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Extra Lives: Access to Knowledge (A2K) vs. exclusive regimes

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Abstract
The ratcheting up of global patent standards, fuelled by technology-exporting countries under the pressure of industry lobbies, erodes access to affordable drugs in the developing world. In response to increasing tensions with developing countries and A2K (Access to Knowledge) advocates, the TRIPS agreement was partially reengineered. As a result, a re-regulation process took place suspending key treaty provisions -article 31(f)-, and erecting a burdensome mechanism for importing generics under compulsory license. Reasonably, more effective policy options are still available.

Keywords
A2K, life-sciences, exclusive rights regimes, patents, generics.

Vida extra: acceso al conocimiento versus derechos exclusivos

Resumen
El aumento de los estándares internacionales de protección de patentes, impulsado por los países exportadores de tecnología bajo presión de los lobbies de la industria, erosiona el acceso a medicamentos asequibles en el mundo en desarrollo. En respuesta a las crecientes tensiones con países en desarrollo y los activistas del acceso al conocimiento, el acuerdo del TRIPS ha sido objeto de algunos cambios. A resultas, se produjo un proceso de re-regulación, suspendiendo disposiciones de dicho acuerdo -artículo 31(f)-, y estableciendo un gravoso mecanismo para importar genéricos bajo licencia obligatoria. Razonablemente, políticas más efectivas están todavía disponibles.

Keywords
A2K, ciencias de la vida, regímenes de derechos exclusivos, patentes, genéricos.

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1. Of patent lords

Health-care and treatment infrastructures in developing countries are costly, long-term, open-ended investments involving significant resources. General access to affordable medicines thus requires efficient procurement policies as well as public health infrastructures (i.e.: trained staff, supplies, buildings, information systems and distribution channels).

Any sound policy incentive to invest in these public policies will be cancelled out if a steady stream of medicines at affordable prices is not first secured. However, the internationalisation of trade-related intellectual property (IP) protection is adding extra difficulties.

The Trade Related Intellectual Property (TRIPS) agreement standardizes the global propertization of intangibles. The first three sections of this text explore its origins (section 1), the feasibility of reengineering its rules through the legal prism of so-called flexibilities (section 2), and the work done in this direction since 2001 (section 3). The last two sections explain the ineffective solution regarding access to *imported* medicines in developing countries (section 4) and, finally, briefly dissect some pro-trade reasonable alternatives (section 5).

Nowadays, the ratcheting up of global IP standards (read exclusive rights regimes) is exacerbating the historical tensions characterising patent protection. Conflicts of values and competing interests are severely confronted in socially sensitive areas (Drahos and Braithwaite, 2002; Ryan, 1998). The relationship of patent protection and access to affordable medicines in the developing world is one of these; here, more reasonable policies are needed to balance public health (rights of citizens-patients) and private property (rights of patent holders) in the field of life-saving or life-extending products.

The Uruguay Round of trade negotiations incorporated IP by sustaining its "trade-relatedness" and, as a result, new global standards of IP protection were established under the Agreement on Trade Related Intellectual Property. However, the provisions of this agreement do not establish "IP-related" public health protection with similar sensitivity. Consequently, TRIPS agreement has been in need of strategic re-engineering from the very first day that it entered into force in 1996.

The agreement is designed to establish minimum protection standards for IP, applying a top-down approach towards harmonisation (Stephan, 2002). Certainly, it is the most far-reaching and comprehensive legal regime concluded in the intellectual property area in history (Correa and Yusuf, 1998: xvii).

Developing countries agreed to negotiate this agreement in exchange for trade concessions on textiles and agricultural products under the complementary (and strong) pressure of US trade unilateralism (Watal, 2001; Okediji, 2003: 819-918). The agreement was in fact negotiated in the shadow of unilateral trade sanctions pursued by the United States Trade Representative (USTR) "diplomacy".[1]

Developing countries such as Brazil, India, Argentina, Cuba, Egypt, Nicaragua, Nigeria, Peru, Tanzania and Yugoslavia were among the most active General Agreement on Tariffs and Trade (GATT) Contracting Parties opposing IP lawmaking in the Uruguay Round; arguing that the multilateral trade system was primarily concerned

[1] 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 (1998: 558-559).

with trade in goods and not property rights in intangibles (Bradley, 1987: 81). However, their initial resistance for a narrower interpretation of the mandate for the Uruguay Round negotiations (Ministerial Declaration of 1986) on this issue broke down in 1988, with the second amendment reforming Section 301 of the US Trade Act of 1974: the so-called Special 301.

Entering into operation in 1989, Special 301 granted USTR the authority to apply unilateral trade sanctions against countries providing 'insufficient' protection of intellectual property. Interestingly, 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 Reports on International Property Rights – IPRs- (Abbott, 1989: 689 and 708-709).

As a result, the original legal framework of WTO law today contains an agreement on trade-related IP protections; and its rules are not only here to stay, but 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 textiles and agriculture) (Commission on Intellectual Property Rights, 2002: 8). Last, but not least, the TRIPS agreement is producing some unforeseen adverse effects in the pharmaceutical policies of the developing world[2].

The negotiations on the side of developed countries were obviously fuelled by the fact that technological and scientific advancement accounts for a growing portion of domestic productivity increases in their economies.[3] However, as Drahos (2001: 13) explains, both developed and developing countries alike were generally in ignorance about its likely effects on information markets.

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, not to develop solutions for key social issues such as access to medicines in the developing world.

It is fair to say, in any case, that finding a proper balance between patents and health is not itself an easy task, as interests and values are at odds in this disputed area of international law and global politics.[4]

Conventional thinking on patents argues that effective patent protection is a prerequisite for research and development, as well as a lever for economic development in general.[5] According to this view, IP friendly environments promote foreign direct investment (FDI) and technology transfer (i.e., foreign technology

[2] On the perverse distributional effects of TRIPS patent protection with regards to pharmaceuticals see, in particular, Benvenisti and Downs (2004: 21-52).
[3] On the evidence that TRIPS substantially amplified the returns to technology-exporting countries since its adoption see Abbott (2005) and accompanying references.
[4] 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 Helfer (2003: 47).
[5] For the first reports produced by global institutions on the interaction between IP protection, FDI and technology transfers see OCDE (1989) and United Nations Department of Economic and Social Development (1993).

licensing, and joint ventures).[6]

Conversely, critical thinking argues that less burdensome mechanisms could alternatively obtain similar outcomes without incurring the social burdens inherent in modern patent systems. Numbers provided by the industry itself tend to bear this out. For example, the figure provided by Pharmaceutical Research and Manufacturers of America –PhRMA- (2011: 2) itself in its 2011 industry profile reached $ 67.4 billion on Global R&D by all private companies in 2010. For that same year, the estimate on global sales by industry-friendly IMS Health Market Prognosis (2011) reached $ 856 billion.

For the critics, in addition, access to affordable medicines in any given society has a significantly more positive impact on development in general than it has on securing high standards of pharmaceutical patent protection and enforcement. (Kremer, 1998: 1137-1167 and Love, 2003).[7]

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, particularly (but not exclusively) regarding access to affordable medicines in the developing world.[8]

2. Flexible rules

As Mancur Olson (1965) explains, small groups tend to be more adept than the general public at organising the ways in which they pursue their interests: their free rider problems and transaction costs are lower. In this sense, the drafting of TRIPS agreement was a trade diplomat driven-process permeated by industry interests from the developed world. As a result, developed countries over-protected the interest of their industries in this agreement.

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.[9] 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 and other developed countries followed suit.[10]

The TRIPS agreement is to a great extent a global regulatory product of the corporate agenda (Drahos and Braithwaite, 2009). 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. (Dutfield, 2003). In the bold words of Susan Sell (*Id*.: 96), twelve corporations made public law for the world.

[6] See Business and Industry Advisory Committee to the OECD (2004).
[7] For a comment on some of these proposals see Baker (2004).
[8] See in particular World Health Organisation - WHO (2006) and UK Commission on Intellectual Property Rights (2003).
[9] In the words of Sell (2003: 4): "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".
[10] For an insightful business case study on the participation of Pfizer in the development of international trade law see Sontoro and Sharp Paine (1995).

The capacity of developing countries to influence outcomes was limited by the pressure of 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 (Drahos, *id.*: 13). Thus, the model of IP protection which originated in the developed world has been transplanted to the developing world through international law.[11]

Therefore, flexibility is seriously needed. The way the TRIPS agreement originally approached development was too simplistic, and based merely on transitional periods. The balancing of patent protection and health protection was envisioned as an issue to be approached by buying time, instead of adapting its rules to the changing levels of development of WTO Members (phase-ins) and linking its compliance to technology transfer. Transitional periods are unconditional by definition and thus merely cover phase-outs, granting developing countries some (limited) time to bring domestic legislation and practices into line.

Generally, WTO members had to implement the TRIPS Agreement at the end of the 1996–2000 transition period. In addition, an extra term was granted until 1 January 2005 in the area of pharmaceutical product patents for certain WTO Members. As a result, these members were allowed to delay product patent protection in areas not protected by their legal systems at the time that the TRIPS Agreement entered into force (TRIPS Article 65.4). These 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.

Finally, a third transition period was granted covering patent protection of pharmaceuticals and exclusive marketing rights that 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 (27 June 2002).[12]

However, transitional periods are inevitably incapable of regulating the complexities of pharmaceutical patent protection in the developing world. Consequently, almost from the very first day of its entry into force, WTO Members have been involved in a complex re-engineering process to adapt the TRIPS disciplines to the health realities of the developing world.[13]

In fact, in 2000, the problem became a public relations disaster for the new WTO, 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 and still open).

In those days, health advocates and public health representatives managed to effectively question the state of affairs of pharmaceutical patent protection in the

[11] On this issue, see generally, Tully (2007).

[12] The Decision of the Council for TRIPS of 27 June 2002, extended the transitions period for least-developed countries under Article 66.1 an additional ten years for pharmaceutical products. The *waiver* was approved on 1 July 2002. See WTO - Council for TRIPS (2002).

[13] 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 Cottier (2006: 779-821), taking as a case of study the patenting pharmaceutical products.

developing world and blamed TRIPS rules in part for the difficulties that developing countries were facing in gaining access to affordable medicines.

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 WTO Members. The world trading system was under pressure on this highly sensitive issue but also had an opportunity to demonstrate its flexibility in the beginning of the Doha Development Round. (Gold and Morin, 2010: 563-587 and 578).

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 (Ehlermann, 2005: 51-75 and 64). In essence, WTO Members entered into a complex re-regulatory learning process.

The sign of the times is clearly captured in the reaction of WTO Members, in April 2001, to the settlement of the highly publicised 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 from the WTO Director-General himself.

The Press Release on this event actually refers to it as a 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" (WTO News, 2001a).

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. However, 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 *statu quo*.

It was in June of 2001 that TRIPS Council had its first special meeting on access to medicines, requested by the African Group. It was also that same month that the US withdrew its WTO complaint against Brazil's pharmaceutical policies in order to convey a change in attitude and to suggest its willingness to adapt TRIPS rules to the health realities of the developing world (WTO – Dispute Settlements, 2001).

The rationalisation of TRIPS rules began in an intense 7-hour session of that special meeting, with interventions from over 40 delegations in June 2001.[14] In that

[14] See the working paper submitted by the African Group and 17 developing countries (WTO – Council Discussion on Access to Medicines, 2001).

session, WTO Members shared some initial interpretations built on the idea of TRIPS inner "flexibility".

In the words of 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 pragmatic legal narrative, the TRIPS Council "reinforced" the security that countries "can use" the available "flexibility" in TRIPS agreement. Furthermore, should any improvements be needed, as "nothing is perfect", these improvements could be obtained during the Doha Round negotiations (WTO News, 2001b).

Access to medicines was onboard the WTO agenda in the Doha Ministerial Conference of Qatar, opening the so-called Doha "Development Round". In fact, the Ministerial Declaration opening the Round had already stressed the importance of *implementing* and *interpreting* the TRIPS Agreement in a way that would support public health "by promoting both access to existing medicines and the creation of new medicines" (paragraph 17).

The first milestone in this process was the Doha Declaration on Public health and access to medicines, adopted by all WTO Members in November 2001. As the current WTO DG himself, Pascal Lamy, recalled at the 5th High-Level Symposium on Global Health Diplomacy, held in Geneva to mark the Declaration's 10th anniversary (23 November 2011), this decade-old WTO Declaration has certainly reinforced health policy choices worldwide (WTO News, 2011).

The key idea underlying this historic instrument is formal recognition that the TRIPS agreement provides for some "flexibilities" that can be used by developing countries to extend state regulatory autonomy with regard to patent protection in the health policy area.

The flexibilities of TRIPS rules recognised 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."

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.*"

From a public policy angle, the Declaration determines that the TRIPS agreement "does not and should not prevent members *from taking measures to protect public health*" (Doha WTO Ministerial, 2001). In this regard, 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 reaffirm the right of WTO Members to use, "for this purpose" and "to the full", those provisions providing with flexibility.

The legality of devices such as compulsory licensing of pharmaceutical generics is thus secured under the new flexibility rationale. The term "compulsory licensing" (CL) did not expressly appear as such in TRIPS agreement but as "other use without authorisation of the right holder" in the title of article 31. In any case, the right of governments to grant CL was made clearer in these terms than under article 5A of the Paris Convention.[15] However, some doubts were producing a chilling effect in pharmaceutical policy- making in developing countries.

Pursuant to the 2001 Declaration, the right to issue CL was reworded in broader terms to avoid any misinterpretation: "each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted" (paragraph 5.b).

In addition, general legal exceptions based on public health crises were also recognised: "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).

In short, as it stands, the 2001 Doha Declaration facilitates pro-health readings of the TRIPS agreement and provides for major (TRIPS compatible) policy space. The Declaration has dramatically increased TRIPS flexibilities on several health patent-related issues. In fact, even well known IP critics such as James Love himself recognise its historical importance: "Basically, post Doha TRIPS is much different than Pre-Doha TRIPS" (Love, 2011).

"Flexibility" is certainly a powerful re-regulatory concept. Once it is generally recognised as a regulatory "valve" to administer a given treaty, creativity in the administration of that treaty may not only increase but rise dramatically. The real meaning of "TRIPS flexibility" is entirely dependent on the political will of those who can authoritatively interpret and waive TRIPS rules through WTO decision making-processes. However, it offers major policy space for pro-health approaches to TRIPS rules.

3. Regulatory fluxes

The 2001 Doha Declaration explicitly 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, the Declaration was unable to give solutions to other issues and mandated the TRIPS Council to make additional efforts in some areas.

One of those areas is the so-called "Paragraph 6 issue", which requires finding a solution to ensure the feasibility of importing generics under compulsory

[15] In the words of Reichman (2009: 248), such a 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. For a history of article 31 see also Gold and Lam (2003: 5-32).

licensing in developing countries with a lack of or insufficient pharmaceutical manufacturing capacity. The legal issue at stake was TRIPs article 31(f) determining that production under compulsory licensing must be "predominantly" for the domestic market.

TRIPs Article 31 (*Other use without authorisation of the right holder*) already grants WTO Members the right to override patents under certain conditions and thus allows ordering of generics from domestic producers. However, article 31(f) also establishes that "any such use shall be authorised predominantly for the supply of the domestic market of the Member authorising such use".

This wording prevented countries without pharmaceutical manufacturing capacity to import generics from countries where the patented pharmaceutical was produced. In addition, by using the expression "predominantly", the export-oriented production was directly limited to an unspecified volume of production.

Most developing countries lack the resources to produce generics and are thus fully dependent on WTO law which allows those countries with production capacity to export them. As a result, the wording of the issue in Paragraph 6 of the 2001 Declaration was unequivocal and imperative in its terms: "to find an *expeditious solution* to this problem before the end of 2002". The Doha Ministerial Conference (2001: par. 17) transferred this controversial question to its ongoing negotiating process.

Thus, within the corridors of the WTO, the issue of developing countries lacking pharmaceutical manufacturing capacity began to be considered in a different light. The 'solution' to the paragraph 6 issue was reached with the so-called "Motta text" (named after Perez Motta, the former Chairman of the TRIPS Council), after a previous proposal was blocked by the United States in December 2002.[16]

The WTO General Council (2003) finally managed to adopt a Decision on the implementation of paragraph 6 of the Doha Declaration on 30 August 2003. In the words of Supachai Panitchpakdi, Director-General 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" (WTO News, 2003).

Adopted just before the Cancun Ministerial Conference, this instrument waives article 31(f) requiring that production under compulsory licensing must be "predominantly" for the domestic market for allowing the import of generics under compulsory licensing in cases of lack of pharmaceutical manufacturing capacity in the territory of WTO Members.[17]

In order to make this *waiver* operational, the Decision created a regulatory structure establishing a notification procedure for both importing and exporting countries planning to trade in generics: (1) notifications by importing WTO Members (notifications of intention to effect specific imports), (2) notifications by exporting WTO Members (notifications of intention to effect specific exports covered by the system) (WTO – TRIPS: TRIPS and Public Health 'Paragraph 6' System, 2005). This regulatory structure allows the import and export of generics on a case-by-case, drug-by-drug, country-by-country basis.

[16] For a comment see generally Abbott (2005: 317-358) and Matthews (2004: 73-107).
[17] In fact, former WTO Director, Supachai Panitchpakdi, described the Decision as 'an historic agreement' (WTO News, 2003).

The 2003 Decision, originally pre-negotiated by the United States, India, Brazil, South Africa and Kenya, helped WTO Members at the Cancun Ministerial Conference (September 2003) to keep the ongoing Doha negotiating process on track. Article 31(f) was not suitable to the social and economic realities of the developing world, and exporting-technology WTO Members were persuaded to waive and substitute it with an innovative new member-driven mechanism.

The solution strikes a complex balance between the requirements of potential importers (mainly in Africa, Asia and America), pressure from potential exporters of generics (such as India and Brazil) and the economic interests of the patent-holders from technology-exporting countries.

The 2003 Decision also establishes that WTO Members may notify the TRIPS Council of their intention not to use the system as an importing country or their intention to use it only in a limited way. Practically all OECD countries have issued notifications in this regard, under the pressure from their 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.

In addition, 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.

The chairperson also attaches to his separate statement a shortlist of guidelines (selected "best practices" from producers) to reduce and minimise product diversion (anti-diversion measures) and thus to ensure market segmentation.[18]

Technically, the 2003 Decision is an interim *waiver* to be applied until the (unlikely) amendment of the article (WTO – TRIPS and Public Health, 2003): the wording of the provision expressly determines that it should last until the TRIPS agreement is amended. In this regard, the WTO General Council adopted a Protocol of Amendment on 2005, once TRIPS Council missed the deadline for agreeing on

[18] See WTO - General Council (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.

the amendment[19]. The instrument, opened to acceptance by WTO Members before 1 December 2007, contains an elaborate article 31bis to be incorporated as an Annex to the TRIPS agreement if accepted by two thirds of WTO Members (General Council, 2005).

By the time this article was finished, only 45 WTO Members (WTO – Intellectual Property: TRIPS and Public Health, 2013) had already accepted the Amendment including the United States -17 December 2005- and the European Communities -20 November 2007- (Council of the European Union, 2007). The difficulties of ratification are explored with great clarity in the EU Parliament debates on this issue. (European Parliament, 2007: par. K.7)[20]

Taking into consideration these difficulties, an unlimited extension to the waiver was finally delivered by a new Decision of WTO Members in 21 December 2007: "The period […] shall be extended until 31 December 2009 *or such later date as may be decided* by the Ministerial Conference" (WTO – General Council, 2007). In this regard, it is reasonable to argue that WTO Members are well aware that the Protocol of Amendment is unlikely to enter into force, at least not in the near future.

Last but not least, the amendment itself is overly cumbersome. African countries, with the support of Brazil and India, proposed an alternative less burdensome amendment but the US opposed it. After the failure of a subsequent "middle ground" solution proposed by EU members, the original text was adopted (Bradford and Lee, 2007: 3). Such a time-consuming and ineffective measure should certainly have been avoided, particularly because the amendment transforms the non-functioning 2003 Decision in treaty law, with all its (self-evident) long term legal implications.

4. Legal "solutionism"

The 2003 Decision was created to constitute "an expeditious solution" for "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector" who faced difficulties in "making effective use of compulsory licensing under the TRIPS Agreement". However, it is fair to say that it makes access to generics in developing countries far from clear.

In fact, there is only one successful compulsory licence under the 2003 Decision to date, involving a generics transaction between Rwanda -Notification of intent to import on 17 July 2007- (Council for Trade-Related Aspects of Intellectual Property Rights, 2007a) and Canada -Notification of intent to export on 4 October 2007- (Council for Trade-Related Aspects of Intellectual Property Rights, 2007b)[21] of 260000 packs of TRIAvir (an HIV/AIDS combination therapy), manufactured by Apotex Inc.

In addition, a failed transaction between India and Nepal was withdrawn in the very first stage of the paragraph 6 mechanism. In September 2007, an Indian

[19] For a complete legal study on the universe of available policy options to tackle this issue see Abbott (2002).

[20] See 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).

[21] The information on the shipment (quantities and distinguishing features) is posted on the licensee's website pursuant to paragraph 2(c) and 2(b)(iii) of the Decision of 30 August 2003. See also Apotex (2014), available on line at: http://www.apotex.com/apotriavir/abouttriavir.asp (Date of access: February 28, 2014).

generic manufacturer applied in India for a compulsory license for three medicines to be exported to Nepal but decided to withdraw the request in India as the Nepal authorities had not granted the compulsory licence to import the medicines, nor had the TRIPS Council been notified of its intention to import under the paragraph 6 mechanism.

Leaving aside the reasons why this transaction was aborted, it is easy to understand why developing countries are repeatedly calling for real-life experiences to be looked at in the Annual Reviews of the mechanism by the TRIPS Council.[22] However, developed countries are not particularly eager to admit that the mechanism is not functioning properly (and thus needs to be simplified). In consequence, developing countries are pushing in the area of determining facts: is the mechanism functioning or not?

Developed countries are acting like the emperor and his new clothes, and buying time in the meantime to negotiate TRIP+ bilateral treaties with key developing countries. It is hard to see how this will not lead to major tensions in the mid-term. It is noteworthy that the Annual Reviews of paragraph 6 mechanism already contain an agenda item with the illustrative title “Any alternatives to the use of Paragraph 6 System to achieve the objective of access to medicines.”

There are some explanations for the failure to use the 2003 Decision. To begin with, advance notifications to the TRIPS Council of the intention to use the procedure leave those developing countries willing to import generics under CL open to pre-emptive political pressures. Thus, a strong political barrier is effectively raised against weak developing countries at the outset.

But the Decision also erects a burdensome member-driven procedure. The very fact that it is member-driven is also one of the critical factors in its failure to function: generic companies are directly excluded from the possibility of using the mechanism to trade in generics, since any global transaction requires a dual authorisation (from both importing and exporting countries) for it to operate.

In short, the mechanism certainly suffers a paradoxical (WTO!) anti-market and anti-trade approach. In essence, the procedure regulated by the 2003 Decision compartmentalises transactions on a case-by-case, drug-by-drug and country-by-country basis through a dual compulsory licensing scheme (Abbott and Reichman, 2007: 921-987). As a result, notifications under this scheme require issues to be determined in advance, such as to whom will the license be extended, what volume, at what royalty rate, and on what grounds. Consequently, there is no automaticity but stronger procedural market segmentation. Thus, the attainment of the economies of scale required to stimulate generic production and competition are inhibited and by extension, so are the inner virtues of international trade.

Market-driven mechanisms are part of the solution, not the problem. In this regard, generics manufacturers are dependent on sufficiently large production to achieve economies of scale. In order to apply for an export-oriented compulsory licence (CL) under the current procedure, generics companies have to be convinced that making use of it will not only be economically viable but also beneficial.

In this sense, it is highly unlikely that the paragraph 6 mechanism will ever provide sufficient economic incentives for generic companies, since authorisations

[22] See i.e. WTO – Council for Trade-Related Aspects of Intellectual Property Rights (2011: par. 56).

are granted drug order by drug order and only upon request by the public authorities of another country.

There are also critical obstacles in place such as, to name just one key example, the condition to produce only the amounts needed to satisfy the requirements of licensees as notified to the TRIPS Council. As Abbott and Reichman (*id.*: 932) explain, the procedure is saddled with unnecessary administrative hurdles that make the export of generic versions of patented drugs neither simple nor expeditious.

The devil is certainly in the details. Notifications must specify the names and expected quantities of the product needed over a specific period of time, the royalty rate that will be paid, and outline the evidence for the lack of or insufficient manufacturing capacity.

It is also important to underline that article 31(h) requires that adequate remuneration be paid to the patent holder. However, the 2003 Decision states that it is the exporting country that is required to remunerate or compensate the patent holder.[23] Requiring the exporting country to compensate the patent holder is equal, in practice, to adding yet another obstacle.

Obviously, the governments of technology-exporting countries have no incentive to promote the export of generic products by their industries when they bear the burden of paying the fee. Certainly, alternative solutions could easily have been designed (Cahoy, 2007: 148-153).

For many, the procedure is designed to make it difficult for countries to issue compulsory licences and to hinder the functioning of domestic procedures. In the words of Stiglitz (2009: 365), "if [trade advocates] wanted developing countries to have access to essential drugs, they should have allowed automatic licences for all drugs except those that are not essential". In this regard, the black letter law produces difficulties that could easily have been avoided by using an automaticity rule.

Last but not least, the 'implementation game' is also a difficult one (Deere, 2008). Potential exporting countries such as Canada, India, Norway, China and the European Union itself have already adopted legislation to implement the Decision in order to enable the production and export of generic medicines under compulsory licences (Hoen, 2009: 36-37). However, some of these domestic regulations have added further administrative requirements which could further hamper use of the Decision. Interestingly, while Canada's Access to Medicines Regime (CAMR), passed in 2004, contains 200 articles, India's implementing legislation consists of a scant 3 paragraphs (Kohler, 2008: 143-172 and 166).

CAMR was the first enabling legislation for the production and export of generic medicines under compulsory licences to developing countries lacking pharmaceutical manufacturing capacity (Elliot, 2006: 94-112). For many, CAMR is considered to be fraught with deficiencies and epitomises the flaws of the implementation game (Cotter, 2008: 177 and 185-186; Cohen-Kohler, Esmail and Perez Cosio, 2007: 12 and Hestermeyer, 2007). However, it is also true that it is the first and only successful compulsory licence under the 2003 Decision to date involving a generics transaction from Canada.

[23] For an analysis on remuneration and its problems see in particular Cahoy (2007: 131-192 and 150).

Developing and developed countries differ in their explanations for why the mechanism is not being used. Interestingly, this issue is so sensitive in social and political terms that Canadian representatives –Canada being the first and only country to export generics under 2003 Decision– have began to pro-actively intervene in international fora in order to give their version of what went wrong in their particular experience.

On 27 October 2010, for example, Canada delivered three interventions related to the review of the mechanism in the WTO TRIPS Council. For Canada, CAMR worked efficiently, effectively and in a timely fashion. The length of time needed to export to Rwanda was not caused by the paragraph 6 mechanism, but instead by other factors. Canada explained that the paragraph 6 mechanism is a member-driven process. As such, it only applies to instances where countries are seeking a generic version of the patented drug.

In this sense, once the eligible importing country (Rwanda) had notified the WTO of its intention to import under the mechanism, the CAMR process (starting with a request for voluntary licences and ending with the granting of a CL) was completed in just over two months. For Canada, in short, the delays incurred in Apotex's export of medicines to Rwanda were "separate" from CAMR.

In this regard, Canada recalled that it took 3.5 years for Apotex to develop the drug, identify a recipient country, secure a supply contract, manufacture the drug and export it. Thus, under this rationale, Canada underlines that it is not a company (Apotex) but rather a country (Rwanda) which is in practice required to use the mechanism in order for it to become operational.

Indeed, this is certainly the case. The major structural flaw of the mechanism is that its functioning depends on the political will of Member States. Alternatively, the 2003 Decision would have been more efficiently designed if the inner rationale of free trade promotion (instead of extra market segmentation and barriers to trade) would have been taken into consideration. This is to say, designing a pro-trade mechanism that takes advantage of the strong economic incentives of potential generics producers and distributors in this area.

The 2003 Decision is obviously not being used. As a result, alternative legal grounds are inevitably beginning to be considered by developing countries in order to avoid taking the path of the paragraph 6 mechanism and the related article 31 provision[24]. For many, article 30 (*exceptions to rights conferred*) still remains an alternative option with regard to compulsory licensing generally.[25]

Interestingly, Belgium adopted a new regulation in 2005 to grant compulsory licenses on legal grounds of TRIPS articles 8 and 30, which respectively allow "measures necessary to protect public health" and limited exceptions to the patentee's exclusive rights (Debrulle, De Cort and Pettit, 2007: 159 and 163).

This is certainly a more effective policy approach, as limitations and exceptions to patent rights function as a critical lever for development. In fact, the issue is already under consideration in implementation measures of the (World

[24] The use of the exceptions clause of article 30 is not foreclosed by the 2003 Decision. See Garrison (2006).

[25] The restrictive interpretation of Article 30 by the panel in the *Canada-Generics* case is not relevant as it was adopted prior to 2001 Doha Declaration, which placed Article 30 in a new interpretative framework. See WTO – Dispute Settlement (2000).

Intellectual Property Organization (WIPO) Development Agenda. The WIPO Standing Committee on the Law of Patents (SCP) has been considering "Exceptions and Limitations to Patent Rights" as an agenda item since 2008. In June of that year, the SCP asked the WIPO Secretariat to establish preliminary studies on “exceptions from patentable subject matter and limitations to the rights, inter alia research exemption and compulsory licenses”.

In 2010, Brazil proposed setting up a working programme in order to hold a wide-ranging and sustained debate on this issue with a view to drawing up a WIPO manual of exceptions and limitations. (WIPO – Standing Committee on the Law of Patents, 2010).

However, tensions are running high. For example, Delegates at the 18th session of the WIPO Standing Committee of the Law of Patents (SCP) between 21 and 25 of May 2012 were unable to reach agreement on the committee’s future work programme, as a result of the strongly diverse opinions regarding work on agenda items such as patents and health, exceptions and limitations to patent rights, quality of patents and technology transfer.

Positions between Group B (industrialised countries) -particularly United States and EU- and developing countries were irreconcilable when a joint proposal on this future programme was tabled by the African Group and the Development Agenda Group.

In addition, recent US judicial practices regarding CL permanent injunctions are already being considered by developing countries as potential new alternatives for extending policy space with regard to export-oriented pharmaceutical CL.

In this regard, compulsory licences granted under Part III of the TRIPS (enforcement), and therefore those based on article 44 (injunctions), are subject to a different regime from that of the compulsory licences granted under the procedures of Part II (standards), as the former are not subject to the restrictions existing for article 30 and 31.

As a result, in the chessboard politics of global IP standards, the African Group/DAG made a strategic move in 2011 by requesting that the International Bureau of WIPO “organise a technical workshop on state practice involving the compulsory licensing of medical technologies, including the application of TRIPS Articles 30, 31 and 44” (WIPO- Standing Committee on the Law of Patents, 2011).

The balance between exclusivity (patent rights) and public interest is generally considered to be provided through the subtle interplay of articles 30 and 31. Thus, it is through this interplay that TRIPS-consistent policy options are conventionally defined nowadays, as article 30 details substantive criteria for exceptions to exclusivity, and article 31 contains a list of procedural requirements to limit that exclusivity. However, article 44 also potentially provides further flexibility with regard to permanent injunctions.

In fact, some US cases regarding CL injunctions with export-oriented elements are already being tracked by developing countries as a result of a landmark US Supreme Court judgment on CL in 2006: *eBay Inc. v. MercExchange.* In this high-profile case, in which MercExchange alleged that eBay had violated its patents and requested that the Court grant a permanent injunction, the Supreme Court held

that the plaintiff had to satisfy a four-factor test based on equity before a court could issue a permanent injunction in respect of compulsory licences.

For the court, this four-factor test for permanent injunctions is necessary on the grounds of principles of equity, namely criteria such as (1) having suffered an irreparable injury, (2) inadequate legal remedies (i.e.: compensation) being unable to compensate the injury, (3) balancing the "hardships between the plaintiff and defendant", and (4) not disserving the public interest. Following this judgment on the issuance of compulsory licences, there have been several such cases in the United States (Mace, 2009: 233-266 and Cotropia, 2008: 557-583).

Thus, for example, in the case of *Edwards Lifesciences v. CoreValve* in 2011, a compulsory licence was granted in the US for manufacturing an export-oriented medical device to treat aortic valve stenosis, without being affected by the restrictions of TRIPS article 31 on exports under a compulsory licence and the paragraph 6 mechanism.

The African Group/DAG, and particularly India, are already benchmarking those judicial experiences in order to obtain further policy space for their export-oriented generic industries outside the procedures of the paragraph 6 mechanism (WTO – Council for Trade-Related Aspects of Intellectual Property Rights, 2012: par. 221-223).

Such a policy approach is probably more useful for health policy formation than focusing on article 31(f) and the unpromising paragraph 6 mechanism. It is reasonable to argue that, since TRIPS agreement entered into force, enough time and efforts have been dedicated to article 31(f) by developing country health and trade officials, NGOs and A2K advocates. Any cost-effect analysis would suggest finding a more simple and automatic procedure to avoid the ongoing and exhausting allocation of resources to the multiple (global and domestic) battles related to this issue.

The high transaction cost involved in the paragraph 6 mechanism is clearly described by Sell (2009: 87): "even when single battles are won with regard to a specific medicine needed by any given country, the whole process must then be wound up and started over again for the next drug in the next country, with all the legal, economic, and political costs to be repeated". The resulting "patchwork quilt of territorial measures and countermeasures", as she recalls, increases the transaction costs of all the stakeholders while not appreciably stabilising access to essential medicines for citizens in poor countries as a whole.

Political science literature offers some interesting insights on why the 'solution' contained in the 2003 Decision was made. For Gold and Morin (2009), for example, NGOs and developing countries became trapped in consensus-seeking rhetoric, making it preferable for all parties involved to agree on adopting a flawed mechanism, and thus save face in a particular momentum. In this regard, the Decision certainly provided for a 'media-visible solution' of a highly 'symbolic issue' (Hudec, 1996:9-15).

According to their narrative, the process of rhetorical action led to adopting an *unworking agreement* in the sense of an arrangement made of 'sham standards', "permitting a claim to the *de jure* existence of a mechanism and relieving pressures for the continuation of the debate as previously framed". Thus, the authors sum up why the whole process went wrong in the following vein: "[w]hen consensus-seeking,

mistrust, and rhetorical action are combined, when actors are unwilling to suffer reputations costs and unprepared to trust each other, only an unworking agreement having the appearance of consensus can free them from their collective entrapment" (Gold and Morin, 2009: 563-587 and 580).

Certainly, by rendering the 2003 Decision unworkable, technology-exporting countries and their industries obtained a public relations (PR) success without the need to incur the foreseeable reputational losses associated with insisting on restricting, for example, its coverage to a limited number of products and/or diseases. For Hoen (*id.*: 36-37 and 38), according to this line of reasoning, the Decision is a textbook example of a compromise with little practical use: "at the end of the day, the objective was to reach an agreement –any agreement– without regard to the effectiveness of the compromise".

The WHO Commission on Intellectual Property, Innovation and Public Health – CIPIH (2006: 120) had already predicted these problems and in fact recommended that the effectiveness of the Decision needed to be kept under review "and appropriate changes considered to achieve a *workable solution*, if necessary".

Interestingly, generic producers kept a very low profile during the 2003 Decision negotiations. Shadlen (2007: 576-577) sheds some light on this issue, as her interviewees working with the generics industry explained their preference for dedicating efforts to other policy issues, as they considered the whole procedure to be a predictable failure.

For Pugatch (2006: 257-274 and 270-271), the 2003 Decision closed the door on further contention over the legitimacy of the TRIPS agreement. In his words, IP owners had learned the lesson of PR mistakes with regard to access to medicines in the past,[26] and thus adopted a proactive, rather than defensive, strategy: for the industry, it was politically necessary to conclude negotiations in a manner that would be perceived as beneficial to least developed countries. On the other hand, by signing the 2003 Decision, developing countries were essentially declaring that TRIPs rules "no longer obstruct efforts to promote public health."

To summarise, the 2003 Decision is not functioning enough efficiently to facilitate access to generic medicines in developing countries lacking pharmaceutical capacity. Some argue that the paragraph 6 mechanism is equally effective when used as when it is not being used, since it functions both as a deterrent (threat of compulsory licensing) and a negotiating chip (promotion of voluntary licensing) with regard to licences. However, such a conclusion is at best questionable, as the legal departments and lawyers of global pharmaceutical companies are well aware of the scant use of this mechanism.

Consequently, it is reasonable to consider that it is generally the post-Doha TRIPS scenario, and particularly the 2001 Doha Declaration (not the 2003 Decision), that has critically transformed the original *statu quo,* in which developing countries and pharmaceutical companies now negotiate their deals.

[26] Particularly, the legal challenge (February 1998) in the running up to the Doha WTO Ministerial Conference by 39 drug companies against the government of South Africa, alleging that the Medicines and Related Substances Control Amendment Act of 1997 violated TRIPS and the South African Constitution.

In this sense, it is generally recognised that the 2001 Declaration has critically promoted the negotiation of voluntary licences between patent holding companies and their generic manufacturing counterparts under both the threat (by generic companies) of a request for a compulsory licence or (by public authorities) of the issuance of a compulsory license (Reichman and Hasenzahl, 2003).

In addition, the 2001 Declaration as well as the WTO general discourse on TRIPS flexibilities are also being used by health authorities in developing countries as leverage in their price negotiations *vis à vis* pharmaceutical patent holders. In practice, the Declaration is functioning as a bargaining chip for governments to alternatively negotiate brand-name price reductions subject to issue of a compulsory license.

For some experts, the use of compulsory licensing is limited. Certainly, as Attaran (2003: 743-780) recalls, no generic medicines, or practically none, have been manufactured this way in the 90s, in fact only a single (and powerful) middle-income developing country, Brazil, succeeded in doing so. However, things are gradually changing. Beneath the surface, in the words of Reichman (*id.*: 249-250), health Ministries quietly began to use the threat of compulsory licences to rein in the prices of selected medicines, particularly AIDS drugs. As these negotiated deals are often kept secret, the surface calm appears more assured than it really is.

Interestingly, an authoritative case study on the use of TRIPS flexibilities, for the treatment of AIDS between 2004 and 2008, documented 65 formal statements by developing countries authorising the procurement, import and use of generic medicines (Hoen, *id.*: 59-60). In addition, as Hoen et alia (2011: 15) recall in a later study, 26 out of 32 LDCs authorised generics imports with express reference to paragraph 7 of the 2001 Declaration (delaying the granting and enforcing of patents on medicines until 2016).

Therefore, it is reasonable to conclude that the 2001 Declaration, as well as the institutional discourse on flexibilities, has been of great use for the reinforcement of both the legality and legitimacy of public health policies based on measures such as CL on pharmaceuticals. The health ministry from Brazil, for example, has been among the most successful in using compulsory licensing threats to obtain major concessions by brand-name companies.

In short, governments are making companies negotiate price reductions under the threat of issuing a CL but also generic companies are directly negotiating voluntary licences with patent-holding companies under the threat of requesting a CL. These negotiations are being pursued without the need to use the paragraph 6 mechanism.

However, it is important to underline that not all developing countries could obtain similar success by pursuing these strategies. Inevitably, as the procedure of 2003 Decision to import generics under CL is not delivering, CL threats by developing countries are only credible when they are backed by a burgeoning local generics industry (read China, India and Brazil).

Finally, as Benvenisti and Downs (2004) suggest, price breaks under CL threats should be considered more as isolated victories, materially important in the short term but “institutionally irrelevant in the long term". In this sense, the only real victory is the availability of cheap quality drugs in developing countries as a result of a thriving global generics market pushing prices down globally; and the procedure

contained in the 2003 Decision is certainly not providing such result. In consequence, we see policy solutionism (failure to fully analyze a problem before offering a policy to solve it),[27] at best.

5. Lost in translation

Fortunately, the 2003 Decision is not the only road to facilitating access to medicines in the developing world. The TRIPS agreement permits major flexibilities to balance public health and private monopoly rights (patents) other than importing generics under CL by developing countries lacking pharmaceutical production capacity.

In this regard, WTO Members are allowed to adopt complementary measures that may facilitate access to medicines, as set out in articles 7 and 8 of the agreement, and explicitly recognised by the health-related WTO Declarations and Decisions.[28] In summary, as Anand Grover, the Special UN Rapporteur on the right to health (2009) recommends, developing countries may adopt a variety of measures to make full use of TRIPS flexibilities:

- Adoption of the principle of international exhaustion and provision for parallel importation with simplified procedures.
- Application of pro-competition measures to prevent the abuse of the patent system with regard to access to medicines.
- Incorporating all possible grounds upon which compulsory licences may be issued.
- Providing straightforward, transparent procedures for rapid issue of compulsory licences.
- Incorporating both Bolar (early working) and research, experimental and educational exceptions.
- Establishing liberal pre-grant, post-grant opposition and revocation procedures, etc.

The existence of enabling legislation, as mentioned above, is critical in this respect. Suitable legal provisions should be enacted beforehand in order to use these and other TRIPs flexibilities in domestic law and policies. As WTO rules and acts are not self-executing, it is essential that adequate provisions be enacted in domestic laws in order to enable developing countries to make use of flexibilities.

However, as Musungu recalls, the major problems here are a "widespread lack of clarity about the options available, coupled with the lack of local legal and technical expertise for incorporating and implementing TRIPS flexibilities in national law and policy".[29]

With regard to CL in particular, for example, it is crucial to establish straightforward, simple and clear decision-making processes as well as domestic provisions which will avoid its suspension as a result of an appeal by the patent

[27] See Anonymous (2013: 2). From the solutionism trend in the technological area see Morozov (2013).
[28] See generally Correa (2010).
[29] See Musungu and Oh (2005: 119-120).

holder.[30] In addition, domestic royalty rates are also an issue of concern as there are no general binding rules on the matter.

Voluntary licence rates generally set royalty rates from 4 to 5 percent (Mayharduk and Rimmington (2009: 323-350). In turn, the WHO-UNDP Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies (Love, 2005) suggest royalties from 0 to 6 percent of the price charged by the generic competitor. In practice, this lack of clear-cut recommendations results in developing countries authorising CL with rather different royalty rates nowadays.

Precise legal criteria on this issue would be of major importance. Predictability in setting the remuneration or compensation required by Article 31(h) is an imperative for improved functioning of generic markets.

Developing countries have to adopt adequate legislation for making the most of TRIPS flexibilities. This is particularly relevant for export-oriented generics producers. In this regard, it is useful to recall that, before 1995, developing countries with exporting generics manufacturers such as India, Brazil, South Africa, Singapore and China engaged in a robust trade in generics.

Thus, many 'pre-TRIPS' drugs entered the market in generics-manufacturing countries, and are still produced and exported as generics (Hoen, *id.*: 36-37). As a direct result, many developing countries are nowadays importing generic medicines from these export-oriented producers.

However, new developed drugs are likely to be patented in multiple jurisdictions today and to be subject to at least 20 years of patent protection in all WTO Members but LDCs (until 2016). Obviously, the rationale of patent protection requires granting patent holders exclusive rights to produce and sell their products and thus, inevitably, restrict global trade in generics for those newly discovered medicines.[31]

In consequence, as transitional periods are ending, the sources of new generics from these export-oriented producers are in danger of drying up, and thus limiting the pipeline of generic drugs for developing countries (Correa, 2004).

Technology-exporting countries and brand-name pharmaceutical industries tend to concentrate their pressure on IP infringement in emerging economies and middle-income developing countries. In this regard, not only their potential shares of the pharmaceutical market, but also their capacity to export generics, make these countries global targets for patent enforcement (bilateral TRIPs+ treaties, etc).[32]

However, strong patent protection for new pharmaceuticals in these countries risks adversely affecting the sources of export-oriented generic production. If these sources are impaired, not only will emerging economies and middle-income developing countries have less generics suppliers for both old and new medicines, but also so will LDCs in general (Hoen, *id.*: 62).

[30] In addition, when compensation is appealed, it would also be useful to place the onus on patent holders to disclose the economic data to justify claims of inadequate royalty rate in order to discourage unjustified claims from patent holders. See Musungu and Oh (*id.*: 67).

[31] See generally, Scherer and Watal (2001) and Mrazek (2002: 43-50).

[32] Although these economies only represent today approx 5% of the global pharmaceutical market, the opportunity to increase pharmaceutical sales in emerging economies is rising fast as the size of their markets is growing. The GDP of the so-called E7 emerging economies (China, India, Russia, Brazil, Mexico, Indonesia, Turkey) is expected to triple by 2020, compared to only a 40% increase in the G7 countries (Price Waterhouse Coopers, 2007:3).

Therefore, alternatives have to be seriously considered. One of the most interesting new ideas under the current legal *statu quo* was recently put forward by Jerome Reichman (UNCTAD last October) by suggesting the creation of loose trade agreements between developing countries (as long as they involve at least an LDC) to establish a regional pharmaceutical supply centre in one LDC member country (exempted from patent protections until 2016) and to re-export generics drugs imported under double compulsory licenses throughout the entire group of Members.

Importing and re-exporting generics among participants is not possible but pooled procurement with separate deliveries, by developing country, would certainly be an option. Pooling several CL under such a scheme could probably give producers sufficient scale to justify the investment in producing generics for export to these countries and even setting up production in one of these countries.

This initiative could also be an opportunity to help developing countries build regional manufacturing capacity and thus satisfy the technology transfer provision of TRIPS agreement. In this regard, ministers could offer incentives to patent holders to set up a regional factory, supervise production quality, and supply the member states from that facility. If the patent holder declined the offer, generic exporting countries such as India, Brazil or China could be approached.

The scheme would also amplify the bargaining power *vis á vis* the industry, as it would allow health ministers, acting jointly, to hold their bundle of compulsory licenses and go to the original patent holder and offer the possibility of supplying the entire regional market, if the required drugs were offered at affordable prices. Taking this road instead of issuing individual CL also cancels out the risks of playing alone against the global pharmaceutical lobby.

Under this pooled scheme, it would be more difficult to threaten a developing country successfully with domestic lawsuits. In addition, developing countries could in any case, also pool the costs of defending themselves.

Notwithstanding anything to the contrary, the *statu quo* is not an option. In this regard, the measures taken so far in the 2003 Decision are not proving sufficiently effective to facilitate pro-health pharmaceutical policies for improving access to medicines in the developing world.

WTO Members have been involved in an open re-regulatory process in the health area since the Doha Declaration (2001). However, regulatory structures such as the 2003 Decision are at odds with the inner functioning and rationale of the multilateral trading system.

Alternatively, (TRIPS-compatible) market-driven solutions need to be explored, and ensuring global generic competition is one such solution. In this respect, the multilateral trading system could make a better contribution by leaving aside bureaucratic controls and market segmentation and concentrating on what it does best, namely, promoting market formation on a global scale.

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