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PATENTING DRUGS FROM 1ST JANUARY 2005: IMPLICATIONS AND PROBLEMS

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Abstract

January the 1st 2005 is a very important deadline for the policy on patented drugs in developing countries: implementation of the agreement concerning paragraph 6 of the Doha Declaration is going to be put into practice, with all its controversial organisational procedures. The 2001 Doha Declaration represented a step forward the acknowledgement for the importance of public health and the rights of WTO member states, under emergency conditions, to adopt all the necessary flexibilities of Trade Related Aspects of Intellectual Property Rights (TRIPS) in order to protect public health. Among these flexibilities, compulsory license is the tool for overriding patents by producing generic versions of medicines, thus reducing the price of patented drugs too. But compulsory license is fully exploitable by those countries with pharmaceutical manufacturing facilities, leaving the majority of Least-Developed Countries incapable to use it. The required procedures seem to be very complex and cumbersome and are likely to be practically unfeasible. The pharmaceutical industry proved very powerful in defending its interests from the emerging generic producers of developing countries. Meanwhile, the United States, in particular, is going to sign several bilateral commercial agreements including more stringent provisions for TRIPS than the international standards, which will reduce the spirit of Doha Declaration to a mere out of fashion commitment.

Introduction

Starting from January 1st 2005, something is going to radically change in resource-constrained countries for what regards their policy on patented drugs. In fact, from that date, countries like India, Thailand and Brazil will be expected to entirely apply the rules on protection of patented pharmaceuticals, as signed within the framework of the World Trade Organisation (WTO) Agreement. This deadline is postponed to 2016 for the so-called least-developed countries (LDCs)1, but, despite that, some relevant consequences will occur in their capabilities to procure the corresponding generics of patented drugs2. And the so much publicised agreement of 31st August 2003, laboriously reached eighteen months after Doha Declaration, will be tested, as far as its controversial procedures are concerned.

How is it working now?

The Agreement on the Trade-Related aspects of Intellectual Property Rights (TRIPS), which constitutes one pillar of the WTO, requires all member countries to adhere to minimum standards of intellectual property protection (thus including pharmaceuticals as innovative inventions). Although the Agreement had been first signed in 1994, becoming operational in 1995, developing countries (DCs) could benefit of a waiver for applying it. They were in position to utilise a transitional period until January 2005, during which they were expected to modify and harmonise their domestic legislation according to international rules and obligations (Stefanini 2000). Indeed, some countries had overzealously introduced some restricting elements earlier than requested, thus missing the benefits of the transitional period (DfID 2003)..The World Health Organisation (WHO) itselfecommended to all Developing Countries to fully exploit the flexibilities provided by the TRIPS Agreement (WHO 2003). Actually, since its birth the TRIPS Agreement suffered adverse criticism regarding public health implications; it is generally acknowledged that the incentive for making DCs to accept such an inconveniently binding Agreement was the promise for greater access to western markets of their manufactured goods and agricultural products (Sun 2002).

The TRIPS Agreement's 73 articles cover basic principles, standards, and use of patents, enforcement and a set of other subjects (WIPO 1997). The key requirements for pharmaceuticals are included mainly in four articles (WHO 2001):

- article 7, specifying that "…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…"; this article has generally been interpreted as the promise of foreign direct investment and technology transfer to developing countries in return for becoming signatories to the TRIPS Agreement (Bartelt 2003);
- article 8, which acknowledges that "...members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health (...), to promote the public interest in sectors of vital importance (...) *provided that such measures are consistent with the provision of TRIPS Agreement*..." (the added italics intends to underline the different interpretability of the concept of "consistent measures");
- article 30, which highlights that "...members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions *do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner*..."(here, the added italics wants to point out another area of potential dispute);
- lastly article 31, which handles the matter of other use without authorisation of the right holder. This article is the one giving way to the *compulsory license* - though not explicitly mentioning it. The compulsory license enables a competent government authority to license the use of an invention to a third party or government agency without the consent of the patent-holder, in cases of extreme necessity.

Therefore, according to what the previous articles state, the primary objective of the Agreement apparently seems to be the protection of the public interest, rather than the private interest of the patent owners.

However, this shallow impression fades away immediately after reading the specifications contained in article 31, specifying the limited circumstances for the use of compulsory license.

Compulsory license

Compulsory licensing is a legal procedure that allows governments, in case of national emergencies or other circumstances of extreme urgency, to commission someone else to produce the patented product without the consent of the patent owner. In overriding patent rights, it allows to produce generic medicines, whose competition with the patented ones results ultimately in a decreased price and increased availability of drugs. In the pharmaceutical sector, the option for using the compulsory license has ever represented a leverage to negotiate a lower price from the patent-holder industries: this makes it a powerful tool in the hands of governments, that are seldom forced to use it practically. This was the case of Brazil government, that in summer 2001 obtained a substantial price decrease by Glaxo industry for some anti-retroviral drugs; also the US government, in the anthrax crisis of October 2001, advocated the use of compulsory license on the patented drug Ciprofloxacin, in order to have it at a lower price by Bayer (Fink 2003).

Obviously, pharmaceutical industries look at the possibility for a government to issue a compulsory license as a threat for their own interests and try to limit the legal framework of its use or to restrictively interpret article 31 of TRIPS Agreement that allows it.

A first paragraph of Article 31 requires that a reasonable period of time is allowed to negotiate a voluntary license with the right holder on the basis of commercial terms, though this requirement of prior negotiation can be waived in the event of a national emergency. Besides, whenever a compulsory license is awarded, an adequate remuneration for the patent holder is expected to be paid by the government.

But the true limitation that heavily reduces the scope of compulsory license is represented by the requirement that the production of the generic version of a patented drug under a compulsory license "...*shall be authorised predominantly for the domestic market of the Member authorising such use*". The term "predominantly" implies that at least the 51% of the production must be used in the producing country: under this scenario, the "non-predominant" share (49%, if not less) would be available to supply other countries. This may not be enough for their needs: moreover, it would be necessary the same problem of public health be concurrently present in more countries (of which at least one with good manufacturing capacities), which is not always the case.

So, a country with all the required technology, or hosting pharmaceutical industries capable to produce good-quality generic drugs in a sufficient amount to fulfil an increased demand, can issue a compulsory license in case of a national emergency or any other serious event threatening public health (for example, the HIV/AIDS pandemic, whose affected people live mostly in developing countries) (UNAIDS 2004). However, only few DCs can be part of this group: China, India, Brazil, South Africa and few more.

But the majority of poor countries will not be able to use compulsory licenses to produce their own medicines because they lack the capacity to do so, nor will they be able to use a compulsory license to import medicines, because those medicines must be produced predominantly for the domestic market. If they could do it, it was only for the transitional period in which TRIPS regulations were not yet incorporated into their respective legislation. This is going to happen starting from January 2005 for the DCs (including those with an effective manufacturing capacity).

How to solve this dilemma, then? This was the difficult task assigned to all WTO Members at the Doha Declaration.

The Doha Declaration

The 4th Ministerial Conference of the WTO took place in Doha, the capital city of Qatar, in 2001 and was a (first? isolated? ephemeral?) breakthrough in international discussion on TRIPS and access to medicines (T'Hoen 2002). Generally, Doha Declaration is associated to an extraordinary success for the African Group, who arrived at the Conference as a solid, united group, bringing the shared concern of the serious public health implications of TRIPS. Though the importance of intellectual property rights for innovative medicines was not debated during the Conference, for the first time a word was spoken in an official forum that acknowledges the potentially negative effects of TRIPS for public health in DCs (Balasubramaniam 2002). The eventual adoption of the Declaration on TRIPS and public health consequences was the successful outcome of a carefully elaborated strategy; the Declaration was adopted by consensus, on the basis of last minute compromise and a delicate balance of wording (Correa 2002). Among other things, the Declaration states that "...TRIPS Agreement does not and should not prevent Members from taking measures to protect public health (...); 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" (WTO 2001).

The introduction of flexibilities in the adoption of TRIPS by DCs, the acknowledgement of the Members' right to determine what constitutes a national emergency, the extension of the transitional period for the LDCs before introducing TRIPS into their national legislation are all important - as well as unexpectedly achieved - results (or perhaps allowances by rich countries, in particular by the United States, still shaken by the terrorist attack of September 11th). In particular, paragraph 5 of the Declaration employs the expression "compulsory license" - which is not mentioned in the TRIPS Agreement itself - as an opportunity for any WTO Member, not even limiting the ground to grant it: therefore, each Member "has the right to determine what constitutes a national emergency or other circumstances of extreme urgency" where compulsory license can be utilised. In paragraph 6 a delicate issue is addressed: how can Members lacking manufacturing capacity make effective use of compulsory license, since article 31 of TRIPS prescribes the predominance of the domestic market for generic drugs produced under this procedure. No decision is reached at this regard, but the Declaration requests the Council for TRIPS "to find an expeditious solution to this problem before the end of 2002".

Negotiations start immediately after, but they show from the beginning the ideological distance separating the opposite positions of the African Group and the developed countries in search of a viable solution for the pending paragraph 6 (Oxfam 2002a): a warning sign of the difficult effort for reaching an acceptable compromise.

The debate following Doha Declaration

Among the different proposals discussed as a solution to paragraph 6 of Doha Declaration, two in particular raised major interest (Matthews 2004). One supported a broader interpretation of article 30 of TRIPS Agreement, in the sense to authorise the parallel import (that is the importation of a product from a country where price is more convenient) of patented public health related products by developing countries in order to fulfil unmet public health needs. The other one supported a possible waiver or amendment to article 31, in particular the paragraph concerning the aspect of using a drug produced under compulsory license predominantly for the domestic market. The second option, however, could not be so "expeditious" as the Doha Declaration prescribed, since it dealt with a substantial modification of the signed agreement.

But the major difference between the two proposals was another one: the former, supported by the African group, India and Brazil, could make poor countries to have a quicker and simpler access to generic drugs, with very few procedural arrangements. The latter, supported mainly by the United States, implied the introduction of strict protection measures against reexportation and drug diversion, and a limited number of diseases for which compulsory license could be granted.

The failure of negotiations of Geneva, in December 2002, heavily criticised by the civil society, NGO and activists worldwide (MSF 2002, Oxfam 2002b), was primarily due to the uncompromising position of the United States - the only member to reject the draft presented -, but also the European Union (EU) fell victim of its own uncertainties and ambiguity (similarly to Canada, European countries appeared to exert aggressive internal controls designed to limit pricing power of patent holders, with external policy aimed at protecting patent rents from developing countries) (Abbott 2003). For its part WHO, although encouraging countries to make use of compulsory licenses, it remains prisoner to an opaque method of operating and an outdated view of its role (Bulard 2000), often ignoring the legal mandate of being the international governmental agency responsible for global health (Velasquez 2003). And in one of its editorial, The Lancet asked with provoking intention "whose interests does the WTO serve?" (The Lancet 2003), pleading for a fresh round of discussions.

New consultations started again (Moran 2003), trying to reach a satisfactory solution before the WTO Conference of Cancan in September 2003 (MSF 2003). The Cancun Conference will prove a failure, testifying the shortcoming of WTO, but an agreement will be signed few days before the Conference opening and unreasonably acclaimed as another success for the African Group and the "party" of negotiations at any cost.

The agreement of 30th august 2003

International reactions to this agreement were very different, if not opposite, reflecting the different perspectives of the protagonists. The EU Trade Commissioner, Pascal Lamy, claimed the "crucial demonstration that the Doha Development Agenda is more than just fine words", the WTO general director Supachai Panitchpakdi defined it "a historic agreement, which proves once and for all that the organisation can handle humanitarian as well as trade concerns"; the president of the International Federation of Pharmaceutical manufacturers called it a "balanced agreement"; but the reaction of the most relevant NGOs engaged in this challenge was very harsh, talking of "betrayal, disappointment, cosmetic deal" (EPHA 2003, BBC news 2003).

The details of this agreement are not much different from previous proposals, and, particularly, is extraordinarily similar to the proposal of December 2002 - presented, discussed and rejected - about the waiver to article 31 of TRIPS. According to the agreement, a country without drug manufacturing capacity (hereafter the "importing country") will be allowed to grant a compulsory license (in case of national emergency) and to commission to another country (hereafter the "exporting country") the generic version of the needed drug, no longer bound to be predominantly for the domestic market. However, the whole procedure is far from being simple and straightforward, because it requires a good number of pre-conditions to be fulfilled (Matthews 2004).

First, the importing country - theoretically any WTO Member, practically those identified as LDCs - has to seek a voluntary license from the patent holder on reasonable commercial terms. If this is not possible, the importing country must then assess its generic industry's capacity to produce the medicine locally and notify the WTO with a detailed justification of the decision to grant a compulsory license. The importing country must then notify a potential producer, which must in turn seek a compulsory license from its own government on a single-basis country. The importing country, ultimately, must adopt all the arrangements to prevent re-exportation or any diversion of the drugs to other markets (though it is unclear what the consequences of non-compliance will be). Similarly, the exporting country must take measures to prevent trade diversion: only the amount necessary to meet the needs of the eligible importing country may be manufactured; products produced under the license shall be clearly identified through a special shaping and colour of medicines or a different packaging; before shipment begins, the licensee shall post on a website information on the quantities being supplied to each destination and the distinguishing features of the product; finally, the exporting country has to notify the TRIPS Council of the grant of the license, including the conditions attached to it (Chandrasekhar et al. 2003).

How it will work starting from 1st january 2005

It is amazing that at the end developing countries agreed to a decision so restrictive and unworkable and with cumbersome and complicated procedural arrangements to apply; and even more surprising are the similarities with previously rejected drafts. It may be possible that reaching an agreement before the Cancun WTO Conference could represent a good will sign, preparing for tougher discussions and challenges already on the Cancun agenda. Or possibly the negotiating shrewdness of rich countries (and the negotiate fatigue of poor countries!) made the deal to appear a good bargain after a long period of frustrating discussions and unsuccessful proposals. Even more important, it is worthy to observe that, by signing the deal, DCs and LDCs essentially declare that the TRIPS agreement no longer obstructs efforts to promote public health and access to medicines.

After reaching this agreement, the implementation of paragraph 6 of the Doha declaration is going to be much more captious and burdensome for the African countries and definitely less desirable for the generic products industries, starting from 1st January 2005.

In fact, in those countries where the TRIPS domestic legislation is not yet in place (the LDCs, until 2016), importing a generic version of a patented drug will not require a compulsory license. However, this is necessary for the exporting country, since the majority of DCs with manufacturing capacity are in the group whose deadline to comply with TRIPS regulations is 2005; but in future it is not unlikely that two compulsory licenses will be needed, from both the importing and the exporting country (Oh 2003). Rumours are spreading that some Indian industries are planning already to open branches in Bangladesh or other LDCs (Matthews 2004).

Besides, concerns remain that the added costs associated with altering packages, pill size, shape and colour will have a detrimental effect on the final production cost (and, ultimately, on the availability of essential medicines in DCs). All these terms and conditions may act as a disincentive or a barrier against the use of this agreement. In particular, a generic manufacturer would have to be convinced that it would be convenient and viable to accept an order from a LDC for producing a generic drug, considering not only the administrative burden associated with the procedural arrangements, but also the cost implications that undermines that crucial element for reducing prices embodied by the scale-economy. This depends on large production (and large enough orders, not necessarily guaranteed, for instance, in the antiretroviral scaling-up policies of LDCs) to make business attracting, while the trade diversion measures of differentiating the batches may prevent this from happening. So, the potential competition among generics producers, envisaged as a tool to reduce medicines prices (patented drugs included), is seriously under threat (Oxfam 2002c). Not to mention that notification to the WTO and TRIPS Council scrutiny of the documents attached to the compulsory license will results in lengthy delays for the consignment of the drugs.

In short, after dropping the insistence to cover only few diseases under paragraph 6 solution and after abandoning the attempt to limit eligibility of countries having access to this solution, the United States (and Big Phrma) achieved the same outcome, by rendering the whole agreement cumbersome and unworkable!

Just a matter of patents?

Perhaps, not all the problems related to health care access (one third of the global population is estimated not to have any access to essential drug treatment) (Quick 2002) are due to patents and intellectual property rights: some badly required improvements are needed in the procurement and distribution systems, in the prescribing patterns and in patients' compliance. Probably, as a document by WHO states, "...some reasons are well known and include inadequate financing and poor health care delivery (...). The total pharmaceutical expenditure is linked to the economic development level of a country and tends to increase only when GDP increases" (WHO 2002a). Another (debatable) opinion was that "the extreme dearth of international aid finance, rather than patents, is most to blame for the lack of antiretroviral treatment in Africa" (Attaran et al. 2001).

Concurrently to the challenge between supporters of public interests (the basic right for health care) and those of private interest (property rights), another match - though not so striking - was being played in the same arena: the opponents were the big pharmaceutical industry (Big PhRMA) and the emerging generics industry. Their competition is becoming more and more inflamed: though the developing countries market yet represents a small portion of the global share, the campaign for making patents more flexible is a very sensitive field for both sides (Pugatch 2003). Nothing is given for granted, nothing is left untried, including, perhaps, a concern for humanitarian, moral or philanthropic issues, which openly clashes with the (obvious) primary objective of maximising profits, pursued both by established Big PhRMA and new-comers Cipla, Hetero or Ranbaxi.

Finally, we should not forget that of the 300 drugs listed by WHO on its 12th Model List of Essential Drugs, less than 5% are under patent protection anywhere in the world (Watal 2001). Surely, in the next future, further developments in the pharmaceutical research will produce new effective anti-retrovirals, anti-malarials, second-line TB drugs, all subjected to the rigid regulations on intellectual property rights: it is easy to foresee that their high costs (under a patent protection) will reduce availability where they are more needed. But we cannot neglect the relevant role that irrational use, inconsistent prescriptions, polipharmacy and pilferage play in the chronic shortage of drugs that affect most African hospitals and health facilities (WHO 2002b, WHO 2002c, Ferrinho 2004). Therefore, patents represent a major problem but not the only one causing the reduced access of the population to essential medicines.

The next threat: Free Trade Agreements

The whole discussion about TRIPS, patents on pharmaceuticals and differential prices of the same products was not confined to DCs only: the consequences in industrial countries are going to be profound, too. In fact, it has generated the consumers' awareness that the discrepancy between the cost of supplying drugs by generics producers and the prices charged for patented drugs in industrial countries is unacceptable (Subramanian 2004). On their side, the pharmaceutical industries claim that high prices are justified by heavy costs in research and development (R&D) of new products, including those that never reach the stage of registration and marketing (The Panos Institute 2002, Troullier 2002). We are not going to move into the "quick sands" of the debate about the true costs for innovative drugs, where industries' view is contrasted by consumers' view (DiMasi 2003, Love 2003). However, it is worth to remind that American consumers pay at wholesale 2.5-3.5 times the prices in Australia and other countries with similar regulations about patents; but there is no evidence of increasing contributions to R&D (Light et al. 2004).

Ultimately, another threat for poor countries is going to appear on the scenario drawn by the 31st August agreement. In fact, the United States are on the move to sign bilateral commercial agreement where they intend to include more stringent TRIPS provisions than international standards: extension of pharmaceutical patent terms beyond 20 years, no marketing approval for generic medicines if the patented version of the product is registered, other severe restrictions for generic competition, preclusion to utilise compulsory license (MSF 2004). This is already taking place within the Central American Free Trade Agreement (CAFTA), where single countries can be more easily challenged (and bullied!) than they are in international arenas, where they negotiate as a more solid group.

The United States have recently concluded Free Trade Agreements (FTA) with Jordan, Singapore, Chile, Australia and Morocco and there is a considerable list of FTA under discussion. According to the drafts available, the elements concerning pharmaceuticals appear as an effort to rewrite the TRIPS Agreement and particularly the Doha Declaration (Abbott 2004). But not only poor countries are actually under the pressure of the US negotiators: even Australia was pushed to modify its domestic policy on pharmaceutical patents and generic medicines in a more stringent way (Drahos et al. 2004), offering a convenient opportunity more to the US pharmaceutical industry than to local customers! Even more deceitful is the technical assistance that the US offer within the framework of the bilateral aid, encouraging assisted countries to amend their patent laws and to limit competition from generic equivalents: such assistance, moreover, is usually perceived just as neutral advice to draft intellectual property laws. US technical assistance was behind Uganda's new TRIPS-plus Industrial Property Bill of 2002, introduced after consultation with USAID, which would make Uganda TRIPS-compliant earlier than due, restricting access to generics. Pressure from activist groups and unease from part of the government have prevented adoption of the law (Oxfam 2003); however, it did not discourage at all the US aid agency, that proposed once again unsuccessfully - the same "poisonous" deal to Nigeria government.

It seems that a new season of negotiations has opened, moving from the multilateral to the bilateral arena. The complete failure of 2003 WTO Cancun Conference has not stopped any attempt to re-design and re-write the agreement ruling TRIPS. Governments, civil society, NGO are all expected to exert a solicitous and careful monitoring (Ford 2004) of what will happen after January 2005, especially for what concerns the possible trade-off between attracting trading opportunities offered by rich countries and a commitment by poor countries to modify their TRIPS legislation towards a more rigid way: a rigged game where vague promises are exchanged for counterproductive and relentless obligations.

End Notes:

1) The term "Least Developed Countries (LDCs)" describes the world's poorest countries with following 3 criteria: **Low-income**, as a GDP per capita under $750; **Human resource weakness**, based on indicators of nutrition, health, education, and adult literacy; **Economic vulnerability**, based on indicators of the instability of agricultural production, of exports of goods and services, on the economic importance of non-traditional activities. Countries included in this group by UN and WTO are: Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Cape Verde, Central African Republic, Chad, Comoros, DR of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea Bissau, Haiti, Kiribati, DR of Lao, Lesotho, Liberia, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Samoa, Sao Tome, Senegal, Sierra Leone, Solomon Islands, Somalia, Sudan, Timor, Togo, Tuvalu, Uganda, Tanzania, Vanuatu, Yemen, Zambia (source: United Nations http:// www.un.org/special-rep/ohrlls/ldc/default.htm).

2) A generic drug is a drug which is equivalent to a brand drug in dosage, safety, strength, route of administration, quality, performance characteristics and intended use but is usually cheaper than the branded version. Generic drug can be legally produced by any pharmaceutical company for drugs where the patent has expired (usually after 20 years) or for drugs which have never held patents.

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