A precautionary approach to compulsory licensing and tempering the data exclusivity obstacle for access to medicines

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ABSTRACT

This article takes up further on a framework developed for a precautionary approach (PA) which developing countries should adopt for granting compulsory licences in a national health emergency. Working within the legal mechanism of the precautionary framework developed from the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) under the World Trade Organization (WTO) and the Agreement on Trade-Related Intellectual Property (TRIPS), the PA redefines a framework for compulsory licensing based on an adequate margin of safety when there are reasonable grounds for concern about uncertain risks that *significant* harm to human life and health may occur. The rationale adopted is based on legitimate differential treatment, precaution and risk management for a prescriptive, moderate and least restrictive measure to trade to enable access to medicines.

Compulsory licensing under the TRIPS Agreement was developed as a buffer for tempering patent protection and health to "allow for other use of the subject matter of a patent without the authorisation of the right holder" subject to certain conditions. The August 2003 Doha Declaration and subsequent TRIPS amendments for all member countries to be eligible to import provided a breakthrough for access by poorer countries to cheaper generic drugs. The chilling effect of the waiver is shrouded by obvious reticence on the part of developing countries to adopt the WTO language of "national emergency" and "extreme urgency" as a condition for compulsory licensing. The bold efforts by Thailand and Brazil in issuing compulsory licences in 2007 were adopted on grounds of "public non-commercial use" and "public interest". An objective mechanism to trigger the grant of compulsory licensing would not leave developing member countries at the mercy of possible trade retaliation and sanctions that result only in price reduction bargains instead of a proper use of the inbuilt flexibilities under Article 31(f) of the TRIPS Agreement.

In addition to the patent obstacle, data exclusivity under the ambiguous Article 39.3 of the TRIPS Agreement poses another obstacle for access to medicines and the production of generic drugs even under compulsory licensing. Such regulatory protection of undisclosed pharmaceutical test data and the application of confidentiality to test data submitted by pharmaceutical companies so as to be able to obtain marketing approval of the products creates a data monopoly. It prevents the marketing of generic drugs even though the patent licences may have been granted by the government as generic drug manufacturers are unable to access the data. The authors query the obligation set out under Article 39.3 and consider the question of an implicit data exclusivity exception. The authors further argue holistically from a human rights perspective that a wider application of the precautionary approach to temper data exclusivity as a justification for disclosure in a public health emergency would enhance its prescriptive value. This article contemplates a parallel approach to overcome the issue of data exclusivity in the international trade and intellectual property regimes once a precautionary approach is adopted for compulsory licensing.

1. Introduction

The health and trade worlds collide when intellectual property protection falls under the World Trade Organization (WTO) umbrella.[1] Two worlds debate as controversy on data exclusivity centres between developing countries' needs and developed countries' wants in the context of public health.[2] Access to essential medicines remains a crucial issue for countries affected by humanitarian crises.[3] The Doha Ministerial Declaration[4] on TRIPS and Public Health ("Doha Declaration") for public access to medicines culminated in the Decision of 30 August 2003[5] recognising the serious public health problems in developing countries and difficulties faced in making effective use of compulsory licensing.

Against the backdrop of the global AIDS epidemic one of the most remarkable achievements in recent public health history was the rapid expansion of antiretroviral therapy in saving lives,[6] a pace that needs to be sustained to be able to reach 15 million lives by 2015.[7] In 2004 it was reported that only seven per cent of the people in developing countries received the very expensive anti-retroviral (ARV) therapy for HIV/AIDS,[8] and that around five to six million in developing countries would die within two years without access to the drug.[9] In 2012 there remained a 30 per cent gap between resources that were available and what would be needed annually.[10] In 2004, of the 40 million people reported to be infected with HIV world-wide, more than 90 per cent were in Sub-Saharan Africa, India and Asia (less than five per cent were in the high-income countries);[11] in 2011 there were still 34 million people living with AIDs globally with Sub-Saharan Africa the most severely affected. [12]

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[1]Since 1948 the General Agreement on Tariffs and Trade (GATT) was the principal international agreement regulating trade in goods between nations in almost all aspects from promotion, negotiation and dispute settlement until the establishment of the World Trade Organization (WTO) in January1995 under the Uruguay round of negotiations. The WTO took over the GATT as the principal forum for trade adding on the General Agreement on Trade in Services (GATS) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). With the advent of TRIPS, intellectual property rights were brought into the GATT-WTO system for the first time for protection and enforcement (See Understanding the WTO at <http www.wto.org >).

[2] See also discussion of the conflict between world trade and the human rights regimes in H Hestermeyer *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press, 2007), pp 172-3.

[3] UNAID 2012 Report on the Global Aids Epidemic, 51 (at http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/20121120_UNAIDS_Global_Report_2012_en.pdf).

[4] WT/MIN(01)/DEC/2, 20 November 2001, Declaration on the TRIPS Agreement and Public Health at <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm>.

[5] WT/L/540, Council for TRIPS, Decision of August 30, 2003, Implementation of Paragraph 6 of the DOHA Declaration on the TRIPS Agreement and Public Health at <http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm>.

[6] UNAID 2012 Report on the Global Aids Epidemic, p 50.

[7] Ibid. One of the ten targets countries pledged in the 2011United Nations Political Declaration on HIV and AIDS: Intensifying Our Efforts to Eliminate HIV and AIDS.

[8] UNAID/WHO "2004 Report on the Global Aids Epidemic" Executive Summary, p 4 (at <http://www.who.int/hac/techguidance/pht/13911.pdf>).

[9] Ibid, p 13.

[10] UNAID 2012 Report on the Global Aids Epidemic, p 5.

[11] Figures calculated from UNAID/WHO "2004 Report on the Global Aids Epidemic" pp 5-7.

[12] UNAID 2012 Report on the Global Aids Epidemic, p 8.

As pharmaceutical patent protection unjustifiably interferes with access to medicines in developing countries[13] there is support advocating that international intellectual property law should be harmonised with human rights law and arguably removed from the control of the WTO.[14] However, an interpretive approach to TRIPS would augur well from a human rights perspective as flexibilities in the Agreement allow discretion for members to take measures to safeguard health albeit the fact remains that developing countries cannot afford to engage in "trade wars".[15] The Agreement on Trade Related-Aspects of Intellectual Property Rights (TRIPS)[16] does not protect human rights but, as Hestermeyer asserts, a core of the intellectual property rights within the Agreement does.[17] In line with this, once there is a trigger for compulsory licensing to be granted the data exclusivity obstacle needs to be considered in the same spirit as the Article 31(f) waiver for an encouraging way forward. Otherwise, the Doha Declaration is a pyrrhic victory for developing and least developed countries.

2. A Precautionary Approach to Compulsory Licensing to Temper Patent Protection

The precautionary approach (PA) to compulsory licensing establishes that a margin of safety is necessary when harm has crossed a significant threshold but scientific evidence has not been established. The principle of precaution developed from international environmental legislation and adapted for human food and health safety has been touted for its ethical application[18] based on the notion that precaution should take priority over scientific justification "where the threat of a particular harm is serious and the damage is irreversible".[19] The adaptation of the PA for the trade and intellectual regimes aims to supplement the inadequacy of a traditional evidence approach.

Working within the legal mechanism under the WTO[20] trade umbrella the prescribed PA framework establishes an objective mechanism to trigger the grant of compulsory licensing rather than leave developing member countries at the mercy of possible trade retaliation and sanctions that results only in price reduction bargains instead of a proper use of the inbuilt flexibilities under the TRIPS Agreement. The legitimacy of adopting the PA for compulsory licensing is established with regard to the Application of Sanitary and Phytosanitary Measures (SPS) and TRIPS Agreements by:

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[13] H Hestermeyer *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press, 2007), pp 137 & 169.

[14] C Sexton "Editorial - Can Intellectual Property Laws Effectively Work to Advance Human Gene Research and Equitable Global Healthcare?", Journal of the Intellectual Property Society of Australia and New Zealand Inc, Dec 2012.

[15] Ibid, pp 207 & 255.

[16] Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization.

[17] H Hestermeyer *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press, 2007), p 198.

[18] Freestone, D. and Hey, E. "Origins and Development of the Precautionary Principle" in Freestone, D. and Hey, E. (eds) (1995)*The Precautionary Principle and International La*w, The Hague, pp 3-15.

[19]PC Hung, "The Precautionary Approach under the Right to Health Dilemma", 24(1) International Review of Law & Technology (2010) 73-82.

[20] The relevant WTO instruments embodying a precautionary approach are: The General Agreement on Tariffs and Trade (GATT 1947) – with reference to the health and security exception provisions in Article XX and Article XXI, Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), Marrakesh Agreement Establishing the World Trade Organization, Annex 1A: Multilateral Agreements on Trade in Goods, and Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) - see Article 30 and the Doha Declaration. Though the concept of precaution has been incorporated into human health protection in WTO law its application, however, is somewhat fragmented with different weights given to different headings.

i) examining and incorporating the structure of the risk analysis in compulsory licensing;

ii) exploring the extent to which members can exercise their precautionary entitlements in determining the grant of a compulsory licence;

iii) justifying legitimate differential treatment of health technologies through the adoption of the precautionary approach in world trade and intellectual property based on a "like-product" non-discriminatory analysis;

iv) achieving the least trade restrictive approach;

v) examining the implications of health technologies for society; and

vi) setting various sub conditions.

Once there are reasonable grounds for concern that *significant* harm to human life and health may occur, developing countries should adopt a precautionary approach for granting compulsory licences to manufacture medicines which might be needed for national health emergencies such as HIV/AIDS, malaria and the Severe Acute Respiratory Syndrome (SARS) as set out below:

> When confronted with a public health emergency, on the basis of the best information available, there are reasonable grounds for concern that *significant* harm to human life and health may occur, scientific uncertainty should not prevent states' precautionary entitlements from adopting a temporary limitation on the exclusiveness of pharmaceutical patents to prevent/abate this harm for achieving an appropriate level of public health protection while avoiding unnecessary interference to international trade.

The inbuilt flexibility for compulsory licensing under Article 31 of the TRIPS Agreement on pharmaceutical patents in a public health emergency sets out explicitly a buffer for tempering patent protection and health.[21] As a provisional measure, it can be regarded as a precautionary health measure offering a margin of safety to suspend the exclusiveness of intellectual property protection to safeguard public health.[22] Specifically through the interpretation of the Doha Declaration it can be implied that the notion of precaution has been incorporated, or at least accepted, under the TRIPS Agreement.[23]

The paradox posed under Article 31(f) of the TRIPS Agreement requiring production under compulsory licensing to be predominantly for the domestic market effectively limited the ability of developing and least developed countries without manufacturing capacity to import cheaper generics. The much sought for waiver of Article 31(f) allowing all member countries to import was viewed to be a breakthrough,[24] allowing access to cheaper generics by poorer

[21] Article 31 of the TRIPS Agreement is a key provision allowing for other use of the subject matter of a patent without the authorization of the right holder" subject to certain conditions.

[22] PC Hung, "The Precautionary Approach under the Right to Health Dilemma", 24(1) International Review of Law & Technology (2010) 73-82.

[23] Ibid.

[24] All WTO member countries are allowed to import under the Aug 2003 Decision though 23 developed countries announced voluntarily not to import generic drugs under the system. The countries are Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America (See Note 3, WT/L/540, Council for TRIPS, Decision of August 30, 2003). Countries such as Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei,

countries, many of whom had felt cheated in the way the commitments of the Uruguay Round had been implemented.[25] Nevertheless, the chilling effect post waiver is evidenced by the lack of attempts on the part of developing countries to pursue compulsory licensing until 2007 when Thailand and Brazil did so for the drugs Plavix and Efavirenz respectively.[26] Even so, these were issued for "public non-commercial use" and the "public interest" conspicuously avoiding the WTO language in Article 31(b) of "national emergency" and "extreme urgency" as a condition for compulsory licensing.[27] While the amendments post Doha under Article 31bis[28] of the TRIPS Agreement (spelling out the prescriptions on the flexibility to grant compulsory licences) are deemed to solve the dilemma for access to medicines, developing countries would benefit from a wider application of the precautionary principle beyond compulsory licensing in public health emergencies to enhance its prescriptive value.

3. Another Obstacle: Data Exclusivity and Article 39.3 of the TRIPS Agreement

A broader holistic approach for the PA framework beyond compulsory licensing for access to medicines would help temper the data exclusivity obstacle under Article 39.3 of the TRIPS Agreement, which creates another barrier for access to medicines. Regulatory protection for pharmaceutical products concerns test data submitted to national authorities for verification of the efficacy and non-toxicity of drugs before obtaining marketing approval. Prior to the TRIPS Agreement test data protection existed mainly in the United States and Europe. Most countries were able to rely on data provided for the first registration to grant approval for a second comer's "similar" product.[29] It was legal for developing countries with manufacturing

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Turkey and United Arab Emirates stated that if they do import it would be only be for emergencies or extremely urgent situations. (Press/350/Rev.1, 30 August 2003, "Decision removes final patent obstacle to cheap drug imports" at <http://www.wto.org/english/news_e/pres03_e/pr350_e.htm>).

[25] R P Buckley "Introduction: The Changing Face of World Trade and the Greatest Challenge Facing the WTO and the World Today" in R P. Buckley (ed) *The WTO and the Doha Round: The Changing Face of World Trade* (Kluwer Law International, 2003) ch 1, 2.

[26] Brazil issued a compulsory licence on Efavirenz on grounds of "public interest" to ensure the supply of the drug for its national AIDS programme after a series of negotiations with the patent holder, Merck, broke down. at http://www.accesstopharmaceuticals.org/case-studies-in-global-health/efavirenz-brazil/ (retrieved 27 Jan 2013). Thailand had issued a compulsory licence on the grounds of "public non-commercial use" drug for heart disease, Plavix in January 2007.

[27] TRIPS Agreement, Article 31(b) spells out a government may issue a compulsory licence to produce generic drugs without the authorization of the patent holder where negotiations fail to obtain authorization on reasonable commercial terms. The negotiations may be waived in cases of national emergency, extreme emergency or non-commercial use.

[28] See General Council decision of 6 December 2005 WT/l/641 (Amendment of the TRIPS Agreement) in response to the Doha Declaration (WT/MIN(01)/DEC/2, 20 November 2001). The General Council has extended the deadline to formally incorporate the August 2003 Waiver into the TRIPS Agreement when two thirds of the WTO's members have accepted the change to 31 December 2013 at http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

[29] C Correa *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, South Centre 2002 at < http://www.southcentre.org/publications/pubindex.htm#books>. Post TRIPS, in *Otsuka Pharmaceutical Co Ltd v Towa Yakuhin K.K.*, Tokyo High Court, Civil 6th Division, Case No. 3498(ne), 31 March 1998; affirmed by Second Petty Bench of the Supreme Court, Case No. 1998 (ju) 153, April 16, 1999, the Japanese Supreme Court held that "use for regulatory review purposes was sheltered from infringement liability by the experimental use defence in Japanese law, and the use of a patented invention for purposes of obtaining a licence to market a generic version of a patented medicine was not an infringement of the patent." The German Supreme Court in *Klinische Versuche II German Federal Supreme Court 1998 RPC 423* held that "the intention to use the results of experiments and trials for the purpose of obtaining regulatory approval was irrelevant to the determination of whether an act fell within the experimental use exception". See WT/DS114/R, Canada - Patent Protection of Pharmaceutical Products - Complaint by the European Communities and their Member States - Report of the Panel, 17 March 2000, para 5.7.

capacity to produce generic medicines of drugs under patent protection in the developed world, an opportunity foregone with minimum standards of patent protection for pharmaceuticals introduced under the TRIPS Agreement. Developing member countries would have to wait for the expiry of the patent term to produce generics.

Patent protection and data exclusivity terms are both important incentives to the research and development outlays by pharmaceutical companies to ensure that there are returns to investment over a limited duration.[30] However, where the drug is covered under patent protection, data exclusivity may extend after the patent has expired creating another obstacle to access (where marketing approval was obtained towards the end of the patent period) and block generic competition even when compulsory licences have been granted.[31] Producers with the capacity and willingness to supply the world market with low-priced medicines under patent in developed countries are located mainly in developing countries such as Argentina, Brazil, China, India, South Africa and Thailand.[32] Thus the strongest impact of data exclusivity would be in countries such as India and Brazil which did not have patent protection for medicines until required to be TRIPS compliant.

Emanating from different legislative frameworks such as unfair competition laws,[33] law of confidentiality of Information and Product [34] or Food and Drug Regulations, [35] data exclusivity now falls under the guise of intellectual property protection and free trade rules. The application of confidentiality to pharmaceutical test data submitted for approval provides what is sometimes deemed a trade secrets obstacle to access in addition to the patents obstacle. Article 39 of the TRIPS Agreement on unfair competition and the protection of undisclosed test data states:

> 1. In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.
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> […]
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> 3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

The concern as to exclusivity arises primarily in the need for protection of "undisclosed test or other data". Under the two limbs in Article 39.3, once member countries require test data to be submitted for marketing approval, compliance is mandatory to ensure protection of the

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[30] Ibid, in para 4.21 the Panel noted that product development, application and regulatory review processes for innovator drugs take between eight to 12 years while the process for generics takes up to three to six and a half years.

[31] "Data exclusivity in international trade agreements: What consequences for access to medicines?" *Médecins Sans Frontières* whitepaper at http://www.msfaccess.org/content/data-exclusivity-international-trade-agreements-what-consequences-access-medicines (retrieved 14 Dec 2012)

[32] H Hestermeyer *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press, 2007), p 10.

[33] Antigua & Barbuda, Brazil, Trinidad and Tobago.

[34] Argentina.

[35] See, for example, *Food and Drug Regulations* C.R.C. 1978, c. 870, C.08.004.1(1), Canada.

data submitted *first*, against "unfair commercial use" and in *addition* (i.e secondly) against "disclosure". Thus, the primary purpose of Article 39.3 is not about protecting secrecy of data but to guard against "unfair commercial use" by generic competitors obtaining marketing approval without having to conduct clinical trials to produce their own data,[36] and secondly its secrecy.[37] The qualifier that follows provides for two exceptions for disclosure of the test data "where necessary to protect the public" *or* "unless steps are taken to ensure that the data are protected against unfair commercial use". The first exception is subject to a necessity test under WTO's rules while the second allows for disclosure when there is no unfair commercial use.

The text and language of Article 39.3 of TRIPS is reproduced almost verbatim under Article 1711 of the North American Free Trade Agreement (NAFTA) for trade secrets:[38]

> 5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.
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> 6. [..] no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval….

Interestingly, the first limb of Article 39.3 "to protect against *unfair commercial use*" is conspicuously missing from paragraph 5 of the NAFTA text. Paragraph 6 of the NAFTA text specifies a 5 year exclusivity period that was not included in the TRIPS text at the insistence of developing countries.[39] Nevertheless, government drug regulatory agencies are deemed to be under the obligation to ensure non-disclosure of the test data registered by an original manufacturer of a new innovative drug to be used for the registration of a generic equivalent for a fixed period of 5 to 10 years.[40]

The term of protection for data exclusivity for human use drugs varies from country to country ranging from five to eight years.[41] Australia[42] and New Zealand[43] have specific legislation providing for a 5-year data exclusivity period. The European Union amendments to the Directive relating to medicinal products for human use introduced a new data exclusivity system for original medicines and provided for an abridged process whereby the

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[36] N de Carvalho *The TRIPS Regime of Patent Rights* (Kluwer Law International, 2005) Sec. 7, p 392.
[37] Ibid (See pp 389 – 393 for a more in-depth discussion of unfair commercial use).
[38] North American Free Trade Agreement of 17 December 1992, Article 1711 section 5 at http://www.nafta-sec-alena.org/en/view.aspx?x=343&mtpiID=149#A1711.
[39] Ibid, section 6.
[40] An important issue concerned the direct or indirect use of the test data for subsequent registrations of similar products. In the negotiating history of Article 39.3 a period of less than 5 years was put forward but not included in the final text. See the Brussels Draft in GATT document MTN,TNC/W/35/Rev.1, 3 Dec 1990, Art. 42.4A. (See Carlvaho p 391 fn 982),
[41] United States: 5 Years for new pharmaceutical chemical entities, 3 years for new indications for pharmaceutical drugs, and 12 years for biologic products. European Union: 8 Years (+ 2 Years market exclusivity + 1 year for new indication); Japan: 8 Years; China: a protection period of 6 years was promised by the government for pharmaceutical drugs when applying for membership to the World Trade Organization.
[42] Data Exclusivity Provision of the Therapeutic Goods Act (Cth) 1989 (Australia), s.25A.
[43] Introduced under the Medicines Amendment Act Commencement Order 1994 in compliance with the TRIPS Agreement.

public agencies can only grant permission for generic drugs after the exclusivity period provided for the original drug or medicinal product.[44] There is an eight-year exclusivity period in place of the six to 10 years adopted by different countries in the European Union. It introduces also a requirement under the term "market exclusivity" that disallows the marketing of a generic equivalent for a further two years from the expiry of the data exclusivity period,[45] effectively evergreening the patent for a further period of time.

4. Tempering the Data Exclusivity Obstacle

Data exclusivity creates a data monopoly that potentially defeats the purpose of any grant of a compulsory licence for developing countries to benefit from cheaper medicines preventing generic drug manufacturers from accessing the data. Public and private interests diverge as the research-based pharmaceutical industry has never considered compulsory licensing a necessary or sustainable means of improving access to medicines.[46] While there is a public interest for patent protection to encourage invention of new medicines for the prevention and cure of diseases, the private interest is essentially solely profit driven.[47] Understandably, as pharmaceutical companies incur huge financial outlays on research and development crucial to the search for new cures (research and development expenditure by pharmaceutical companies in 2002 amounted to US$45 billion[48]), it would be unfair that generic drug producers should be able to free ride on the data and obtain competitive advantage without any investment on their part.

The inbuilt flexibility for compulsory licensing to temper patent protection explicitly spelt out in Article 31 is not reflected under Article 39.3. Without an explicit provision to temper the data exclusivity obstacle there is a quest for the interpretation of an implicit exception to overcome the obstacle for access to medicines. This section explores the views of leading commentators mostly holding the stance that the obligation under Article 39.3 does not set out exclusive rights. Correa, a leading commentator, considers Article 39.3 to be "narrowly drawn" allowing countries to maintain "substantial flexibility in implementation" as public interest must ensure that it does not constitute an obstacle for generic competitors of off-patent drugs and access to medicines.[49] Interpreting "unfair commercial use" Correa views that defining what "unfair" means is at the discretion of each national government. Inasmuch as it may be fair for the United States and the European Union to want regulatory data protection, it is likewise fair that developing countries deem so otherwise. Thus "granting market approval to a second entrant" based on the latter product's similarity to the first registered product is not prohibited under Article 39.3 in the absence of "dishonest" uses,

[44] See Council Directive 2004/27/EC, 31 March 2004 (amending Directive 2001/83 relating to medicinal products for human use) introducing a new data exclusivity system for original medicines.
[45] Art. 10(1)(a)(iii) Council Directive 2004/27/EC, 31 March 2004.
[46] European Federation of Pharmaceutical Industries and Associations "Statement on Compulsory Licence for Export" <http://www.efpia.org/3_press/20030830.htm> (EFPIA Statement).
[47] F M Abbot "The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference" Occasional Paper 7, 5 (Sep 2001) Quaker United Nations Office.
[48] See International Federation of Pharmaceutical Manufacturers Association *Research & Development* at http://www.ifpma.org//issues/issues_research (retrieved 13 Dec 2012). The pesticide industry, for example, typically spends $5 million to $15 million over a period that may well stretch between 14 to 22 years to develop a commercially viable product before expecting returns to investment to be able to successfully market 1 out of every 10,000 chemicals (See *Ruckelshaus v Monsanto* 104 S.Ct.2862, 2870 (1984)).
[49] C Correa *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, South Centre 2002, Executive Summary.

fraud and breach of confidence.[50] He takes the stance that countries are not obligated under Article 39.3 to confer exclusive rights for test data submitted to the government for approval as the broad coverage advocated by pharmaceutical industries and some countries[51] is not supported by the text of negotiating history of the TRIPS Agreement.[52] Likewise, Yamane argues that flexibility within Article 39.3 allows leeway for developing countries. Article 39.3 is not to be construed in terms of the obligation perceived by developed countries that data submitted for marketing approval must remain exclusive to the originator of the data for a period of time.[53]

Correa asserts too that the two exceptions "where necessary to protect the public" or where the data are "protected against unfair commercial use"[54] in UNCTAD's view authorise the use of test data to assess third parties' subsequent applications for registration of similar products.[55] Carlvaho, another commentator, likewise, interprets the first exception as implicit permission to disclose in the public interest (though he thinks that it is not workable in practice as test data can be used by generic manufacturers in other countries).[56]

Correa's interpretation of a wholly voluntary Article 39.3 has met with some strong criticisms. Wadlow strongly suggests, Article 39.3 must necessarily be construed not in isolation but in the light of Article 10*bis* of the Paris Convention for the Protection of Industrial Property on unfair competition to which it relates,[57] which concerns situations of competition between competitors rather than legislative acts of governments.[58] A national authority in its public duty to fairly balance the "rights and legitimate expectations of individual subjects" cannot be said to be engaged in unfair competition even if it disadvantages a business competitor.[59] Such legislative acts of governments would be fair.[60] Analysing Article 39.3 as it stands retrospectively, the western countries were not interested in legislating against unfair competition more so than responding to the lobbying by pharmaceutical companies whose main concern was to obtain mandatory international protection of test data but India led the way opposing trade secrets status for test data under the intellectual property regime.[61] However, while disagreeing with Correa's conclusion that Article 39.3 imposes no international requirement on all WTO members, Wadlow concedes that:[62]

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[50] Ibid.See also the Report of the Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, London, September 2002, pp 50-51 and 163.
[51] C Correa *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, South Centre 2002, p 46.
[52] Ibid, Executive Summary.
[53] H Yamane *Interpreting TRIPS: Globalisation of Intellectual Property Rights and Access to Medicines* (Hart Publishing, 2011), p 471.
[54] See C Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, South Centre 2002, p 21 (*emphasis* added).
[55] Ibid, p 46.
[56] N de Carvalho *The TRIPS Regime of Patent Rights* (Kluwer Law International, 2005), pp 389 & 394.
[57] See Article 39.1 of the TRIPS Agreement .
[58] C Wadlow "Regulatory data protection under TRIPs Article 39(3) and article 10bis of the Paris Convention: is there a doctor in the house?" (2008) IPQ, 355, 370.
[59] Ibid, 371-372.
[60] Ibid, 372.
[61] Ibid, 381-382.
[62] Ibid, 379 (citing A X Fellmeth, "Secrecy, Monopoly and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPs Agreement" (2004) 45 *Harvard International Law Journal* 443, 460).

> Article 39 of the TRIPs Agreement does not encompass a data exclusivity obligation per se as a matter of positive law, particularly not when disclosure of marketing approval data is 'necessary to protect the public.'

The essential purpose under Article 39.3 is to prevent "parasitic behaviour" and "free-riding" by competitors entering the market with bio-equivalents,[63] and so ensure governments do not allow the registration of competing products. Data exclusivity though housed under the TRIPS regime is not an extension of patent protection and is separate from undisclosed information and the confidentiality of perpetual trade secret information (such as secret formulas and compositions) submitted to governments under Article 39.2. Such data protection does not prevent the production of generic versions of new drugs and products (even during the data exclusivity period) as long as the second entrant does not use or rely on the original test data.[64]

The United States' Supreme Court decision in *Ruckelshaus v Monsanto*[65] supports the view that national authorities are able to rely on test data provided for the first registration to grant approval for a second comer's "similar" product. The legislative history of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 1947 shows while FIFRA specifically prohibited disclosure of "any information relative to formulas of products",[66] it was silent on the use of health and safety data.[67] Amendments, in 1972, specifically provided under a mandatory data-licensing scheme to consider data (not designated as "trade secrets or commercial or financial information") submitted by one applicant for registration in support of another application for a similar chemical with compensation to the original submitter of the data.[68] Data designated as "trade secrets or commercial or financial information" could not be used to support a subsequent registration unless the first original applicant consented.[69] Further amendments in 1978 specified a 10-year exclusivity period on new active ingredients.[70] A new subsection provided for "disclosure of all health, safety, and environmental data to qualified requesters, notwithstanding the prohibition against disclosure of trade secrets[71] where such disclosure was "necessary to protect against an unreasonable risk of injury to health or the environment".[72] The overriding philosophy of the Supreme Court was summed up as:[73]

> [T] public purpose behind the data-consideration provisions is clear from the legislative history. Congress believed that the provisions would eliminate costly duplication of research and streamline the registration process, making new end-use products available to consumers more quickly.

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[63] See N de Carvalho *The TRIPS Regime of Patent Rights* (Kluwer Law International, 2005), pp 392-3.
[64] See generally "Data exclusivity: Encouraging Development of New Medicines" Jul 2011, International Federation of Pharmaceutical Manufacturers Association at http://www.ifpma.org/fileadmin/content/Publication/IFPMA_2011_Data_Exclusivity_En_Web.pdf (retrieved 13 Dec 2012).
[65] *Ruckelshaus v Monsanto* 104 S.Ct. 2862 (1984).
[66] FIFRA §§ 3(c)(4) and 8(c)
[67] *Ruckelshaus v Monsanto* 104 S.Ct. 2862, 2867 (1984).
[68] FIFRA § 3(c)(1)(D).
[69] *Ruckelshaus v Monsanto* 104 S.Ct. 2862, 2867 (1984).
[70] FIFRA § 3(c)(1)(D)(i) for data registered after September 30, 1978.
[71] Ibid, § 10(d), 7 USC § 136h(d).
[72] Ibid, §§ 10(d)(1)(A) to (C).
[73] *Ruckelshaus v Monsanto* 104 S.Ct. 2862, 2879 (1984).

In *Bayer v Canada (Attorney General)*[74] the Canadian Federal Court of Appeal in reconciling the language under its Food and Regulations Act and NAFTA[75] held that the data exclusivity provision does not apply where there has been no reliance on the first applicant's test data. No protection is required if the national authority approves a second entrant's application without examining the original applicant's test data where the products are similar or bio-equivalents:[76]

> Subsection C.08.004.1(1) […] provide for the use of that [test data] by the government on behalf of the generic manufacturer and when that occurs, the minimum five year protection from competition for the innovator applies. Where the government does not use that confidential or trade secret information on behalf of the generic manufacturer, the provision is not applicable.

Thus when a competing generic manufacturer files an "Abbreviated New Drug" submission for a pharmaceutically equivalent and bioequivalent product based solely by comparing the innovator's product that is publicly marketed and the Minister does not need to examine or rely on the test data filed, the exclusivity period of 5 years does not apply.[77]

5. A Parallel Approach: PA for Compulsory Licensing and Waiver of Article 39.3

As noted above, an explicit compulsory mechanism for tempering data exclusivity is absent under Article 39.3.[78] However, the object of the TRIPS Agreement under Article 7[79] on intellectual property and Article 8[80] on public health does not necessarily confer exclusive rights for test data. The current interpretation as it stands requiring generic manufacturers to repeat clinical trials for test data already known would be duplicating the process and cause unnecessary delay.[81] With the global need for access to essential medicines, the World Health Organisation opposed requirements for tests to be repeated in its entirety amounting to multiple human testing because of resource implications for developing countries.[82] This also illustrates that the consideration of regulation of data exclusivity involves a "public interest" nature, which should be distinguished from a pure private property dimension. One option to temper data exclusivity is compulsory licensing of the test data. Another would be to consider a waiver of Article 39.3 to avoid repeating clinical trials for the same data already available.

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[74] *Bayer v Canada (Attorney General)* 1999 CarswellNat 1047, 243 N.R. 170, 87 C.P.R. (3d) 293, 243 N.R. 170, 87 C.P.R. (3d) 293.

[75] Ibid, [15] referring to NAFTA, Article 1711 sections 5 and 6 and the Canadian *Food and Drug Regulations* C.R.C. 1978, c. 870, C.08.004.1(1).

[76] Ibid, [18].

[77] Ibid, [7] - [8].

[78] C Wadlow "Regulatory data protection under TRIPs Article 39(3) and article 10bis of the Paris Convention: is there a doctor in the house?" (2008) IPQ, 355, 358.

[79] TRIPS Agreement Article 7 states that the protection and enforcement of intellectual property rights should be mutually advantageous in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

[80] TRIPS Agreement Article 8 (1) allows the adoption of "measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic […] development".

[81] See Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement,* South Centre 2002, p 44.

[82] Developing International Standards for the Generic Pharmaceutical Industry, Presentation to International Generic Pharmaceuticals Association by Dr. Juhana E. Idanpaan-Heikkila, Special Advisor, Quality Assurance and Safety, World Health Organization, June 1999. (See WT/DS114/R, Canada - Patent Protection of Pharmaceutical Products - Complaint by the European Communities and their Member States - Report of the Panel, 17 March 2000, para 4.38 and fn 275).

First, national laws can temper data exclusivity depending on the applicable legal system for the approval of a second-entry marketing application. Correa had canvassed an option for national authorities to "examine and rely upon the data submitted by the originator to evaluate the second-entrant application". Such use would not amount to a "commercial use" of the data" as the second comer generic manufacturer would not use the data (only the government would).[83] As the Canadian Federal Court of Appeal surmised the five-year protection applies only when there has been reliance on the test data.[84] In the WTO Panel for *Canada-Patent Protection of Pharmaceutical Products*, Australia's view was that, hypothetically, "a regulatory system could approve the proposed marketing of an image product solely through documentary cross-referencing and without any relevant use or manufacture of the patented pharmaceutical".[85]

Secondly, there is clearly an avenue for compulsory licensing of test data with or without compensation when the United States required Dow Chemicals to license *inter alia* quality control data and other research materials without compensation when it acquired the Rugby-Darby Group Companies.[86] Likewise, under the United States FIFRA it is possible to use test data belonging to the originator (without their consent) for the grant of approval in subsequent applications with some form of compensation.[87] Thus though Article 39.3 is silent as to an explicit exception for data exclusivity, compulsory licensing of test data is possible and feasible under the GATTS/TRIPS umbrella.[88] The authors view, though (in terms of practicality), that it would not do justice to require the developing world and least developed countries when confronted with a public health emergency to pursue separately a duplicate process of compulsory licensing for access to test data.

Correa's views support a waiver as a data exclusivity regime cannot be allowed to be an obstacle for the execution of a compulsory licence or government use. Carlhavo considers, likewise, that use of test data from clinical trials covered by a patent is fair where a government grants a compulsory licence of the patent to a generic manufacturer for the marketing of the generic version of a drug,[89] as otherwise, it would be ineffective and cause delay to require independent clinical trials and data.[90] Such use of test data is intrinsically fair under compulsory licensing of the patent as the generic product and the original drug are the same as "like" products rather than "competing" products. Needless to say, a waiver of the data exclusivity regime would be an intuitive corollary of the PA to compulsory licensing in

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[83] See Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, South Centre 2002, p 31.
[84] *Bayer v Canada (Attorney General)* 1999 CarswellNat 1047, 243 N.R. 170, 87 C.P.R. (3d) 293, 243 N.R. 170, 87 C.P.R. (3d) 293, [18].
[85] WTO Panel Report, *Canada - Patent Protection of Pharmaceutical Products*, WT/DS114/R, 17 March 2000, para 5.7.
[86] See http://www.cptech.org/pharm/cl.html (retrieved 4 Jan 2013)
[87] C Correa *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, South Centre 2002, p 45. See also p 31 fn 19.
[88] N de Carvalho *The TRIPS Regime of Patent Rights* (Kluwer Law International, 2005), p 397 n 992.
[89] Ibid, p 395.
[90] See *Communication from the European Communities and Their Member States – The Relationship Between the Provisions of the TRIPS Agreement and Access to Medicines*, WTO document IP/C/W/280, 12 June 2001, at [16]: "The EC and their member States consider, though, that Article 39.3 neither obliges Members to have marketing approval procedures, nor does it prescribe what those procedures should be. The provision should certainly not be interpreted in such a way as to weaken or nullify Members' rights under other Articles of the Agreement, such as the 'fast track' procedure in case of emergency foreseen under Article 31(b), which is a recognition of the need, in certain circumstances, for compulsory licences to be given immediate effect." at http://www.wto.org/english/tratop_e/trips_e/paper_eu_w280_e.htm (retrieved 12 Dec 2012).

order to achieve a systematic and coherent interpretation of the legal text. The PA should be equally applicable to compulsory licensing and to data exclusivity in order to swiftly address domestic stockpiling needs for drugs via an expedient track under a pending public health emergency.

The authors consider this a logical approach parallel to the grant of compulsory licensing for pharmaceutical patents in a public health emergency. Thus once the PA serves as a trigger for compulsory licensing it "may be necessary to waive the rights conferred under data exclusivity" to obtain marketing approval of the product.[91] As noted above, the legitimacy of adopting the PA framework for access to medicines justifying a safe margin and trigger for compulsory licensing had traversed the grounds of a risk analysis and the extent to which WTO members can exercise their precautionary entitlements. To justify legitimate differential treatment of adopting a PA for health technologies associated with significant risks to human life and health, a "like-product analysis" was made between such health technologies and other technologies, to ensure it is "non-discriminatory" and achieves the least trade restrictive approach. Thus rather than attempting to justify a separate compulsory licensing argument for data exclusivity, a waiver of the exclusivity period once a PA for compulsory licensing of the patent is adopted is necessary from a commonsense and holistically human rights view, which will be further discussed in the next section.

The same arguments negate a tailor-made PA to temper data exclusivity.[92] When all the factors for a precautionary approach to trigger the compulsory licence are fulfilled and patent protection on a drug is removed, a parallel grant for disclosure of the data would not be unfair commercial use. The PA can temper data exclusivity as a *justification* for access as a matter of *necessity* once the prerequisite of declaring a public health emergency to empower a state with emergency powers is dealt with to enable government to allocate appropriate resources to combat the epidemic. A compulsory licence for access to medicines is of no use without access to data for the same medicines. The precautionary approach is perceived by the European Court of Justice (ECJ) as constituting "an integral part of the decision-making process leading to the adoption of any measure for the protection of human health".[93] The intention of the phraseology "approach" adopted hints at a more flexible application of precaution.[94]

So far access to AIDS medicines has eclipsed other needs but the SARS outbreak in China and South East Asia and the anthrax scare should serve as a wake-up call to the world community at large. These must incite in each and every party be it the pharmaceutical industry, non-government organisations, least developed countries and developing or

[91] C Correa "Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements" UNCTAD-ICTSD Dialogue on Moving the pro-development IP agenda forward: Preserving Public Goods in health, education and learning, Bellagio, 29 November – 3 December 2004, p 12.

[92] As Stein J of the New South Wales (NSW) Land and Environment Court had stated: "the precautionary principle is a statement of commonsense and has already been applied by decision-makers in appropriate circumstances prior to the principle being spelt out". In *Leatch v Director-General, National Parks and Wildlife Service* 81 LGERA 270 1993 WL 1405558, 282.

[93] ECJ Case C–236/01, *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others* (*Monsanto*), ECR 2003 I–08105, adopted 9 September 2003, para 133.

[94] See for example, Laing J's view that "adopting an *approach*, rather than a principle, appropriately imports a certain degree of flexibility and tends, though not dispositively, to underscore reticence about making premature pronouncements about desirable normative structures" in Separate Opinion of Judge Laing, *Southern Bluefin Tuna Cases* (*New Zealand v Japan*; *Australia v Japan*) 27 August 1999, para 19 at http://www.itlos.org/fileadmin/itlos/documents/cases/case_no_3_4/Separate.Laing.27.08.99.E.pdf (retrieved 19 Dec 2012)

developed countries the understanding that we are all part of this fabric. Clinical test data should be treated as a "public good" requiring the most transparency rather than secrecy.[95] The regulation of clinical test data carries with it the conflicting natures of public and private considerations and one must constantly be weighed against the other depending on the circumstances. In times of emergencies when the protection for civilians outweighs the private dimension of data exclusivity, a waiver should be called to balance the two agendas, with a view to facilitating an adaptable and organic intellectual property regime.

6. A Human Rights Perspective

With developing countries such as Argentina, Brazil, China, India, South Africa and Thailand with the manufacturing capacity to supply the world market with low-priced medicines, developing countries must take a stand as their people come perilously close to dying from AIDS while in dire need for access to affordable medicines.[96] The lives of their people depend on it. India's generic producer, Cipla, took a humanitarian stand to produce generic ARV drugs on patent in the United States, Europe and South Africa for supply to AIDS patients in Africa at affordable prices.[97] A major manufacturer it offered supply of the AIDS drug to Medicins Sans Frontieres at 65 per cent below patented prices, which distributed it free in Africa.[98] India was protected from foreign competition for decades without patent laws. Producing generics, the Indian drug industry at its most competitive in 2004 met 25 per cent of the global generics market for low cost drugs.[99] Reports showed that prices for certain generic AIDS medicines have fallen to US$300 per patient a year compared to an all-time high of US$10,000-US$12,000 for patented drugs in the year 2000.[100]

The developing world had mustered the political will to achieve the Doha breakthrough for access to medicines. Brazil led the way and showed that the real impetus must come from them. Brazil managed to arm-twist the pharmaceutical giants, Roche and Merck, under the threat of compulsory licensing to manufacture generic AIDS drug for its domestic use in 2001. Both companies succumbed and agreed to reduce costs to 30-40 per cent of what it would have cost in the United States, allowing Brazil to provide free medication for millions

[95] See J H Reichman "Undisclosed Clinical Trial Data under the TRIPS Agreement and its progeny: A Broader perspective" UNCTAD-ICTSD Dialogue on Moving the pro-development IP agenda forward: Preserving Public Goods in health, education and learning, Bellagio, 29 November – 3 December 2004, p 17. See also C Wadlow "Regulatory data protection under TRIPs Article 39(3) and article 10bis of the Paris Convention: is there a doctor in the house?" (2008) IPQ, 355, 403 fn 154, and Skillington and Solovy, "The Protection of Test and Other Data required by Article 39.3 of the TRIPs Agreement" (2003) 24 *Northwestern Journal of International Law and Business* 1, 51.

[96] Note even Canada was concerned that it needed another policy tool to address cost containment for medicines as expenditures on therapeutic drugs had been rising steadily by significant amounts from $1.1 billion annually in 1975 to $8.6 billion by 1992-93 noting balances needed to address the concern about the costs to the health care system that enhanced protection under the TRIPS Agreement would entail. Canada's $400 million generic drug industry annually accounted for approximately 40 per cent of all prescriptions filled in 1997, but only amounted to about 15 per cent of the total cost of such drugs. See WT/DS114/R, Canada - Patent Protection of Pharmaceutical Products - Complaint by the European Communities and their Member States - Report of the Panel, 17 March 2000, para 4.21.

[97] See also H Yamane *Interpreting TRIPS: Globalisation of Intellectual Property Rights and Access to Medicines* (Hart Publishing, 2011), pp 279 fn 68.

[98] B Condon "The Twin Security Challenges of AIDS and Terrorism: Implications for Flows of Trade, Capital, People and Knowledge" in R P. Buckley (ed) *The WTO and the Doha Round : The Changing Face of World Trade* (Kluwer Law International, 2003), 277.

[99] J Hepburn "Implementing the Paragraph 6 Decision and Doha Declaration: Solving Practical Problems to Make the System Work" (May 2004) Quaker United Nations Office, 6, at <http://www.quno.org.>.

[100] UNAID/WHO "2004 Report on the Global Aids Epidemic", p 14.

of victims. The threat made price reductions as advantageous as the cost of manufacturing in the government laboratory to reach an optimal price for the drugs and combat the infection rate to 0.65 per cent.[101]

Following the Anthrax scare (a bio-terror threat via mailing of anthrax-laden powder in the Washington DC area), the United States and Canada similarly threatened Bayer successfully for the drug Cipro.[102] It drew a new focus on patent protection and access to essential drugs and showed up starkly the double standards of the developed countries,[103] to place firmly on the Doha agenda the need for a better bargain under the WTO in terms of access to affordable medicines for developing countries themselves.[104] The developed world in copying Brazilian tactics and the threat of compulsory licensing for the drug Cipro[105] well understands that no responsible government should place the public health of its citizens at stake for the sake of the pharmaceutical industry.[106]

Compounding the data exclusivity term of protection and monopoly are blatant US bilateral "free trade agreements" with other countries in flagrant disregard of the Doha Health Declaration.[107] In June 2004, Thailand, with manufacturing capacity to produce a generic version of the AIDS drug for export to eligible countries, was indirectly pressured in the form of favourable trading deals in exchange for agreement not to issue compulsory licences,[108] though change is evident in the bold efforts of both Thailand and Brazil in 2007 by issuing compulsory licences.[109] The United States had also negotiated "data exclusivity provisions" with their trading partners in Central America as well as Sri Lanka, Vietnam, Cambodia and Laos.[110]

The Dominican Republic–Central America Free Trade Agreement (DR-CAFTA) includes test data exclusivity provisions that such data can be kept secret which would make it very

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[101] B Condon "The Twin Security Challenges of AIDS and Terrorism: Implications for Flows of Trade, Capital, People and Knowledge" in R P. Buckley (ed) *The WTO and the Doha Round : The Changing Face of World Trade* (Kluwer Law International, 2003), 266-269.

[102] F M Abbot "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO" (2002) 5 JIEL 469, 487.

[103] H Sun 'The Road to DOHA and Beyond: Some Reflections on the TRIPS Agreement and Public Health' [2004] 15 (1) EJIL 123, 134.

[104] B Condon "The Twin Security Challenges of AIDS and Terrorism: Implications for Flows of Trade, Capital, People and Knowledge" in R P. Buckley (ed) *The WTO and the Doha Round : The Changing Face of World Trade* (Kluwer Law International, 2003), 271.

[105] Ibid, 270.

[106] F M Abbot "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO" (2002) 5 JIEL 469, 488.

[107] F M Abbot "The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements" Occasional Paper 14, (Apr 2004) Quaker United Nations Office, 2, at <http://www.quno.org.>

[108] S Boseley "France Accuses US of Aids Blackmail" *The Guardian* 14 July 14, 2004 at <http://www.guardian.co.uk/international/story/0,,1260695,00.html>

[109] The bold action of Thailand in issuing a compulsory licence for the drug Plavix for chronic diseases treatment viewed by some critics as overstepping the appropriate application of compulsory licensing saw Abbot Laboratories retaliating by refusing to market its new pharmaceutical products in Thailand and withdrawing registration applications of new pharmaceutical products. Thailand was also placed on the US Special 301 Priority Watch List. See Abbott Pharmaceuticals in Thailand: Fact Sheet, 13 April 2007 at <http://www.oxfamamerica.org/whatwedo/campaigns/access_to_medicines/news_publications/Abbott% 20in%20Thailand>.

[110] A X Fellmeth "Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law" (2004) 45 Harv. Int'l L.J. 443, 455- 456.

expensive for generic drug manufacturers to redo the tests.[111] This would impede access to essential lifesaving medicines for AIDS, malaria, and tuberculosis. As opposition to CAFTA-DR shows as well, manufacturing costs of generic drugs are much cheaper relative to the costs involved in test data and drug trials. For Guatemala, for example, generics will have to wait another five years under CAFTA. Otherwise, Guatemala introduced patents only in 2000 after WTO's transition period and generics would have been legal for drugs which were not patented in Guatemala before 2000. [112]

The previous WTO Director-General, Dr Supachai Panitchpakdi had hailed the Doha Declaration as a historic agreement:[113]

> [T..] The final piece of the jigsaw has fallen into place, allowing poorer countries to make full use of the flexibilities in the WTO's intellectual property rules in order to deal with the diseases that ravage their people. It proves once and for all that the organization can handle humanitarian as well as trade concerns.

The then European Union Trade Commissioner, Pascal Lamy, had added:[114]

> [..] the deal on access to medicines. Vital if we are to show that the WTO and the multilateral system is not just about mindless liberalization, or kow-towing to globalization. Of course, we have much more work to do to ensure delivery in practice, on the ground. But the deal, however long we waited for it, shows that the WTO can and will put people before markets.

Reichman,[115] in support of either compulsory licensing or waiver, argues that above all the integrity of the spirit at Doha[116] must be preserved to minimise the social cost of any data protection regime adopted. [117] His interpretation of Article 39.3 favours disclosure as member states are "always free to refer to at least the majority of the clinical trial data of any innovator company, when considering an application for a generic equivalent, without committing any breach of international law". [118]

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[111] CAFTA-DR (Dominican Republic-Central America FTA), Article 15.10: Measures Related to Certain Regulated Products at http://www.ustr.gov/sites/default/files/uploads/agreements/cafta/asset_upload_file934_3935.pdf (retrieved 25 Feb 2012).

[112] "Data exclusivity in international trade agreements: What consequences for access to medicines?" *Médecins Sans Frontières* whitepaper at http://www.msfaccess.org/content/data-exclusivity-international-trade-agreements-what-consequences-access-medicines (retrieved 14 Dec 2012)

[113] (Press/350/Rev.1, 30 August 2003, "Decision removes final patent obstacle to cheap drug imports**"** at <http://www.wto.org/english/news_e/pres03_e/pr350_e.htm>).

[114] WT/MIN(03)/ST/5, 10 September 2003, Ministerial Conference, Fifth Session, Cancún, 10 - 14 September 2003, Statement by Mr Pascal Lamy European Union Commissioner for Trade.

[115] J H Reichman "Undisclosed Clinical Trial Data under the TRIPS Agreement and its progeny: A Broader perspective" UNCTAD-ICTSD Dialogue on Moving the pro-development IP agenda forward: Preserving Public Goods in health, education and learning, Bellagio, 29 November – 3 December 2004, p 17.

[116] See para 4 of the Doha Declaration (WT/MIN(01)/DEC/2, 20 November 2001): "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose".

[117] J H Reichman "Undisclosed Clinical Trial Data Under the TRIPS Agreement and Its Progeny: A Broader Perspective" UNCTAD-ICTSD Dialogue on Moving the pro-development IP agenda forward: Preserving Public Goods in health, education and learning, Bellagio, 29 November – 3 December 2004, p 3.

[118] C Wadlow "Regulatory data protection under TRIPs Article 39(3) and article 10bis of the Paris Convention: is there a doctor in the house?" (2008) IPQ, 355, 402.

The UNAID exhorts:[119]

> Strategies to manage intellectual property that are oriented towards public health goals, such as the full use, as required, of flexibilities permitted under international regulations such as the Agreement on Trade-Related Aspects of Intellectual Property Rights administered by the World Trade Organization, will play a critical role. International actors should avoid provisions in free-trade agreements that potentially undermine access to affordable, life-saving medicines and health technologies.

7. Conclusion

The legal status of the Doha Declaration has been incorporated under the amendments in Article 31bis of the TRIPS Agreement.[120] Of the competing options for a less ambiguous interpretation of Article 39.3, it is best to consider seriously in parallel a waiver of the data exclusivity period once the PA triggers the grant of compulsory licensing for public health emergencies. Swift access in a timely manner is crucial for drug supply systems to be more reliable. The authors would like to conclude that employment of the PA into the intellectual property regime would serve to promote a balance in the rights and obligations of patent holders, and legitimise a safety factor for the world for access to medicines in a public health emergency. It is a forceful and viable proposal that data exclusivity protection must go hand in hand once a compulsory licence is issued under the framework developed. The "precautionary approach" as a separate and different legal regime can be justified,[121] and would be intrinsically fair.[122] From a human rights perspective, developing countries' obligation entails protecting access to medicines and guaranteeing against excessive pricing by pharmaceutical companies,[123] and a broad approach of the application of the PA beyond compulsory licensing for access to medicines in public health emergencies would benefit developing countries.

[119] UNAID 2012 Report on the Global Aids Epidemic, p 56.

[120] Before the amendment, the legal status of the Declaration was deemed ambiguous and would not constitute a binding legal instrument in the sense of definitively interpreting the TRIPS Agreement. See S Charnovitz "The Legal Status of the Doha Declarations" (2002) 5 JIEL 207 and F M Abbot "The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference" Occasional Paper 7, (Sep 2001) Quaker United Nations Office, 33.

[121] See N de Carvalho *The TRIPS Regime of Patent Rights* (Kluwer Law International, 2005), p 389.

[122] Ibid, p 395-6

[123] H Hestermeyer *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press, 2007), p 136. In the case of GlaxoSmithKline and Boehringer Ingelheim had priced their antiretrovirals at almost 230 per cent of the generic version.