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Intellectual property, transfer and accessibility of medical technologies: between the market and public health

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The development and circulation of medical technologies have never depended exclusively or even primarily on market mechanisms. Although today's market for health products is huge, and patents on medical technologies have increased substantially since the 1960s – especially in the mid-1990s with the TRIPS agreements –, market mechanisms have to compromise with public health policies and with the ethics of medical access defended by doctors, patient organizations and other NGOs. There is thus a biopolitics of drugs, supported by states and various collectives of actors, which cannot be reduced to the health product market. This market is in fact strongly regulated by the biopolitics in question, including the drug agencies which control the quality and utility of products. In this paper I consider four current or historical cases to show the respective manifestations and extension of this biopolitics and of the health product market.

1- Globalization of Pasteur's vaccines in the late 19th and early 20th centuries

The human vaccines invented in the late nineteenth and early twentieth centuries circulated relatively freely in many countries once it became possible to duplicate both the preparation methods of these vaccines – which had a status of free, common goods not appropriated by intellectual property rights – and adequately equipped local production laboratories. Pasteur was quick to promote the creation of local laboratories for the production of the rabies vaccine, as it was essential for these laboratories to be close to patients who had been bitten

and who needed freshly prepared vaccines. For that purpose he recruited chemists, to teach them the production method, and gave them the required raw material in the form of rabbits inoculated with the rabies virus. By circulating knowledge, chemists and rabbits, he disseminated the production and distribution of vaccines. No patent was filed on the rabies vaccine preparation method, and medical ethics accelerated its being put into circulation.

The same applied to the BCG strains produced by Calmette in the early 1920s, which were made available to any laboratory that requested them. Here the strains clearly had the status of common, non-appropriated goods. This free accessibility of BCG strains was to have the unfortunate consequences of the vaccine accident and the ensuing Lubeck trial in Germany in the early 1930s. The accident, which was imputed to an error in the preparation of vaccines, highlighted shortcomings in the control of laboratories which could obtain the strain and prepare vaccines. Calmette drew the following conclusion: it was important to exercise some control over the local laboratories that were likely to obtain strains to produce vaccines. The globalization of vaccine preparation methods implied not only their unrestricted access – their status as a common good – but also the extension of the regulation of good manufacturing practices and a standardization of vaccines. In this context, in the absence of state regulation, and where the spread of Pasteur institutes abroad was a means to globalize vaccines – including under the colonial policies of the French empire – , it was scientists and medical institutions that invented the biopolitics of medical technologies.

2- Globalization of insulin between the wars: a biopolitics of drugs invented by a university

The discovery of insulin in 1922 was truly a revolution in the treatment of diabetes. Because insulin was a product whose preparation and use could be

dangerous for patients, and because its discoverers cultivated a certain defiance regarding the commercial exploitation of their discovery, the University of Toronto decided to patent the new drug. Its wish was not to construct a commercial monopoly or to extract a rent from their discovery, but rather to exercise control over the industry via patents and licences granted to private pharmaceutical laboratories, and thus to prevent any monopoly on insulin. With its patents the University of Toronto had the power to control both the quality of batches of insulin produced by its licensees, and their publicity and prices. It also demanded the sharing of all inventions and patents obtained on the production of insulin, so that no laboratory could be excluded from the market. To this end it created a patent pool. The globalization of insulin was thus set up on the initiative of a university which used its property rights to regulate the quality of products – thereby playing the role of future drug agencies – and to construct a non-exclusive drug market in which its patents were collective or public goods. This particular economic policy applying to insulin was extended to North America, most European countries, South America and certain African countries.

3- Globalization of medical technologies in the context of patents and exclusive markets: breast cancer technology at the dawn of the 21st century

In 1994 and 1995 two breast cancer predisposition genes were discovered, which enabled genetic tests to be developed for family forms of cancer. The globalization of breast cancer genetic tests has been marked by conflict between a private laboratory which wants to build up a monopoly on the breast cancer market by way of its numerous patents on genes and diagnostic methods, and a host of university and hospital laboratories which have the technology and wish to carry on offering these tests freely to patients. In Europe the hospital laboratories have opposed patents and have won the battle in so far as patents

have been cancelled or considerably reduced by the European Patent Office. Breast cancer predisposition genes have thus retrieved the status of free or common goods and laboratories can offer their tests without restrictions. In this case it is legal opposition that has curbed the extension of an exclusive market on new medical technologies. In Europe BRCA genes can now be used freely by all laboratories. In the context of this conflict, several European states created a compulsory licence for biological and genetic tests, with a view to protecting them from possible monopolies, for public health reasons.

4- Globalization of ARVs at the dawn of the 21st century in the context of copying in India and Brazil

The production of ARVs for treating Aids spread in Brazil and India as the result of an asymmetry of intellectual property rights between these countries and those of the North. In the early 1990s Brazilian and Indian pharmaceutical laboratories were able to engage in the licit copying of these drugs patented elsewhere. In India the main driver of the copying of ARVs was the market. In Brazil, whereas private laboratories likewise engaged in the copying of ARVs to take advantage of a lucrative market, the copying of these drugs corresponded to a public health policy. In other words, it was the outcome of both private motives and public incentives. Public laboratories, owned by the ministry of health or the individual states, were the means for implementing the Brazilian state's biopolicy which established universal access to ARVs.

The local production of these drugs owes nothing to technology transfers under voluntary licences. It is the outcome of the reverse engineering practised by Brazilian and Indian chemists, who sometimes also directly exchanged information and samples, and who partially rediscovered the products and synthesis technologies of these drugs which were imperfectly and incompletely described in international patents. The practice of reverse engineering requires

well-trained chemists in universities, quality-control laboratories and international pharmaceutical laboratories – which in the case of FarManguinhos were combined in one laboratory. Reverse engineering allowed for the dissemination of health technologies by way of their local recreation and the rediscovery of paths that had already been designed elsewhere. This copying resulted in technological learning in the local laboratories that created or reinforced their R&D capacities and quality control. The production of ARVs also required learning in terms of good production practices and drug certification, even if such learning is still incomplete in Brazilian laboratories which often produce similar drugs or generics certified by the national drug agency.

5- Extension of TRIPS and the challenging of local health product manufacturing: using compulsory licences for public health purposes

The local production of drugs was challenged once there was no more asymmetry of IP rights between Brazil and India on the one hand and countries of the north on the other. From then on the dissemination of health technologies via their licit copying was no longer an option unless compulsory licences were used to satisfy the domestic or export market. Compulsory licences imply the reverse engineering of disputed drugs by local laboratories. This was done in Brazil when, on several occasions, it was decided to introduce compulsory licences for the production of ARVs patented in that country. Note that these compulsory licences allow the perpetuation of technological learning and the dissemination of health technologies. In the past they were used primarily by countries of the North, especially in the 1950s and 1960s in Europe and the UK, for pharmaceuticals. New possibilities were opened by compulsory licences for exports, provided for in the August 2003 WTO agreement and now incorporated into the TRIPS agreements. Their mechanism consists of a dual licence for the

country importing the licensed drug and for the country exporting it, and strict regulations on products and their circulation. Yet we believe that the possibility of compulsory export licences should be used by countries of the South, including Brazil, especially to enable private laboratories producing ARVs to export them. We think that, despite difficulties involved in implementing these licences, they should be supported by legal decisions, and that a South-South market for active principles and drugs should be constructed. This would require the use of two possibilities contained in these licences: first, the possibility of circulating drugs produced or imported under compulsory licence in a regional system, 'to allow a pharmaceutical product produced or imported under compulsory licence in this Member to be exported to markets in other developing or less advanced countries which are party to the regional trade agreement and share the health problem in question' (amendment to the agreement on ADPIC – 'legal aspects of intellectual property relating to trade'); and second, the organization of technology transfers between exporting and importing countries. Contrary to common belief, the law on these licences has yet to be made. For example, in February 2004 the Malaysian government decided on a compulsory licence for importing four ARVs as provided for in Paragraph 6 of the Doha Declaration. The ARVs were produced by Cipla in India. Indonesia also decided on a compulsory licence for exportation, in October 2004, and India integrated compulsory export licences into its new patent law. In terms of Indian law importing countries can either take out compulsory import licences or simply decree authorization to import the drug in question.

Conclusion

Intellectual property plays an increasing part in the diffusion and accessibility of health technologies. Yet in the case of medical technologies certain measures

provide for exceptions – the non-patentability of surgical methods in many countries – or for flexibility – compulsory licences for the domestic or export market. This nevertheless remains an area in which these measures have to be endorsed by favourable legal precedents.

The regulation of the quality and therapeutic utility of health products also plays a key part in the dissemination of medical technologies. It is nevertheless necessary to organize a gradual process of certification, to favour learning rather than creating new barriers to the entry of new actors in the field. For example, in Brazil experts recently concluded that public and private laboratories producing generics for HIV/Aids complied with the standards of the Brazilian national agency and could easily meet WHO and FDA standards if they acquired additional training and the equipment to produce certain pharmaceutical forms.