2.1. Global health policies

2.1.1. Health and intellectual property rights: the never-ending war

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The TRIPS Agreement and access to treatment

One of the most controversial debates in the international arena hinges on the conflict between the right of access to essential medicines in poor countries and the protection of intellectual property rights, i.e. the monopoly privileges granted to multinational pharmaceutical firms as incentives to encourage innovation[1].

It has been estimated that one third of the world population – more than 50% in Africa and Asia – does not have access to essential medicines[2]. Research and development in pharmaceuticals is guided more by market forces than by real health needs: of the 1,556 new pharmaceuticals developed between 1975 and 2004, only 20 (1.3%) are useful for the treatment of tropical diseases and tuberculosis, which constitute 12% of the global burden of diseases[3].

The global scenario behind this conflict, between the right to life and the right to profits, is strictly related to the complex rules of international trade.

The Agreement on the Trade Related Aspects on Intellectual Property Rights (TRIPs) which entered into force in 1995 as one of the main norms of the World Trade Organisation, contains 73 articles setting the minimum standards for intellectual property rights protection through which it aims to promote trade liberalisation and economic growth. With the TRIPS Agreement, patentability is effectively extended to all industrial sectors and technological innovations, including pharmaceutical products. The twenty year period of exclusive intellectual property protection is somewhat balanced by measures that Member States are allowed to adopt in order to "protect public health and nutrition". The main safeguards are:

– the compulsory licence: this measure enables national public authorities to allow the utilization of a patent by a third party – for example, a local industry – without the patent owner's consent. In this way, the third party is entitled to produce a generic version of the patented drug upon payment of an adequate remuneration to the patent holder, taking into account the economic value of the authorization;
– the parallel importation: this allows the possibility of importing branded drugs from a country in which the price of the patented product is lower due to competition from generic medicines;
– the Bolar exception: this provision allows producers of generic medicines to finalise the clinical dossier of a drug still under patent so as to ensure faster registration of their generic equivalent and its immediate ingress onto the market once the patent has expired.

The formal equilibrium between intellectual property rights and the right to health is the result of long running arm-wrestling with developing countries, particularly with India, Brazil and Thailand in particular. However, given its origins, the TRIPS Agreement remains a product of the corporate agenda and, consequently, a social contract heavily skewed to serving the interests of the private sector[4,5]. Ever since it was ratified in January 1995, the risk has been clear and unequivocal that this globalisation of patents would reduce the availability of essential medicines at affordable prices in low income countries. Furthermore, promises made to these countries that, in exchange for their endorsement of the TRIPS provisions and standards, they would benefit from increased sharing of scientific and technological knowledge – a vital asset given the modest capacities within their pharmaceutical industries, and from wider access to agricultural markets in high income countries, have not been kept.

The Doha Declaration

The flexibilities granted to member states to protect public health and achieve access to essential medicines were further elaborated in 2001 in the Doha Declaration on "TRIPS and Public Health", negotiated at the 4th WTO Ministerial Conference in Qatar. The Declaration re-affirms that the TRIPS Agreement should be interpreted and implemented in such a way as not to violate the right of member states to protect public health and to promote universal access to essential medicines. It reasserts both the need to resort to the safeguards to neutralise the undesired side effects of the Agreement, and the margin of manoeuvre that governments have to this end. Lastly, the Declaration postpones to 2016 the deadline for least developed countries to comply with the agreement.

However, the Doha negotiation left one crucial question unresolved, namely the issue of procurement of essential medicines for countries with no manufacturing capacity. Thus, production for export became the focus of painstaking negotiations which ended with a definitive amendment to Article 31(f) of the TRIPS Agreement being made in Hong Kong, in 2005. Article 31 allows a manufacturing country to export medicines upon issuing a compulsory license only if this medical product is already the main product in use on the domestic market, thus limiting, or even *de facto* blocking, exportation to countries with no manufacturing capacity. Although this provision allows for compulsory licences for domestic consumption and export there are numerous and complex conditions attached to the importation of medicines by countries in need. Bureaucratic procedures and the need to combine the diverse licenses (for exportation and importation) render procedures interminable and create enormous difficulties when applying the new set of norms.

Canada, Norway and the UE have tried to translate the amendment into law. However, not until July 2007 was an attempt made to put them into practise when Ruanda announced that it intended to introduce a compulsory license to import antiretroviral medicines. In October 2007, Canada notified the WTO that it had licensed local production of a triple combination AIDS drug (Apo-TriAvir®, by

Apotex) for export to the African country. Six years had passed since the signing of the Doha Declaration, which had stressed the need for fast solutions!

"Not all men are equal before the law"

The Doha Declaration was hailed as a "watershed in international trade"[6] because, even without any rewriting of the text of the TRIPS Agreement it prioritised, the argument of the right to health over the right to protect intellectual property. Despite this, today, a series of politically motivated impediments, along with pressure from pharmaceutical multinational corporations, still make it hard for those governments most in need to fully exploit the flexibilities contained in this multilateral agreement and any who try to exploit it risk heavy economic retaliation, as described below.

The Gleevec case: India versus Novartis

On the 1st January 2005 India joined the TRIPS Agreement. A few months later the government approved a new law to replace the one that had been in force since 1970, which excluded patent protection on medicines. It was a hard blow for those low-income countries which had always considered India to be the pharmacy of the poor. The new law did, however, take the need for a balance between protecting patents and protecting patient rights into account. The new law was successful in integrating all the necessary safeguard measures, including severe patentability standards which aimed to reward true innovation and to prevent "evergreening", commonly adopted practises used to unduly extend patents beyond the exclusivity terms. Evergreening takes place once the period of exclusivity has ended: at that point many pharmaceutical companies will try to extend its duration by creating new dosage forms or new formulations of the same drug (for example drops instead of pills) and then argue that the patent should be extended because of the "new use" of the existing product. This is a widespread practise used to extend monopolies and avoid both competition from generic products and loss of market share.

This is precisely what happened with Gleevec®, an anti-cancer drug which, in 2006 alone, made a net profit of 7.2 billion US$ for the Swiss multinational Novartis[7]: the available generic version of this drug cuts the price per month of treatment from 2,000 to 200 US$[6,8]. On the basis of the provisions of the new law, the Indian government decided to reject Novartis' application for a patent for Gleevec®, explaining that the medicine did not contain any real novelty or innovation when compared with an earlier formulation already produced by Novartis. So the Pharma company took the Indian government to court, accusing it of failing to abide by WTO rulings. The case was finally resolved in August 2007, when the Court of Chennay emitted a historic decision and, finding in favour of the Indian government, declared that the Swiss multinational was in the wrong.

However, both sides recognised that this legal battle went far beyond the simple question of Gleevec®. Lawyers representing Novartis explained that the drug was

supplied free-of-charge to 99% of patients who need it in India and that the real reason behind their challenge to the Indian law had more to do with their the need to defend patents and pharmaceutical research. Humanitarian organisations who mobilised to defend the law, and the 500,000 people worldwide who signed a petition to support it, interpreted the case as an attempt to block the Indian generics industry, which is a world-leader in the production of antiretroviral drugs against HIV/AIDS.

Thailand, compulsory license and Abbott

In November 2006, even while India was still confronting Novartis in the courts, a new frontline was opened by Thailand, when it issued a compulsory license (CL) to produce the antiretroviral drug *efavirenz* (Sustiva®, Merck & Co.). This was a perfectly legitimate decision in line with both the TRIPS Agreement and with Thai national legislation on patent protection, passed in 1979, in order to maintain the efficacy of their national AIDS control programme. However, the decision was seen as a provocation by the new Bangkok government, a military regime which had seized power through a bloodless coup d'état. Compulsory licenses for government use are merely the most recent chapter in the long history of a country that has struggled for years, with hard-won coherence, to guarantee the universal right to health and free access to medicines for poor people in need [9]. After *efavirenz,* two more compulsory licenses were issued in 2007: one for a second-line antiretroviral combination *lopinavir+ritonavir* (Kaletra®, Abbott) and the other for *clopidogrel* (Plavix®, Sanofi-Aventis), a new drug for the treatment of ischemic heart disease. Drug prices reacted immediately, not only in Thailand. The effect of the compulsory license made the international cost of *efavirenz* plummet from 1,800 to 670 US$, while that of the *lopinavir/ritonavir* combination dropped from 2,500 to 1,000 US$. However, the political price that Bangkok has had to pay has been enormous. Firstly, Abbott immediately withdrew all the registrations of new medicines underway in the country; international pressure escalated, and there were threats of economic and financial retaliation (withdrawal of foreign investment in the country)). Furthermore, in April 2007, the US Office for Trade (USTR) unilaterally included Thailand in the special watch-list of countries that were threatening the patent protection norms set out in section 301 of the US Trade Act[10].

The trap of bilateral agreements

The Free Trade Agreements (FTA) which came into force in quick succession (not only in the USA) after the Doha Declaration opened up new markets for agricultural and textile products from low-income countries, but this was only granted in exchange for stricter standards of intellectual property protection, including that for pharmaceutical products. These "TRIPS-plus" provisions effectively restrict the opportunities for a government to resort to, and benefit from, the established health exceptions – compulsory licenses and parallel importation. As regards the FTAs ne-

gotiated within the Americas, the biggest and most important of these bilateral agreements, compulsory licenses are only permitted either after the patent has expired or in situations of "national emergency" after the nomination of a special body with powers "over and above" those of the WTO set up to resolve any disputes[11]. In the FTA between the USA and Australia, medicines produced under compulsory license are excluded from parallel importation, even when they are used to help in humanitarian crises in neighbouring countries[12]. Similar measures have been introduced in the FTAs signed between the USA and Morocco and between the USA and Singapore, and are currently being negotiated with numerous other countries[6].

One of the most insidious ways of getting around the TRIPS Agreement in FTAs is through extension of the term of the patent beyond the customary 20 years – as has occurred in bilateral agreements drawn up between the USA and Jordan, Chile and Australia[13,14] – and, also through the practice of *evergreening*.

The "TRIPS-plus" measures also reinforced the data exclusivity norms set out in the TRIPS agreement, thereby allowing multinationals to pre-empt or delay competition with generics. The extension of data exclusivity may even include the time required for drug registration procedures by the originator. In Guatemala, for example, producers of equivalent antiretrovirals must wait for 15 years after the date of approval of the originator drug before they can obtain registration of their generic version; this means that it may only be put onto the market once the patent has expired anyway. This type of restriction supersedes the Bola exception, provided for in TRIPS, and currently recurs in almost all other bilateral agreements (see, for example, Morocco or Malaysia). In Jordan, out of the 103 medicines registered and marketed after the 2001 USA-Jordan FTA was signed, 79% have no generic competitors as a result of the data exclusivity clause introduced by the bilateral agreement[14].

The pandemic that was not there: avian flu, Indonesian viruses and the WHO

In February 2007, Indonesia suddenly decided to stop sharing its samples of H5N1 virus (avian influenza A) with the 7 Centres who were collaborating with the WHO. Indonesia, with 81 deaths, had until then been one of the countries hardest hit by avian flu. Collaborating centres are the reference laboratories of the WHO, which form the *Global Influenza Surveillance Network* (GISN). Their task is to carry out research into the threat of pandemics. Djakarta's action provoked both consternation and criticism[15]. However this decision was the disconcerted and legitimate reaction of the Indonesian government to the news, published in the *Jakarta Post*, that an Australian firm had offered to sell vaccines, developed from Indonesia's own viral strains, to their Ministry of Health. These vaccines had already been patented, without the prior consent of, and without compensation being offered to, the Indonesian government. Hence the latter's decision to try to find a commercial agreement with an Australian company, Baxter International, to supply them with the virus so they could develop a vaccine only for Indonesia.

The avian flu controversy dominated the debate throughout 2007 and, still to-

day, remains one of the more obscure incidents involving the WHO in recent years. The Agency has been accused of violating its own guidelines regarding *influenza virus sharing*, by handing over viruses, or parts of them, to pharmaceutical companies without seeking prior permission from the laboratory of origin, a procedure that was stipulated in the Convention on Biodiversity. The issue is even more serious if one considers the implications of an avian flu pandemic an event which would turn research on vaccines into a global public need and not an activity that only obeys profit logics. Currently, vaccine production capacity is concentrated in only nine countries – Australia, Canada, France, Germany, Italy, Japan, the Netherlands, the United Kingdom and the USA – and global strategies do not, and cannot, ensure fair, equitable and sustainable access to vaccines by developing countries, despite the fact that they would be the most at risk in a pandemic.

Because of this, Indonesia decided to play one of the few winning cards she held and which gave her power to negotiate. Indonesia has the best available viral and bacterial strains without which the health authorities are unable to perform the necessary surveillance and provide informed recommendations on vaccines. In this way the Indonesian government managed to highlight the dangers of the pathological temptations within a system based on intellectual property rights. In a worst case scenario there is a real risk that patents could seriously impede the use of vaccines against avian flu in low-income countries.

The case of the Indonesian virus samples is reminiscent of yet another thorny question, that of biopiracy, or rather of biofraud (as it is now called). Biofraud is the illicit appropriation of indigenous medical knowledge, something which has become a profitable source of income for many pharmaceutical companies.

The WHO Inter-Governmental Meeting (IGM) held in November 2007 called for a system of equitable and reliable sharing and 2008 was designated the year in which the issue would be solved, mainly so as not to further damage the faltering credibility of the WHO. But the crucial debate was put off until November 2008 while members waited for a proposal (a text by the IGM Chair) that would be able to offer an exit strategy. Developing countries remain sceptical, they seriously doubt whether vaccine producers (and the governments who host them) are really willing to undertake the massive transfers of technology, on an industrial scale, that would be necessary to both increase local production and ensure that poor countries achieve vaccine self reliance: i.e. have secure access to the low cost diagnostics and vaccines which would be essential to prevent a pandemic.

On her part, Indonesia has demanded a more transparent and efficient mechanism than the GISN currently in place. Indonesia is not the only one to make this demand.

Public health, innovation and intellectual property rights: negotiations within the WHO

After years of bitter, intractable debate within the WHO, debate interwoven with numerous resolutions and partisan positions taken by individual governments,

Member States did finally agree to set up a negotiating forum to tackle controversial questions concerning the effect the norms protecting intellectual property rights were having on the right to health and, in particular, on access to the fruit of scientific research in the field of medicine.

The creation of the *Intergovernmental Working Group on Public Health, Innovation and Intellectual Property Rights* (IGWG) was triggered by a resolution presented by Kenya and Brazil to the World Health Assembly in 2006 (WHA 59.24). The resolution sought to propose new policies to support needs-driven health and bio-medical research and was especially designed for people in developing countries. Basically, this would entail extending the crucial value of "essentiality" to health innovation in line with "the essential medicines concept" that, thirty years before had provided important guidance in defining national and international health policies. Indeed, in 1977, when the essential medicines concept was first introduced it was considered to be "a peaceful revolution" within the WHO.

"Innovation is pointless in the absence of the conditions that allow people in poor countries to have access to new and existing products", is the clear message of the report by the Commission of WHO experts on Intellectual Property Rights, Innovation and Public Health[16] that is now the main reference document for IGWG negotiation. After three years of work the Commission has come up with an articulated diagnosis of the structural weaknesses and inefficiencies of the current regime of incentives for medical research, incentives which are based entirely on a market logic. This is an iniquitous choice for poor people, the report would seem to imply, because where there is no purchasing power the market does not and cannot determine an appropriate value. But this system of incentives for research and development in the field of medicine poses difficult questions in rich countries too, where innovation capacities are seriously in crisis despite the continually increasing investments made in pharmaceuticals and the rising cost of medicines[17].

The IGWG, where negotiations are ongoing, has a politically sensitive task. It must provide a global strategy and plan of action "to secure an enhanced and sustainable basis for needs-driven essential health research and development relevant to diseases which disproportionately affect developing countries, by proposing clear research objectives and priorities and estimating funding needs in this area".

Thus the remit of the IGWG lies at the heart of the conflict between patient rights and intellectual property rights. Thanks to the new WHO negotiations, for the first time, the link between pharmaceutical innovation and access to medicines has become the new area of action, indeed, *the* slogan of diplomacy. This process has been defined by some analysts as the most important initiative in pharmaceutical policies in recent decades[18]. The discussion is focused on research priorities and new incentives for innovation. A new knowledge sharing argument has come to the fore in negotiations where governments are discussing open source models and a new political style of leadership. Member States are also discussing the real costs of research and the need to escape from the stranglehold of monopolies. They are also trying to draw up innovative policies for public health focussed management of patients and have suggested new mechanisms for funding research – for example a currency transaction tax or the idea of a new international treaty to fi-

nance public reseaearch[19]. Another new development is the key role played by developing countries who appear to be determined to regain the ground they lost within the WHO during the TRIPS negotiations.

On the eve of the 61st Assembly of the World Health Organisation, the results of this process mark a decisive step forward in the way in which innovation and access will be linked in the future[20]. Global strategy, which at times seemed to hang by a thread during the tough negotiations, now supports the achievements of the Doha declaration and, surprisingly, is introducing new clarity on a series of controversial issues; such as the urgent need for actions that governments must undertake in order too promote competition and prevent any abuses of intellectual property rights. The strategy also affirms that governments must play a leading role in defining medical research priorities and calls for the development of new mechanisms to encourage research and stimulate technology transfers. It demands clear rules that will favour access to essential medicines and encourages developing countries to become protagonists within the debate. Lastly, the new strategy has also led to the setting up of a group of experts whose task is to study coordination of funding and suggest new ideas for sustainable ways of financing future research.

The plan of action is currently still the subject of heated negotiation and will not be finally approved until the next WHO Assembly. However, this should not stop governments taking immediate action to take advantage of those measures that have already been approved. If they do so, it would be one way of evaluating how well the new strategies are going to function before the negotiations are concluded in 2009.

In a scenario where "*venture philanthropists*" like Bill Gates risk becoming the ones who establish the rules of global health, especially in the field of pharmaceuticals, this sudden awakening of governments and the WHO could make us think that all is not yet lost.

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