TRIPs and the Compulsory Licensing Problems of Developing Countries

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1.0 Introduction

Before the adoption of the Doha Declaration,[1] pertinently, of the relevant part of the text of its Article 6,[2] it was more or less universally accepted that Article 5(A)(2) of the Paris Convention protects the fundamental right of member states to grant compulsory license's. (The compulsory license is an instrument a state can use to act against a patent monopoly if doing so is in the public interest.) Articles 8 and 31 of the TRIPs[3] have since 'set in stone' the conditions that determine the grounds of that grant. Whereas the Paris Convention's provision is direct and simple,[4] the TRIPs provisions are loose and inviting of efforts to minimize them. Not only that, but they also succeed to deprive least- developed countries of urgently needed medication. The author will argue that the provisions of TRIPs regarding compulsory licensing enable the perpetration of abuses of human rights, albeit an unintentional enabling. It is true that Article 31 of TRIPs allows for the granting of compulsory license's in cases of abuse of patent-monopoly power, or when public interest demands it. But it is also true that developing countries rarely make use of this instance of TRIPs flexibility, and that least-developed countries are unable to make use of it. It will nevertheless be conceded that Colleen Chien[5] makes a potentially valid point that the TRIPs provisions are a safeguard against the reduction of drug prices by compulsory licensing to the point where their cheapness inhibits innovation. But Chien's failure, like the failure of others who make the same point, is that she tenders no empirical evidence of the fact that there is a reduction in R&D when drugs become cheaper. She, like her fellow travellers, merely asserts that incentive for R&D investment reduces with the fall in price of drugs. This is so despite the fact that Scherer's account[6] of the research into this subject (an account that appeared well before Chien's work) undermines that assertion quite drastically. The well-meant 2003 WTO decision on compulsory licensing is timely, and its recognition that least-developed countries need its flexibility is sound. But the WTO to date has not taken account of the fact that the amended Article 31 of the TRIPs has not rendered the compulsory licensing facility usable by least-developed countries. The human right to health is therefore far from being recognised and promoted by the TRIPs.The special cases of China and India with regard to the TRIPs provisions for compulsory licensing will be examined, and on the basis of that examination, an argument will be propounded for the need for compulsory licensing provisions to be enforceable.

1.1 Nature of the TRIPs

Before setting out upon the main argument, it is expedient to sketch an outline of the nature of TRIPs. This sketch will take a seemingly irrelevant look at the TRIPs and its provisions concerning geographic indicators (G1s). The purpose in doing this is to call attention to the tremendous efficiency of the TRIPs in purely trade-related matters. In such matters it is almost facetiously precise, and its provisions are enforceable. It is instructive to compare this with the TRIPs approach to compulsory licensing.
The Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement was formulated during the WTO's Uruguay Round of talks in 1994. The TRIPs is regarded as the principal international treaty governing intellectual property rights (IPR). It has brought IPR protection firmly into the realm of international trade. This feat was not easy to bring off. The US had been displaying its dissatisfaction with the insufficient protection of intellectual property that the Paris Convention, and its Administrator, the World Intellectual Property Organization (WIPO) afforded. The US aim was to transfer IPR discussions to the GATT forum. It was frustrated by a widespread sentiment that WIPO and not the GATT[7] is the appropriate forum for the discussion of intellectual

[1] Doha Ministerial 2001, WT/MIN(01)/DEC/1, 20 November 2001, WTO website, http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm#electronic.
[2] We recognize that under WTO rules no country should be prevented from taking measures for the protection of human, animal or plant life or health, or of the environment at the levels it considers appropriate, subject to the requirement that they 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, and are otherwise in accordance with the provisions of the WTO Agreements
[3] Agreement on Trade-Related Aspects of Intellectual Property Rights (**TRIPS**)
[4] Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.'
[5] Chien, Colleen, 'Cheap drugs at what price to innovations: Does the compulsory licensing of Pharmaceuticals hurt innovation?', vol. 18, Berkeley Technological Law Journal, 2003, pp. 853-907.
[6] Scherer, FM and Watal, J, 'Post-TRIPs options for access to patented medicines in developing nations', vol. 5, Journal of International Economic Law, 2002, note 250, pp. 13 - 16.
[7] General Agreement on Tariffs and Trade (**GATT**)

property. It was only in 1989, when Brazil and India consented to it, that IPR discussions were transferred to the GATT forum.[8] Its successor, the WTO, then assumed full control. The WTO tells us the following of what TRIPs does:

The agreement covers five broad issues:

(i) How basic principles of the trading system and other international intellectual property agreements should be applied,
(ii) how to give adequate protection to intellectual property rights,
(iii) how countries should enforce those rights adequately in their own territories,
(iv) how to settle disputes on intellectual property between members of the WTO, and
(v) special transitional arrangements during the period when the new system is being introduced.[9]

Every member of the WTO is under obligation to implement TRIPs in both letter and spirit. TRIPs provides for the registration and protection of patents and copyright, and determines the administrative aspects of copyright protection. The Agreement provides inter alia for the protection of computer programming innovations by categorizing them as 'literary' works. (This protection most suits those countries whose development is strongly propelled by the information and communication technology sectors, particularly India and China, and those, notably the US, who are major exporter of entertainment- industry products.
The Agreement provides also that WTO member countries must develop legislative frameworks regarding patent laws, especially so as to cover technological innovations and botanical discoveries that are considered related to the hard work of individuals and nations:

> **Provisions within the Agreement also demand that national protection for patents and copyright be limited. In terms of these rights, citizens should not receive favoritism from national governments.**[10]

1.2 Concept of 'compulsory licensing'

The compulsory licensing scheme applies to pharmaceutical products, and, like all TRIPs provisions, is it must be implemented by WTO members. Compulsory licensing vests national governments with the power to insist that a patent-right holder relinquish his rights to another manufacturer who has been granted government permission to produce and sell his product. The government concerned fixes the amount of compensation payable to the right-holder, and sets the life-time of the compulsory license. Compulsory licensing is legal, pursuant to TRIPs provisions, in a variety of circumstances. These circumstances include some loosely defined 'national interest' requirements.[11]

The TRIPs Agreement has enabled developing countries to make use of compulsory licensing, provided that their respective governments pay appropriate and adequate compensation to the patent holder. Article 8.1 of the Agreement provides that:

> **Members may in formulating or amending their laws and regulations adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development.**

Article 31 of the Agreement, entitled 'Other Use without Authorization of the Right- holder', provides that:

> **Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected...**

Several conditions are stipulated, one being that the original patent-holder must receive royalties from the holder of the compulsory license. Compulsory licensing is meant to ensure that medicaments are available at comparatively low prices in developing countries when those medicines are 'necessary to promote public health'. The compulsory licensing privilege of, for instance, South Africa, is well protected by Article 1 of the Agreement against opposition by, for instance, the US. This Article provides that the members of the WTO are obliged to 'give effect to the provisions of this Agreement'. There is therefore no choice but to give effect to Articles 8 and 31. Choice obtains only in the matter of 'implementing in their law more extensive protection than is required by this Agreement'. And it is this choice-proffering provision of TRIPs that succeeds to be the ammunition that kills off the possibility of least developed countries' benefiting from the compulsory licensing facility of TRIPs.

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[8] Reiling, Ron, 'Intellectual Property Regimes for the Information Age: Policies of the United States, the European Union and the World Intellectual Property Organization', vol. 3, no. 9, Boston University Journal of Science & Technology Law, 1997, pp. 9 - 11.
[9] World Trade Organisation, Intellectual Property: Protection and Enforcement' http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm .

[10] Incorporated into the Code de la Consommation (Law No 93-949 of July 23, 1993, Journal Officiel, July 27, 1993, amended in 1994, Journal Officiel, January 4, 1994.
[11] Buchner, Sara, 'Trade Briefs: Compulsory Licensing', Trade Law Centre for South Africa, http://www.tralac.org/scripts/content.php?id=19.

1.3 WTO stand on compulsory licensing

On 30 August 2003, the WTO ratified a set of new rules with a view to improving the access of developing countries with severe public health problems to patent medicines.[12] The rules have since been implemented to amend Article 31 of the TRIPs. This was the WTO's response to the by-then-widespread indignation that the TRIPs rules were themselves constructing obstacles to least-developed countries' access to essential medicines. This marked the first ever, and so far the only, amendment of a WTO agreement. The WTO's 30 August 2003 decision inserted three waivers of the provisions of Article 31

(i) the provision of 31(f) that compulsory licensing rights are to be deployed for supply of the domestic market only;

(ii) the provision of 31(h) that the country importing under compulsory licensing must remunerate the original patent holder; and

(iii) the provision of 31(f) that prohibits the export of pharmaceuticals imported under compulsory licensing. (The latter waiver now permits the re-export if pharmaceuticals, so long as their destinations are confined to members of a regional trade agreement, and if at least half of those members are least-developed countries.)But there is a hitch. The new rules must be implemented at national level before they can be acted upon. And implementation of them is fully voluntary. The only exporting (of pharmaceuticals) WTO member countries to implement them so far are Canada, India, Norway and the EU. China and Korea have introduced some changes in their domestic legislation, but have not formally notified the WTO of them.[13]No instance of importation under the new rules by developing countries has yet occurred, nor is there evidence to date that potential importing countries have modified their domestic law to include the new Article 31 amendments.[14]

1.4 Opposition to compulsory licensing

Theorists who have given expression to views that condemn the concept of compulsory licensing argue along the following lines: It cannot be expected to have a positive impact on pharmaceutical prices. This legal phenomenon inhibits pharmaceutical companies' incentive to introduce new medicines. Although the TRIPs Agreement addresses some specific issues relating to compulsory licensing, it does not offer a sufficient level of legal certainty, thereby creating a larger risk of litigation. Since compulsory licensing confers the right to produce or import a product without the express consent of the original patent-holder, members' domestic licensing laws properly attempt to inhibit the use of compulsory licensing. Considerably more substantive than the criticism of compulsory licensing just outlined is the set of criticisms that take the WTO to task for the laxity of the TRIPs provisions for it. A major criticism of this kind is that the TRIPs completely neglects to regulate selling practices and licensing restrictions. As Keith Maskus[15] notes that leaves IPRs open to exploitation by the cartelization of horizontal competitors through licensing agreements that fix prices, limit output or divide markets. Cartels might also acquire exclusive rights to products and technologies that began their patent or compulsory-license life as competitors. TRIPs has not made a point of closing off loopholes for the abuse of compulsory licenses. In view of the exhaustively-worked provisions for the protection of GIs regarding wine that was outlined above, the GATT panel responsible for this neglect deserves censure.

A common claim is that TRIPs has not been effective at reducing the price of pharmaceuticals sufficiently to enable developing countries to manufacture and sell them. On the contrary, the prices of patented medicines have been allowed to soar, for the TRIPs has left pricing completely unregulated.[16] A related criticism is that pursuant to TRIPs there is a twenty-year minimum patent protection period for pharmaceutical products and processes. This long protection period amounts to a grant of secure monopolies to manufacturers of pharmaceuticals, enabling them to eliminate competition from alternative, low-cost producers.

1.5 Compulsory licensing and India's pharmaceutical industry

It is curious that the pharmaceutical industry actually benefited from the latitude that the Paris Convention had allowed to the compulsory licensing facility. Admittedly, the benefit did not accrue to the US pharmaceutical giants. Rather, it accrued to India's. The spectacular success of India's pharmaceutical industry is owed largely to the fact that before the advent of the TRIPs, it had no domestic legislation regulating the protection of pharmaceutical patents, nor, thanks to the then-dominant Paris Convention regarding it, did anyone have the means of forcing a domestic legislation on this country.

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[12] WTO General Council Decision, 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health', WT/L/540, 30 August 2003, http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

[13] Nottage, Hunter and Sebastian, Thomas, 'Giving legal effect to the results of WTO trade negotiations: An analysis of the methods of changing WTO law', vol. 9, no. 4, Journal of International Economic Law, 2006, p. 993.

[14] Musungu, Sisule F, and Oh, Cecilia, 'The use of flexibilities in TRIPs by developing countries: can they promote access to medicines?', the South Centre in collaboration with the World Health Organization, 2006.

[15] Maskus, Keith E. 'Competition Policy and Intellectual Property Rights in Developing Countries: Interests in Unilateral Initiatives and a WTO Agreement' note 333, pp. 28 - 29. http://siteresources.worldbank.org/INTABCDEWASHINGTON2000/Resources/maskus. pdf.

[16] Abbott, Frederick M, 2006, 'The cycle of action and reaction: developments and trends in intellectual property and health, in Roffe, Pedro, Tansey, Geoff and Vivas-Eugui, David (eds), Negotiating health: Intellectual property and access to medicines, International Centre for Trade and Development, pp. 28-29.

With the advent of TRIPs, India made clever use of its Article 65.4, which allows developing countries a transition period for TRIPs compliance. (This transition period for pharmaceuticals expired in 2005).[17] Having obtained a long transition period, India was able to operate without TRIPs constraint until January 2005. In the interim, it had developed a large industry in generic medicines, having been left free to practice the reverse engineering and copying of medicines patented.

India's pharmaceutical industry has one further TRIPs benefit. That exists pursuant to the Article 70 'mailbox' provision for filing patent applications after 1995. India is now TRIPs compliant, so it can apply to its patent office for a grant of a patent that would enable it to continue producing generic medicines for the remainder of the original patent's twenty-year life. That means that India can rely on its off-patent behavior well beyond 2005.

However, India is not a least-developed country, so no further direct benefit can accrue to it from the TRIPs provisions regarding compulsory licensing. Or so it appears. In fact, one cannot but wonder what will happen in least-developed countries, and in some developing ones, when the supply of cheap generic medicines by India begins to dry up. The hole that will develop in the global supply is enormous, for the Indian pharmaceutical industry currently occupies 1.5% of the value of the global pharmaceutical market, and supplies 20% of the global consumption. It produces 22% of all generic medicines worldwide. Together with China, India produces a lot of active pharmaceutical ingredients and is a major supplier of vaccines.[18] Furthermore, almost half of the India's pharmaceutical exports go to developing and least-developed countries.[19] Clearly, the TRIPs does not provide for a future reduction of the medicine supply from India. Will the WTO be moved to allow India's pharmaceutical industry to live outside TRIPs regulations? It will have to do something to soften its pharmaceutical- patents regime if it is to avert a health crisis in the poor developing countries, not to mention the least-developed ones.

1.6 Doha Declaration and WTO Decision of 2003

What immediately strikes a surveyor of the legal status of compulsory licensing is that there is an unwarranted assumption to the effect that the 2001 Doha Declaration on TRIPs and Public Health began the process of facilitating least-developed countries' access to life-saving medicines, and that the 2003 WTO Decision completed it by implementing the Doha Declaration to amend Article 13 of the TRIPs: 'Implement' would, surely, in some part of its sense-making rationale, include the notion 'make workable'. True, the Doha Declaration made clear an intention to ensure a working capacity. Its Article 6 charges the Council for TRIPs with that task:

> **6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. We instruct the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002.**

It is also true that Article 8 of the 2003 WTO Decision provided for the monitoring of the working condition of the amended Article 13 of the TRIPs:

> **8. 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.**

Glaringly obvious, however, is that the Council for TRIPs has not exerted itself in this direction. It met most recently on 13-14 March and 17-18 June 2008.[20] Its previous meetings since 2003 made not the slightest disclosure about what the Council for TRIPs thinks of the working health of the compulsory-licensing amendments. One must hope that the now-well-publicised Médecins Sans Frontières claim that it is not working at all will not have eluded the Council's attention. But one is nevertheless at a loss to know what the Council might do to enable the working of compulsory licensing against the US's Special 301 law.

It is well known that Special 301, which exists pursuant to section 182 of the Trade Act of 1974, is a formidable trade weapon for inhibiting applications for compulsory licensing, even when those applications are fully TRIPs compliant. On the authority of Special 301, the United States Trade Representative (USTR) annually reviews US trading partners' intellectual-property-protecting behaviors, and 'lists' those whom it deems to be giving inadequate protection to US intellectual property. It then requires the offending countries to rectify their behaviors, and threatens trade sanctions on their failure to do so. Thailand, for instance, made it to the USTR's 'priority watch list' for issuing three compulsory licenses on two HIV/AIDS and one heart disease medicines. All three issuances were TRIPs compliant.

[17] TRIPs Article 65(2) and (4).
[18] Grace, Cheri, 2004, 'The effect of changing intellectual property on pharmaceutical industry prospects in India and China', DFID Issues paper: Access to Medicines, June 2004, p.14.
[19] Médecins Sans Frontières, 'Examples of the importance of India as the "pharmacy for the developing world" ', 29 January 2007.
[20] Intellectual Property Watch, `WTO TRIPs Council To Meet Amid Broader Negotiation Backdrop',
June 2008, http://www.ip-watch.org/weblog/index.php?p=1098.

The TRIPs is helpless against this instance of the blatant undermining of its provisions concerning compulsory licensing. The undermining is so blatant that the US Senate has itself passed a resolution to the specific effect that Special 301 should not be invoked to undermine the 2003 Doha Declaration concerning compulsory licensing:

Resolved, that it is the sense of the Senate that the United States should:

1. honor the commitments the United States made in the 2001 World Trade Organization Doha Declaration on the TRIPs Agreement and Public Health, which allows member states of the World Trade Organization to use `to the full' the flexibilities in the Agreement on Trade-Related Aspect of Intellectual Property Rights (in this resolution referred to as `the TRIPs Agreement') `to protect public health and, in particular, to promote access to medicines for all,' including the issuance of compulsory licenses on grounds determined by member states;
2. not place countries on the `Special 301' Priority Watch List under section 182 of the Trade Act of 1974 (19 U.S.C. 2242) for exercising the flexibilities on public health provided for in the TRIPs Agreement, such as issuing compulsory licenses to obtain access to generic medicines in accordance with the Doha Declaration;
3. not ask trading partners who are developing nations to adopt measures to protect intellectual property rights that relate to public health in excess of protections required in the TRIPs Agreement; and
4. support new global norms for promoting medical research and development that seek to provide a sustainable basis for a needs-driven essential health agenda.[21]

It is suspected (as noted above) that Special 301 is the likely cause of the inertness of China's compulsory licensing laws, and presumably of the least-developed countries' comprehensive failure to make use of them. Yet the entire TRIPs legislative framework is without any provision that might serve to protect the Doha Declaration on compulsory licensing, and the consequent 2003 WTO Decision to amend Article 31 of the TRIPs, against the depredation of even the signatory states. Not even the above US Senate resolution, which in a normal legal context would serve as an admission to a US breach of an international law, can have the slightest force in the WTO. Despite this striking lacuna, no-one has to date expressed hope that it might be remedied, nor yet faulted the Agreement for it, on purely legal grounds. ('Lacuna' is no doubt used eccentrically in the TRIPs 'compulsory licensing' context, given that this is a context in which the key is voluntary implementation of enabling legislation. That is, member states may, but need not, enact enabling legislation. It is therefore not the binding-law context in which 'lacuna' is typically identified. The term is nevertheless used, and used provocatively, in anticipation of the argument that follows to the effect that the compulsory-licensing provisions of the TRIPs should be binding law if they are to be at all consequential.

1.7 Conclusion

This author attempted to make out an argument to the effect that the TRIPs should implement as binding law specific demands upon the form and content of domestic legislatures to be capable of response to requests from least-developed and developing countries acting on the compulsory licensing facility. If the TRIPs can make such demands for the protection of GIs, then nothing prevents it from doing so to make its compulsory licensing facility workable. This argument was derived from a context that

i. estimated the Paris Convention provisions regarding compulsory licensing above the TRIPs provisions;
ii. gainsaid Chien's view that compulsory licensing somehow harms the pharmaceutical industry;
iii. outlines the TRIPs GI regime to serve as a comparison with its compulsory licensing regimes;
iv. celebrated India's clever handling of the interim between the Paris Convention and the TRIPs that earned her a sound pharmaceutical industry; and
v. noted the exposure by Médecins Sans Frontières that the compulsory licensing facility was unworkable by the least-developed countries, and, according to another source, is inert in China for fear of trade reprisals; and
vi. condemned the bullying tactics of the US 'Special 301'.

The argument itself relied upon a distinction (of considerable pedigree) between 'the rule of law' and 'rule by law', making use of Intan Ramli's method. The crux of the argument was there while WTO member states are free to implement domestic legislation (or not implement it) with regard to their response-styles to requests for production and importation of medicines under the compulsory licensing facility, that facility is not grounded in law. Law and only law confers rights, and only law enables the redress of the denial of rights. The TRIPs compulsory licensing facility is therefore not law. Notably, the TRIPs regime regarding GIs in the wine and spirits industry is law. It was urged that if TRIPs can construct real law to protect wines and spirits, it can construct real law to protect the right to essential medicines of the peoples of least-developed countries.

[21] Senate Resolution 241/House Resolution 525, 110th Congress, 1st Session, In the Senate of the United States, (House of Representatives) June 20, 2007 (June 28, 2007).