

# WORLD POLICY BATTLES ON PHARMACEUTICAL PATENT PROTECTION: MICRO-HISTORY OF A FORUM SHIFT AND ITS LEGAL IMPLICATIONS\*

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**Resumen:** la internacionalización de la protección de la propiedad intelectual e industrial fue objeto en los años 90 de un desplazamiento de foro desde la OMPI a la OMC, bajo la presión de los países exportadores de tecnología y sus empresas: el producto fue el ADPIC. Este acuerdo fue diseñado para elevar los estándares de protección empleando una estructura regulatoria basada en meros periodos de transición y minusvalorando los efectos sociales de la eventual pero previsible falta de capacidad de producción farmacéutica en muchos países en desarrollo (artículo 31.f). A resultas, los países exportadores e importadores de tecnología están inmersos hoy en día en un proceso de reregulación dirigido a asegurar las “flexibilidades” inherentes al ADPIC, bajo el estandarte del acceso a medicamentos asequibles en el mundo en desarrollo.

**Palabras clave:** regulación, propiedad intelectual, flexibilidades, patentes farmacéuticas, acceso a medicamentos, genéricos, comercio.

**Abstract:** the internationalization of intellectual property protection was subject to a historical forum shift from WIPO to WTO in the 90s under the pressure of technology-exporting countries and their IP constituencies: the TRIPs agreement was its product. However, the agreement was designed to ratchet up global IP standards under a narrow regulatory structure based on mere phase-ins, and without considering social realities such as the eventual lack of pharmaceutical manufacturing capacity in many developing countries (article 31.f). As a result, technology-exporting and technology-importing countries are immersed in a tense ongoing re-regulatory process aiming to secure TRIPS inner “flexibilities”, under the banner of access to affordable medicines in the developing world.

**Key words:** regulation, intellectual property, flexibilities, pharmaceutical patents, access to medicines, generics, trade.

**Sumario:** I. From IP to trade. II. TRIPs in context. III. Playing the flexibility card... IV. A complex re-regulatory process.

## I. From IP to trade

1. The internationalization of intellectual property standards is exacerbating the historical tensions that characterise patent and health protection. Private interest and public values are in serious conflict here<sup>1</sup>. In addition, technology-exporting (read developed) countries and technology-importing

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<sup>1</sup> See generally, S. PICCIOTTO, *Regulating global corporate capitalism*, Oxford University Press, 2011 (particularly chapter 9), S. SELL, *Private Power, Public Law: The Globalization of Intellectual Property Rights*, Cambridge University Press, 2003 and M.P. RYAN, *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property*, Brookings Institution Press, 1998.

(read developing) countries are shifting for a vertically and horizontally battling to ratchet up or down IP protection<sup>2</sup>. As a result intellectual property (IP) constituencies and A2K (Access to Knowledge) constituencies, not to mention different ministries in the same government cabinet (e.g: trade ministers / health ministers), have strategically organised their lines of battle on multiple fronts in order to defend their values and interests.

2. These regulatory fluxes produced the first critical forum shift to the benefit of IP constituencies during the Uruguay Round. This shift is already part of modern world history, as it officially inaugurated a relentless and serious game of global “chessboard politics” on the protection, limitations and exceptions to knowledge-based private monopoly rights<sup>3</sup>.

3. At the beginning of 1980s, parties to the Paris Convention for the Protection of Industrial Property, the oldest convention providing protection for patented inventions outside the domestic laws, applied the rules of non-discrimination and national treatment to patents and patent applications but retained country autonomy in substantive criteria for the functioning of domestic patent systems such as the patentability of pharmaceuticals<sup>4</sup>.

4. In the 1980s and early 1990s, a Diplomatic Conference held under WIPO auspices attempted to revise the Convention. However, developing and developed countries could not agree on critical issues such as compulsory licenses (CL)<sup>5</sup>. In fact, the attempts by developing countries to upgrade its CL provisions (article 5A) brought the Conference to an end<sup>6</sup>.

5. The failure of this Conference persuaded IP constituencies to promote a forum shift to the ongoing GATT Uruguay Round. Interestingly, by the time of the launch of the Uruguay Round (1986), 49 of the 98 members of the Paris Convention excluded patent protection for pharmaceutical products<sup>7</sup>. In essence, US IP constituencies shifted their strategy from the IP to the trade regime and pushed the United Trade Representative (USTR) to follow suit as a final effect of the crises facing the WIPO in its dealings with the US, when WIPO became a forum for legal criticism of copyright and patents in the 1960s and 70s.

6. The move to the multilateral trading system also aimed to benefit from the comparative institutional advantages of the new dispute settlement mechanism that was being negotiated in the Uruguay Round (e.g: binding multilateral jurisdiction and authorization of sanctions/suspension of concessions)<sup>8</sup>. Interestingly, the ministers represented in WIPO reacted with celerity launching negotiations to produce a (WIPO) dispute settlement treaty, but the initiative was derailed<sup>9</sup>.

<sup>2</sup> P. DRAHOS, “Four lessons for developing countries from the trade negotiations over access to medicines” 28 *Liverpool Law Review* (2007): 33.

<sup>3</sup> K. ALTER AND S. MEUNIER, “The International Politics of Regime Complexity”, 7 *Perspectives on Politics* (2009): 13-24.

<sup>4</sup> Paris Convention for the Protection of Industrial Property, March 20, 1883, as revised at Stockholm (1967), 21 UST 1583, 828 UNTS 305.

<sup>5</sup> See, e.g., J. H. REICHMAN and C. HASENZAHN, *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA.*, UNCTAD/ICTSD-Project on IPRs and Sustainable Development, Issue Paper No. 5, 2003.

<sup>6</sup> Compulsory licensing is as old as patent law. For the historical origins of the patent system see, in particular, MGBEOJI, I. “The Juridical Origins of the International Patent System: Towards a Historiography of the Role of Patents in Industrialization” 5 *Journal of History of International Law* (2003): 403-422.

<sup>7</sup> See *Existence, scope and form of generally internationally accepted and applied Standards/Norms for the Protection of Intellectual Property-Note prepared by the International Bureau of WIPO* (15 September 1988). MTN.GNG/NG11/W/24/Rev.1.

<sup>8</sup> For the negotiating history see J.C. ROSS and J.A. WASSERMAN, “Trade-Related Aspects of Intellectual Property Rights” in T.P. Stewart and C.J. Callahan, C.J.(ed.) *The GATT Uruguay Round: A Negotiating History (1986-1992)*, Volume II, Kluwer Law and Taxation Publishers, 1993, pp.2241-2313 and GERVAIS, D. *The TRIPS Agreement: Drafting History and Analysis*, Sweet and Maxwell, 1998.

<sup>9</sup> See *WIPO Proposed Treaty on the Settlement of Disputes between States in the Field of Intellectual Property*, WO/GA/XXI/2 (30 April 1997) and *Background information document*, WO/GA/XXI/3 (30 April 1997).

7. Therefore, a pure jurisdictional reallocation or “forum shifting” has taken place in the area of global IP protection. Trade-related IP rights are now part of a “WTO covered agreement” and thus enforceable through its binding dispute settlement mechanism<sup>10</sup>. Wanted or not, WIPO has had to learn to ‘share’ its original competences with WTO and nowadays provides legal advice and technical assistance on TRIPs implementation in accordance with their cooperation agreement of 1995<sup>11</sup>.

8. In short, the Uruguay Round of trade negotiations incorporated IP by sustaining its “trade-relatedness”. As a result, new global standards for IP protection were established under the Agreement on *Trade related to Intellectual Property* (TRIPs). Thus, ministers of trade and finance managed to expand their IP competences in the multilateral trading system by using a strategic association of ideas: “trade-relatedness”. It is self-evident that the “trade-relatedness” invention opens up a world of possibilities for global policy formation in all areas, and also to multiple jurisdictional reallocations. Almost everything is interrelated in some way or another.

## II. TRIPs in context

9. The TRIPs agreement is designed to establish minimum protection standards for trade-related IP, applying a top-down approach towards harmonization<sup>12</sup>. Basically, it is the most far-reaching and comprehensive legal regime ever to be concluded in the intellectual property area<sup>13</sup>. However, it is fair to say that its provisions do not establish “IP-related” public health protection with similar sensitivity. Consequently, the TRIPs agreement has been in need of strategic re-engineering from the very first day that it entered into force in 1996.

10. But history is also important here. Developing countries agreed to negotiate the TRIPs agreement during the Uruguay Round in exchange for trade concessions on textiles and agricultural products, and under the pressure of US trade unilateralism<sup>14</sup>. The agreement was in fact negotiated in the shadow of unilateral trade sanctions pursued by the USTR “diplomacy”<sup>15</sup>.

11. GATT Contracting Parties such as Brazil, India, Argentina, Cuba, Egypt, Nicaragua, Nigeria, Peru, Tanzania and the former Yugoslavia were among the most active GATT Contracting Parties opposing IP lawmaking in the Uruguay Round, arguing that the multilateral trade system was primarily concerned with trade in goods and not property rights in intangibles, which was particularly reasonable.<sup>16</sup> However, their initial resistance for a narrower interpretation of the mandate for the Uruguay Round negotiations on this issue (Ministerial Declaration of 1986) broke down in 1988, with the second amendment of the Section 301 of the US Trade Act of 1974, the so-called Special 301.

<sup>10</sup> For the first studies on the *forum-shifting paradigm* see J. BRAITHWAITE and P. DRAHOS, *Global Business Regulation*, Cambridge University Press, 2000, pp.564–571 and L.HELPER, “Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking”, 29 *Yale Journal of International Law* 1 (2004): 1-83.

<sup>11</sup> For a detailed overview see WIPO Annual Reports, available at <http://www.wipo.int>.

<sup>12</sup> P. STEPHAN, “Institutions and Elites: Property, Contract, the State, and Rights in Information in the Global Economy”, 10 *Cardozo Journal of International Law and Comparative Law* (2002): 305-306.

<sup>13</sup> C. CORREA and A.A. YUSUF, *Intellectual Property and International Trade: the TRIPs Agreement*, Kluwer Law International, 1998, p.xvii.

<sup>14</sup> See generally K. WATAL, *Intellectual Property Rights in the WTO and Developing countries*, Oxford University Press, 2001 and R. OKEDIJI, “Public Welfare and the Role of the WTO: Reconsidering the TRIPs Agreement”, 17 *Emory International Law Review* 2 (2003): 819-918.

<sup>15</sup> The Omnibus Trade and Competitiveness Act in 1988 amended section 301 of the US Trade Act of 1974 and required USTR to identify inadequate domestic IP protection and unilaterally enforce market access. See, particularly, RYAN, M. “The Function-Specific and Linkage-Bargain Diplomacy of International Intellectual Property Lawmaking”, 19 *University of Pennsylvania Journal of International Economic Law* (1998): 558-559.

<sup>16</sup> J.A. BRADLEY, “Intellectual Property Rights, Investment, and Trade in Services in the Uruguay Round: Laying the Foundations”, 23 *Stanford Journal of International Law* (1987): 81.

**12.** Entering into operation in 1989, Special 301 granted USTR the authority to apply unilateral trade sanctions against countries providing ‘insufficient’ protection of intellectual property. Indicatively, five of the ten countries in the hard line group which was against incorporating IP protection in the negotiations were listed for bilateral attention in the first USTR announcement of Special 301 country targets. Countries such as Argentina or Egypt were placed on the Watch List, while both Brazil and India, the leading opponents of the US agenda, were placed on the *Priority Watch List*, Special 301 most serious country-category (USTR’s annual Special 301 IPR Reports).<sup>17</sup>

**13.** As a result, the original legal framework of WTO law today contains an agreement on trade-related IP protections, and the rules will be here to stay for decades to come. However, almost a decade since it entered into force, there is growing criticism among developing countries as they have to live with the ‘burden’ of stringent IP standards while developed countries have not equally honoured their trade commitments (lowering tariffs and subsidies on agriculture and textiles)<sup>18</sup>. Last, but not least, the TRIPs agreement is producing some unforeseen adverse effects on the pharmaceutical policies of the developing world<sup>19</sup>.

**14.** The negotiations on the side of developed countries were fuelled by the fact that technological and scientific advancement accounts for a growing portion of the increased domestic productivity in their economies<sup>20</sup>. However, as Drahos explains, both developed and developing countries alike were generally in ignorance about its likely effects on information markets<sup>21</sup>.

**15.** The information revolution and its knowledge-based economy have reduced production costs, significantly raising the (legal) value of knowledge. TRIPs rules were precisely designed to promote the legal protection of these knowledge-production processes; and the result was a failure to develop solutions for key social issues, such as access to medicines in the developing world, among others.

**16.** In any case, finding a proper balance between patents and health is not itself an easy task, as interests and values are seriously at odds in this disputed area of global politics<sup>22</sup>. Conventional thinking on patents argues that effective patent protection is a prerequisite for research and development, but also a lever for economic development generally<sup>23</sup>. According to this view, IP friendly environments promote foreign direct investment (FDI) and technology transfer (i.e, foreign technology licensing, and joint ventures)<sup>24</sup>.

**17.** Conversely, critical thinking argues that less burdensome public mechanisms could alternatively obtain similar outcomes without incurring the social burdens of modern patent systems. And,

<sup>17</sup> F.M. ABBOTT, “Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework”, 22 *Vanderbilt Journal of Transnational Law* (1989): 689, 708-709.

<sup>18</sup> See *Integrating intellectual property rights and development policy*: Report of the Commission on Intellectual Property Rights (2003): 8.

<sup>19</sup> On the perverse distributional effects of TRIPs patent protection with regards to pharmaceuticals see, in particular, E. BENVENISTI and G. W. DOWNS, “*Distributive Politics and International Institutions: The Case of Drugs*”, 36 *Case Western Reserve Journal of International Law* (2004): 21-52.

<sup>20</sup> On the evidence that TRIPs substantially amplified the returns to technology-exporting countries since its adoption see e.g. F.M. ABBOTT, “Toward a New Era of Objective Assessment in the Field of TRIPs and Variable Geometry for the Preservation of Multilateralism”, 8 *Journal of International Economic Law* 77 (2005), and accompanying references.

<sup>21</sup> P. DRAHOS, “Developing Countries and International Intellectual Property Standard-setting”, *Study Paper 008 of the Commission on Intellectual Property Rights*, United Kingdom, 2001, p.13.

<sup>22</sup> On the two main schools alternatively suggesting a conflict (primacy of human rights) or co-existence (need for a balance) of human rights with IP monopoly rights, see in particular L. HELFER, “Human Rights and Intellectual Property Rights: Conflict or Co-existence?”, 5 *Minnesota Intellectual Property Review* (2003): 47.

<sup>23</sup> For the first reports produced by global institutions on the interaction between IP protection, FDI and technology transfers see *Economic Arguments for Protecting Intellectual Property Effectively*, OCDE, Paris, 1989 and *Intellectual Property Rights and Foreign Direct Investment*, United Nations Department of Economic and Social Development, New York, 1993.

<sup>24</sup> See e.g., *Creativity, Innovation and Economic Growth in the 21<sup>st</sup> Century: An Affirmative Case of Intellectual Property Rights*, Business and Industry Advisory Committee to the OECD, January 2004.

numbers provided by the industry itself tend to bear this out. For example, the figure provided by PhRMA itself in its 2011 industry profile reached \$ 67.4 billion on Global R&D by all private companies in 2010<sup>25</sup>. For that same year, the estimate on global sales by industry-friendly IMS Health Market Prognosis reached \$ 856 billion<sup>26</sup>.

18. For the critics, adding to it, access to affordable medicines in any given society has a significantly more positive impact on development than high standards of pharmaceutical patent protection and enforcement<sup>27</sup>.

19. Notwithstanding the dilemmas raised by the patent and health relationship, a variety of authoritative diagnostics reveal that a more nuanced balance between public health (rights of citizens/patients) and private property (rights of patent holders/corporations) is needed on a global scale, particularly (but not exclusively) regarding access to affordable medicines in the developing world<sup>28</sup>.

### III. Playing the *flexibility* card...

20. Small groups tend to be more adept than the general public at organizing the ways in which they pursue their interests: their free rider problems and transaction costs are lower<sup>29</sup>. As a result of that, developed countries over-protected the interest of their industries in TRIPs agreement. Its drafting was basically a trade diplomat driven-process permeated by the latter. Indeed, its very existence (and much of its substance) owes much to a group of global firms that guided the USTR strategy during the Uruguay Round negotiations with a generously staffed team of business advisors and IP experts<sup>30</sup>. In essence, the USTR acted as a proxy for the technology and pharmaceutical industry (through the US Advisory Committee on Trade and Policy Negotiation) and the EU representatives as well as other developed countries followed suit<sup>31</sup>.

21. The TRIPs agreement is to a great extent a global regulatory product of global corporate capitalism<sup>32</sup>. Its drafting was seriously and strongly influenced by a precisely circumscribed coalition of private technology exporters, namely, the twelve companies that originally founded the Intellectual Property Committee (IPC) in 1986 in order to mobilise support for the trade-related IP adventure<sup>33</sup>. In the bold words of Susan Sell, twelve corporations made public law for the world<sup>34</sup>.

<sup>25</sup> See 2011 PhRMA industry profile, page 2.

<sup>26</sup> See "Total Unaudited and Audited Global Pharmaceutical Market: 2003 – 2010", *IMS Health Market Prognosis* (March 2011).

<sup>27</sup> See e.g., M. KREMER, "Patent Buyouts: A Mechanism for Encouraging Innovation", 113 *Quarterly Journal of Economics* 4 (1998):1137-1167, LOVE, J. *From TRIPS to RIPS: A Better Trade Framework to Support Innovation in Medical Technologies*, Paper presented at Agence Nationale de Recherches sur le Sida, University of the Mediterranean, Marseille, 2003 and T. HUBBARD and J. LOVE "A New Trade Framework for Global Healthcare R&D" *Plos Biology*, 2(2): e52. doi:10.1371/journal.pbio.0020052.

For a comment on these proposals see D. BAKER, *Financing Drug Research: What Are the Issues?* Center for Economic and Policy Research, 2004.

<sup>28</sup> See in particular *Public Health, Innovation and Intellectual Property Rights: Final Report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health*, WHO, 2006 and *Integrating intellectual property rights and development policy: Report the UK Commission on Intellectual Property Rights* (2003).

<sup>29</sup> M. OLSON, *The logic of collective action: public goods and the theory of groups*, Harvard University Press, 1965, pp.22-36.

<sup>30</sup> In the words of Sell: "it was not merely their relative economic power that led to their ultimate success, but their command on IP expertise, their ideas, their information, and their framing skills (translating complex issues into political discourse)". See *Private Power, Public Law*...op.cit. p.4.

<sup>31</sup> For an insightful business case study on the participation of Pfizer in the development of international trade law see M.A. SONTORO and L. SHARP PAINE, "Pfizer: Global Protection of Intellectual Property", *Harvard Business School Case study* No. 9-392-073, 1995.

<sup>32</sup> See S. PICCIOTTO, *Regulating* ...op.cit and P. DRAHOS and J. BRAITHWAITE, *Global Business Regulation*, Cambridge University Press, 2000.

<sup>33</sup> See G. DUTFIELD, *Intellectual Property Rights and the life science industries: A Twentieth Century History*, Ashgate, 2003.

<sup>34</sup> See S. K. SELL *Private Power, Public Law* ...op.cit: 96.

22. The capacity of developing countries to influence outcomes was limited by US unilateralism but also as a result of the scant exposure of some developing country negotiators to the arcane technicalities of western (read US) intellectual property law<sup>35</sup>. Therefore, the model of IP protection which originated in the developed world has been transplanted to the developing world through the tools of international law<sup>36</sup>.

23. In consequence, legal flexibility is strongly required. The way the TRIPs agreement approached development is based merely on transitional periods and is therefore too simplistic. The balancing of patent protection and health protection was envisioned as an issue to be approached by buying time, instead of adapting its implementation to the changing levels of development of WTO Members (phase-ins) and linking its compliance to technology transfer.

24. Generally, WTO members had to implement the TRIPs Agreement at the end of the 1995–2000 transition period. In addition, an extra term was granted until 1 January 2005 in the area of pharmaceutical product patents for certain developing WTO Members. In consequence, these were allowed to delay product patent protection in areas not protected by their legal systems at the time that the agreement entered into force (TRIPs Article 65.4). Developing countries (less than twenty developing countries including India and Brazil) were required to accept patent applications from 1995 onwards (the so-called patent “mailbox”) until the pending patent applications began to be assessed in 2005.

25. Finally, a third transition period covering patent protection of pharmaceuticals and exclusive marketing rights was granted to provide Least Developed Countries (LDCs) with a longer phase-out to comply with TRIPs obligations. As a result, LDCs enjoyed a temporary waiver originally expiring on 1 January 2006 that has been further extended to 1 January 2016 through a Decision of TRIPs Council in 2002<sup>37</sup>.

26. However, transitional periods are inevitably incapable of regulating the complexities of pharmaceutical patent protection in the developing world. As mentioned above, transitional periods are unconditional, merely based on granting developing countries time (phase-outs) to implement the given rules. In consequence, they are not easily adapted to the changing realities of regulated entities (developing countries, in this case) and are thus particularly inefficient in regulatory terms.

27. As a result direct result, WTO Members are currently involved in a regulatory learning process to re-engineer the TRIPs disciplines in order to address the health realities of developing countries, and have been almost since the entry into force of the agreement<sup>38</sup>. In fact, the problem became a public relations disaster for the new WTO in 2000, immediately following its first (and failed) Round of negotiations (the so-called Millennium Round, derailed in 1999), and prior to beginning a second attempt (the Doha Development Round, initiated in 2001) still ongoing.

28. At the beginning of a new decade, century and millennium, health advocates and public health representatives managed to effectively question the state of affairs of pharmaceutical patent protection in the developing world and blamed TRIPs rules in part for the difficulties that developing countries were facing in gaining access to affordable medicines.

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<sup>35</sup> P. DRAHOS, “Developing Countries and International Intellectual...op.cit.p.13.

<sup>36</sup> On this issue, see generally, TULLY, S. *Corporations and International lawmaking*, Martinus Nijhoff, 2007.

<sup>37</sup> See IP/C/25 *Extension of the Transition Period under Article 66.1 of the TRIPs Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, Decision of the Council for TRIPs of 27 June 2002, Council for TRIPs (1 July 2002).

<sup>38</sup> For a proposal on graduation of general substantive rules, based on recourse to economic factors, aiming to make WTO law more responsive to the needs of developing countries see T. COTTIER, “From progressive liberalization to progressive regulation in WTO law”, 9 *Journal of International Economic Law* 4 (2006): 779–821 (taking as a case of study the patenting pharmaceutical products).

**29.** With the WTO's legitimacy being questioned before a new negotiating round, finding a solution was considered an institutional priority by the WTO Secretariat and most, if not all, WTO Members. The world trading system was under pressure to deliver consensus-based solutions on this highly sensitive issue, and also had a major opportunity to demonstrate its "flexible" legal culture in the beginning of the Doha Development Round<sup>39</sup>.

**30.** Thus, trade ministers concentrated on negotiating some collective (re)interpretations to extend the scope within TRIPs agreement for pursuing public health policies in developing countries. In this regard, the TRIPs Council had the complex task of developing a consensus-based formula (acceptable for 147 WTO members) for reinterpreting TRIPs obligations on this issue<sup>40</sup>. In practice, WTO Members collectively entered into a complex re-regulatory learning process which is still ongoing.

**31.** This sign of the times is clearly captured in their reaction, in April 2001, to the settlement of a famous domestic lawsuit against the South African Medicines and Related Substances Control Amendment Act. Interestingly, the settlement of this lawsuit brought by the South African Pharmaceutical Industry Association and several affiliated companies merited an unprecedented welcome by the WTO Director-General himself. Even the Press Release takes advantage of the event as proof of the flexible nature of WTO law (!): "the settlement *shows* that the WTO agreements, such as TRIPs, contain the necessary flexibility to meet the health needs of developing countries *and can be used as a basis for resolving difficult issues* concerning access to essential drugs"<sup>41</sup>.

**32.** However, arriving at a new legal balance with regard to health-related patent protection was not going to be easy. Here, the African Group, Brazil and India took the lead inside WTO corridors and meeting rooms, while social activists were effectively voicing the issue in the global media. The pressures of technology-exporting countries against any substantial policy change with regard to patents and health were critical; but the anthrax cases in the United States, and the subsequent intention of the US administration to issue a compulsory license for Cipro (a Bayer antibiotic), secured some policy space and momentum to upgrade the legal *status quo*.

**33.** It was in June 2001 that TRIPs Council had its first special meeting on access to medicines, requested by the African Group. That was also the same month that the US withdrew its WTO complaint against Brazil's pharmaceutical policies, thus conveying a change in attitude and suggesting a willingness to adapt TRIPs rules to the health realities of the developing world<sup>42</sup>.

**34.** The rationalization of TRIPs rules began in a 7-hour session of that special meeting, with interventions from over 40 delegations in June 2001<sup>43</sup>. In that intense session, trade representatives developed some (first) common interpretations on TRIPs inner "flexibility".

**35.** For the WTO Director-General, TRIPs rules "strikes a carefully-negotiated balance" between providing IP protection and "the flexibility to ensure that treatment reach the world's poorest and most vulnerable people". Pursuant to this, the TRIPs Council "reinforced" the security that WTO Members "can use" the available "flexibility" in the agreement. Furthermore, should any improvements

<sup>39</sup> See E. R. GOLD and J-F. MORIN, "Consensus-seeking, distrust and rhetorical entrapment: The WTO decision on access to medicines" 16 *European Journal of International Relations* 4 (2010): 563-587 (578).

<sup>40</sup> See C.D. EHLERMANN and L. EHRING, "Decision-making in the world trade organization", 8 *Journal of International Economic Law* 1 (2005): 51-75 (64).

<sup>41</sup> See WTO News: Speeches—DG Mike Moore. *Moore welcomes news of settlement of South Africa drug lawsuit*, Geneva (19 April 2001).

<sup>42</sup> See *Brazil Measures Affecting Patent Protection*, WTO Doc WT/DS199/3 (January 9, 2001).

<sup>43</sup> See the working paper submitted by the African Group and 17 developing countries. IP/C/W/296, *TRIPs and Public Health* (June 29, 2001).

be needed, as “nothing is perfect”, these improvements could be negotiated in the Doha Round (Mike Moore, Press release 2001)<sup>44</sup>.

**36.** Access to medicines was on board the so-called Doha “Development Round” in the Ministerial Conference of Qatar. In fact, the Ministerial Declaration opening the Round had already underlined the critical importance of making a pro-health *implementation and interpretation* “by promoting both access to existing medicines and the creation of new medicines” (paragraph 17).

**37.** The Doha Declaration on public health and access to medicines, adopted in November 2001, was certainly the milestone in the whole process. In the words of the current WTO DG, at the High-Level Symposium on Global Health Diplomacy, held in 2011 to mark the Declaration’s 10th anniversary, this historic instrument has reinforced health policy choices worldwide<sup>45</sup>.

**38.** The key idea underlying the Declaration is formal recognition that the TRIPs agreement provides for “flexibilities” to secure state regulatory autonomy in the patents and health policy area.

**39.** The flexibilities of TRIPs rules recognized in the 2001 Declaration are to be found and developed through the interpretative prism of the objectives and principles of the agreement:

— Article 7 (objectives): “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and *in a manner conducive to social and economic welfare, and to a balance of rights and obligations*”.

— Article 8 (Principles): “[Members may 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*, provided that such measures are consistent with the provisions of this Agreement”.

**40.** Interestingly, Paragraph 5 of the 2001 Declaration itself expressly recalls how flexibility needs to be built upon those provisions: “*In applying the customary rules of interpretation of public international law, each provision of the TRIPs Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles*”.

**41.** The Declaration determines that the TRIPs agreement “does not and should not prevent members *from taking measures to protect public health*”<sup>46</sup>. In this sense, 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” (paragraph 4). Its provisions also refer to a right to use those rules, “for this purpose” and “to the full”.

**42.** The legality of *compulsory licensing* is thus secured under this legal rationale. The term was not regulated as such in TRIPs agreement but as “other use without authorization of the right holder” in the title of article 31<sup>47</sup>. In any case, the right to grant compulsory licenses was made clearer than under

<sup>44</sup> See WTO News: Speeches—DG Mike Moore. *Moore: Countries must feel secure that they can use TRIP’s flexibility* (20 June 2001).

<sup>45</sup> See WTO News: *10-year-old WTO Declaration has reinforced health policy choices, Lamy tells symposium* (23 November 2011).

<sup>46</sup> See WT/MIN(01)/Dec/2, Doha WTO Ministerial 2001: *Declaration on the TRIPs Agreements and Public Health* (20 November 2001), paragraph 4.

<sup>47</sup> For a history of article 31 see also R. GOLD and D.K. LAM, “Balancing Trade in Patents: public non-commercial use and compulsory licensing”, 6 *Journal of World Intellectual Property* (2003): 5-32.



article 5A of the Paris Convention<sup>48</sup>, and was thus reworded in broader terms to avoid misinterpretations: “each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted” (paragraph 5.b).

43. Legal exceptions based on health crises were, in addition, formally recognized: “each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent national emergency or other circumstances of extreme urgency” (paragraph 5.c).

44. To sum up, the 2001 Doha Declaration facilitates pro-health implementation, providing for extra (TRIPs compatible) policy space based on re-regulation and flexible interpretations. Certainly, the reach of “TRIPs flexibility” depends on the political will of those who can authoritatively interpret and waive TRIPs rules through WTO decision making-processes. As even well-known IP critics recognize, in any case, the Declaration has critically increased and reinforced the legality of TRIPs flexibilities on health-related areas<sup>49</sup>.

#### IV. A complex re-regulatory process

45. The Declaration confirms that WTO Members have the “right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted”. However, it also mandated the TRIPs Council to make additional efforts in some areas, and particularly with regard to the so-called “Paragraph 6 issue”: TRIPs Article 31 recognizes the legality of granting CL to order generics but also determines that “any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”.

46. As a result, the provision not only prevented developing countries without manufacturing capacity (which was most of them) to import generics from countries in which the patented drug was produced. It also limited production to an unspecified volume, by using the expression “predominantly”.

47. The wording of the paragraph 6 issue of the 2001 Declaration was precisely framed under the policy pressure of the new pro-development Doha Round: “to find an *expeditious solution* to this problem before the end of 2002”<sup>50</sup>.

48. The ‘solution’ was reached with the so-called “Motta text” (named after Perez Motta, the former Chairman of the TRIPs Council) in December 2002<sup>51</sup>, and was finally adopted on 30 August 2003 through a General Council Decision -interestingly, not a TRIPs Council Decision- on the implementation of paragraph 6 of the Doha Declaration<sup>52</sup>. In the words of Supachai Panitchpakdi, Director-General

<sup>48</sup> The right of governments to grant CL on virtually any ground (including public interest, abuse or anticompetitive conduct, or for noncommercial government use, among others) was incorporated in TRIPs agreement thanks to the fortitude and analytical skills of the Indian delegation. See J. REICHMAN, “Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options”, *Journal of Law Medicine* (2009): 248.

<sup>49</sup> See J. LOVE, “What the 2001 Doha Declaration Changed”, Knowledge Ecology International, 16 September 2011.

<sup>50</sup> See WT/MIN(01)/Dec/1, Doha WTO Ministerial 2001: *Ministerial Declaration* (20 November 2001) paragraph 17.

<sup>51</sup> See in particular F. ABBOTT, “The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health”, *99 American Journal of International Law* 2 (2005): 317-358 and see D. MATTHEWS, “WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on TRIPs Agreement and Public Health: A Solution to the Access to essential medicines problem?”, *7 Journal of International Economic Law* 1 (2004): 73-107.

<sup>52</sup> See WT/L/540, *Implementation of paragraph 6 of the Doha Declaration on the TRIPs Agreement and public health*, Decision of the General Council of 30 August 2003 (1 September 2003).

of the WTO at that time, the “final piece of the jigsaw” had fallen into place with this Decision; proving “once and for all” that WTO “can handle humanitarian as well as trade concerns”...<sup>53</sup>.

**49.** In essence, the Decision waives article 31(f) requiring production under CL to be “predominantly” for the domestic market. The object of this waiver is particularly reasonable, as it is simply an unachievable requirement for compliance by developing WTO members that lack pharmaceutical manufacturing capacity<sup>54</sup>. As mentioned above, these inevitably have to be supplied by global generics markets.

**50.** In order to provide, the *waiver* creates a member-driven mechanism allowing the import and export of generics on a case-by-case, drug-by-drug, country-by-country basis. The regulatory structure of this member-driven (paradoxically not market-driven) mechanism is based on a notification procedure for both importing and exporting countries planning to trade in generics<sup>55</sup>.

**51.** The Decision, pre-negotiated by the United States, India, Brazil, South Africa and Kenya, basically helped WTO Members to keep the ongoing Doha negotiating process on track at the Cancun Ministerial Conference (September 2003).

**52.** The negotiated instrument aims with questionable success to strike a balance between potential importers of generics (mainly in Africa, Asia and America), potential exporters (such as India and Brazil), and technology-exporting countries<sup>56</sup>.

**53.** The 2003 Decision also establishes that WTO Members may notify their intention not to use the system as importers, or to use it only in a limited way. Practically all OECD countries have issued such notifications, under pressure from their patent-holding industries. Thus, the instrument includes a list of developed countries who will formally refrain from importing generic medicines, as well as a list of countries that will commit to importing generic drugs only in cases of extreme urgency or national emergency.

**54.** The Decision is accompanied by a separate statement of the General Council chairperson ensuring that it would not provide a backdoor for commercial use of those generics, by re-entering non-exempted markets. The statement expresses several “shared understandings” regarding the Decision and the way it has to be interpreted and implemented:

- (1) the system has to be used “in good faith”, undertaking not to pursue “industrial or commercial objectives”;
- (2) all reasonable measures should be taken to prevent market diversion (re-exports);
- (3) issues arising from the Decision have to be solved expeditiously and amicably and finally,
- (4) notifications should include information from the Member on the ways and means it has employed to conclude that there is insufficient manufacturing capacity in the sector.

**55.** The chairperson also attaches to his separate statement a short list of guidelines (selected “best practices” from producers) to reduce and minimize product diversion (anti-diversion measures) and thus to ensure market segmentation<sup>57</sup>.

<sup>53</sup> See WTO News: 2003 Press Releases, Press/350/Rev.1, *Decision removes final patent obstacle to cheap drug imports* (30 August 2003).

<sup>54</sup> In fact, former WTO Director, Supachai Panitchpakdi, described the Decision as ‘an historic agreement.’ See WTO News: 2003 Press Releases (9 September 2003).

<sup>55</sup> See <[http://www.wto.org/english/tratop\\_e/tripos\\_e/public\\_health\\_notif\\_export\\_e.htm](http://www.wto.org/english/tratop_e/tripos_e/public_health_notif_export_e.htm)>

<sup>56</sup> For a comment see generally F. ABBOTT, “The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health”, 99 *American Journal of International Law* 2 (2005): 317-358 and D. MATTHEWS, “WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health: A Solution to the Access to essential medicines problem?”, 7 *Journal of International Economic Law* 1 (2004): 73-107.

<sup>57</sup> See WT/GC/M/82, *General Council Chairperson’s Statement* (13 November 2003). These schemes built on the previous experience of anti-diversion business practices by companies like Novartis, Merck, Pfizer and others, differentiating regular products from products supplied through discounted pricing or through donor policies.

**56.** The 2003 Decision is an interim *waiver* to be applied until the TRIPs agreement is amended<sup>58</sup>. As a result, the General Council adopted a Protocol of Amendment in 2005<sup>59</sup>. Open to acceptance by WTO Members before 1 December 2007, this protocol contains an extremely elaborate (...bad) article 31bis to be incorporated as an Annex to the TRIPs agreement if accepted by two thirds of WTO Members<sup>60</sup>.

**57.** WTO law is made-up of a complex legal world based on dynamic annexes producing critical regulatory implications in multiple public policy areas. However, it is certainly not easy to incorporate this Amendment to its covered regulatory structure in order to deliver its promised positive effects. By the time this article was completed, less than 50 WTO Members<sup>61</sup> had accepted the Amendment including the United States (17 December 2005) and the European Communities (20 November 2007)<sup>62</sup>.

**58.** Interestingly, a new Decision of WTO Members in 21 December 2007 finally established an unlimited extension to the waiver, probably taking into due consideration the obvious difficulty of ratification by WTO Members: “The period [...] shall be extended until 31 December 2009 *or such later date as may be decided* by the Ministerial Conference”<sup>63</sup>. In short, the self-evident political difficulties to ratify the Protocol suggest that it is unlikely to enter into force, at least in the near future<sup>64</sup>.

**59.** In any case, it is also important to recall that its wording is overly burdensome<sup>65</sup>. In fact, African countries, Brazil and India strongly (and reasonably) opposed the provisions contained in the amendment itself without much success. Basically, the amendment transforms into treaty law the (non-functioning) member-driven mechanism created by the 2003 Decision. Certainly, it was not an efficient (and reasonable) move, as reality has proved. In this regard, it is reasonable to suggest that it is not cost-efficient to allocate significant public resources to that ratification.

**60.** Developing countries without pharmaceutical manufacturing capacity have legal (and legitimate) expectations to access generics in global pharmaceutical markets. In this regard, market mechanisms tend to function better when strong vested interests are involved. A member-driven mechanism such as the paragraph 6 mechanism (requiring a double compulsory licence from both the importing and exporting country to trade in generics) is inefficient vis a vis market mechanisms.

**61.** In this regard, it is not only dependent on the unnecessary bureaucratic processes of public decision-making in both the potentially exporting and importing countries, but it is also highly exposed to the pharmaceutical brand-name industry pressures against the CL which are required to make it function. Therefore, it not difficult to conclude why the mechanism has only been used once since its 2003 inception<sup>66</sup>, involving a generics transaction between Rwanda and Canada (260000 packs) of an HIV/

<sup>58</sup> See *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health - Decision of 30 August 2003*, WT/L/540 (29, august 2003).

<sup>59</sup> For a complete legal study on the universe of available policy options to tackle this issue see ABBOTT, F.M. “Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on public health”, *QUINO Paper n.9*, 2002.

<sup>60</sup> See WT/L/641, *Amendment of the TRIPS Agreement* (8 December 2005).

<sup>61</sup> See <[http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm)>.

<sup>62</sup> See SGS/166652, *Instrument of Acceptance, Council of the European Union* (Brussels, 19/11/2007).

<sup>63</sup> See WT/L/711, *Amendment of the TRIPS Agreement-Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement* (21 December 2007).

<sup>64</sup> See *European Parliament Resolution on the TRIPS Agreement and access to medicines*, B6-0288/2007 (9 July 2007), paragraph K.7, the study commissioned by its Committee on International Trade as well as *European Parliament Debates CRE 11/07/2007-18* (7 July 2007) and *PV 11/07/2007-18* (7 July 2007).

<sup>65</sup> See V. BRADFORD and K. LEE, “TRIPS, the Doha declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?” *Globalization and Health* (2007) 3:3

<sup>66</sup> See IP/N/9/RWA/1, *Council for Trade-Related Aspects of Intellectual Property Rights - Notification under paragraph 2(a) of the Decision of 30 August 2003 - Rwanda* (19 July 2007) and IP/N/10/CAN/1, *Council for Trade-Related Aspects of Intellectual Property Rights - Notification under Paragraph 2(c) of the Decision of 30 August 2003 - Canada* (5 October 2007), respectively.

AIDS combination therapy (TRIAvir) manufactured by Canadian Apotex Inc<sup>67</sup>. In consequence, it is easy to understand why developing countries are urging to renegotiate alternative solutions.

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<sup>67</sup> On this transaction see in particular C. COTTER, "The Implications of Rwanda's Paragraph 6 Agreement with Canada for Other Developing Countries", 5 *Loyola University of Chicago International Law Review* (2008): 177 y 185-86, J-C. COHEN-KOHLER, L-C. ESMail, and A. PEREZ COSIO, "Canada's implementation of the Paragraph 6 Decision: is it sustainable public policy?", *Globalization and Health* (2007) 3:12 and H.P. HESTERMEYER, "Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines", 11 *ASIL Insight* 28 (December 10, 2007).