Patents and Health

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]abs[Abstract

]p[The history of patents in the health field has been characterized by conflicts and exceptions since the early nineteenth century. Many states, both in Europe and in the global South, excluded medicines and medical methods from patenting for a long time, while the codes of ethics of medical organizations and faculties proscribed patenting by doctors and scientists. Today the pharmaceutical industry patents more innovations than any other, and is also the industry whose patenting practices are challenged the most by states and civil society. Contrary to the postulates of jurists who believed that the industrialization of pharmaceuticals and the growth of investments in research unquestionably justified the patenting of medicines under common patent laws, the normalization of medicine patents was rapidly called into question by the AIDS epidemic. The globalization of 20-year medicine patents which occurred with the creation of the World Trade Organization in 1994 triggered opposition and challenges to the innovation patent model. Economists and NGOs now vie with each other in proposing ways of reconciling innovation and access to treatment.

]k[Keywords: AIDS; globalization; human rights; pharmaceuticals; public health

]p[The health field is a locus of strong tension between private appropriation of innovations and access to them, between the payment of a monopoly rent and calls for a "right to health" or a "right to life" (Foucault 1976). In 2001, for instance, the organization Treatment Access Campaign advocated for "Patent rights against patients' rights" in South Africa. Pharmaceuticals is the industry with the most patents on its innovations (Mansfield 1986), and the one whose patenting practices are challenged the most by the state and civil society. Even though patents reward the inventor's efforts and merit, and are indeed an incentive to research and industry, in the health field patenting has to come to terms with people's right to health, with states' public health objectives, and with the ethics of doctors who tend to oppose any impediment to their activity due to the existence of patents.

]a[**The Long History of Exceptions to Patents**

]p[The history of patents in the health field is marked by opposition and exceptions to exclusive property rights. The first French law on invention patents in 1791 extended patents to "all kinds of industry," including pharmaceuticals. In 1810, however, the state set up a system of public procurement of medicine inventions, in parallel with patents. The formulas bought by the state were to be put into the public domain to further the advancement of knowledge and to satisfy public health needs by "increasing the means useful to the art of healing." Thus, during the first half of the nineteenth century in France, two systems of property rights existed for medicines. With the reform of the patent law in 1844, parliament decided, against the government's initial recommendation, to exclude medicines from patenting. The idea was to ensure that the granting of patents did not facilitate trade in fraudulent remedies developed by charlatans. It was also to prevent the creation of monopolies on essential goods: "Based on the law and common sense there is incompatibility between a pharmaceutical composition that is useful for humanity and an exclusive exploitation for the profit of a single interest" (Parliament, Le Moniteur Universel, 1843). The non-patentability of medicines led to the copying of foreign patents, primarily German patents, and the constitution of a modern pharmaceutical industry including, notably, the firm Rhône-Poulenc. In the early twentieth century this firm undertook the systematic copying of German patents in collaboration with the Pasteur Institute. This regime of non-patentability lasted in France until 1959, when a "special medicines patent" was created, and finally, medicines fell under common patent law in 1968.

In North America as a whole, there was strong opposition to patents within medical associations and university medical faculties, although the law had authorized medicine patents since the late eighteenth century. The 1847 code of ethics of the American Medical Association condemned patenting by doctors or scientists: "Equally derogatory to professional character is it, for a physician to hold a patent for any surgical instrument, or medicine" (Swann 1988). When doctors at Toronto University discovered insulin in the early 1920s, the norm of private non-appropriation of pharmaceutical inventions was soundly entrenched in the academic world – apart from a few mavericks like E. C. Kendall (Rasmussen 2004). The University of Toronto eventually decided to file for patents on the new pancreatic extract that it had isolated and on the extraction and purification processes that it had developed, not to derive an innovation rent but as a means to have control over industry. More precisely, the university wanted to control the quality, price, and accessibility of insulin for patients. In the early 1920s it set up a collective management of these patents in the form of a patent pool that was to bring together all patents on insulin preparations until the 1950s. While the patenting of insulin by the University of Toronto facilitated changes in academics' norms with regard to patents during the interwar

period, the fact of doctors or university researchers filing for patents was justified at the time by the aim of controlling the exploitation of medicines in the public interest, rather than transferring university research (*JAMA* 1939). Debate on medicine patents reappeared in the USA at the end of the 1950s, after an anti-trust inquiry into the pharmaceutical industry, conducted by Senator Estes Kefauver. In order to reduce the price of medicines, he proposed a steep decrease in the length of the right to exclusive exploitation granted to patent holders. While the validity of patents was still 17 years, the exclusive right to ownership of medicine patents would be cut to three years, at the end of which patent holders would have to grant licenses to other firms, in exchange for royalties. In case of deadlock, the senator recommended the granting of a compulsory license, which permits a third party to use a patent without the owner's authorization. The Association of the Pharmaceutical Industry vehemently opposed this bill and highlighted the discoveries of American research. In the end President John Kennedy rejected the bill. Research by economist Frederic Scherer has shown, however, that on several occasions in the 1950s and 1960s, the US government used anti-trust legislation to break up monopolies in the health field (Scherer 2000). Debate on compulsory licenses was triggered again in the USA in autumn 2001 during the anthrax crisis. Congressmen and women engaged in campaigns for access to medicines petitioned the government to suspend Bayer's patent on Cipro and to authorize generic medicine producers to manufacture and supply antibiotics for the National Pharmaceutical Reserve. However, the state secretary for health eventually excluded the option of generic medicines and endorsed the incentive role and legitimacy of the patent system.

In the early 1970s two large emergent countries, India and Brazil, decided to exclude pharmaceutical substances from patenting. In Brazil, neither pharmaceutical products nor processes were patentable, while in India, seven-year process patents were still applicable. The fact that pharmaceutical products were being placed in the public domain facilitated the copying of international patents and the upsurge of a powerful generic medicine industry, especially in India.

]a[**The Impossibility of Normalizing Patents in the Health Field**

]p[While medicines could not be patented in Brazil, India, and many other countries of the global South, the patent model has tended to be consolidated in Europe and Japan. Patents on pharmaceutical products were authorized in France in 1960, in Germany in 1968, in Japan in 1976, in Italy in 1978, and in Spain and Sweden in 1992. The extension of the patent model was justified by the steep rise in the cost of research and development and the need for firms to recoup their investments in developing a medicine. Scherer (1998) estimated this cost at US$98

million per medicine in 1980, including clinical research and failures. Grabovski (2002) pointed out the increase in the number and size of clinical trials in the 1990s, and put forward the figure of US$400 million for the late 1990s. The 1980s and 1990s were marked by a vigorous offensive in the United States and large innovating countries to reinforce the patent system on a global scale and to close the space that had been opened for copying in Brazil and especially in India. In 1997 the US Academy of Science published the report *America's Vital Interest in Global Health: Protecting Our People, Enhancing Our Economy and Advancing Our National Interest* (Institute of Medicine 1997). The authors of this report denounced China's and India's "pirating" and recommended the strengthening of intellectual property (IP) rights on a global scale. In the meantime, in 1994 signature of the trade-related intellectual property rights (TRIPS) defined the new intellectual property norms set out in the agreements of the World Trade Organization, created in 1994 – agreement had been set as a condition for the WTO's adoption of 20-year patents on medicines.

Paradoxically, the globalization of 20-year medicine patents via the WTO precipitated opposition and challenges to the intellectual property rights model. The AIDS epidemic, more than others, triggered the creation of social movements advocating access to treatment, which intervened directly in the intellectual property rights field. From 1996, Act Up demanded "Access for All" to tri-therapies for HIV/AIDS. In 1998 Médecins sans Frontières (MSF) launched its campaign for access to essential medicines. In 2001 a cartel of 38 international pharmaceutical firms challenged the South African government over a clause in the country's new law on medicines, authorizing imports of generic versions of patented medicines from countries where prices were lower. The Pretoria trial was a key event in the confrontation between the "right to health" and patent rights. Faced with strong mobilization by NGOs and public opinion, international pharmaceutical firms eventually withdrew the charges. They did nevertheless obtain an undertaking from the South African government that it would not use compulsory licenses to produce patented medicines locally, unless authorization was obtained from the patent owner.

In November 2001 the WTO, under pressure from India, Brazil, and certain NGOs, signed a declaration in Doha on intellectual property and public health. It recognized the right of states to use flexibilities in the TRIPS agreements, especially the possibility of using patents without authorization from the holders, in situations of public health crisis: "we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." In 2005 the TRIPS agreements were amended to introduce compulsory licenses for exports to and imports from countries that did not have a local pharmaceutical industry. While these

measures were complex in practice, they did ratify the possibility of building a generic medicines market to cover the public health needs defined by states.

The 2000s were marked by decisions taken by countries of the South to implement compulsory licenses, whereas until then such decisions had been taken only by countries of the North (Scherer 2000). Compulsory licenses were decreed in Thailand in 2006 and then Brazil in 2007, following intense mobilization by civil society and local health ministries. In Brazil the state president authorized the local production of Efavirenz, an AIDS anti-retroviral (ARV), for "a public non-commercial use." The aim was to supply Brazil's national AIDS programme which distributed these medicines freely to patients (Cassier and Correa 2008). In Brazil and India, sometimes jointly, patient organizations and generics laboratories initiated opposition procedures to obtain the cancellation of certain patents. In 2008 this opposition resulted in patents on Tenofovir, another HIV/AIDS ARV, falling into the public domain, in both India and Brazil. Generic drugs producers in these two countries can now produce freely. In India an opposition procedure initiated by a cancer patient organization and several generic drugs producers resulted in cancellation of Novartis's patent on Glivec, in the name of public health. This decision was upheld on appeal: "Thus, we also observe that a grant of product patent on this application can create havoc to the lives of poor people and their families affected with the cancer for which this medicine is effective. This will have a disastrous effect on society as well" (Novartis v. Union of India, Intellectual Property Appellate Board, may 2009). On 3rd april 2013, The Supreme Court of India confirmed the rejection of the Novartis patent on Glivec (Novartis v. Union of India, Supreme Court of India, april 2013).

The normalization and globalization of medicine patents triggered an increase in intervention by governments and citizens to regulate intellectual property and access to treatment. The AIDS epidemic and campaigns for access to essential treatment also had the effect of shifting these interventions to countries of the South. President Lula's decree on a compulsory license was the first of its kind in Brazil. In parallel, the 2000s witnessed strong mobilization by doctor and patient organizations, and by some countries in Europe as well as Canada, the United States, and Australia, against patents and commercial monopolies on genes and on breast cancer genetic predisposition tests.

]a[**Solutions to Reconcile Patents and Public Health**

]p[Despite citizens' and states' intervention to secure access to medicines – via the demand for compulsory licenses or the initiation of opposition procedures – tensions for access to treatment increased following the gradual closure of the copying industry in India and Brazil as these

countries granted patents on new molecules (from 1997 in Brazil and 2005 in India). Whereas generic copies of the first HIV/AIDS ARVs had made it possible to broaden the scope of access to treatment, the prices of new generations of patented ARVs is now threatening that progress.

Several solutions have been put forward to widen accessibility of patented medicines: grants for research and development on neglected diseases, and no royalties or very low rates for developing countries (Grabovski 2002); suspension of patent rights in countries of the South when the firm had filed a patent in a country of the North (Lanjouwe 2002); purchase of patented inventions by an international organization that would then put them in the public domain (Kremer 1998); and encouragement of developing countries to use all the flexibilities of medicine patent laws to reduce the scope of monopolies (Correa 2007). MSF and then UNITAID proposed the creation of a patent pool containing all ARV patents. The idea was to facilitate the development of combinations of molecules and the distribution of licenses to all manufacturers who requested them. At this stage the patent pool created by UNITAID in 2008, on the basis of voluntary contributions by firms, has received patents from only national institutes of health sciences (NIHs) and the firm Gilead. We recall that during World War II, the US government was able to demand that firms engage in contracts with the Office of Scientific Research and Development distribute non-exclusive licenses on their patents to other contracting parties. At the time, the US and British governments agreed to form a patent pool for inventions relating to penicillin.

Several actors have proposed a system of automatic compulsory licenses such as the one applied in Canada in the 1970s, or that envisaged by Senator Kefauver at the end of the 1950s in the United States. Between 1969 and 1992, the Canadian patent authorities granted no fewer than 613 compulsory licenses authorizing the importation of patented pharmaceutical material for producing generic medicines locally. The Canadian medicines were 50 percent cheaper than those patented in the United States. This system was abolished in 1992 and replaced by a control on medicine prices. Note that compulsory licenses do not cancel the intellectual property rights of patent holders. Instead, the rate of royalties is lower (1.5% for the compulsory license on Efavirenz in Brazil) and the patent holder loses the right to exclusive exploitation.

New solutions have appeared in the field of neglected diseases. We know that the proprietary innovation model has turned away from diseases found mostly in poor populations, and from "tropical" diseases. Between 1975 and 1999, only 0.1 percent of all new chemical entities were intended for tropical diseases (Trouiller 2002). In 2002 a consortium initiated by Médecins sans Frontières and administered by the DNDI (Drugs for Neglected Diseases Initiative) launched a pharmaceutical innovation project to design new combinations of

molecules against malaria. This consortium was based on a technological development model shared between the North (the University of Bordeaux in partnership with a start-up and Sanofi Aventis) and the South (the federal pharmaceutical laboratory Farmanguinhos in Brazil). The DNDI imposed a policy of non-patenting of the new medicines obtained. Two new drug combinations developed in 2006, ASAQ and ASMQ, are now produced by a laboratory in Morocco and by the generic drugs producer Cipla in India. These firms use technology transfers between France and Morocco, and between Brazil and India. In 2009 the WHO's World Health Assembly recognized the necessity to work on innovative solutions as alternatives to the patent system, despite much resistance, primarily from the United States which opposed WHO involvement in this type of process (Velasquez 2011).

SEE ALSO: Biopolitics; Biopolitics and Biological Citizenship; Drugs: Public Policy; Health and Globalization; Health Care Delivery System: Brazil; Health, Political Economy of; HIV/AIDS, Health Services Utilization Among People Living with; Pharmaceutical Industries

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