not cover any manufacturing process technology developed by the Indian company. Also, if the Indian company develops a similar product that is simply different from the customer's product and not covered by the customer's patents, such a product may not constitute an "improvement" to which the customer is entitled.[27]

Broader language that the customer includes may assert ownership of "any IP relating to" the products produced or services performed under the contract, or of "any IP developed" by the Indian company during the course of performance of the contract (note that this last term type may obligate assignment of technology completely unrelated to the products or services that are the subject of the contract). The interpretation of such language can vary significantly in the United States, depending on the jurisdiction involved (e.g., the contract will be interpreted under the state law of the particular state that is found by a court to be applicable for making such interpretation).

3. Other Contract Issues

The contract presented by the customer may also include a number of other terms that directly or indirectly affect IP rights of the Indian company. In many cases, these terms are designed to assist the customer as favourably as possible in collecting damages or obtaining injunctive relief in the event of a perceived breach of the contract.

For example, the contract may specify that it was written and should be interpreted in the English language, as governed by the laws of the country in which the customer is located, such as the United States. The provisions may also require use of arbitration with regard to any disputes under the contract, which is often perceived as more reliable than depending on courts outside the customer's country. To aid in enforcement, the Indian company may also be required to expressly submit

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[27] However, the Indian company is cautioned in these cases to look to other terms of the contract that could apply. For example, "non-compete" terms may prevent the Indian company from selling or producing products that compete with the customer's products.

and consent to the jurisdiction of the courts of the customer with regard to actions for which injunctive relief or enforcement of an arbitrator's decision is sought.

Generally, a contract for the purchase of goods[28] between parties of different nations will be governed by the United Nations Convention on Contracts for the International Sale of Goods[29] (CISG), unless the contract specifies that it will be governed by other code, such as the Uniform Commercial Code (UCC) of a particular state in the United States. Of particular interest regarding IP, though specific representations and warranties concerning non-infringement may be expressly stated in the contract, the UCC and CISG both provide for warranties that goods sold will not infringe IP rights of third parties. In some cases, the applicable non-infringement warranty provided by the UCC (§ 2-312) may not apply to the Indian company, as the provision only applies to "merchants regularly dealing in goods of the kind". Article 42 of the CISG, which also provides the purchaser with a warranty of non-infringement, does not place a similar limit on the type of seller to whom the warranty implies. However, the UCC is generally considered to be more favourable to buyers than the CISG in terms of providing for damages and other remedies.[30] Thus, a range of risks and circumstances may be involved, depending on whether the customer asserts that the contract will be governed by the CISG or the UCC.

In addition to representations, warranties, and indemnities expressed in the contract with the customer, and any implied warranties provided by the CISG or UCC, the customer may attempt to negotiate arrangements that enhance the customer's ability to enforce and collect against breach of such provisions. For example, arrangements such as insurance, letters of credit and similar mechanisms may be used. If the Indian company owns property in the United States, use of such property as collateral to secure the Indian company's compliance with the contract may be sought. Similarly, if the Indian company has an affiliated entity located in the United States, a guarantee from such affiliate may be required. Additionally, if the customer obtains a right to offset any payment owed to the customer, the credit terms of the purchase of the device being manufactured or service being performed under the contract may include some protection against breach by the Indian company. Finally,

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[28] The definition of 'goods' under both the CISG and UCC does not include the development of software (which is considered a service), but may include the sale of packaged software products. Joseph Lookofsky, *Digesting CISG Case Law: How Much Regard Should We Have?*, 8 Vindobona J. Int'l Com. L. & Arb. 171, 188 (2004).

[29] United Nations Convention on Contracts for the International Sale of Goods, Apr. 11, 1980, 1489 U.N.T.S. 3.

[30] *See* Avery W. Katz, *Remedies for Breach of Contract under the CISG,* 25 Int'l Rev. L. & Econ. 378, 388–389 (2005).

regardless of contractual arrangements and statutory provisions, the customer may insist on cooperation by the Indian company with regard to performing due diligence on the risk of breach.

4. Other Issues Potentially Affecting Contract Terms and Negotiation Strategy

Obviously, commercial circumstances may greatly affect the Indian company's ability to negotiate such contract terms as described above. For example, one practical issue is simply the size and bargaining power of the customer. Larger size and market share can allow the customer to leverage its agreements to its great advantage. Also, the more the Indian company desires the working relationship, in general, the more the customer can require indemnification, warrantees, and other concessions favourable to the customer. In addition, size and market share often dictate the number and quality of competing Indian companies bidding for the contract, thereby often providing additional leverage for IP and other control by the customer through potential competition among the Indian companies.

As a practical matter, despite all of the contractual requirements a customer may obtain with the Indian company, these requirements may be useless to the customer in many situations. For example, if the Indian company is small, in the event that the customer asserts contract provisions, the Indian company may simply default, close up shop, and reopen as a new company. Outsourcing companies may also find it difficult to enforce the contract in India. As a result, the new "rebadged" Indian company may then proceed to (or continue to) manufacture the customer's products for other buyers. In this situation, the customer's only fallback position may then be to assert IP rights. However, if the customer has not obtained sufficient rights in India or other countries to which the product may be sold and/or enforce or has difficulty enforcing these rights in India or other countries in which the product is to be sold and/or manufactured, there may be little risk to the Indian company. The Indian company in this situation should consider, however, that it may have difficulties selling in the customer's country (e.g., the United States) and any other countries where IP rights have been sufficiently protected and may be enforced as a practical matter by the customer.

As briefly alluded to above, another issue potentially affecting IP ownership and liability between the parties is the nature and degree that the customer directs manufacture or performance of services. While a customer may attempt to shift liability (including attorneys fees) through contract provisions, if the customer dictates and approves the specifics of manufacture or performance of services, particularly if the customer has knowledge of (or more specific intent with regard to) patents, the customer may still find itself subject to significant liability concerns and legal costs,

rather than, or in addition to, the Indian company. To address some of these issues, one option that some customers will select is the use of middlemen or consultants to direct manufacture, which potentially adds a layer of liability insulation between the customer and the Indian company. As discussed above, one aspect of such a relationship is the addition of yet another link in the chain of shifting liability and assignment obligations that must be completed for the customer to obtain rights and for liability to be transferred from the customer.

III. EVALUATING THE IP PROTECTION OF THE CUSTOMER

A. Determining and Limiting the IP Rights of the Customer

As discussed above, one decision point for IP rights determination occurs at the time of contract negotiation between the Indian company and the outsourcing manufacturer. The IP issues must be evaluated based on the specific terms used in the contract, considering the relative importance of the need to perform the work, the relationship involved (e.g., whether it is part of an important, long-term relationship), and the specifics of the IP involved (e.g., whether patents have been obtained by the customer and whether any new technology is likely to be developed by the Indian company). The Indian company may also need to consider the terms and its negotiation position in the context of any long-term strategy being developed. For example, if the Indian company plans to produce competing products and will conduct research and development simultaneously with performing contract obligations, surrender of all developed IP to the customer may be unwise.

Of course, as a practical matter, the Indian company may be in a "take it or leave it" situation, in which the customer asserts it will not accept any contract modifications. In this case, the Indian company should first evaluate the contract terms, but also consider putting forth persuasive arguments, despite the asserted position of the customer. For example, in the United States, many software consultants successfully limit IP ownership for a contracting party by arguing that they cannot surrender rights that are necessary for them to consult for other parties. This type of argument has more potential for success for Indian companies that are more in demand and therefore able to decline work for outsourcing companies that are unwilling to negotiate.

Another factor to consider during negotiations is the nature of the technology involved. For example, many types of software are not patentable in India. The agreement by the Indian company to assign all patent rights for such technology to the customer will not give rise to patent liability in India (and many other countries),

and the Indian company is therefore free to duplicate the functionality of such software, so long as other rights are not infringed (e.g., copyright rights).[31] On a more sophisticated level, for some technologies, it may be possible to determine the potential patentability of the technology or to identify existing old art technology that can be duplicated to perform the same function.

B. Practical Tools for IP Aspects of the Evaluation

The above analysis suggests another aspect of IP that the Indian company may wish to consider: using IP analysis tools to evaluate risks, identify options for exploitation, and identify and protect IP.

1. Patent Searches

Most companies are familiar with the basic idea of the prior art or patentability search. This type of search potentially provides information on the likelihood that a patent will be grantable, based on the prior art. An Indian company may want to conduct this type of search if the company believes it has identified a potentially patentable technology that is not owned by the customer. The results of such searching can also be useful as part of a larger strategy for business development. For example, it may be discovered that a product or service of interest is patented in North America, Europe, and Japan, but not in the remainder of Asia. Such a product or service may thus be a candidate for sale in India or China, free of patent infringement concerns. Of course, the product will also not be patentable for the Indian company in those countries, so competing companies will likewise be able to sell the product in those countries. It is important to know that such a search is not required for filing an application in the United States, and that such searching has potential negative consequences if the United States is a potential country for patent protection by the Indian company. For example, one potentially negative aspect is the requirement in the United States to provide all relevant known or discovered information to the Patent Office. It is possible that the search may uncover prior art that the United States Patent and Trademark Office wouldn't have discovered on its own, thereby potentially reducing the likelihood of obtaining a patent. On the positive side, if a patent is obtained after this information is provided, the patent is theoretically stronger, since the Patent Office has granted a patent even knowing this information, and a presumption therefore exists that the granted patent is valid over this information.

Another possible negative aspect of the prior art/patentability search (as with any type of patent search) is the discovery of a patent that would be infringed if a product were produced that is covered by the patent. While it may at first glance

[31] Patent Act, section 3(1)(j) (India).

appear to those unfamiliar with patent searching that any prior art that negatively affects patentability would give rise to an infringement concern, this conclusion is normally not warranted. The reason for this apparent contradiction relates to the difference between types of searches and what patents cover: the prior art/patentability search generally involves examining the description of the patents and applications only, as well as any other references of interest, such as articles describing technology; infringement analysis, however, involves examination of the claims, which provide the formal legal scope of the patent. Claims by their nature cannot cover the entire scope of what is included in the patent description, and what the patent actually covers is often much less than what is described in the patent. Thus, for example, many references that are highly important to determining patentability will not be relevant to infringement.[32]

The concern nevertheless remains that a patent having claim scope that covers a product or service to be produced by the Indian device company will be uncovered. In this case, absent prophylactic action, it is possible that the Indian company could become liable for increased damages for any infringement that occurs. The most common type of prophylactic activity in the event of a patent of concern being discovered is the preparation of a non-infringement or invalidity opinion.[33]

Despite all of these concerns, the prior art/patentability search should generally be used, assuming it is warranted in the business context. For example, if conducted early in the process, such a search can help the Indian company make decisions on how and whether to proceed with both manufacturing and patent protection.[34] In addition, the search can help with determining the scope of claim coverage in any patent applications filed, and, if potential patents of concern for infringement are discovered, the company may change its product strategy or design, or seek appropriate licenses, for example.

The above discussion lends itself readily to discussion of the second common type of search, called a "clearance" or "freedom to market" search. This type of search, unlike the prior art/patentability search, focuses on the claims of issued patents. The

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[32] The reverse can also occur. For example, a patent on a seemingly unrelated technology may contain a very broad claim that covers the search product, while the patent itself has little or no effect on patentability.

[33] *See* Albert P. Halluin, *Incorporation of Parts into the Whole: Avoiding Liability When Incorporating Nanotechnology Improvements* 3, NANOTECHNOLOGY L. & BUS. 25, 36 (2006).

[34] Of course, if warranted in the context of a negotiation with a customer, such a search may also be useful in assisting the Indian company with understanding its IP rights under a contract. However, the patentability and possible infringement effects may be visited upon either or both the Indian company and the customer.

best outcome of such a search is typically a determination that no patent of concern is identified, and production of the product or performance of the service may proceed with reduced concern of patent infringement. In the event that a patent of concern is uncovered, the Indian company may wish to obtain a non-infringement (possibly also involving a product redesign) or invalidity opinion, if possible, to reduce the potential risk of manufacture.

Another type of search/analysis that many companies use is referred to as a "landscaping" search or analysis. Landscaping is generally similar to both prior art/patentability searches and clearance/freedom to market searches, but is broader in scope than a search for a specific product. The landscaping results can be used for patentability and clearance purposes, to provide greater information on possible claim scope and potential areas of additional product development, and to identify competitors in the technology area. The drawbacks of this type of search/analysis are generally the same as those for the other searches described above.

2. Comparing Products to IP rights

Another step in the Indian company's process may be evaluation of patents and other IP relative to a product to be produced. For example, if a customer owns a patent, but does not claim rights to developed or related products in its contract with the Indian company, the Indian company may want to develop similar products or improvements on the customer's technology. An evaluation may be needed of the scope of the customer's patent and whether a potentially produced product would infringe the patent.

The evaluation of such scope or infringement issues is generally complex and as a general rule requires both legal and technical expertise. Under United States patent law, infringement is measured solely as a function of comparison of the claims of the patent to the product or service potentially covered. Many complications can arise in this analysis, most often relating to the meaning of specific terms in the claims. In many situations, and especially when a close call is involved as to whether infringement is a concern, a legal opinion as to non-infringement or invalidity of the patent in question may be appropriate.[35] In the United States, such patent legal opinions are generally expensive, yet only provide "insurance" against wilful infringement of a patent, not complete insulation against being sued. Other options for dealing with a patent of concern include: 1) ceasing (or cancelling plans for) manufacture; 2) licensing

[35] There is also no guarantee that a court that later interprets an infringement or validity issue regarding the patent will reach the same conclusion as the attorney rendering such an opinion. However, even if wrong, such an opinion is normally able to support a strong presumption that no "wilful" infringement has occurred.

or buying the patent; 3) "designing around" the prior art; and 4) ignoring the concern and risking greater damages. Clearly, the particular business circumstances will greatly influence which of these options is most practicable.

Of these other options, one that may often be of interest to an Indian company is designing around a patent. The idea of designing around is to evaluate the claims of the patent and to produce a product that deliberately does not meet the requirements of the patent. The degree of "how different" the product is from the claims in the patent can often be varied to a level of comfort for the company. However, in many cases, the design around product is still close enough to the patent to warrant obtaining an opinion, so as to minimise the downside risk if the patent were found to be infringed.

A similar approach may be used when other IP is at issue. For example, if software is to be developed and copyright issues are the concern, a common technique for avoiding infringement in the United States is to produce software having the same or a very similar functionality to the copyrighted software using a technique called "clean-rooming" (as referred to earlier). With clean-rooming, a programmer is provided with functional requirements for the software to be produced, but is prevented from using or even seeing the copyrighted software. The anticipated result is software that performs the same functions as the copyrighted software, but that has not been copied or otherwise can be considered a derivative work of the copyrighted software.[36]

The tools described above may serve to support the both the Indian company's analysis of IP issues as part of a relationship with a customer and in the potential development of products and services for other markets.

IV. PRACTICAL APPROACHES TO MAXIMISING AN OUTSOURCED COMPANY MARKET

A. Understanding and Leveraging Potential IP that the Outsourced Company Retains

As alluded to above, several elements of information may help the Indian company with analysing its IP issues.

Firstly, analysis and negotiation of the contract with the customer will provide a baseline of IP limitations. Generally, the more ownership of developed IP that is retained and the less additional restrictions on IP related issues that apply under the

[36] Jonathan Owens, *Software Reverse Engineering and Clean-rooming: When Is It Infringement?,* 9 Santa Clara Computer & High Tech. L.J. 527, 557–558 (1993).

contract to the Indian company, the more freedom that remains available for the Indian company to develop improvements, manufacturing and other process techniques, and new products and services.

Secondly, consideration of the nature of the technology involved in the analysis of the IP protectability of this technology should be made. For some technologies, simply knowing that no IP protection may be afforded in certain countries (both India and other countries) may be valuable to the Indian company.

Thirdly, to the extent that IP protection may be obtained for the technologies of interest, searching can be used to determine the existence and extent of such protection. This analysis can include both the technical aspects of the protection (e.g., whether the IP covers the developments and new technology of interest) and the geographic range of the protection (e.g., whether protection has been obtained in India and other countries of possible interest for manufacturing or sale).

Fourthly, an assessment can be made of the nature of the customer and its potential level of concern regarding IP and market exploitation by the Indian company. For example, does the customer regularly enforce its IP and contract rights in its home country and elsewhere? How big is the customer, and what is the likely budget and willingness to enforce rights? What are the implications of competing with the customer, either directly or indirectly (e.g., are there long-term implications for the relationship with this or other companies if competition occurs, regardless of IP issues)?

B. The Protection of IP

1. Utility Patent Protection

This type of protection should generally be used as extensively as the business can reasonably afford, to the degree appropriate for the expected sales of a product, as tempered by the nature of the technology and countries involved, as well as what is known about the technology (e.g., prior art). With regard to costs, investment in protection of the technology should be reasonably calculated so as to enable the company to protect the technology, to the extent sales warrant. For example, if the cost of patent protection represents only a few percent or less than one percent of the value of the expected return on the product, it would appear an unusual case that such protection would be unwise.

Strongly weighing in on the decision — and the scope of protection to be obtained (e.g., the number of patents to be obtained relating to the technology) — is the nature of the technology and the scope of the prior art. Just as entering into manufacturing for a product that is already manufactured by many other companies presents potential

upsides and significant downsides from a competition viewpoint, selecting to pursue a technology for which many patents have issued and for which the possible scope of protection is narrow should only be made with careful consideration. However, the company should be aware that the knowledge gained by such searching can sometimes be a double-edged sword, potentially providing the information needed to decide on manufacture, licensing, and IP protection, but also possibly making the company aware of infringement of patents, an increased liability compared to infringement in the absence of knowledge of patents.

2. Design Patent Protection

As is likely apparent from the nature of the protection that design patents afford, while inexpensive, these types of patents should generally only be sought where competitors or unauthorised copiers are likely to precisely duplicate everything about a product, including its ornamental appearance.

3. Trademark and Other Branding Protection

The protection of the Indian company's trademarks, whether words, phrases, or symbols, and other distinctive aspects closely associated with the product, should be fully protected as part of a long-term branding strategy.

4. Copyright and Trade Secret Protection

Copyright, which may be most useful, for example, with protection of software, is limited in that it only protects against actual copying of the work involved. Thus, even if the functionality is reproduced exactly, but without using the medical device company's software or other works, no action will lie for infringement. Trade secret protection, as previously alluded to, should rarely, if ever, be relied upon to protect a product, particularly if the product is made in a country having questionable legal protection for trade secrets.

5. Continuation Strategy

Another potentially useful tool for the Indian company when patenting in the United States is the use of additional patent applications to further cover a product or product line. A continuation or divisional application contains the same description as its parent application, but has different claims (as claims cannot ever cover every aspect of the described invention, this process can occur many times over). A similar type of application, called a continuation-in-part, allows some priority to be maintained to an earlier application, but also to include additional description, such as a new development, feature, or variation of a product. Both types of applications can be useful in providing the Indian company with flexibility in its patent protection in the event that competitors develop features not claimed in the original patent

application. Any of these continuation applications can be filed at any time, so long as another patent application in the chain remains pending.[37]

V. CONCLUSION

Indian companies that provide outsourcing services can place themselves at an additional competitive advantage if they understand the laws and customs of their customers. Customers in the United States typically negotiate on the basis of the United States' legal structure, which provides a broad array of protections and contractual options for the parties. As in any negotiation, the market and bargaining power of the parties will be paramount in determining the risks and advantages to the Indian company and the customer. However, by understanding a customer's expectations, and being prepared to address issues such as ownership, liability and IP protection (as such issues would be addressed under the laws of such customer's home country), an Indian company will be in the best position to increase its business, while protecting itself from risk based on misinterpretation of contractual provisions or a misunderstanding of applicable law. Thus, a working knowledge of the law and practice as discussed above is key to efficient management of the customer's intellectual property rights management by outsourcing service providers in India.

[37] 35 USC. § 120.

THE INDIAN JOURNAL OF LAW AND TECHNOLOGY
Volume 2, 2006

PROPERTY RIGHTS IN CYBERSPACE GAMES AND OTHER NOVEL LEGAL ISSUES IN VIRTUAL PROPERTY

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ABSTRACT

A major challenge faced by the law as it struggles to keep up with advances in technology is the surprising rate at which it canters along, throwing up new varieties of disputes, new types of transactions and even new types of property. This note examines the concept of virtual property and the problems that may arise from it in the specific context of cyberspace games, as well as the ways in which such problems have been dealt with by the law in the past and how they may be better dealt with in the future. It also discusses the existing debate over the need for legal regulation of virtual property and endeavours to see if the provisions of Indian law are sufficient to deal with cases such as these.

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Sections of this article were excerpted from an article originally published in the August 9, 2005 issue of the New York Law Journal titled *Novel Legal Issues in Virtual Property*.

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I. INTRODUCTION

In March 2005, Chinese newspapers reported that Qiu Chengwei, a 41-year-old player of the online game Legend of Mir III, called the police to report that a friend to whom he had loaned his Dragon Sabre (a videogame-generated, enchanted virtual sword) had sold the virtual sword to another gamer for real money. When the police refused to act on the complaint because "virtual property doesn't count", Qiu killed his friend.[1] The incident highlights a growing debate over the "virtual property" that gamers can accumulate in online video games, and how this new form of property should be treated under the law. This paper will discuss some of the novel legal issues that are raised by this unique species of property, and how those issues are beginning to be dealt with by major gaming companies, game players and legal systems.

II. ONLINE VIDEO GAMES: A BRIEF HISTORY

The world of video games once consisted primarily of freestanding video machines featuring the likes of Pac-Man, Space Invaders and Asteroids, and television-based (or "console") games produced by such companies as Atari and Nintendo. Both types of games provided limited opportunities for interactive play between gamers. The world of video games, however, was transformed dramatically by the introduction of "massive multiplayer online role-playing games" (MMORPGs).

The predecessor to MMORPGs was the Multi-User Dungeon (MUD), which first appeared in the late 1970s.[2] Run on a bulletin board system (BBS), these games were text-based and the players created the characters, storylines and searches, which usually required them to fight monsters as the games progressed in order to become more powerful. As the Internet began to grow in the early 1990s, online games became

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[1] Cao Li, *Death Sentence for Online Gamer*, China Daily, June 8, 2005, http://www.chinadaily.com.cn/english/doc/2005-06/08/content_449600.htm.

[2] The acronym MUD is also used to mean Multi-User Dimension or Multi-User Domain.

operational only through proprietary network providers such as Genie and CompuServe, because, at that time, commercial use of the Internet was restricted by the National Science Foundation Network (NSFNet), and organisations using the Internet were required to sign usage agreements with the agency to access the public Internet. These services offered the customer the ability to participate in a game for an hourly fee.[3]

As Internet restrictions were loosened, proprietary-based gaming became more Internet-based. In the early 1990s, the games still remained largely text-based, but by 1996, Meridian 59, which some claim to be the first MMORPG, was introduced. In 1997, Electronic Arts' Ultima Online hit the market, using a flat monthly subscription fee, as opposed to the hourly-pricing scheme that previously dominated the market for hardcore gamers, thereby opening the door for "massive" playing.

Today, these Internet-based video games allow thousands of players to interact simultaneously in multimedia, online virtual environments and this gaming format continues to grow in popularity worldwide. In South Korea,[4] for example, it was estimated that in 2003, 1 in 4 teenagers "are hooked on multiplayer games"[5] and that during that same year, the online game Lineage "[was] more popular than television" among its residents.[6] According to one report, the worldwide market for online games will reach $9.8 billion in 2009, representing a 410% increase over a revenue of $1.9 billion in 2003.[7]

III. WHAT IS VIRTUAL PROPERTY?

Generally speaking, virtual property is defined as an asset collected within an MMORPG, such as money, weaponry, clothing, land, or other goods that have "value"

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[3] As early as 1984, Islands of Kesmai, the first-text based commercial MMORPG, created by Kelton Flinn and John Taylor, was offered through the CompuServe online service at a cost of $12 per month, allowing players to use 1,200-baud modems to participate in the game. *See* Darren Gladstone, *Online Evolution Massive Multiplayer Games Continue to Grow, but Where are They Going? Part 1: Origin of the Species*, at http://www.1up.com/do/feature?cId=3145358.

[4] Korea represents the country with the most MMORPG players, with markets expanding in other Asian countries, such as China and Taiwan. Markets also are expanding in North America and Europe.

[5] *See* Soo-Jeong Lee, *Online Game Craze Sweeps South Korea*, Montana Standard, May 10, 2003, http://www.mtstandard.com/articles/2003/05/10/featuresscience/hjjgjejbiagdei.txt.

[6] F. Gregory Lastowka & Dan Hunter, *The Laws of the Virtual Worlds*, 92 Cal. L. Rev. 1, 5 n.5 (2004) (citing the Lineage website at http://www.lineage-us.com).

[7] Press Release, DFC Intelligence, DFC Intelligence Forecasts Significant Growth for Online Games (Aug. 3, 2004), at http://www.dfcint.com/news/praug32004.html.

inside the particular game's virtual world. Each of these items is used, traded or sold within the virtual world to increase the status and power of the gamer's avatar. Online avatars are human-like characters with unique, game-related appearances and attributes that move through the virtual world and can be saved and used over a period of time. The avatar is essential to the game because it is through him that the player exists in the virtual world and is able to accumulate virtual property.

The nature of these assets and the manner in which they are acquired vary with the type of online game being played. For example, in the fantasy-based virtual world of Ultima Online, power and status are achieved by slaying monsters, which either drop valuable tools or relinquish experience points to the player's avatar. Conversely, in the real-world simulation game There, characters purchase homes, cars and other everyday items with the use of 'Therebucks', the game's currency. Thus, unlike arcade games of yore, such as Pac-Man or Donkey Kong, where players simply strived to achieve a 'high score', MMPORG players seek virtual assets, such as land, advanced weaponry, or status within the game.

IV. THE MARKET FOR VIRTUAL GOODS

There are benefits to possession of virtual goods by the gamers' avatars. A rare tool or object in the virtual world generates status and revenue within the virtual community. Gamers and entrepreneurs alike have established a marketplace for selling their goods in the real world and delivering them in the virtual world. In fact, game companies and economists estimate that in recent years over US $100 million per year has been spent on virtual goods.[8] Indeed, through the purchase and sale of virtual assets, a real-world profit can be made by some gamers.[9]

The value of virtual property is reflected in the amount of money that people will pay to acquire particular game assets, either within the game or via online auction sites.[10] In autumn 2005, a Miami resident, using some of his in-game winnings, purchased a virtual space station for $100,000 in the science-fiction-based game

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[8] Alex Pham, *Virtual Power Brokers*, L.A. TIMES, May 16, 2005, at A1.

[9] Whether the Internal Revenue Service will act with respect to profits made in the virtual world remains unresolved.Under current US law, players who convert their virtual assets into real-world currencies are required to report their incomes to government authorities such as the IRS. Daniel Terdiman, *IRS Taxation of Online Game Virtual Assets Inevitable*, *at* http://news.com.com/IRS+taxation+of+online+game+virtual+assets+inevitable/2100-1043_3-6140298.html.

[10] *See, e.g.*, Daniel Terdiman, *$50,000 for 'Second Life' Sex Business*, *at* http://news.com.com/2061-10797_3-6170860.html.

Project Entropia.[11] Project Entropia (now Entropia Universe), released by Swedish game developer MindArk, was the first major online game to allow for the exchange of real world money for virtual goods. The game has no subscription fee, but players must use real world money to purchase necessary or valuable items within the game. While playing the game, Entropia currency, known as PED (Project Entropia Dollars), can be earned through, among other things, the sale or trade of items, work performed, and virtual investments within the game. Project Entropia is one of the first games with a convertible in-game currency, where virtual cash can later be converted back to real world dollars or vice versa, since PED has a fixed exchange rate with the US dollar.

In an effort to accumulate assets, some individuals have resorted to technological means, using bots (i.e., automated computer scripts) to perform the same function, such as slaying a dragon over and over, while others have even recruited third parties for the sole purpose of playing to acquire game assets for later sale. [12] In fact, it was reported late last year that some wealthy online gamers who have less time to devote to the hobby even have outsourced playing to China, where it is estimated that over 100,000 young people, working in so-called 'game-playing factories', are paid to play MMORPG games daily on behalf of the principal gamer.[13] In some games, the faster the player can advance in the game, the more virtual wealth he can accumulate, which can potentially be sold for real world dollars via online auction sites.[14]

Certain game publishers, however, have attempted to limit or prevent the sale of virtual goods. For example, Sony, the maker of the popular game EverQuest, took a more aggressive approach toward the trading and sale of virtual property. In addition to convincing the online auction house eBay not to list EverQuest items on its site, Sony also sued other auction sites that engaged in the trading of EverQuest virtual property.[15] Still, despite these actions, Sony softened its position when it created a site called Station Exchange in the summer of 2005 to use real world money to buy and sell virtual property.[16] Using an auction-type format, players are limited by a

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[11] *See* CNN, *Virtual Property Yields $100,000*, *at* http://www.cnn.com/2005/TECH/biztech/11/10/virtual.real.estate.ap/index.html.

[12] *See* Daniel Holevoet, *Role Playing Games Provoke Legal Concerns*, *at* http://www.yaledailynews.com/articles/view/14983.

[13] *See* David Barboza, *Ogre to Slay? Outsource It to China*, N.Y. Times, Dec. 9, 2005, http://www.nytimes.com/2005/12/09/technology/09gaming.html.

[14] *See, e.g.,* Rob Hof, *Second Life's First Millionaire*, BusinessWeek, Nov. 26, 2006, http://www.businessweek.com/the_thread/techbeat/archives/2006/11/second_lifes_fi.html.

[15] *See* David Becker, *Real Cash for Virtual Goods: Racket or Way of Life?*, *at* http://news.com.com/Real+cash+for+virtual+goods/2100-1043_3-5566704.html?tag=item.

[16] Rob Walker, *The Buying Game*, N.Y. Times, Oct. 16, 2005, http://www.nytimes.com/2005/10/16/magazine/16consumed.html?.

"sanity cap" of $2,000 on the sale of any item, with the company overseeing the exchange.[17]

Similarly, advanced characters for Ultima Online can be purchased by players through the Electronic Arts official website for the game, but the company's end user license agreement (EULA) does not encourage the sale and purchase of virtual property through external or online auction sites.[18]

V. REGULATING THE INTANGIBLE —AND SOME INTELLECTUAL PROPERTY ISSUES

Although property rights are generally thought of in terms of tangible items with physical characteristics, regulating intangibles is not an unfamiliar concept. The concepts upon which video games are built require the regulation of intangible intellectual property rights (e.g., copyrights in the visual components and trademarks in the game characters of video games). In fact, the law deems the owners of certain types of intellectual property to hold exclusive ownership rights for only a limited period of time. Owners of intangible rights are able to, among other things, sell, license, or transfer their property, but in some situations are required to allow public use at the conclusion of the term. For example, a patent-holder for a new video game controller would have no right to stop somebody from making or using similar controllers at the expiration of the patent term. Some have suggested that the same should occur for virtual property, though for shorter periods than traditional intellectual property.[19]

As subscriptions to many virtual worlds are time-limited and contingent upon payment, the case may be made that virtual property rights should be given to players for similar restricted periods. Within the virtual world context, the contention is that the player cannot claim property interests in the entire world, but might legitimately claim interests in each small entity of the virtual world where his labour composes

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[17] *Id.*

[18] *See* Electronic Arts, *EA Online Privacy Policy and Terms of Service*, *at* http://www.ea.com/global/legal/tos.jsp. Section 3 (Online Credit) of the TOS reads, in pertinent part, " . . . Electronic Arts does not recognise or condone any outside service that may be used for the exchange of points, assets or attributes that you may accumulate as a result of participating in the Service or playing your EA game. This includes the exchange of points or EA Elite cards on services including eBay™ or Yahoo! ™ Auctions. We don't assume any responsibility for, and won't support, such transactions."

[19] *See generally* Lastowka & Hunter, *supra* note 6.

the greatest part of the value of that entity.[20] Therefore, some may reason that an extension of time-limited property rights for these items may not only enhance the individual's play for the current time, but also enhance the overall virtual world upon the item's public release at the end of the term.

Individual players of MMORPGs often feel that the time and money spent to acquire virtual property is substantial enough to warrant legal protection for these items. Some gamers maintain that playing the games comprising these virtual worlds can involve at least as much effort as real world work, with many players spending a substantial amount of real world money to improve their avatars in the virtual world. These gamers believe that the real world markets for virtual items shows that these goods possess value and deserve protection under the law.

Many players see virtual property in terms of functionality, both in the virtual world and in the real world. In the virtual world, each item has a purpose and function within the video game and can be traded for another item to be used for a different purpose. In addition to company-created exchange sites, players have established real world trading blocks through websites and online auctions such as eBay, as well as virtual world trading blocks at various locations within the game where items may be traded and delivered to the player's avatar inside the virtual world.

In one popular game, World of Warcraft, there was US $682,000 in sales of the game's gold in October and November of 2005 on eBay, despite eBay's efforts to curtail such sales.[21] In fact, in December 2005, the makers of World of Warcraft shut down 18,000 gamer accounts that were using illegal software to cheat at the game by acquiring the game's gold and other assets using the software and then selling them on third-party auction sites.[22] Blizzard Entertainment, the maker of the game, maintains a notice on its website, www.worldofwarcraft.com, that the company will "continue to actively monitor all World of Warcraft realms in order to protect the service and its players from the negative effects of cheating" and that the sale of the game's items "can result in the permanent removal of the involved accounts from World of Warcraft."[23]

Those opposed to the extension of legal rights to virtual property owners express concern over possible liabilities. For example, some gaming companies worry that

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[20] *Id.* at 63.

[21] *See* Red Herring, *Blizzard Shuts Down Cheaters*, *at* http://redherring.com/Article.aspx?a=15004&hed=Blizzard+Shuts+Down+Cheaters.

[22] *Id.*

[23] This notice was put up on December 21, 2005. Jane Pinckard, *Over 18,000 Accounts Cancelled in World of Warcraft*, *at* http://www.1up.com/do/newsStory?cId=3146573.

they could be held liable for economic losses suffered by players when the company chooses to discontinue the game. Moreover, they fear that if players are given legal interest in virtual property, their profits will be depleted by an influx of demands for restoration of property or compensation for permanent losses. In addition, extending property rights to virtual items creates further incentives for system hacking and game manipulations. When hackers or pirates enter the virtual world to plunder virtual property and then sell it in the real world, they often prevent dedicated players from being able to acquire or keep these assets through play alone. These acts potentially could make the virtual economy unstable and wipe out virtual fortunes, which might leave game companies responsible for compensating their players.

Some game developers view ownership of virtual property as rights arising from the underlying computer code or data that produces the desired output which is seen as an object on the video screen when the game is played. Therefore, according to this formalist view, the display of a picture (e.g., a magical sword) without the underlying software-based attributes has no real value worthy of protection.

To date, there are no regulatory rules or statutory laws in the United States that directly or explicitly govern virtual property. Instead, a common method to address legal issues that may arise in online gaming is through the use of computer code and contracts.[24] Through the code used to design and run the online game, the maker may unilaterally control what takes place in the game (e.g., changing the virtual landscape, enhancing or limiting the powers of the players, and regulating who can participate).[25] Still, it remains an open question whether gamers should have any due process or property rights with respect to the disposition or removal of their virtual holdings.

From a contractual point of view, the game makers' End User License Agreement (EULA) and/or Terms of Service (TOS) augment their ability to regulate the game, defining the respective rights and responsibilities of the parties. Most, if not all contracts, will provide rules to be followed during play and the consequences of failing to follow these rules. Nonetheless, it has been argued by certain commentators that current legal rules (such as TOSs and EULAs) may not be enforceable in all cases if valuable property interests are at issue.[26] By way of example, if the maker of an online game were to decide to unilaterally terminate the game for business or other reasons, those players that may have accumulated real world wealth in their virtual property

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[24] *See generally* Jack M. Balkin, *Virtual Liberty: Freedom to Design and Freedom to Play in Virtual Worlds,* 90 VA. L. REV. 2043 (2004).

[25] *Id.* at 2049-2051.

[26] *E.g., id.* at 2071-72.

might be left without a remedy under certain terms of the maker's TOS or EULA provisions, unless a court, using traditional contract and equitable principles, were to decide otherwise. It is important to note, however, that these agreements may differ from game-maker to game-maker with respect to the rights granted, including intellectual property rights, to users in the virtual property that they amass or create.[27]

With online games becoming increasingly popular, particular issues concerning intellectual property matters have begun to emerge, with some resulting in litigation. In one of the first cases concerning IP issues, Marvel Entertainment Inc. sued NCSoft Corp., the publisher of the online game "City of Heroes." At the heart of the case was whether players, using a content creation engine in the game, could create avatars that resembled famous Marvel comic characters such as Spider-Man and The Fantastic Four, without implicating the plaintiff's copyright and trademark rights.[28] The case was ultimately settled in December 2005, with its terms undisclosed.[29]

However, numerous unanswered questions remain regarding a game maker's exposure to copyright and trademark liability. For example, could a software company be secondarily liable for infringement by merely providing software tools that enable a user to create an avatar that mimics another entity's trademark or copyrighted work? With respect to trademark law, the sale of virtual goods in virtual worlds may constitute "use in commerce" under the Lanham Act. In another trademark context, what rights and control, if any, do real property owners have over how their property is depicted?

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[27] For example, in autumn 2003, Linden Lab, the creator of the online world Second Life, modified its TOS to allow subscribers to retain full intellectual property in content that they create. On the other hand, some game-makers, such as Blizzard Entertainment, take a different approach towards ownership. In its online game World of Warcraft, the company for example, retains ownership in the game and its virtual property. Press Release, Linden Lab, Second Life Residents to Own Digital Creations (Nov. 14, 2003), http://lindenlab.com/press/releases/03_11_14; *compare* Linden Lab, *Second Life Terms of Service, at* http://secondlife.com/corporate/tos.php, *with* Blizzard Entertainment, *World of Warcraft End User License Agreement*, *at* http://www.worldofwarcraft.com/legal/eula.html. (Compare clause 5.3 of the Second Life TOS with clause 3A of the World of Warcraft EULA).

[28] Daniel Terdiman, *Faux Hulks Can Keep Fighting Evil Online*, *at* http://news.com.com/Faux+Hulks+can+keep+fighting+evil+online/2100-1043_3-5995628.html?tag=nefd.pop.

[29] According to a statement jointly released by the parties, the settlement "allows them all to continue to develop and sell exciting and innovative products, but does not reduce the players' ability to express their creativity in making and playing original and exciting characters." Press Release, Marvel Entertainment et al., Marvel Entertainment, Inc., NCsoft Corporation, NC Interactive, Inc., Cryptic Studios, Inc. Settle All Litigation (Dec. 15, 2005), http://www.gamespot.com/pc/rpg/cityofheroes/news.html?sid=6141254.

Can the unauthorised creation of trademark goods give rise to possible dilution claims against gamers?[30]

Although copyright and trademark issues may be raised in virtual worlds, alleged trademark violations seemingly pose other legal issues than their copyright counterparts, particularly since the Digital Millennium Copyright Act (DMCA) safe harbour provisions do not apply to Lanham Act violations. Furthermore, it is still unclear whether the immunity provisions of the Communications Decency Act (CDA) would protect game-makers from trademark violations by gamers in virtual worlds.[31]

For many online gamers, advancement in the virtual world may be important not only for entertainment purposes, but also for monetary gain, given the existence of the sale of virtual goods in online auctions and the ability within some games to exchange virtual assets for real world cash. Consequently, software developers have introduced "cheating" applications that allow gamers to bypass a game's internal controls and advance more rapidly without the usual required time and effort, thereby raising novel issues related to copyright and contract law.

Besides copyright and trademark infringement, issues regarding right of publicity have also been the subject of litigation. In a state appellate court decision, a California court ruled against a celebrity plaintiff who commenced an action alleging state common law and statutory right of publicity and privacy claims, as well as trademark violations, against a video game maker whose character resembled the celebrity.[32] Videogames, which garner a degree of protection under the First Amendment,[33] have the potential to create a tension between creative expression and a celebrity's right of publicity. Generally speaking, the right of publicity involves the unauthorised use of the plaintiff's identity to the defendant's advantage by appropriating the plaintiff's name, voice, or likeness. In affirming the trial court's dismissal of the plaintiff's right

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[30] Alan Sipress, *Where Real Money Meets Virtual Reality, The Jury Is Still Out*, WASH. POST, Dec. 26, 2006, http://www.washingtonpost.com/wp-dyn/content/article/2006/12/25/AR2006122500635.html.

[31] *Gucci v. Hall* may suggest that the CDA does not offer such protection given its holding that CDA immunity was limited by virtue of the language of 47 USC. § 230(e)(2), which inter states: "Nothing in this section shall be construed to limit or expand any law pertaining to intellectual property." According to the court, ". . .Section 230 does not automatically immunize ISPs from all intellectual property infringement claims. To find otherwise would render the immunities created by the DMCA from copyright infringement actions superfluous." Gucci America, Inc. v. Hall & Associates, 135 F. Supp. 2d 409, 416 (S.D.N.Y. 2001).

[32] Kirby v. Sega of America, Inc. 144 Cal. App. 4th 47 (2nd App. Dist. 2006).

[33] Interactive Digital Software Ass'n v. St. Louis County, 329 F.3d 954, 957 (8th Cir. 2003).

of publicity claims in the context of online gaming, the appellate court wrestled with the balance between a celebrity's right to control the commercial exploitation of his or her likeness or identity and the First Amendment right of free expression, which can be an affirmative defence to an allegation of misappropriation of one's likeness.[34] The appellate court determined that the video game character was indeed "transformative" and therefore protected under the First Amendment.[35] As for the Lanham Act violation, the court found that given the many dissimilarities between the video game character and the plaintiff, any public confusion arising from a mistaken assumption is easily outweighed by the public interest in free artistic expression, so as to preclude application of the Lanham Act.[36]

VI. LEGAL DEVELOPMENTS INVOLVING VIRTUAL THEFT

Most game players expect that their virtual assets will be protected within the game environment against theft or destruction. Generally speaking, virtual theft involves the hacking or subverting of the online game system by another, causing a player to loose any or all of his virtual assets. Virtual mugging, a form of virtual theft, usually occurs through the use of software bots, which assault other characters in an online game and steal their assets.

In what was probably the first reported case of its kind, *Li Hongchen v. Beijing Arctic Ice Technology Development Co.*,[37] a Chinese appellate court, affirming a lower court decision, ruled that the defendant was required to restore the plaintiff's virtual property to him after it had been stolen by a third party through hacking of the plaintiff's account. Li claimed that he had accumulated a virtual arsenal composed of weapons after spending tens of thousands of yuan and playing for thousands of hours, and that the company failed to protect his property. The lower court had determined that the defendant should restore the weapons at a cost of 1,140 yuan (about US $138)

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[34] *See* Comedy III Productions, Inc. v. Gary Saderup, Inc., 25 Cal. 4th 387, 404, 406-07 (2001) (nothing that the First Amendment can be raised as an affirmative defence to an allegation of appropriation if the defendant's work "adds something new, with a further purpose or different character, altering the first with new expression, meaning, or message. . ."). As the court commented, in other words, the new work must contain significant "transformative elements".

[35] Kirby v. Sega of America, Inc. 144 Cal. App. 4th 47, 61-62 (2nd App. Dist. 2006).

[36] *Id*. at 62.

[37] Full opinion available at http://www.chinacourt.org/public/detail.php?id=143455 (Chinese language website), *cited in* Joshua A.T. Fairfield, *Virtual Property*, 85 B.U. L. Rev. 1047, 1084 n.188 (2005).

and pay most of Li's court costs.[38] The case is noteworthy because although the court used principles of contract law in reaching its decision, its reasons for doing so were to "protect a distinct property right – the right of the owner to control the property as against the world, not merely as against the party who committed a wrongful action (here, the third party)."[39]

Despite the lack of judicial decisions on virtual crime, its commission is not confined to isolated or sporadic incidents. In South Korea, an astounding 22,000 claims of virtual property theft were reported to police in 2004.[40] In another matter, a Chinese exchange student in Japan was arrested on suspicion of using software bots to commit a virtual mugging in the game Lineage and selling the stolen items for real money on an auction website.[41]

At the legislative level, a number of countries have responded to virtual theft by enacting or considering laws addressing virtual property crimes. Legislatures in South Korea and Taiwan have enacted laws that make infringement upon virtual property a crime. The South Korean law instructs that online virtual property holds value independent of the game's parent company/creator. The lawmakers reached the conclusion that there is no fundamental difference between virtual property and money deposited in the bank. Alternatively, Taiwan decided that virtual property qualifies as electromagnetic records and should be considered movable property in cases of fraud and theft. Under Taiwanese law, the looting of virtual property can carry a maximum sentence of up to three years imprisonment.[42] In late December 2003, a group of 19 lawyers in China submitted a proposal to the Law Committee of the National People's Congress seeking a law to protect virtual property.[43] These lawyers suggest that virtual property legislation is essential to protect the development of the online video game industry. To date, no legislation has been passed.

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[38] *See* Reuters, *Online Gamer in China Wins Virtual Theft Suit*, *at* http://edition.cnn.com/2003/TECH/fun.games/12/19/china.gamer.reut/.

[39] Fairfield, *supra* note 37, at 1085; s*ee also* Will Knight, *Gamer Wins Back Virtual Booty in Court Battle*, NEWSCIENTIST.COM, (Dec. 23, 2003), http://www.newscientist.com/article.ns?id=dn4510.

[40] Mark Ward, *Does Virtual Crime Need Real Justice*?, BBC News, *at* http://news.bbc.co.uk/1/hi/technology/3138456.stm.

[41] Will Knight, *Computer Characters Mugged in Virtual Crime Spree*, http://www.newscientist.com/article.ns?id=dn7865.

[42] Zhang Tingting & Daragh Moller, *Legislation Proposed to Protect Virtual Property, at* http://www.china.org.cn/english/2004/Jan/85502.htm.

[43] Li Jianguo, *Virtually Mine*, 47(12) BEIJING REV. (Mar. 25, 2004), http://www.bjreview.com.cn/200412/Forum.htm.

Security issues can extend beyond the theft of virtual assets, with the game itself being targeted. In May, for example, it was reported that Linden Lab, the maker of the popular game Second Life, suffered a series of denial-of-service attacks.[44] In August, Microsoft Corp. warned both online gamers and developers of the growing threat of cyber crimes committed in online gaming, noting that online gaming assets were being sold on the black market alongside credit card accounts and other items such as fraudulent passports.[45] Moreover, cyber thieves have begun using malware in the form of Trojan horses sent through e-mail or peer-to-peer platforms that surreptitiously install on users' computers to facilitate the theft of login and password information for online video games with an eye toward selling these virtual assets on Internet auction sites.[46]

VII. SOME POTENTIAL JURISDICTIONAL AND CHOICE OF LAW CONCERNS

As the idea of granting online gamers property rights over virtual property progresses, additional legal issues are likely to surface. Courts may be faced with jurisdictional questions never before posed.[47] For instance, with gamers from across the globe engaging simultaneously in virtual worlds, should there be a theft within this virtual world involving players from different countries, the legal systems of at least two nations (e.g., the home countries of the victim and the thief) might then

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[44] Daniel Terdiman, *'Second Life' Fending Off Denial-of-Service Attacks*, *at* http://news.com.com/2100-1043_3-6067003.html. Essentially, a denial-of-service attack involves the use of a computer or group of computers for the purpose of causing damage or service outage to a company's network by flooding the network and inhibiting or shutting down a company's genuine network or e-commerce traffic.

[45] Reuters, *Microsoft Warns Game Developers Of Security Risk*, *at* http://news.zdnet.com/2100-1009_22-6105609.html.

[46] *See, e.g.*, Gregg Keizer, *Trojan Snags World Of Warcraft Passwords To Cash Out Accounts*, *at* http://www.techweb.com/headlines_week/showArticle.jhtml?articleId=187002726.

[47] Given the lack of judicial precedent, a US court confronted with jurisdictional questions involving virtual property disputes might look to the developing case law involving other Internet-related jurisdiction matters. Indeed, the international nature of Internet commerce has raised issues with respect to United States subject matter and personal jurisdiction and extraterritorial service of process. See, e.g., *McBee v. Delica Co., Ltd.*, 417 F.3d 107 (1st Cir. 2005), in which the appeals court ruled that a US court has subject matter jurisdiction in a trademark dispute involving a foreign defendant only if the activities of which the plaintiff complains "have a substantial effect" on US commerce. The court ruled that the US resident plaintiff failed to show the requisite effect on US commerce merely from the availability of the website and its appearance on Internet search engines, and there was no showing that the availability of the website either resulted in sales of infringing goods into the United States or caused consumer confusion.

grapple with jurisdictional as well as conflict of law issues. In such a situation, a court might have to decide if any prior agreement as to jurisdiction and governing law for virtual world infractions and disputes (e.g., those made through a EULA or TOS) is valid or, in the absence of any such agreement, which country's law would apply. Depending on the nature of the dispute, the facts of the particular case, and the parties involved (which can include players and/or the game maker), the jurisdictional and choice of law issues may prove even more challenging for a court.

To avoid forum and choice of law disputes, many EULAs and TOS now contain arbitration clauses, which has resulted in little precedent regarding disputed issues between players and game makers. In addition, arbitration clauses also make it easier for players to raise issues and for gamers to respond to them in a cost-effective manner. Some gamers have even begun to lobby game-makers to include virtual arbitration processes in their TOS.

VIII. CAN VIRTUAL PROPERTY BE BROUGHT WITHIN THE CURRENT INDIAN LEGAL REGIME?

Nothing in the Indian Contract Act, 1872, precludes the recognition of virtual property transactions. A "contract" is defined as any set of promises which form consideration for each other and "consideration" simply means to do or abstain from doing something at the desire of the other party to the contract.[48] Under common law, however, consideration has been interpreted to necessarily be real and have some value in the eyes of the law.[49] Since the transactions involving virtual property that we have discussed are carried out using money, it seems possible to squeeze them into the existing contract law framework. The next question, however, is whether virtual property will fit into the *specific* regulatory framework dealing with property in India, which is governed by the Sale of Goods Act, 1930 (dealing with sale of movable goods) and the Transfer of Property Act, 1882 (dealing with other forms of property).

Under the Transfer of Property Act, 1882, transfer of property is defined as an act by which a living person conveys property to one or more other living persons.[50] Property of any kind can be transferred unless such transfer is prohibited by any law.[51] The concept of an "actionable claim" is recognised under this Act. It has been

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[48] Indian Contract Act, sections 2(d) & 2(e).

[49] *See* William Reynell Anson, Anson's Law of Contract 98 (Jack Beatson ed., 28th ed. 2002) (noting that consideration must have some value in the eyes of the law).

[50] Transfer of Property Act, section 5.

[51] *Id*. at section 6.

defined to mean a claim to any debt which the Civil Courts recognise as affording grounds for relief. This debt may be existing, accruing, conditional or contingent.[52] Transfer of an actionable claim is permitted under this Act.[53] This definition is wide enough to incorporate within its ambit virtual property as well. Thus, if A sells any virtual property within an MMORPG to B for consideration, he has a right to sue B for recovery of the amount due as consideration as that would clearly fall within the ambit of an "actionable claim" under the Transfer of Property Act.

The Sale of Goods Act, 1930 defines "goods" as every kind of actionable property other than actionable claims and money.[54] The Supreme Court in *Tata Consultancy Services v. State of Andhra Pradesh*[55] held that software programs are goods and elaborated: "[A] transaction sale of computer software is clearly a sale of 'goods' within the meaning of the term as defined in the said Act. The term 'all materials, articles and commodities' includes both tangible and intangible/incorporeal property which is capable of abstraction, consumption and use and which can be transmitted, transferred, delivered, stored, possessed etc. The software programmes have all these attributes." This decision by the Supreme Court paves the way for recognition of sale of virtual property as 'goods' within the purview of the Sale of Goods Act, 1930.

Under Section 22 of the Indian Penal Code, 'movable property' would include corporeal property of every description except for land and things attached to earth or permanently fastened to anything that is attached to the earth. The definition of 'moveable property' is inclusive and not exhaustive, and the conception of property in the context of criminal law was elaborately discussed by the Supreme Court in *Dalmia v. Delhi Administration*.[56] Discussing whether breach of trust could be committed in respect of funds of a company, the Court held:

> *We are of the opinion that there is no good reason to restrict the meaning of the word 'property' to moveable property only when it is used without any qualifications in Section 405 or in other Sections of the Code. Whether the offence defined in a particular section of the Indian Penal Code be committed in respect of any particular kind of property will depend not on the interpretation of the word property but on the fact whether that particular kind of property can be subject to acts covered within that Section.*

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[52] *Id.* at section 3.

[53] *Id.* at section 130.

[54] *Sale of Goods Act, section 2(7).*

[55] *Tata Consultancy Services v. State of Andhra Pradesh,* A.I.R. 2005 S.C. 371.

[56] *Dalmia v. Delhi Administration,* A.I.R. 1962 S.C. 1821.

Given the liberal interpretation preferred by the Apex Court in this case, it is not inconceivable that various offences mentioned in Chapter XVII of the Code may be interpreted so as to criminalise misdemeanours relating to virtual property as well. Thus theft, breach of trust, cheating etc. can all be applied to virtual property as well. Take "breach of trust" for example. Section 405 defines it as dishonest misappropriation of property by one who is entrusted with it. Thus, Qiu Chengwei might possibly have been able to successfully initiate proceedings against his friend within the criminal law framework as there is dishonest misappropriation of (virtual) property by someone to whom it had been loaned. However, given the absence of any jurisprudence on the point in India and the probable unfamiliarity of Indian law enforcement officials with the possible legal ramifications of virtual property disputes, Qiu might well have received the same response in India as he did in China.

IX. ALTERNATIVE/ADDITIONAL REGULATIONS

As MMORPG continues to gain popularity, legal scholars and commentators in the United States have begun to weigh in on the current state of applicable law and the possibility or even the need for alternative and/or additional legal regulation. Some have suggested that as virtual worlds develop, virtual world norms, which would affect virtual property, develop along with them. In some games, such as The Sims 2, a virtual community exists where players can post their own blogs, participate in podcasting, post to bulletin boards and engage in live chats. Accordingly, virtual world norms would be handled in the virtual world, free of real world interference and be treated as jurisdictions separate from our own with their own distinctive community norms, laws, and rights.[57]

Other commentators, however, suggest a different approach, contending that the virtual items bought and sold in the real world warrant legal protection. In fact, one commentator has stated that "the single most important development that will lead to legal regulation of virtual spaces is the accelerating real-world commodification of virtual worlds."[58] Accordingly, it has been argued that current legal rules (e.g., TOS

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[57] *See* Lastowka & Hunter, *supra* note 6, at 72-73 (quoting David Johnson and David Post's statement: "If the sysops and users who collectively inhabit and control a particular area of the Net want to establish special rules to govern conduct there, and if that rule set does not fundamentally impinge upon the vital interest of others who never visit this new space, then the law of sovereigns in the physical world should defer to this new form of self-government.").

[58] *See* Balkin, *supra* note 24, at 2046-47 (noting that "virtual worlds are full of items that either are or will be protected by intellectual property laws").

and EULAs) may not be enforceable in all cases if valuable property interests are at issue.[59] By way of example, if the maker of an online game were to decide to unilaterally terminate the game for business or other reasons, those players that may have accumulated real world wealth in their virtual property, might be left without a remedy under certain terms of the maker's TOS or EULA provisions, unless a court, using traditional contract and equitable principles, were to decide otherwise.

In 2002, BlackSnow Interactive, the founders of a specialty barter and auction site, CamelotExchange, sued Mythic Entertainment, the creator of the virtual world game "Dark Age of Camelot", for unfair business practices. Taking a different position form others against the sale of virtual goods on online auction sites, Mythic Entertainment initiated the shutdown of several BlackSnow auctions, after Mythic discovered that BlackSnow employed workers who played the video game around the clock to acquire virtual items to be later sold on its website. BlackSnow then filed suit in the US Court for the Central District of California, claiming that the actions constituted an interference with "prospective economic advantage" and unfair business practice.[60] Although the case was ultimately dismissed before trial, it is possible that virtual property claims will resurface in the near future.

About a year prior to the BlackSnow lawsuit, a group of plaintiffs in South Korea filed an action against NCsoft, the maker of the game Lineage, alleging that they had lost "Giran Castle," a piece of virtual property within the game, as a result of a program or server error. Like the BlackSnow litigation, the matter did not proceed to trial, but was settled between the parties.

X. AN OPEN-SOURCE ALTERNATIVE?

Open-source software can be broadly defined as any software of which the source code is made available by its owner to the public under a "public license", so that the source code can be read, modified and redistributed by users, subject to certain conditions.[61] The open-source approach is the conceptual and practical opposite of the idea of software as a "closed" proprietary project, distributed in the form of object code only, with the source code form held by the owner as a trade secret.

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[59] *Id.* at 2071.

[60] *See* David Becker, *Game Exchange Dispute Goes to Court*, *at* http://news.com.com/2102-1040_3-832347.html.

[61] One of the most frequently encountered open source licenses is the GNU General Public License, which is promulgated by the Free Software Foundation and commonly refereed to as the "GPL." The GPL has spawned an official variant, the GNU Lesser General Public License (LGPL), which is also offered by the Free Software Foundation, and written to address some of the concerns raised by the "viral" provisions of the GPL.

The application of open source to a virtual world would remove control of the online game from the hands of a corporate game maker by allowing the evolution of the game to be accomplished through the contributions of individuals, many of whom might be the players themselves or those simply interested in the creation of the games. In such a scenario, the players would be required to sign public license agreements, thereby removing any proprietary interest that they may have in the game or its virtual property. By creating a world where liked-minded players, with no proprietary interest in the game or its property participate, some commentators contend that many of the legal issues surrounding virtual property would essentially be eliminated.[62]

Currently, open-source virtual games are in their early stages of development, with only a handful of groups exploring this possibility. Among these platforms are the Open Source Metaverse Project (OSMP), the Croquet Project, and the Multi-User Pedagogy for Enhancing Traditional Study (MUPPETS). [63]

XI. CONCLUSION

With the explosion of online gaming over the past several years, a host of novel legal issues involving virtual property that range from general and intellectual property rights to the theft of virtual assets have begun to emerge. As virtual worlds continue to proliferate, these issues will continue to be addressed by courts and legislatures, forcing both the legal and gaming communities to decide how the delicate balance between property rights and play should be achieved. While potential alternatives, such as the evolution of open-source games, may potentially go some distance to resolve the problem, the question of whether or not legislative "support" (or "interference", depending on how you look at it) is required in this sphere still remains unresolved. Without a clear resolution to this debate, the possibility of legislative action in countries such as the United States, much less a uniform understanding of how to deal with such transactions at federal or international levels, continues to look rather bleak.

Perhaps the main obstacle to a discussion of the way in which such issues may be resolved in India is the absence of actual test cases, although the incidents reported in other Asian countries indicate that India is unlikely to escape such problems on its

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[62] *See* Andrew E. Jankowich, *Property and Democracy in Virtual Worlds*, 11 B.U. J. Sci. & Tech. L. 173, 189-192 (Summer 2005) (discussing creative endeavours in open-source, non-commercial virtual worlds).

[63] *See* Daniel Terdiman, *Gamers Eye Open Virtual Worlds*, www.wired.com *at* http://www.wired.com/news/print/0,1294,65865,00.html.

own shores. At present, using the existing Transfer of Property Act and the Sale of Goods Act to argue that virtual property is "property" is probably the best option for a plaintiff attempting to demonstrate that virtual property deserves the same protection as any other property and that virtual property transactions accordingly deserve the same treatment as other property transactions. However, an uninformed or partly-informed court may easily throw out such a case without understanding its ramifications, and even the most well-informed of Indian courts may consider it a stretch to consider virtual property transactions on par with other property transactions when this was clearly not the legislative intent of India's nineteenth-century and early-twentieth-century statutes on the point. Thus, what seems to be needed is a debate in India on this point so that, if laws are required to support virtual property transactions, they can be discussed and enacted well in advance of any "test case", rather than leaving potential plaintiffs with the unenviable task of wrestling with the existing legal framework – although, one hopes, not with the results that followed for Qiu Chengwei.

THE INDIAN JOURNAL OF LAW AND TECHNOLOGY
Volume 2, 2006

INTELLECTUAL PROPERTY RIGHTS AND THE PUBLIC DOMAIN IN THE NEW WORLD ORDER

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ABSTRACT

The proprietary system of intellectual property rights introduced by the TRIPS regime is premised on Western, neo-liberal notions of the nature of property. This article first highlights a number of recent changes in the global organisation of intellectual property rights. These changes indicate the international convergence of intellectual property law. The repercussions of the TRIPS regime on pharmaceuticals, agriculture, and genetic research are then examined. Finally, it stresses the importance of the idea of "common heritage" as a better way of thinking about the public domain.

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I. INTRODUCTION

The global organisation of property rights in immaterial goods has undergone rapid change in the past few years because of the various changes in the global intellectual property rights regime brought forth by the TRIPS Agreement. TRIPS has imposed Western, neo-liberal notions of the epistemological basis of property on most nations in the world which hitherto had differing conceptions of rights attached to knowledge. I will discuss, with examples, the problems arising out of creating such a proprietary system of intellectual property. I then call for a concerted effort to radically alter our conception of intellectual property by putting forth three arguments, concerning the monopolistic nature of intellectual property, the protection of knowledge in the public domain, and the concept of intergenerational transfer of knowledge.

II. CHANGES IN THE GLOBAL ORGANISATION OF PROPERTY RIGHTS IN IMMATERIAL GOODS

A. Three Landmark Changes

Three landmark changes merit our attention.

1. Alteration of the Iraqi Intellectual Property Rights Regime and the Linking Up of Intellectual Property Protection with Trade

The first change has to do with the new intellectual property laws bequeathed to Iraq by the retiring Administrator of the Coalition Provisional Authority, Paul Bremer, before the "transfer of sovereignty" in June, 2004. Order 81 of the Authority amended Iraq's original intellectual property law of 1970, and is now binding on future Iraqi governments unless and until it is repealed. The Preamble gives a sense of the context it invokes for its actions:

> *Pursuant to my authority as Administrator of the Coalition Provisional Authority (CPA) and under the laws and usages of war, and consistent with relevant UN Security Council resolutions, including Resolution 1483 and 1511 (2003),*
>
> *Having worked closely with the Governing Council to ensure that economic change as necessary to benefit the people of Iraq occurs in a manner acceptable to the people of Iraq,*
>
> *Acknowledging the Governing Council's desire to bring about significant change to the Iraqi intellectual property system as necessary to improve the economic condition of the people of Iraq,*
>
> *Determined to improve the conditions of life, technical skills, and opportunities for all Iraqis and to fight unemployment with its associated deleterious effect on public security,*
>
> *Recognising that companies, lenders and entrepreneurs require a fair, efficient, and predictable environment for protection of their intellectual property,*
>
> *Noting that several provisions of the current Iraqi Patent and Industrial Design Law and related legislation does not meet current internationally-recognised standards of protection,*
>
> *Recognising the demonstrated interest of the Iraqi Governing Council for Iraq to become a full member in the international trading system, known as the World Trade Organisation, and the desirability of adopting modern intellectual property standards,*
>
> *Acting in a manner consistent with the Report of the Secretary General to the Security Council of July 17, 2003, concerning the need for the development of Iraq and its transition from a non-transparent centrally planned economy to a free market economy characterised by sustainable economic growth through the establishment of a dynamic private sector, and the need to enact institutional and legal reforms to give it effect,*

> *In close consultation with and acting in coordination with the Governing Council, I hereby promulgate the following: CPA/ORD/26 April 04/81.*[1]

This order, amongst other changes to legislation governing patents, industrial design, undisclosed information and integrated circuits, also modified Iraq's plant variety law, which had previously prohibited the private ownership of biological resources. The changes mandated by the aforementioned Order make the saving and exchange of seeds by and between farmers illegal whenever the seed in question is of a protected variety.[2] Traditional crop varieties, used by farmers and developed over millennia through selective breeding, are not eligible for protection under this Order because they do not meet the conditions of "distinctiveness, uniformity, and stability" required for registration, traditional crops being variable and unstable unlike scientifically-bred hybrid or genetically-modified crops. Thus, the seeds that farmers will now be allowed to plant – "protected" crop varieties brought into Iraq by transnational corporations in the name of agricultural reconstruction – will be the property of corporations. In many senses, therefore, the new US imposed patent law introduces a system of monopoly rights over seeds.[3] As one commentator tellingly observes: "...the new law is presented as being necessary to ensure the supply of good quality seeds in Iraq and to facilitate Iraq's accession to the WTO. What it will actually do is facilitate the penetration of Iraqi agriculture by the likes of Monsanto, Syngenta, Bayer and Dow Chemical – the corporate giants that control seed trade across the globe. Eliminating competition from farmers is a prerequisite for these companies to open up operations in Iraq, which the new law has achieved."[4]

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[1] Coalition Provisional Authority Order 81, 2004, http://www.export.gov/iraq/pdf/cpa_order_81.pdf. This is an amendment to Iraqi Patents, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law.

[2] A whole new chapter on plant variety protection makes the following actions subject to the authorisation of the breeder (that is, the corporation that owns the rights to the registered variety): "(a) production or reproduction (multiplication); (b) conditioning for the purpose of propagation; (c) offering for sale; (d) selling or otherwise marketing; (e) exporting; (f) importing; or (g) stocking for any of the purposes mentioned cited in this paragraph." Coalition Provisional Authority Order 81, ch. 3, arts. 14-A & B. These rights extend to harvested material, including the entire plants and parts of plants obtained through the unauthorised use of propagating material of the protected variety. A monopoly of twenty years is given for crop varieties and of twenty-five for trees and vines, and the law explicitly promotes the commercialisation of genetically modified seeds. Finally, in case the implications of these provisions are not entirely clear, it is spelled out that "farmers shall be prohibited from re-using seeds of protected varieties." Art. 15B.

[3] Focus on the Global South & GRAIN, Iraq's New Patent Law: A Declaration of War Against Farmers, *at* http://www.grain.org/articles/?id=6.

[4] *Id.*

The Iraqi orders on patents and copyright are an extreme version of the bilateral negotiations favoured by the United States, in which trade concessions are bargained for against increased protection for intellectual property. This gain is then used as the basis for broader multilateral agreements, which build in the highest standards of protection available as the new norm, and these are then ratcheted up in further bilateral agreements, and so on indefinitely. Intellectual property, in this system, "is the price that countries have to pay, largely to American companies, to enter the world trading system."[5] Thus, as legislation that confronts head-on the age-old forms of agriculture that hold no prospect of profit for American corporations, Order 81 is not just evidence of the United States' actual collateral objectives in invading Iraq,[6] but also represents a model of the kind of legislation the superpower wants to see enacted globally. This hypothesis is confirmed by the manner in which the United States has pushed through bilateral agreements in recent years with such equal negotiating partners as Sri Lanka, Cambodia and Afghanistan.[7]

The strategy was initiated in its present form during the Reagan presidency as an amendment to Section 301 of the US Trade Act, in order to link trade access to intellectual property recognition.[8] It was first applied at the behest of Hollywood against Caribbean countries that allowed unlicensed screenings of films.[9] Subsequently, it was also applied against the weak protection given by Brazil to pharmaceutical patents owned by American corporations in 1988. On that occasion, tariff increases were imposed on imports to the United States of Brazilian paper, drugs, and consumer electronics. Brazil responded with a counter-action, charging that Section 301 was illegal under the GATT[10] protocols then in force. However, it capitulated by drafting new legislation in 1990, seeing little chance of a favourable resolution.[11] India was similarly threatened in relation to its failure to adopt US patent standards in relation to pharmaceuticals, but was able to resist because it was less dependent on trade with the United States of America.[12]

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5 Peter Drahos & John Braithwaite, Information Feudalism: Who Owns the Knowledge Economy? 104 (2002).

6 It was ostensibly imposed under the 'laws and usages of war' but is nevertheless in direct contravention of the Geneva Convention, which requires occupying powers to make no major changes to the economic infrastructure of the occupied country.

7 Focus on the Global South & GRAIN, *supra* note 3.

8 Section 301(a) of the Trade Act of 1974 , 19 USC. § 2411 (amended 1996).

9 *See* Drahos & Braithwaite, *supra* note 5, at 94.

10 General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex. IA, Legal Instruments–Results of the Uruguay Round vol. I, 33 I.L.M . 1154 (1994) [hereinafter GATT].

11 Drahos & Braithwaite, *supra* note 5, at 105–106.

12 *Id.*

The strategy embodied in the use of Section 301 is of a piece with the pattern by which US foreign policy is aligned with the interests of major companies. One striking example of this was the response to the decision of the South African government in the late 1990s to begin "parallel importation" of anti-retroviral drugs to control its HIV/AIDS epidemic.[13] The US response to this move was to apply overwhelming diplomatic and trade pressure, including the threat of trade sanctions, and a court action by 41 pharmaceutical companies alleging breach of South Africa's TRIPS obligations.

Further, it is not the case, as is argued by one commentator,[14] that farmers will have a choice whether to use their traditional varieties or to adopt the genetically modified strains owned by multinational corporations. There will be no such choice, the reason being that genetically modified crops contaminate other crops through cross-pollination. As a result, the owners of these contaminated crops will, whether they intend it or not, be infringing on the rights of the breeders. Indeed, the beauty of genetically modified varieties is that they are self-infringing; when propagated naturally, they *copy themselves* and thus produce a criminal act quite independent of the intentions of the grower.

2. Patenting Crops

The second development which deserves our attention is the widely publicised account of a Canadian farmer, Percy Schmeiser, whose canola crop was contaminated by Monsanto's 'Roundup-Ready' gene from genetically modified crops.[15] Earlier this year, the Supreme Court of Canada, ruling five to four, "determined that patent rights on a gene extend to the living organism in which it is found. Consequently, saving and planting seed containing a patented gene without authorisation from the patent holder is illegal."[16] The fact that Schmeiser had no intention of planting Monsanto's seed, did not know that his seed was contaminated, and indeed the fact that Monsanto's failure to guard against cross-pollination destroyed the results of Schmeiser's own selective breeding of his grain, was held to be of no account beside the fact of infringement.

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[13] "Parallel importing" is a term designating the suspension of patent monopolies in a time of national emergency in order to buy in supplies of a drug from the cheapest supplier; the action was entirely in accordance with the emergency provisions built into the TRIPS (Trade-Related Aspects of Intellectual Property) provisions of GATT, provisions that the US itself invoked during the anthrax scare of 2001. TRIPS Agreement, *infra* note 27.

[14] Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47, 55 (2001).

[15] Monsanto Canada, Inc. v. Schmeiser, [2004] 1 S.C.R. 902.

[16] *Genetic Giant Swats Seed-Saving Farmer: Monsanto Notches Up Legal Victory in Canada*, NEW INTERNATIONALIST, Sept. 2004, at 6, *available at* http://www.newint.org/issues/2004/09/01/.

The reality is that, today, the entire canola acreage of western Canada is contaminated with the Monsanto RR gene. The consequence is either that farmers will have to agree to buy Monsanto's seed and sign a technology use agreement, or, like soybean farmers in Brazil, "they could find Monsanto at the grain elevator, waiting to test their harvest for the presence of patented genes and charge them royalties when the genes are detected."[17] Argentina too has witnessed a similar occurrence where, for a number of years, farmers were allowed to save and multiply Monsanto's RR soybean seed.[18] The crop consequently expanded exponentially, reaching 14 million hectares in 2003-4. Farmers then began to be hit with demands for royalty payments, even though Monsanto does not have patent rights over the transgene in Argentina. The pattern is ominously repeated in Brazil and Uruguay with soybeans, in India and West Africa with cotton, and in Mexico with maize.[19] The strategy of the multinationals appears to be simple: "focus on the major cash crops (cotton, soybeans, maize, etc.), find an entry point, contaminate the seed supply, and then step in to take control."[20]

3. The Capitulation of the Indian Government

The final noteworthy (and equally disturbing) development is the capitulation of the Indian government to the TRIPS patent regime. An amendment to the Indian Patents Act, enacted without parliamentary debate, discarded the earlier regime under which patents were granted only on industrial processes, and permitted the granting of product patents on drugs, food, and chemicals for the first time.[21] The stated objective of the amendment was to bring India in line with its obligations under the TRIPS agreement. Yet, the amendment did not include either the redeeming provisions relating to national emergencies in TRIPS or the more explicit provisions spelt out by the "Doha Declaration" of 2001.[22] The Indian government has effectively conceded in full to the demands of the multinational pharmaceutical companies for

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[17] *Id.*

[18] GRAIN, *Monsanto's Royalty Grab in Argentine*, *at* http://www.grain.org/articles/?id=4.

[19] *Id.*

[20] *Id.*

[21] Rajindar Sachar, *Wrong Medicine: Patent Ordinance to Drive up Drug Prices*, Times of India, Jan. 5, 2005, at 18, *available at* http://timesofindia.indiatimes.com/articleshow/980623.cms.

[22] Trade ministers, in the Doha Declaration, affirmed that TRIPS should be interpreted and implemented in a manner supportive of WTO members' rights to protect public health and promote access to medicine for all. Anthony P. Valach, Jr., *TRIPS: Protecting the Rights of Patent Holders and Addressing Public Health Issues in Developing Countries*, 4 Chi.-Kent J. Intell. Prop. 156, 163 (2005).

complete monopoly control, thereby opening the way for dramatically more expensive medicines.[23]

Here is a coda to this third narrative- in May 2003, the World Health Organisation announced an offer of the infrastructural support necessary to provide three million people in poor countries with antiretroviral treatment by the year 2005. This figure represented only about 5% of those in need, but its importance lay in the decision to develop a fixed-dose combination pill using drugs patented by different companies in the same dose. The decision was opposed by the major drug companies, using the argument that the costs of research and development must be fully recompensed if further research is to be funded. The weakness of this argument lies in the fact that most of the AIDS drugs currently on the market were produced through public financing, even through the clinical trial stages.[24] Furthermore, and quite appallingly, the industry spent 27% of its overall budget on marketing, compared with 11% on R&D, as per its own tax records.[25]

In seeking to balance the political image of a concerned administration with the demands of the pharmaceutical industry, the White House initially pledged to support the WHO initiative. No money has yet been forthcoming, however, and indeed, "while President Bush claimed to pledge $15 billion to global AIDS efforts during the State of the Union address [in 2003], it now appears that the United States will only pay if US-based pharmaceutical manufacturers are given the money."[26] In March 2005, the US Department of Health and Human Sciences sought to undermine the decision completely by claiming that, despite its endorsement by international health experts from all countries involved including the US, the WHO approval process for the combination drugs was inadequate and unsafe.

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[23] The writer of the *Times of India* commentary that I follow here makes the point by comparing current Indian prices for generic drugs with prices in Pakistan, which already has a system of product patents. AIDS anti-retrovirals cost $140 in India, and around $12,000 in Pakistan. Ten tablets of the anti-inflexilant *cipro flexocine* cost Rs.50 in India, Rs.400 in Pakistan; the anti-ulcer medicine *ranitidine* is Rs.5 in the former country, and Rs.74 a packet across the border. The mathematics is simple and horrible, and it demonstrates that pattern by which US foreign policy is subordinated to the interests of its major corporations. Sachar, *supra* note 21.

[24] Approximately 85% of the basic and applied research for the top 5 selling drugs on the market were produced through taxpayer funding. Sanjay Basu, *Dollar Diplomacy: US Undermines Initiative to Provide Poor Countries with Access to AIDS Retrovirals*, New Internationalist, May 1, 2004, at 8, *available at* http://newint.org/columns/currents/2004/05/01/dollar-diplomacy/.

[25] *Id.*

[26] *Id.*

B. Conclusions

These developments exemplify certain key moments in the new world order – an order at once of trade and of geopolitical hegemony – established by the TRIPS agreement.[27] The agreement achieved an international convergence of intellectual property law, that is, it required countries with "weak" protection of intellectual property to come up to US standards – and indeed, even US standards tended to be strengthened wherever they happened to be relatively lower than elsewhere. The core of the agreement as far as the developing countries were concerned was the creation of new rights for foreign nationals – meaning, for the most part, non-national corporations. The rhetoric of justice in which the TRIPS case was presented, and the rhetoric of defence against pirates stealing legitimately owned property, disguised the fact that "it pulled off a huge structural shift in the world economy to move monopoly profits from the information-poor to the information-rich",[28] institutionalising a major disadvantage between the major net intellectual property exporters (the US and, to a lesser extent, the European Community) and the rest of the world.[29]

III. THE TRIPS AGREEMENT

A. The Hijacking of the TRIPS Process

The developments delineated above throw light on the process by which – against the interests of almost every country on earth – the TRIPS agreement was forced

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[27] Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 1 (1994), 33 I.L.M. 1125 (1994); Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31 (1994), 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

[28] DRAHOS & BRAITHWAITE, *supra* note 5, at 197.

[29] Drahos, for instance, cites an Australian study of copyright royalty flows during the 1990s which showed that Australia paid out to overseas copyright owners around US$1.2 billion more than it received. More starkly, he describes what he calls the "staggeringly inefficient" results of the post-TRIPS intellectual property order for Africa: if African states import generic drugs from countries such as India having a strong generic drugs industry, the global intellectual property regime punishes them through well-funded litigation by drug companies, threats from Europe and the US to withdraw foreign aid, United States Trade Representative watch-listing, and the threat of bilateral sanctions backed by World Trade Organisation dispute panels. "Whereas the US can credibly threaten trade sanctions, foreign-aid withdrawal, flight of investment and refusal to transfer technology to an African state, an African state cannot credibly threaten the US with any of these things." DRAHOS & BRAITHWAITE, *supra* note 5, at 190.

onto the world agenda and into international law.[30] From the very beginning, the process was driven by a very small interest group, "a small number of US companies, which were established players in the knowledge game, captured the US trade-agenda setting process and then, in partnership with European and Japanese multinationals, drafted intellectual property principles that became the blueprint for TRIPS. The resistance of developing countries was crushed through trader power."[31] Of course, it was also the case that the interests of the holders of intellectual property rights were concentrated and focused, while the interests of those who are net purchasers of those rights were diffuse and differentiated. On crucial questions, the developing world pulled in different directions, and governments which often had little expert advice on the technicalities of intellectual property law failed to coordinate their responses with each other or with the affected industries in their own states. The layered circles of consultation meant that many states, including the vast majority of African states, had no say in the process until draft resolutions were at an advanced stage.[32]

The sheer implausibility of the TRIPS agreement has to do not only with the fact that it seems to run counter to the interests of all states except the United States, Japan and the European Union, but also that its dramatic extension of monopoly rights in intellectual property came about in the context of a trade regime that is ostensibly committed to the reduction of cartels and monopolies and the pursuit of full and free competition. The reality of course is that it is not. The WTO regime has to do with the institutionalisation of hierarchical inequalities between the developed and the developing countries. The trade inducements that were held out to many countries as the *quid pro quo* for the TRIPS provisions have largely failed to eventuate, as the breakdown of the Cancun meeting of ministers in 2003 demonstrated. Seen from a wider perspective, it is clear that the United States is committed to intellectual property protection only when the historical conditions are right. It has a long history of free riding- for most of the nineteenth century, it provided no copyright protection for foreign authors, arguing that it needed the freedom to copy in order to educate the new nation;[33] indeed, the United States did not sign the Berne Convention until 1988. In the same way, parts of Europe built their industrial bases by copying the inventions of others, a model which was followed after the Second World War by

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[30] *See generally* Drahos & Braithwaite, *supra* note 5; Susan K. Sell, Private Power, Public Law: The Globalization of Intellectual Property Rights (2003); Michael P. Ryan, Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property (1998).

[31] Drahos & Braithwaite, *supra* note 5, at 12.

[32] *Id.*

[33] Hal R. Varian, Copying and Copyright, *at* http://www.ischool.berkeley.edu/~hal/Papers/2004/copying-and-copyright.pdf.

both South Korea and Taiwan.[34] Japan also has a history of using patents strategically as a means of absorbing Western technology, while simultaneously denying Western firms power to develop in Japan on the basis of patents obtained there through the Paris Convention.[35] Yet, despite these histories, developing nations today are not allowed the luxury of taking their time over intellectual property rights.

B. Repercussions of TRIPS

Most areas of international trade with a basis in elaborate knowledge have been affected by the new world order initiated by the Uruguay round of the GATT. These include the film and music industries, scholarly publishing, libraries and archives, the electronics industry, Internet protocols and domain names, and many other areas. Problems that have arisen in the three key areas of pharmaceuticals, agriculture and genetic research are analysed hereunder.

1. Pharmaceuticals

In 1982, the then Indian Prime Minister, Indira Gandhi, told the World Health Assembly that "the idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death".[36] The statement is still a thought-provoking one, because it highlights so clearly the tension between the way things should be – the ethical basis on which we would expect the world to be organised – and the way things are – diametrically opposed to the ethical notion that monopolistic proprietary rights in the form of patents should not be granted for pharmaceutical products. Not only are there medical patents, and not only is there profiteering from life and death, but patents form the entire basis of the research and development strategy of the major US and European pharmaceutical companies.

Currently, only six countries have serious generic manufacturing capacity,[37] and all are now obliged to comply with TRIPS. The structural reality is that we are moving

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[34] Gavin Stenton, *Biopiracy Within the Pharmaceutical Industry: A Stark Illustration of How Abusive, Manipulative and Perverse the Patenting Process Can be Towards Countries of the South*, 26 Eur. Intell. Prop. Rev. 17 (2004). On the history of US patent strategies, see generally Doron Ben-Atar, Trade Secrets: Intellectual Piracy and the Origins of American Industrial Power (2004).

[35] William Kingston, *Why Harmonisation is a Trojan Horse*, 26 Eur. Intell. Prop. Rev. 447, 454 (2004).

[36] Carlos Braga, *The Economics of Intellectual Property Rights and the GATT: A View from the South*, *in* Trade-Related Aspects of Intellectual Property 253 (Connie T. Brown & Eric A. Szweda eds., 1990).

[37] Namely Brazil, Argentina, China, India, Korea, and Mexico.

towards a world in which large pharmaceutical companies have the capacity to assert patent (and other) rights against any potential competitor. The effects of this situation are simple: the monopoly rights given by patents (the development of which depends heavily on public-sector research) increase costs substantially beyond what they would otherwise be; and research is oriented almost exclusively to diseases of affluence, not to the diseases of the Third World.

2. Agriculture

The market distortions introduced by the current intellectual property regime in the agricultural sector are attributable to the monopoly control of crop varieties by a small number of corporations which have bought out the smaller players in the seed business, and which are mostly chemical companies that view agribusiness in terms of the symbiosis between the seeds they design and the pesticides they require. These corporations are driving a revolution in farming, both in the developed and the developing worlds, in which the saving and re-use of seed is becoming both physically and legally impossible. From being a self-sufficient unit producing most of its own requirements, the farm now becomes a site of capital-intensive and technology-driven production where "purchased inputs account for the bulk of the resources employed".[38]

On the other hand, however, the technological dimensions of this revolution are dependent upon the importation of biological resources and agricultural knowledge from those regions, mostly in the underdeveloped world, with the greatest biological diversity. The name for this largely unrecompensed exploitation of resources is biopiracy, namely, "the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control over these resources and knowledge".[39] As Stenton notes, "with some 80% of the world's biological diversity lying in the tropical and sub-tropical regions of the South, accompanied by the fact that 56% of the top 150 prescribed drugs in the United States are based on chemicals derived from plants…the potential economic rewards for the undeveloped world are enormous, as is the temptation for pharmaceutical companies to commit acts of biopiracy".[40] The situation is exacerbated by the inadequacy of legislation in the developing countries "to prevent the

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[38] Jack Kloppenburg, First the Seed: The Political Economy of Plant Biotechnology 1492–2000 at 10 (1988).

[39] Stenton, *supra* note 34, at 17 (as defined by the Action Group on Erosion, Technology and Concentration).

[40] *Id.* Such acts of biopiracy are frequently committed through the raiding of public domain materials held in gene banks and cell libraries and collected from indigenous communities.

unauthorised collection of germplasm especially by the transnational corporations";[41] and by the fact that, unlike the UK and Europe, the US recognises prior art only in domestic terms: "if the knowledge hasn't happened in the United States, it hasn't happened". This facilitates the theft and patenting of traditional knowledge from all other nations and carries the consequence that nations that do not permit the patenting of plants and animals can provide no bar to a patent being obtained in the US[42]

3. Genetic Research

In March 2000, the US and British governments signed a joint decision not to patent the human genome, a decision precipitated by attempts by US biotechnology companies to patent large tracts of the human genetic commons.[43] There has been a continuing tension, however, between patent law in the United States and in the rest of the world. In the United Kingdom, for example, DNA *per se* is not patentable, but functional methods or products arising from it are. In the USA, "raw" DNA itself can be patented, with the US patent office routinely granting patents on genes, the only country in the world to do so. This allows the holder to charge fees if anyone uses them for a commercial purpose.[44] Thus, it is US law which is causing the current problems in the human genome project, and which is driving the rest of the world towards the greater protection given by the American system in order to maintain investment in their own biotechnology industries and to attract investment from US-based multinationals. By September 2004, over three million genome-related patent applications had been filed worldwide,[45] and more than half a million patents had been granted or were pending on genes and partial gene sequences. The European Patent Office had a backlog of some 15,000 biotechnology patent applications.[46]

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[41] Tshimanga Kongolo & Folarin Shyllon, *Panorama of the Most Controversial Intellectual Property Issues in Developing Countries* 26 Eur. Intell. Prop. Rev. 258, 259 (2004).

[42] Stenton, *supra* note 34, at 20. Such nations include Mexico, Brazil and Argentina.

[43] Scott D. Locke & David A. Kalow, *Preparing for Bioinformatics Litigation: How will the Courts Confront the Next Generation of Biotechnology Patents*, 1 Buffalo Intell. Prop. L.J. 76 (2001).

[44] Patenting the Human Genome, http://www.biotechanalytics.com/Topics/Human%20Genome%20Patenting.htm.

[45] Human Genome Project Information, http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml.

[46] *Patent Applications: Full List*, The Guardian, Nov. 15, 2000, http://www.guardian.co.uk/genes/article/0,,397503,00.html. A report in *The Guardian* of that year found that one French firm, Genset, had applied for patents covering more than 36,000 human gene sequences, and that patents were pending on genes controlling processes in the human heart, teeth, tongue, colon, skin, brain, bone, ear, lung, liver, kidney, sperm, blood and immune system. James Meek, *The Race to Buy Life*, The Guardian, Nov. 15, 2000, http://society.guardian.co.uk/health/news/0,,397887,00.html.

Although the human genome itself was delivered to the public domain by the team that mapped it, with the sequences deposited in GenBank, the publicly accessible database, the partial gene sequences coding for particular functions are not in the public domain. The granting of a patent requires both identification of the function of the invention, and some difference, however small, from the object in its naturally occurring state. Patent offices now, however, routinely ignore these requirements. A grant of patent on gene sequences whose function is described only in the most general terms has the effect of blocking the more detailed research required to make this basic identification useful. The criticism is that "over the past quarter century…proprietary claims have reached further upstream from end products to cover fundamental discoveries that provide the knowledge base for future product development".[47] Corporations, universities and research laboratories have expanded the opportunities to file patent applications on the "fundamental research discoveries that broadly enable further scientific investigation", including such things as "new DNA sequences, protein structures, and disease pathways, that are primarily valuable as inputs into further scientific research".[48] The result of this rapid expansion of property rights in the area of genetic research is the creation of what Rai and Eisenberg call "an anticommons, or 'patent thicket' ",[49] which slows research down by making it at once more difficult and more expensive. More generally, the tradition of open science, built on the free flow and exchange of information, is eroded by the commercial drive to secrecy.

IV. THE IP REGIME IN A NEW WORLD ORDER

A. Trends in devising an IP regime in the New World Order

The issues discussed above touching upon intellectual property law give rise to a broader set of questions. In the first place, these are questions about the cultures that enable different forms of relation and interaction between people and things. By culture, I mean here the broad context of norms and values that govern social exchange, and which decide whether particular valued objects, attributes and institutions may be exchanged against others or should be withdrawn from exchange; and whether such exchange takes the form of gift transactions or of the alienation of objects in a market. In part, this is a question about the kind of personal tie that exists between persons and things – and, thus, about how the categories of "person"

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[47] Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 Law & Contemp. Probs. 289 (2003).

[48] *Id.* at 291.

[49] *Id.* at 297.

and "thing" are constituted differently within different contexts. It is as well a question about the degree of abstraction that may be allowed in social transactions; that is, of the extent to which people are bound up with the things that are theirs, and thus to which things are extensions of persons, or whether things may be ceded in a relatively impersonal way that does not commit the receiver to ties of obligation to the one who gives or sells his things.

These questions about culture are, in turn, questions about how cultures shift in response to pressures from conflicting social interests, and how they draw and redraw the definitions of what is thinkable and what is unthinkable in a given society. The sudden, enforced shift by Iraqi or Canadian farmers from a culture of seed-saving and slow varietal breeding is one example of such a redefinition. Another might be the tension between ordinary music users, who see no harm in downloading music from the web, and the music industry, which conceives this as a criminal action and is trying to bring about a general shift in moral norms to support its view. A third might be the norm of control of the development and supply of drugs by privately owned and profit-oriented pharmaceutical companies rather than by bodies with a direct and accountable commitment to public health.

These are, in one sense, questions about the value form, and about historical changes in what is socially valued. For those of us who live in capitalist societies, they have to do, above all, with the commodity form, and with the changes that have progressively extended it from land and moveable objects to immaterial objects, and from a relatively restricted set of goods to a much broader set, many of which would previously have been withheld from commodification. They are, thus, about some of the fundamental categories of our world: those of nature, the person, knowledge, and the structure of social relations. Philosophically, these historical changes are reflected in the discourse of neoliberal economics, with its vision of a universe of transactions subject to a single scale of cost/benefit analysis; a vision of extraordinary power and simplicity, which has captured the imagination of governments and of policy-makers in most areas of the world.

Intellectual property law, which governs the private ownership of immaterial products, is central to the changes that have taken place in the form of value over the last two centuries and with particular intensity over the last fifty years, as knowledge has become a dominant component of economic value. Yet, the consideration of intellectual property issues raises with particular intensity the question of the balance that this body of doctrine seeks between a limited set of property rights and something that is other than property, or that is a different, communal and non-exclusive kind of property.

The category of the public domain, this counterpart to private property in intellectual products, plays a central structural role in intellectual property law. Jessica Litman calls it "a device that permits the rest of the system to work by leaving the raw material of authorship available for authors to use".[50] It is a realm of materials that can be used but not claimed, and in all developed doctrine, it is the envisaged good that permits, and is actively fostered by, the temporary and limited monopoly rights that are excised from it. Yet, as must now be abundantly clear, these excised rights are no longer either temporary or limited, and the category of the public domain has fallen from view in the formulation of public policy.

What might we do about this? In what terms can we imagine a defence, and even an enlargement, of the public domain? Certain problems immediately confront us. The first is the incoherence of the concept itself: rather than being positively defined, it exists only in the form of a residue, those rights, whatever they might be, that are left over after all other claims have been exhausted. Insofar as its content is defined at all by the law, it consists on the one hand of certain common law rights such as those of fair use or fair dealing, of administrative regulations such as freedom of information, or of statutory protection of free speech, and, on the other, of what Jessica Litman calls a "hodge-podge of unprotectable matter" including – to take a list from US copyright law – "ideas, methods, systems, facts, utilitarian objects, titles, themes, plots, *scenes à faire*, words, short phrases and idioms, literary characters, style, or works of the federal government".[51] Some, but not all, of these categories derive from the dichotomy of idea and expression by which much intellectual property law is structured, and which has proved to be an almost impossibly metaphysical distinction. There are, or there have developed, exceptions to almost all of these textual elements, and most of them are defined in the case law as *exceptions* to a general rule of protection.

Compounding this incoherence of definition is the practical problem that for most purposes, there is no one who can speak for the public domain in the formulation or the administration of public policy. Legislation characteristically responds to the needs of interested parties such as pharmaceutical and chemical companies, publishers, the film and music industries and corporations that have large investments in intellectual property. Quite unfortunately, the interests of the public domain and of the consumers of intellectual property are largely unrepresented. There is nevertheless a broad constituency with an active interest in an open field of knowledge-the open source software community and hackers more generally;[52] librarians, who

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[50] Jessica Litman, *The Public Domain*, 39 Emory L.J. 965, 968 (1990).

[51] *Id.* at 992–3.

[52] *Cf.* McKenzie Wark, A Hacker Manifesto 194–206 (2004).

are often the only ones designated to speak on behalf of the public domain in policy hearings and who have been radicalised by their struggle with the publishing giants which exercise a monopoly control over scientific journals; scientists and academics, who donate their intellectual property free of charge to those journals, and who must then pay to cite copyrighted materials or to use patented research tools; the sick and the elderly in every country on earth who cannot afford the cost of patented drugs, and the health insurance bodies that are forced to carry much of the cost of the pharmaceutical companies' greed; the farmers who have been forced into contracts with the multinational seed companies; and every teenager who risks criminalisation for downloading music from the net.

The peculiar vulnerability of the public domain to encroachment by profit-seekers has at times had the paradoxical consequence that it may seem necessary to privatise parts of it in order to protect public access. One early strategy for keeping the human genome in the public domain was through the patent process. The director of the US National Institute of Health was quoted in 1992 as saying that she "wants the NIH to patent the human, genome to prevent private entrepreneurs, and especially foreign capital, from controlling what has been created with American public funding".[53] In the event the solution came through the success of the publicly funded Human Genome Project in beating its private competitors to the publication of the complete genome, thus making it unavailable for patenting. The same solution was not available, however, for the single nucleotide polymorphisms that are crucial to genetic research. So, in April 1999, ten large pharmaceutical companies and the UK Wellcome Trust philanthropy announced the establishment of a non-profit foundation to find and map 300,000 common SNPs (they found 1.8 million). Their goal was to generate a widely accepted, high-quality, extensive, publicly available map using SNPs as markers evenly distributed throughout the human genome. The consortium planned to patent all the SNPs found, but to enforce the patents only to prevent others from patenting the same information. Information found by the consortium is freely available.[54]

A similar defensive creation of property rights has been exercised in relation to cell lines taken from indigenous people. In 1995, a man from the Hagahi people of the Papua New Guinea highlands (a people which came into regular contact with the outside world only in 1984) ceded his genetic rights to the "inventors" named in the US Government patent, and a medical anthropologist associated with the project argued that this legal mechanism was the only way to ensure that the Hagahi people

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[53] *See* Richard Lewontin, *The Dream of the Human Genome*, N.Y. Rev. Books, May 28, 1992, at 38.

[54] Human Genome Project Information, http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml.

– whose names did not appear on the patent – receive some protection from commercial exploitation.[55]

Such property-based defences of the public domain depend on an assumption of the altruism or the innocence with which "good" property rights will be asserted against "bad" ones. Nothing guarantees, however, that such altruism or such innocence can be either assumed or sustained. The problem lies not, I think, in the use of the category of property itself – since the public domain is a legal construct, not a naturally existing resource – but rather in the way this use reproduces the framework of values within which it is employed under the current intellectual property regime. After all, it remains a matter of private property, of rights excised from the public domain even if only for the purpose of defending it, rather than of property rights which are non-exclusive and communal. Similarly, the institutionalised piracy that expands what we might call the counter-public domain of illegally produced materials is ultimately no more than an alternative form of capitalist production, asserting an alternative set of property rights in the black market which shadows the domain of legal distribution.

B. Creating a Rhetoric of the Public Domain

How can we imagine the shared, non-competing and non-exclusive rights that characterise the public domain, without simply reverting to a defence of piracy or to an idealised communitarian past? One difficulty is that the rhetoric of human rights derives from a whole tradition of legal philosophy that takes the individual as its starting point. Yet it is certainly possible to conceive of rights that are more general. At the last meeting of the World Intellectual Property Organisation in Geneva, for example, Chile fought to put on the agenda of the next meeting a proposal to recognise a human right of access to knowledge.[56] Now, this proposal is far from being unproblematic: the property rights that currently inhere in knowledge will not lightly be given up in the face of a general assertion of this kind; and in any case, the concept of "access" does not preclude the charging of entrance fees, and thus the reinstatement of inequalities between those who can and those who cannot pay. But if the consequences of such a proposal are still to be worked out, it nevertheless seems a reasonable starting point in the struggle over the social costs of knowledge.

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[55] Mary Louise O'Callaghan, *The Selling of Cells*, The Australian, Nov. 14, 1995, at 17. There is extensive coverage of the case in a special issue of *Cultural Survival Quarterly* (20:2, 1996).

[56] Provisional Committee on Proposals Related to a WIPO Development Agenda, 1st Session, Geneva, Feb. 20–24, 2006, A Proposal by Chile, *at* http://www.wipo.int/edocs/mdocs/mdocs/en/pcda_1/pcda_1_2.pdf; *see also* Day 2 of WIPO Development Agenda Meeting, *at* http://www.twnside.org.sg/title2/twninfo359.htm.

In thinking about the politics of intellectual property, there are perhaps useful analogies to be drawn from the environmental movement. As James Boyle points out, it was the development of the concept of "the environment" itself that helped generate an imaginable object of concern for a variety of previously discrete and sometimes antagonistic movements – anti-vivisectionists, rural conservation bodies, indigenous groups, protesters against particular acts of logging or mining, hippies and ferals and duckhunters.[57] The question of politics is always, in the first instance, the question of defining an object of struggle, an achievable aim, and a politically effective rhetoric. Making a similar point, Mark Rose writes that "one element of the task today is to make the public domain visible – to develop an affirmative discourse that will make it a positive and prominent part of the social and cultural landscapes…Rhetoric is crucial."[58]

The rhetoric that currently holds sway in relation to commercially valuable intellectual property is one of protection. Any intellectual property lawyer will define the relevant issues in the field in terms of whether the protection for a particular right-holder is adequate. The question of the adequacy of the countervailing protection for the public domain, and thus for the users of intellectual property, never arises; it is unthinkable within the ambit of the prevailing legal imaginary. The fundamental (and yet the most difficult) of our tasks is to make it conceivable again; to force the question of the *protection of the public domain* back on to the agenda, and to ask the question every time the question of 'protection' arises.

"Protection" is, of course, a loaded word, as is "piracy"; its connotations are of caring, rather than of securing rent from a monopoly grant. "Monopoly" should be a key term in the alternative rhetoric I am trying to define. Its great strength is that it accurately describes the manner in which intellectual property operates, and there is a ready-made armoury of critique to hand in the discourse of economics, indeed in the very rhetoric of neoliberalism which is, in general, so ready to defend strengthened rights for the owners of intellectual property. Monopoly is anti-competitive. The holding of patents in the syntax of gene sequences whose function is not known blocks the more serious research of scientists looking for that function. When the Disney Corporation draws its raw materials from public-domain folk tales and then exercises a strict enforcement of its copyright in the work its employees create from them, it is, in its own terms, as much a free-rider as those who would reuse the characters and stories and music that have entered the public consciousness, if not, legally speaking,

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[57] James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 Law & Contemp. Probs. 33 (2003).

[58] Mark Rose, *Nine-Tenths of the Law: The English Copyright Debates and the Rhetoric of the Public Domain*, 66 Law & Contemp. Probs. 75 (2003).

the public domain. The strengthening of the rights of what the United States Supreme Court once called "first authors" affects the ability of the "second authors" who come after them to use their work as raw materials for creation[59] – and every first author is also a second author; every act of creation involves the use and re-use of materials that have been elaborated elsewhere.

If the anti-competitive force of overly strong intellectual property rights can be brought back into the political conversation, then not only the discourse of economics but also the institutional forms through which it is instituted can be invoked. Those countries that have a competition commission or an anti-monopoly or anti-trust commission should, in principle, be required to apply their analysis to the effects of strong – I would argue excessively strong – intellectual property rights. And by analogy with the figure of the ombudsman, it is possible to imagine the creation of an office of protector of the public domain, an office with the designated function of representing those interests that are otherwise too diffuse and too incoherent to be properly heard in the formulation of policy, in patent hearings, and in trade negotiations.

Let me return, finally, to the question of whether the public domain can be effectively defended by means of a discourse of rights. In general, I am sceptical of concepts of human rights to the extent that they are grounded in a notion of the human person as an entity existing prior to its particular conditions of existence. Yet, there are alternatives to such a humanist conception of rights. In an essay on gift and commodity exchange that I wrote some years ago, I said of the "positive" concept of the public domain that I tried to project then that it was intended as a way around some of the conceptual impasses that flow from the notion of a transcendental and autonomous sphere of personhood which is prior to and essentially untouched by property relations, and which exists in a "private" rather than a "public" space. Public domain rights are those rights that, rather than deriving from personhood, precede and enable it. They are rights to the raw materials of human life: language, ideas, an inherited culture, a "common heritage" of environmental resources, bodily integrity, civil entitlement. These are not "natural" rights, located in an originary contract or a state of nature, but customary social rights, developed and recognised as a provisional end state of the struggle for civilized conditions of life (and of course, whatever their recognition, always contested). Like all rights, they represent a balance between conflicting demands, and they carry with them a corresponding set of obligations to the common good.[60]

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[59] Sony Corporation of America v. Universal City Studios, 464 US 117, 78 L.Ed. 2d 574, at 615.

[60] John Frow, Time and Commodity Culture 214—215 (1997).

V. CONCLUSION

In this article, I have argued that the new intellectual property rights regime that has been imposed by the first world is beneficial only to a handful of Multi National Corporations (MNCs), to the detriment of the developing countries and the ordinary public the world over. To tackle this highly individualistic, rights-based approach, there is a pressing need to focus on the essentially monopolistic character of intellectual property. It also needs to be remembered that all intellectual property is ultimately derived from ideas and resources borrowed from the public domain, and hence it is anomalous to suggest that any individual or corporation has an undiluted or absolute claim to any form of intellectual output. On the contrary, all forms of intellectual property are the result of public synergy transcending space and time. This led me to invoke the notion of a "common heritage" or to put it in terms that economists will understand: the notion of *intergenerational transfer*. This, it seems to me, is a way of thinking about the public domain that gets us beyond the individualism, the essential selfishness of the notion of personal rights. The value that we put on the public domain of raw intellectual materials that can be used by all and claimed by none is a value not just for ourselves, but for those who come after us. Our relation to this domain is not just one of use, but one of stewardship for our children and our children's children. This is a conservative way of putting it, and it may be that it is wrong to think only in terms of preserving what is, in any case, a decreasing heritage. Yet the metaphor of intergenerational transfer has the strength of appealing to something larger than our own interests, however universal we may think these are; and it gets at that element of commonality, which is so crucial to the concept of the public domain. It puts the onus, too, on those who would convert this domain into private property to explain what kind of world they would leave behind.