



The evolution of property regimes has always had a critical effect on wealth accumulation mechanisms, on the harnessing of added value and on the distribution of income. The law relating to intellectual property is no different in this respect and the attempts to find a universal solution within the framework of the TRIPS agreements appear to be driven by the convergence of two dynamics. The technological revolution within existing scientific fields, combined with the new information technologies, are creating the framework of a new knowledge economy while the geo-political and geo-economic fallout following the end of the Cold War has opened the door to market globalisation. It is in this new technological and geo-economic climate that efforts are being made to negotiate or rather impose a new system of intellectual property law, which is perfectly clear as regards the accumulation and distribution of income, but leaves questions unanswered as regards the essential innovation upon which such matters depend and the advances which such innovation is supposed to achieve. This tendency is apparent in public health. We shall first focus on the violation of intellectual property rights (IPR) under the form of counterfeiting of medicines in the international and African context. To explain this phenomena, we shall analyse the standardisation of IPR and the reduction of access to essential medicines. Finally, we shall center on the problematic relationship between intellectual property rights and pharmaceutical innovation.

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Intellectual property regimes have decisive consequences in terms of public health. They tend to define the counterfeiting of medicines, the access to basic drugs in emerging countries and the modalities of pharmaceutical innovation.

According to the World Health Organization, a counterfeit medicine is a product whose identity and source has been deliberately and fraudulently misticketed. Counterfeiting may occur both in respect of branded and generic products and a counterfeit drug may contain the same or different ingredients, without the key therapeutic ingredient being present or without the ingredients being present in sufficient quantities or without the correct packaging being used.<sup>1</sup>

#### COUNTERFEIT MEDICINES : THE INTERNATIONAL AND AFRICAN CONTEXT

Northern countries are not particularly affected by counterfeit medicines since their pharmaceuticals market are regulated and drugs require a doctor's prescription. Internationally, however, the problem is particularly worrying in poor countries, where self-medication is frequent, and there is a lack of a well organised regulatory system to oversee marketing, distribution and testing of drugs, without speaking of the lack of resources for trained public service. It is difficult for ordinary members of the public to identify counterfeits, and medicines are purchased by patients unaware that the therapeutic ingredients they contain are less active than the originals. Indeed, they are sometimes completely inactive, which means that the treatment they provide is useless. A sample analysis of the 771 counterfeit drugs that were reported to the World Health Organization (WHO) in 1999 revealed that fifty-nine per cent did not contain any active molecules, seventeen per cent contained incorrect doses, sixteen per cent contained the

wrong ingredients and only seven per cent contained the same ingredients in the same proportion as the original product.

Jacques Pinel, a pharmacologist at Médecins Sans Frontières (MSF) believes that a distinction should be made between three distinct areas in order to gain a better understanding of the situation: counterfeiting, which exists on a relatively small scale, the manufacture of defective medicines, which is fairly frequent, and the Third-World manufacture of generic medicines, which threatens the intellectual property of the northern hemisphere pharmaceuticals industry.

The counterfeiting of medicines is intended to cheat patients by maximising the profits to be made from public health provision. The deception is sometimes criminal, as revealed in the case of several African Countries, most notably Nigeria, and also in Haiti where eighty-nine people died in 1995 after taking a cough mixture whose main ingredient was paracetamol.

During the meningitis epidemic that swept Niger from February to May 1995, 88,000 Pasteur Merieux and Smith Kline branded vaccination doses were supplied by neighbouring Nigeria. The medicines were an official donation within the context of a vast campaign for the vaccination of five million people and this was supported by various international organisations. Sixty thousand people were vaccinated with counterfeit drugs, including three thousand by MSF teams, before it was discovered that the product was noxious whereupon the remaining doses were destroyed. It is estimated that over two thousand people died as a result of being vaccinated.

The affair has been extensively reported by the press and some news articles claim that "sixty per cent of medicines used in some countries are counterfeit". MSF believes that such claims are largely exaggerated and stresses that the sensational nature of individual cases such as those of Niger or Haiti should not be trivialised. Counterfeit medicines, circulated in error or negligently, constitute a serious risk to public health and are manufactured on a large scale, as in the previous example, or are produced by small-scale cottage industries.

The situation is similar to that of defective medicines, the production of which has become far more commonplace. The production of defective medicines is not intended to deceive the purchaser, but certain controls are absent. This harms the quality and effectiveness of the product in a number of ways including over- or under-dosage, poor preservation, toxicity, inactivity, the wrong therapeutic ingredient, inaccurate labelling. Of the million deaths caused each year by malaria, 200,000 could be avoided if the drugs employed were effective, correctly used and of good quality.

According to the World Health Organization, poor-quality medicines are the result of poverty as manifested by poorly equipped laboratories, inadequately funded regulatory authorities and substandard manufacturing processes. A survey of anti-malaria drugs conducted after the year 2000 in seven African countries (the Gabon, Ghana, Kenya, Mali, Mozambique, Sudan and Zimbabwe) revealed that between twenty per cent and ninety per cent of these medicines did not pass quality tests and consisted of a mixture of local and imported medicines.

The World Health Organization, has launched a global campaign to combat counterfeit and poor-quality medicines, which are also widespread in developing Asian countries. Surveys have shown that defective medicines constitute 8.5 per cent of the Thai and Vietnamese markets and sixteen per cent of the Burmese market, where almost a quarter of anti-tuberculosis drugs and certain children's antibiotics failed to pass quality tests. Although this initiative is perfectly justified, it should not advocate the regulatory standards of northern hemisphere nations. According to Philippe Kourilsky, any globalisation of regulatory standards would merely sacrifice the sick of the developing world insofar as it seeks to impose upon southern nations the extreme levels of protection that prevail among northern nations.

It might be argued that counterfeit and defective drugs are a third-world response to the problem of gaining access to essential medicines. According to Serge Tomasi in many developing countries, the cost of medicines can represent sixty to seventy per cent of the household budget. This burden is often too heavy as demonstrated by the situation in Africa. The French development office has acknowledged the key role of medicines in the wake of the 1994 devaluation of the African Community Franc, which resulted in the doubling of the price of imported medicine. Despite the price reductions obtained by

squeezing pharmaceutical industry margins and despite local production proving possible in some countries, the people have turned to the illicit market in mass in the absence of a regulated monopoly. In Burkina-Faso, twenty to twenty-five per cent of sales by outlying pharmaceutical stores are of illicit products; in Benin, where illicit medicines constitute forty per cent of the total pharmaceuticals market, sixty to eighty per cent of medicines are either counterfeit or defective, i.e. under- or over-dosed; and in Guinea, illicit medicines represent forty per cent of all sales.

This illicit market, where products are considerably cheaper, is being fed by firms copying medicines under licences obtained in Nigeria, Ghana and the Democratic Republic of the Congo, by imports from English-speaking African countries where most of the drugs are freely sold, by international laboratory donations, by local manufacture or even by pharmacists (whether dispensaries, wholesalers or newly qualified graduates). The illicit drugs market is particularly lucrative; behind the small-time dealers lurk the big-time players: corrupt officials and organised crime. According to sources within the trade, this pharmaceutical mafia with friends in high places is also fed by external corruption. Numerous, false and extravagant therapeutic claims are made by vendors who are usually unaware of the dangers of these medicines and whose only income is derived from their sale. Mind-altering drugs are frequently sold at the same time as other medicines. This illicit trade gains a certain respectability from the notion that the law is on the side of the pharmacist and the sale of cheap medicines represents a useful contribution to public health.

The market is also stimulated by the activities of private pharmacists who, unlike their state-sponsored colleagues, do not make much from generic medicines, which are generally available at low prices from public pharmacies. However, the latter rarely respond to consumer demand, often failing to maintain a local presence or to communicate effectively with their patients.

The situation is not irreversible; no illicit market exists in countries such as Ghana, which labour under the same economic problems as Benin, Togo or the Ivory Coast. In Ghana, the authorities have introduced a consistent health policy ensuring access to medicines at affordable prices, and this is supported by local producers, training and regulatory bodies and a network of 8,000 licensed distribution centres.

The absence of any restriction upon the sale of pharmaceutical products and the growth of an illicit and dangerous African market maintained by shady practices has encouraged the sale of numerous products of doubtful value. In France, for example, the authorities have questioned the therapeutic value of several hundred medicines that have been officially registered and licensed for some considerable time. However, according to some experts, several hundred or even several thousand medicines currently used in Africa are in all likelihood completely useless. German Velasquez of the World Health Organization believes that the pharmaceutical market in Africa and in many countries is polluted and that the market and product range should be cleaned up. Counterfeit and defective drugs clearly appear to be illicit or improvised responses to the major global problem of access to essential medicines at affordable prices, which not only constitutes a threat to the wellbeing of the southern hemisphere nations but also to those of the northern hemisphere, given the current spread of infectious disease. On a theoretical level, the eradication of infectious disease ranks with world peace, the atmosphere's capacity to absorb greenhouse gases and advances gained from basic research as a pure public good in the sense that the benefits produced do not entail a corresponding loss of benefit on the part of any other person that consumes this good (the principle of non-rivalry) and that the limitation of its use entails substantial costs (the principle of non-exclusion). The SARS epidemic of 2003 and the bird flu of 2004 brought home the idea that public health issues must be tackled on a global basis.

The problem is best illustrated by AIDS. The pandemic has become a major public health problem and an international security issue, and this has brought into question the TRIPS Treaties negotiated by the World Trade Organization. There are between at least thirty-five million people infected with HIV in the world in 2013, according to the WHO, and more than one million deaths per year since the epidemic first appeared, ninety per cent of which occurred in the Third World. In sub-Saharan Africa, where more than seventy percent of all global cases are recorded, as well as in Asian Pacific countries, only a small minority of the victims had received the anti-retroviral treatment (ART) that had been available since 1996, until the launch of a global strategy of prevention and universal access to treatment by the UNAIDS in 2006 .

In China, the statistics of people infected with HIV have been practically static since 2004. There were 840.000 in 2004 , and 810.000 in 2013, according to the estimates of the National Center for AIDS/STD Control and Prevention which include those who have not yet been diagnosed, out of a total population of 1.36 billion. That is a far lower proportion than India, where UNAIDS says there are more two million people living with HIV, in a slighter smaller total population. Chinese officials have said that growth rates are particularly high among gay men and male sex workers, who are marginalised and stigmatised by mainstream society, but the pandemy is no longer confined to high risks groups, since numerous patients, around 6 % have been infected as a result of blood transfusions, and around half of them are heterosexuals.

The UNAIDS global strategy for prevention and universal access to medicines became effective in the years 2010s: Expanded access to antiretroviral therapy (ART) and a declining incidence of HIV infection led to a steep fall globally in the number of adults and children dying from HIV-related causes. The estimated 1.5 million [1.4 ñ 1.7 million] people dying from HIV globally in 2013 were 22% fewer than in 2009 and 35% fewer than when the number peaked in 2005. Children (younger than 15 years) in 2013 had 31% fewer deaths from HIV compared with 2009 and 40% fewer deaths compared with 2005. Tuberculosis continues to be the leading cause of death among people living with HIV. In 2013, over 9 million people were diagnosed with TB and 1.1 million of these people were also living with HIV.

In 2003, before the peak of 2005, there were three million further deaths and five million people were newly infected. The pandemic, described by Professor Michel Kazatchine, director of the National Aids Research Agency, as an ieconomic, social and political challenge to the problem of developmenti had not been met by an equivalent response from the international community and private sector. AIDS, re-emerging tuberculosis and malaria killed a total of five million victims each year and affected the lives of another 256 million people. In order to better understand the scale of this health crisis, which has developed into a major international issue, the globalisation model, which forms the framework of the WTO TRIPS agreements, needs to be re-examined.

Susan Sell has demonstrated the dominant role of the Intellectual Property Committee, which brought together a dozen chief executives of essentially American-controlled pharmaceutical, IT and entertainment multinationals in the TRIPS negotiations. Edmund Pratt, chief of the pharmaceutical firm Pfizer, was the US delegation's leading private-sector representative during the Uruguay Round. James Love, Director of the Consumer Project on Technology, stressed the role played by lobbyists: iTRIPS is generally believed to owe its conception to the self-seeking interests of Pfizer, IBM and other rights-holders.i

According to Christian Chavagneux, the uniform code of intellectual property rights created by TRIPS is without doubt the most extreme example of corporate pressure, since it incorporates rules into public international law that are intended to serve private interests. As regards pharmaceuticals, it stakes everything upon the unlikely prospect of an expansion in the market for licensed medicines in the developing world. The TRIPS mission statement contained in Article 7 claims that: ithe 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 in a manner conducive to social and economic welfare, and a balance of rights and obligationsi.

However the statements of principle in Article 8 declare: i1. Members may, in formulating or amending their laws and regulations, 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. 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by the rights-holders or the resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology.

Considered in relation to patents, any system serving a general policy specifically devised to confer private rights upon an infinitely greater public interest must, according to the WIPO, create a dynamic synthesis of public and private interests. If any such system is habitually regarded as nothing more than a direct conflict between private and public interests, it will amount to nothing more than a patent regime devised by the legislature for the purpose of subjugating private rights and interests to the requirements of public policy.

Public health is by definition particularly suited to this dynamic synthesis of innovation and dissemination, and private interest and public good. In practice, everything depends upon the absolute or relative weight attached to the enforcement of intellectual property rights. In the wake of the September 11th attacks and the bio-terrorism spread by anonymous anthrax letters, the United States has for example been rightly concerned about access to Cipro, a medicine manufactured by Bayer, which is able to combat certain viral strains, and has threatened Bayer that it would ignore its patent if an adequate supply of the drug was not made available at a reduced price. This is by no means an isolated case since, according to James Love, the United States has imposed hundreds of mandatory licences in respect of technologies as diverse as articulated lorries, cereal strains, pharmaceutical products, genetic, material and software patents.

The European Union has lodged several complaints against the US Government's widespread use of mandatory public interest licences. Under US law (28 US Code Section 1498), the owner of a patent can not sue for damages for infringements resulting from the manufacture or use of items by or on behalf of the American authorities. Patent infringement is frequently practised by the Department of Defence and is widespread among practically all government departments. For obvious reasons, the holders of foreign rights are particularly prejudiced since they are generally unable to ascertain whether their patent is being publicly used while any such use may prevent them from filing a claim against the government. Article 31 of TRIPS imposes an obligation to immediately inform the rights-holder of any public use made of its patent but the United States has hitherto failed to amend its domestic law in accordance with this requirement.

The TRIPS Treaties are, therefore, not binding once the public interest of any state party becomes an issue. The problem is not so much the pliability of the agreements as demonstrated by the attitude of the United States vis-à-vis the international framework of intellectual property rights to which it contributed, but the fact that the same flexibility is denied to other states that infringe patents in the public interest either for defence or in the name of innovation, creativity or research and development; a catchphrase that merely masks various private interests.

Intellectual property rights are private rights and are therefore exclusive. However, their application within the sphere of national and international public health pre-supposes a high degree of intervention by public authorities, since the latter are public goods and therefore non-exclusive. State intervention already exists in industrialised nations: medicine price control in Europe has cut costs by half in comparison to the United States, where a free market exists. However, state intervention is a relatively recent development among industrialised and developing nations.

In order to better understand the tensions and the north-south divide that have resulted from the new model attempted by TRIPS, an examination of the former system of intellectual property rights applicable to medicines may be useful. The inability to patent molecules and the restriction of patents to manufacturing processes were the key factors in the development of the pharmaceutical industry in the Northern nations. It was only in the 1960s and even later in the case of some countries (1976 in Japan, 1977 in Switzerland, 1992 in Spain and 1993 in Canada) that the patenting of molecules became widespread. In 1989, medicines could still not be patented in half the states that had signed the Paris Convention. France did not extend patents to medicines until 1968, thereby preserving the state's power to issue mandatory licences (if, for example, the

price of a medicine was too high or insufficient quantities were available).

Until this time, the unanimous view among legislators was that health was a public issue that required a particular approach. Far from crippling innovation, the inability to patent molecules encouraged a high rate of product renewal over several decades, enabling the growth of pharmaceutical companies able to use a large number of molecules at a low price and concentrate their efforts upon the development of new medicines and the prestige of their brands.

Under the old system therefore, each country was sovereign and could decide to what extent it would permit the international protection of intellectual property to penetrate its borders; a decision that it was free to make according to its stage of development and a cost-benefit analysis. The situation of the US medicines market in 1938, as described by the American historian Harry Marks, was therefore astonishingly similar to that of many African markets today: 'Certain concoctions were basically coloured water, others contained large quantities of alcohol or codeine while others turned out to be ingenious mixtures of new chemical ingredients manufactured in Germany. Once any remedy was launched onto the market all distinctions were quickly erased, the companies being as keen to promote useless products as those that had a therapeutic value'.

The fact that every member of the WTO is bound by the minimum obligatory rules imposed by TRIPS for the protection of intellectual property completely reverses the position. The introduction of a strict timetable for a uniform system of intellectual property, dictated by the northern nations and affording an extremely high level of protection for the rights-holders, deprives the southern nations of an essential feature of their sovereignty, namely the freedom to name the price they are willing to pay for their technological apprenticeship. In these circumstances, the authors of the report by the Council of Economic Analysis entitled 'Intellectual Property' cannot be accused of exaggeration when they conclude that: 'the claim of protecting intellectual property is merely a cover for the ferocious dispossession of developing nations'.

The transfer of resources from north to south as a result of the patent rules imposed by TRIPS occurs hand in hand with frequent bio-piracy, consisting of the patenting by northern companies of the traditional knowledge and genetic resources of the developing world with the assistance of ethnobiological data but without the consent of those who possess the resources and knowledge in question. It is estimated that since 1993, 'seventy-four per cent of the 119 global products manufactured from higher plant species have been derived from traditional herbal remedies'. In 1995, the annual global market for drugs derived from medicinal plants discovered by native peoples was US\$ 43 billion; a sum that exceeded FDA's estimates of the global market in counterfeit medicines, around US\$ 32 billion.

Moreover, the agricultural use of biotechnology in combination with genetically modified organisms may disrupt the conditions in which agriculture is conducted and may even put agricultural activity at risk both in the north and the south under the guise of protecting intellectual property. 'Terminator seed' consisting of plants genetically modified to produce sterile seeds that do not germinate a second crop is currently being perfected and will strip 'farmers of the right to conserve and replant seeds they have harvested'; this amounts to an elimination of a practice as old as agriculture itself and is 'intended to greatly increase dependence upon the commercial seed market'.

Normal daily activities are suddenly seen as infringing trans-national intellectual property rights, since they are regarded as constituting the use of a patent without the permission of the rights-holder while the unlicensed use of patents by public authorities may only be justified in 'urgent national situations or extreme emergencies'. According to Article 31 of TRIPS, the rights-holder must be advised of such exceptional use which shall be non-assignable and predominantly authorised for the supply of the domestic market of the WTO member authorising such use. The manner in which the United States exploits this provision has already been considered. . . .

This situation has rapidly heightened the tensions and disputes that polarise public health issues: the southern states demanded access to medicines at a price they could afford, to head off the AIDS epidemic and the pharmaceutical multinationals pointed to considerable research and development costs and insisted upon the enforcement of the TRIPS agreements as a means of preventing the southern states and NGOs from developing an anti-AIDS strategy based upon generic treatments. In 1999, the Director of the French Pharmaceutical Industry Association stated: 'I fail to see why the pharmaceutical industry

should be required to make a special effort. Nobody asks Renault to give cars to people who don't own one.

Until 2001, the northern pharmaceutical industry clung to an extremely wide definition of counterfeiting, insisting that any drug which was copied without the agreement of the rights-holder was counterfeit irrespective of whether it met WHO quality standards. The trade literature referred to a major attack upon the spirit of innovation claiming that certain countries in the world do not recognise the crime of counterfeiting and do not impose any sanction for the copying of medicines for which patents have been granted in other countries, adding that such counterfeiting is undertaken by both private companies and state authorities which do not enforce TRIPS and is even encouraged by certain international organisations (an allusion to the World Health Organization), which suggest that countries produce for themselves the medicines they need.

This wide definition of counterfeiting not only included defective drugs and criminal counterfeits but also third-world generics manufactured without the consent of the rights-holder, parallel generic imports and surplus production by subcontractors representing a possible consumer risk. It was regularly claimed that the counterfeit market constituted six per cent of pharmaceutical industry turnover i.e. US\$ 12 billion per year. The American Food and Drug Administration estimated that counterfeit and defective drugs constituted ten per cent of global turnover in 2002, i.e. US\$ 32 billion. This extremely wide notion of counterfeiting may be best illustrated in reference to the Pakistani and Chinese markets, where almost fifty per cent of medicines would be considered counterfeit although the production of generic drugs in these two countries had been authorised by TRIPS until at least 2005. Some trade magazines went so far as to claim that counterfeit medicines were the greatest source of income for organised crime after narcotics, although street sales of narcotics were generally believed to be in the region of US\$ 500 billion per year.

In practice, the emphasis upon the protection of intellectual property has meant that the big firms only concentrate upon that part of the southern hemisphere market able to afford medicines produced at northern prices and quality. If all AIDS victims living in sub-Saharan Africa were treated using a triple therapy at US prices, health costs would far exceed the total GDP of all sub-Saharan nations.

The implementation of TRIPS has been claimed as a means of protecting intellectual property rights, wielded in the name of innovation, but has tended to increase medicine prices in southern countries thereby reducing access to health provision. The innovation bias in favour of industrialised nations is so great that the WHO estimates that ninety per cent of the ten million annual victims of infectious diseases (HIV/AIDS, respiratory infections, malaria and tuberculosis) live in the developing world and that only one per cent of all medicines approved between 1975 and 1997 (13 out of 1,223) were for the treatment of tropical diseases.

In February 1998, thirty-nine pharmaceutical companies, mostly multinationals, launched a legal action against the South African government following a change in its domestic law permitting increased access to generic medicines. Mr. Jeffrey Trewhitt, the spokesman for the International Federation for the Pharmaceutical Industry, explained the industry's position, stressing that the South African laws would create a dangerous precedent that could erode the legitimate protection afforded by patents throughout the world. It is likely that this potential danger will spread to many developing countries. The plaintiffs, supported by the US government and the European Union, claimed that the new law was contrary to TRIPS and the South African constitution. Although its government denied the AIDS epidemic, South Africa had been hit harder than any other African nation. Of its 43.8 million inhabitants, almost 5 million had contracted the virus although only ten per cent had full-blown AIDS. Each year regrets were expressed over the 360,000 new cases of infection, and the same number of deaths. According to the South African Medical Journal, between 1998 and 2003 the death rate increased by sixty-eight per cent for adults generally and 168 per cent for women aged between 20 and 49, the group most at risk from the epidemic.

Aware of this situation, American AIDS activists harassed Al Gore's US presidential campaign. By the time the matter came before the South African courts in May 2000, the pharmaceutical industry could no longer rely upon the support of the American or European authorities. The UN Human Rights Commission reminded governments that their human rights obligations took precedence over economic policy, remarking that there are

clear conflicts between the TRIPS system of intellectual property on the one hand and human rights on the other. The European Parliament demanded the withdrawal of all litigation against the South African government. In the meantime, NGOs such as Médecins Sans Frontières (MSF), Health Action International and the Consumer Project on Technology met at Geneva (1999) and Amsterdam and argued for the use of mandatory licences in the treatment of AIDS, establishing a working party at the WTO to review TRIPS and the issue of access to medicines in collaboration with the World Health Organization; the latter adding HIV/AIDS treatments to its list of essential medicines in 2001.

This action marked a change of direction in public policy. In May 2000, President Clinton signed an order favouring the use of mandatory licences to increase access to HIV/AIDS treatments in sub-Saharan Africa. In 2001 the big pharmaceutical players were forced to unconditionally withdraw their action against the South African government following adverse public opinion and resolutions of the European Parliament and the EU commercial directorate favouring a public approach to health issues within the framework of TRIPS. Glaxo chief, Jean-Pierre Garnier, warned that the knock-on effects would be like the folding of a pack of cards if the industry assigned its patents in a single country. According to Philippe Pignare, he was merely expressing the opinion of the entire medicines industry, which is apparently convinced that the automatic, systematic extension of patent protection is an essential condition for the survival of a pharmaceutical industry distinct from generic manufacture. The British government set up a Commission on Intellectual Property Rights headed by Stanford lawyer, Professor John Barton, whose main brief was to achieve the necessary balance between intellectual property rights and third-world development. An initial response to the international health crisis came in the form of the UN global fund for the fight against AIDS, tuberculosis and malaria. Finally the Doha Declaration within the framework of the 4th ministerial conference of the WTO, announced that TRIPS did not prevent measures taken to promote public health and universal access to medicines. As regards less developed nations, it suspended the application of any TRIPS provisions relating to the protection of patented medicines for a further period of ten years (i.e. until 2016).

The manufacture of generic anti-AIDS products by Brazil, Thailand and India and the launch of an international partnership between six pharmaceutical firms and the United Nations (AAI: Accelerated Access Initiative) are the factors most associated with the dramatic price reductions that have enabled southern nations to gain access to medicines. The annual cost of anti-AIDS treatment dropped from US\$ 10,439 to US\$ 200. Bill Clinton announced an even greater fall in annual treatment costs to US\$ 140 when he launched the antiretroviral products manufactured by three Indian laboratories (Cipla, Ranbaxy and Matrix) and one South African laboratory (Aspen). Marginalised during the second international AIDS conference, the United States finally adopted the criteria of the UN Global Fund; the US Secretary of Health defending the best quality medicines at the lowest price including generics. However, these price reductions never materialised. The access to treatment initiative launched in May 2000 by UNAIDS and five pharmaceutical companies within the framework of a new public-private partnership initiated by the UN had only succeeded in treating one per cent of patients in nineteen countries by the beginning of 2003; in other words only 27,000 of the 30 million persons who were HIV-positive.

Northern governments had been slow to react to the conflict between the right of access to treatment and the right to intellectual property, despite certain declarations. The message from Jacques Chirac read to the Barcelona Conference on 9 July 2002 could not be clearer: 'To refuse to grant the poor of the world access to medicines is to be guilty of failing to assist persons in danger given that seventy million men and women are in danger of dying from AIDS in the next twenty years. Our generation will bear a terrible responsibility in the annals of history. . . . I will personally ensure that the discussions taking place at the WTO concerning the link between intellectual property and access to medicines will respect the promise made at Doha: the poor nations of the world must have access to medicines at a price that corresponds to their purchasing power. It is essential that they be granted access to generic medicines, particularly in Africa.'

Global co-operation in the field of public health, which has renewed urgency for both northern and southern nations given AIDS and new epidemics, can only be hindered by the TRIPS agreements negotiated by the WTO and the calendar set for the creation of a uniform system of intellectual property rights. Some pharmaceutical firms may have responded to appeals for access to essential medicines and a differentiated north-south

price structure within the framework of their UN partnership, but during the negotiations that preceded the Cancun WTO Conference in August 2003, the multinationals succeeded in erecting numerous regulatory barriers, which effectively blocked the extension of the market in generic medicines, manufactured by large-scale producers such as Brazil or India, to other countries without their own pharmaceutical industries.

The significance of the Doha Declaration, which appeared to create a public health exemption to the standardisation of intellectual property rights, now seems doubtful. Two conflicting philosophies have emerged. The first has been adopted by some governments and is favoured by NGOs like MSF. It favours the commonplace use of mandatory licences and the extension of their scope to all afflictions suffered by southern nations thereby enabling the emergence of a generic medicines market supplied by large-scale Brazilian and Indian producers capable of guaranteeing the best price-quality ratio. The second has been adopted by the multinationals, who have been forced to concede the principle of price differentiation and accept the emergence of a generic market in the southern nations, but who nevertheless defend the legitimacy of an international patent system as the guarantor of pharmaceutical innovation.

Their plan was to regulate the development of the generic market by invoking certain TRIPS provisions which, read in conjunction with Article 31F, limit the use of mandatory licences to the supply of the domestic market. If southern generic producers wished to export medicines to third-world countries they must obtain authorisation for each transaction from an ad hoc TRIPS committee composed of rights-holders. This new protectionism effectively regulated a market for generic products between southern nations whose only purpose was to enable the less advanced countries to gain access to essential medicines at a price proportionate to their purchasing power.

Such divergent approaches to the international health crisis delayed the implementation of dynamic solutions conforming to the basic principles advocated by the World Intellectual Property Organisation; a body that places the public interest at the centre of the patent system. A study prepared for the WIPO secretariat stated that intellectual property rights are tools that can stimulate or hinder national economic and technological development. Their inappropriate use can paralyse the development of a country . . . and accelerate the health crisis and mortality rate in those categories that concern us.

In the absence of active co-operation between the public and private sectors, counterfeiting, in the sense of the manufacture of generics without the consent of the rights-holders, is considered a necessary response in many southern nations to the blind protectionism imposed by intellectual property rights or as Rony Brauman calls them: patents which make us sick. A lack of co-operation can only reinforce the north-south inequalities that have been building over the previous two decades. Whereas the public and private health expenditure of the United States amounted to US\$ 1,500 billion per year, the African debt burden, estimated at US\$ 15 billion, represented four times the continent's health and education expenditure.

Per capita health expenditure varies between the richest and poorest nations by a ratio of 1 : 700 (or 5 : 3,500 euros). The northern pharmaceutical firms have regularly attempted to block southern production of generics by claiming that they create a risk of parallel imports. This argument is scarcely credible. The generics manufactured by southern nations are not licensed for sale in northern nations where the distribution of drugs is strictly regulated by a pharmaceuticals monopoly and a system of medical prescriptions. Besides under the actual rules, the U.S, which is the first world market, prohibits importing of any drugs from other countries, even the branded drugs. The FDA holds that they cannot determine if imported drugs are safe. Thus U.S citizens are prevented from buying drugs even in Canada and Mexico.

But the resistance to the generics in the southern countries as well as in the northern countries during the first decade of this century slowly changed with the perspectives of the market. According to the IMS Institute for Healthcare Informatics, the global spending on medicines was supposed to grow between 605 billion US \$ in 2005 to nearly 1.100 billion in 2015, with a declining share for the US (from 41 to 31 percent) and Europe (from 27 to 19 percent) a constant share for Japan and South Korea (around 12 percent) and a rising share for the emerging markets led by China (from 12 to 28 percent). Besides, the share of brands in the global pharmaceutical spending was expected to decline between 2005 and 2015 from 70% to 53 %, with patent expiries, and the share of generics

was expected to grow from 20 to 39 % during the same period . As pharmerging markets and generics were expected to be the main drivers of growth, transnational corporations adopted their business models to these new realities.

The cost of a north-south pricing structure appeared a small price to pay, given that defending a system like TRIPS, which is devised to protect intellectual property on a global scale and restrict or control the southern generics market, could have a devastating cost for the twenty or so western firms that control sixty-five per cent of the global market. The institutional investors that ultimately control these firms had long understood the risk; one of Europe's most powerful investment groups, responsible for the management of 940 billion shares, had insisted that pharmaceutical companies adopt a voluntary approach to the looming public health crisis by publishing a code of good practice requiring Astra Zeneca, GlaxoSmithKline and Novartis AG to price their medicines according to the capacity of each market to pay, and to desist from the practice of selling the cheapest medicines to the developing world and imposing patents upon the poorest countries.

Besides the restrictions upon generic imports between southern nations, the new strategy adopted by the multinationals consisted of massively patenting the most effective anti-AIDS treatments in key intermediary markets while granting voluntary licences to generic manufacturers. South Africa was the chief target of this offensive, since it represented seven per cent of the region's population, seventeen per cent of its infections and forty-one per cent of its wealth. As demonstrated by Samira Guennif and Claude Mfuka, the voluntary grant by GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) of a licence to a local producer, Aspen Pharmacare, for antivirals that best meet the needs of developing countries in terms of cost and ease of production and treatment has effectively blocked competition from generic Indian producers and others in what has become a captured market. This strategy have prevented competitors from building sales, benefiting from economies of scale, reducing costs, increasing margins and attempting the transition from imitation to innovation.

The anti-competitive exploitation of intellectual property rights maintains control of the availability and price of products for which substitutes are difficult to find and regulates the conditions under which access is permitted to the most effective drugs. It did so independently of governments, which, particularly in the case of South Africa, lacked the political will to resist. The competition represented by southern generic producers seemed to have been a sufficient threat to close the door, in the medium to long term, upon any model of intellectual property intended to finance innovation. This is why the global pharmaceuticals industry has argued that Indian generic producers, which manufactured about half of anti-retro-viral treatments against AIDS, should be brought into line by TRIPS and made to comply with its timetable for strictly limiting the copying of patented medicines from 2005 .

#### INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL INNOVATION

The question of innovation, its cost and the optimal procedures for its achievement are central issues in the current transition of intellectual property rights. On the one hand, it seems fairly evident that the protection afforded to patent medicines by granting them a monopoly limited in space and time has been: a determining factor in the accelerated growth of the pharmaceuticals industry during the 1960s as pointed out by Marc-Hubert Depret and Abdelillah Hamdouch. On the other hand, the adoption of a uniform system of intellectual property rights via TRIPS is by no means certain to stimulate innovation geared to the requirements of the southern nations, since research and development is strictly determined according to solvent demand and the investment returns available in northern countries.

The notion of some virtuous circle where today's profits become tomorrow's investments and fund the innovations of the future thus contributing to global welfare is nothing more than a fantasy. The better future, which it is promised will arrive following the standardisation of intellectual property rights, will amount to nothing more than a continuation of today's pain and the current cycle of infectious disease and other pathological illnesses exacerbated by the difficulty of access to essential medicines.

Quite apart from the question as to how its benefits are to be distributed, the

nature, cost and most advantageous methods of innovation must be considered. According to William Jack and Jean O Lanjow, research and development should be judged according to whether the investment leads to the discovery of new products and to what extent these new products confer new benefits in comparison to alternative products. The cost of stimulating innovation at all levels is directly linked to the time required to make the discovery.

But the measure of innovativeness in drug development depends largely from the retained definition, as AS Kesselheim, B.Wang and J.Avron have shown in a systematic review of the literature. If we simply define innovation by drugs counts, that is to say the approval of new molecular or new chemical entities (NMEs or NCEs) which are synonymous terms, the trend is constant or positive in most studies published. By contrast, if we rely on other definitions such as economic markers (productivity of R&D, cost-effectiveness, market share), patents rates and their subsequent citations, or therapeutic value measures, the trend of innovation is not favourable in most of the literature. If the therapeutic value measures hold the greatest promise for evaluating the effectiveness of investment in drug development by public and private sources, here again the evaluation of innovativeness differ according to different sources.

A first study, led by P E Barral and commissioned by the firm Aventis, investigated 26 years of pharmaceutical research in the world 1975-2000 and concluded that during this period the proportion of molecules that were truly innovative in their therapeutic contribution and chemical structure only corresponded to ten per cent of new medicines produced by the research departments of pharmaceutical companies. These are the blockbusters; medicines that generate turnover in excess of US\$ one billion and provide the platform for the growth of transnational pharmaceutical companies. At the time of this research, these beacon medicines usually represented more than one-third of sales in the sector and it was estimated that eighty per cent of world sales were generated by only fifteen per cent of products sold. By contrast the new molecules with a chemical structure that had already been discovered and which failed to offer any therapeutic advance constituted 56 per cent of new medicines.

The independent drug bulletin *La revue Prescrire* analyses the therapeutic value of new drugs approved in France. In a synthesis of twenty two years of its annual report, compiled by pharmacologists and doctors for the purpose of aiding practitioners to identify genuine advances, it examines 2,693 new medicines introduced by pharmaceutical firms between 1981 and 2002 inclusive and concludes that 66.1 per cent (1780) do not make any new therapeutic contribution, sixteen per cent may have a minimum added value, 7.9 per cent have some added value, 2.7 per cent represent significant clinical advance and only 0.3 per cent represent a major advance. In the following decade, 2002-2012, 15.6 percent of the drugs represent more risk of harm than benefit, 54.7 percent are without added value, 21.7 percent have a minimum added value, 6.4 have some added therapeutic value, 1.4 represent significant clinical advance, and 0.2 percent (or two drugs) mark a major advance in a new area .

Two other studies have surveyed physicians of 15 specialities in some 30 leading U.S academic medical centres to identify the most innovative drugs approved by the Food and Drug Administration between 1984 and 2009, according to their superiority over pre-existing therapies, the burden of morbidity affected, the overall effectiveness and scientific importance of the drug. These studies have shown that four drugs on the 21 identifies were approved in 2000 or later. Most of the transformative drugs were based on research and development conducted by scientists in academic medical centers, often supported by the National Institute of Health or other public funding, sometimes with the support of industry collaborators at the investigation stage, and always with the support of them at the clinical trial stage. Nine of the 26 (35 percent) innovative drugs were repurposed drugs originally studied for another indication and a disproportionate number of transformative drugs (10 of the 26 or 38 percent) were originally orphan drugs for patient with rare diseases, whose prescription extended for larger indications, especially in oncology.

Thus, research and development are experiencing a serious productivity crisis since 2000, due to the reduction in the number of licences being issued for the sale of medicines following the adoption of more selective criteria (seventeen medicines were approved in 2002 compared to more than fifty 20 years before) and the fact that half the world's 100 best-selling medicines entered the public domain in 2005.

Pure molecular research only represents twelve per cent of R&D costs while pre-clinical development amounts to thirty per cent and clinical development (test phases 1-4) thirty-four per cent, with the remaining budget being absorbed by quality control, registration, bio-availability etc. The general tendency among pharmaceutical firms has been to reduce costs by contracting-out thirty to forty per cent of their R&D to laboratories specialising in pure research or development.

The figure quoted most often for the cost of each medicine launched into the market is US\$ 802 million. However this estimate is provided by research centres largely financed by the pharmaceuticals industry and includes molecules discovered with the help of public subsidies. Moreover half of the sum is purely notional since it represents opportunity costs, being the interest lost by investing capital in a business venture instead of banking it and drawing the interest. Several recent studies and in particular those conducted by Henry and Lexchin (Lancet) and M. Angell, former editor of New England J. Med (Washington Public Citizen) reveal that these costs are over-estimated by four to five hundred per cent and that the true figure is nearer 100 to 250 million euros.

There is therefore a lack of transparency in pharmaceutical industry costs, the allocation of public funds with the National Institute of Health and other public funding contributing approximately eighty per cent of US biomedical research budgets. For example zidovudine and the four other anti-retrovirals that make up the family of nucleosidic inhibitors were invented at Yale University using public funds; the university, like all American higher institutions since the 1980 Bayh-Dole Act, acquired intellectual property in its discoveries, which it transferred to the pharmaceutical giant Bristol Myers Squibb (BMS). Moreover, research and development costs must be viewed in comparison to marketing budgets. R&D costs were estimated to be an average fourteen per cent of sales in the 1990s as against marketing budgets for the big pharmaceutical firms equivalent to twenty-four per cent of sales. Indeed it is not unusual for groups to allocate more than thirty per cent of revenue to promotion and marketing. More than one-third of all staff are employed in the marketing of medicines, while in France, pharmaceutical advertising represents ten per cent of total industrial advertising costs bettered only by soaps, cleaning products, perfume and cars. The US pharmaceutical industry employs nearly twice as many marketing than research staff; the marketing and administration budget for the BMS Group was US\$ 3.86 billion in 2000 while its R&D budget was only US\$ 1.93 billion.

Quite apart from the issues surrounding the cost of innovation, the methods used by researchers changed considerably during the nineties with the advent of the chemical paradigm as a means of understanding biological phenomenon. In 1999 two out of every three medicines approved by the Food and Drug Administration originated from new biotechnology whereas ten years earlier, the figure was one in four. The rapid advance in genomic understanding in its wider sense has led to new forms of co-operation between academic research, biotechnology laboratories and pharmaceutical firms and the integration of the technologies and methods developed by the new laboratories. The multiplication of knowledge and its easy categorisation as intellectual property means that in this new age it has become the principal tool of accumulation, as demonstrated by the 1,273 new laboratories set up in the United States in 2002 compared to 280 in the United Kingdom, 340 in Germany and 250 in France.

In July 1984, France enacted a bioethics law that stated that no part of the human body, its elements or products, nor any total or partial gene structure could be patented. However, Directive 98/44 of the European Community permitted the patenting of a total or partial gene sequence provided it is accompanied by an explanation in concrete terms describing the sequence's function and its industrial application. In the United States, broadly defined patents have been granted without difficulty and have resulted in large profits for biotechnology and venture capital companies. The patents are broadly defined in the sense that the first person to acquire rights to any specific application of a gene may claim the rights to other applications of the same gene without having specified such additional applications when registering the initial patent.

This has delayed medical advances, since the large firms have acquired broadly defined patents allowing them to profit from public research; a situation admirably described by John Sulston, the 2002 Nobel prize-winner for medicine. For example the American company, Myriad Genetics, acquired the patent to the entire BRCA 2 gene associated with breast cancer, which was discovered by the British Institute of Cancer Research. Myriad then systematically exploited its monopoly by attempting to impose

exclusive licences at exorbitant prices upon other research institutions, thereby inhibiting potential discoveries under the guise of protecting intellectual property. The U.S Supreme Court finally overturned the patent in 2013, and determined that DNA in its natural form was not patentable .

This type of case has become commonplace in the United States, where the biotechnology companies complained to the National Institute of Health about the negative impact of patents upon their research while researchers involved in human genome sequencing, achieved in 2003, introduced rules for the immediate and public dissemination of their work in order to avoid duplication between teams, appropriation of research work and the exploitation of intellectual property to prevent the advance of knowledge as they sought to maximise the advantages for the whole of society from a strategically important research and development field. In the year 2000, twenty per cent of therapeutic targets were determined using genomic analysis whereas the current figure is closer to eighty per cent while our knowledge of the human genome and its 30,000 genes will enable a five- to six-fold expansion of the biological targets previously used by the pharmaceutical industry.

A comparison of the commercial attempt at genetic sequencing and genome patenting by Craig Venter and his company Celera Genomics, whose share price plummeted from US\$ 250 to US\$ 14 between 2000 and 2004, and the corresponding public project, championed by John Sulston, finally confirms the effectiveness of international scientific co-operation between public bodies where useful data is universally available notwithstanding the fact that it is patentable. Sulston rightly attributes the extended use of patents to the gulf that has emerged between science and culture and the confusion that now exists between science and technology, the former being subject to the interests of the latter. Scientists are thus driven to commercially exploit their discoveries irrespective of the impact this may have upon society as a whole. Since the number of gene patent applications has already exceeded half a million, there are good reasons for questioning this model of intellectual property science, which, in order to benefit a mere handful of companies, limits the scope of discovery by multiplying the barriers to research.

In the two major branches of today's technological revolution, biotechnology and IT, where the acquisition of knowledge is a cumulative process and each innovation is necessarily built upon previous discoveries, the multiplication of intellectual property rights is inhibiting the innovation that they are meant to encourage. The idea, first developed by Heller and Eisenberg, that patents are counter-productive in sectors where innovation is cumulative has been supported by Bessen and Masin. The current broad scope of patents is permitting the creation of monopolies for the benefit of a handful of companies to the detriment of the public good. In addition to the hold-up tactic used by previous rights-holders to exploit subsequent discoveries that they had not even envisaged, the minefield strategy has emerged, whereby a whole series of patents are accumulated, notwithstanding limited research and development, for the sole purpose of holding to ransom companies that inadvertently infringe these patents in the process of launching successful products. The accumulation of patents and the monopolies they confer thus becomes a huge resource within a remarkably short time and shifts market competition from the laboratory to the courtroom.

The increasing role of lawyers in the economy tends to complement and reinforce its domination by accountants. The growth in patent applications, which doubled in the US during the previous twelve years and which increases by ten per cent annually and currently stands at 300,000 per year, has led to a sharp deterioration in the quality of the work performed by patent offices and a corresponding increase in their use of quantitative criteria. The extension of what may be patented and the ability to acquire a patent within a short period is being increasingly challenged in the biotechnology sector and the computer software and semi-conductor industries where, following an initial phase of vigorous expansion, the US intellectual property model has inhibited both innovation and competition by imposing patents and multiplying barriers to research. As an exclusionary property right, patents are more and more used as a strategic weapon to shape market and to reap monopoly rents through patent monetization, current in many global industries, such as the telecom.

Conversely, any disincentive to investment created by the absence of intellectual property rights may be balanced by free access to existing innovations; the sharing of technology will in time enhance innovation. This communal ownership model has worked when

applied to freely available software and has been successfully practised, as we have seen, in the sequencing of the human genome. It enables the avoidance of the hold-up and ineffectual tactics exploited by firms that accumulate patent portfolios merely to garner profits. The whole future of biology depends upon advances in bio-computer technology, which numerically processes data; the patenting of these databanks will only restrict research by limiting access to knowledge.

Therefore, biotechnology research methods that determine the extent of pharmaceutical innovation are heavily dependent upon intellectual property regimes, which vary between America and Europe. The considerable extension of intellectual property rights and the scope of what may be patented is driven by dynamics contrary to the stated objectives.

## BUSINESS MODELS AND INNOVATION RISKS

The big pharma's old business model based on IP and blockbuster, is challenged by the fall off of patented medicines, the rise of the generic market and the emerging markets, decreased R&D productivity, increased public and private payor pressures for new product pricing. Despite such accumulation of challenges, the net return on revenues of an average U.S major pharmaceutical company has been two to three times higher than the average Fortune 500 companies, from 2000 to 2011. To understand this discrepancy, numerous scholars have resorted to the concept of institutional corruption, first defined by D.F Thompson and Lawrence Lessig. According to Lessig, institutional corruption is manifest when there is a systemic and strategic influence which is legal, or even currently ethical, that undermines the institution's effectiveness by diverting it from its purpose or weakening its ability to achieve its purpose, including, to the extent relevant to its purpose, weakening either the public's trust in that institution or the institution's inherent trustworthiness.

The seventeen contributions edited by Marc Rodwin on Institutional Corruption and the Pharmaceutical Industry in the special issue of The Journal of Law, Medicine and Ethics (Vol. 41:3.Fall 2013) gather further evidence of a massive direct or indirect influence of the pharmaceutical industry on all aspects of public health, from legislation, by lobbying spending in the Congress, where it ranks first, bypassing FIRE (for finance, insurance and real estate) to research and development, production of knowledge, clinical trials selective results, information on the risks of drugs and monitoring of patient safety, marketing, prescription, FDA regulation, and even patients and physicians communications networks.

Innovation in the field of public health sometimes entails lethal risks. By attempting to monopolise information and the scientific evaluation of their products, the pharmaceutical companies are wielding a double-edged sword. They risk alienating consumers alerted by the scientifically proven risks associated with several medicines that have been withdrawn from circulation or carelessly prescribed. These include the Deroxat anti-depressants manufactured by GSK, Zoloft and Pfizer; the Prozac, Eli Lilly, prescribed to 50 million patients throughout the world; the anti-inflammatories Bextra and Celebrex manufactured by Merck and Pfizer respectively; menopausal hormone replacement therapy associated with cardio-vascular risks; the anti-cholesterol Crestor marketed by Astra Zenaca; the anti-asthmatic Serevent produced by GSK; the anti-obesity treatment, Meridia, manufactured by Abbott, the isotretinoin Roaccutane produced by Roche, etc.

Besides, pharmaceutical products can produce, apart from therapeutic benefits, undesirable or even harmful effects such as toxicity and allergic reactions. The most reliable studies indicate that prescription drugs use causes over a million individuals to be hospitalised and between 106,000 and 140,000 deaths in the United States each year, or three to four times the casualties of automobile accidents in the U.S.

Further research would be link this phenomena with the business model of Big Pharma, based on branded drugs and the maximizing of sales volume. In some cases, such

as the anti-biotic market, which answers to an essential need in terms of therapy, this price/volume business model is completely inadapted to the northern market, in the sense that it is a key barrier to achieving more progress on resistance. Apart from the question of antibiotics, the different incentives accorded to manufacturers of orphan drugs (to treat rare diseases affecting less than 200.000 people in the U.S), may not encourage transformative drugs especially in oncology, where the safety of orphan drugs seems worse than nonorphan drugs for cancer treatment.

#### CONCLUSION: MORE OF THE SAME?

Far from adapting to a multilateral world, and to new challenges of innovation, the TNC from the pharmaceutical industry cling to their traditional business model based on IP and worldwide commercialisation of their products. After the implosion of the Anti Counterfeiting Trade Agreement (ACTA), negotiated by the US with mostly high-income economies, the Trans-Pacific Partnership, negotiated secretly since 2008, is part of a global effort to shift power to the TNC by strengthening property rights. According to documents that have been leaked, and reports from NGO and industry meetings, the TPP would require 'evergreening' of the 20 year patents for pharmaceutical and medical devices. Physicians for a National Health Program denounces this tendency : 'whenever there is any change such as a new indication or a new delivery method, the patent must be renewed even if there is no added therapeutic benefit'. In addition the TPP places barriers to new generics by prohibiting the use of data from clinical trials conducted on behalf of the patented medication, project to open patenting to surgical procedures, treatments, diagnostic tests, and permits corporations to sue governments for loss of expected profits if their law that protect public health interfere with profits. A few scholars have underlined that the maximalist view , promoted in the US proposal for an IP chapter in TPP is quite unrealistic and alienating its ultimate expansion to countries the United States is more concerned about, namely China, Brazil and India, which was already hostile to the TRIPS agreement under WTO.

In 2003, the French Council of Economic Analysis concluded its report on Intellectual Property in these terms: 'the system of patents used to protect intellectual property in the developing world is in a sorry state, particularly in the United States. The problem is most severe and most evident in the bio-medical sector but it extends much further. And it is this sorry system that will be forced on the rest of the planet by the TRIPS Treaties negotiated within the framework of the World Trade Organisation'.

Despite considerable progress that has been made in terms of access to medicines in the emerging countries, and especially in the BRICS, the Big Pharma clings to a maximalist view of the IPR, and continues to influence the trade and negotiation agenda.

Intellectual property law as enacted by the state is therefore at the centre of the search for a new balance between the interests of innovators and producers on one hand and those who prescribe medicines and consumers on the other. The necessary evolution of the law, which has been perversely influenced by influential lobbies, will certainly be difficult, since it will involve modifying the accumulation of wealth, the ability to gain from the value added to products, and the distribution of income, features common to every form of property. However, public health is now sufficiently high on the international agenda and plays such a key role in north-south relations that a new political will exist.

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