

## Access to Medicines and Intellectual Property Rights

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Falsified and Substandard Medicines: Current Challenges and Long Term Solutions - a Public Health Perspective

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We can presumably start on the common ground that nobody in this room is promoting increased availability of substandard or falsified drugs, and that there is a shared common objective to promote and protect public health by encouraging and ensuring availability of high-quality, safe and effective medicines.

Each of the IPRs used to regulate the pharmaceutical sector has both restrictive and permissive characteristics. In every country with a history of developing, implementing and applying IPRs, there is a balance struck between the restrictive and permissive characteristics of IPRs. This balancing is applied in the pharmaceutical sector. New medicines are subject to the grant of exclusive rights of patent, allowing the originator pharmaceutical company a temporary right to exclude others from entering the market with the same medicine. But, it is open to potential competitors to challenge the validity of the patent, that is, the basis on which it was granted. Pharmaceutical companies that seek to abuse their rights in patents are subject to remedial action by competition authorities. In all events, when the patent term expires, generic competitors may enter the market. The "brand names" of drugs are protected by trademark, but generic producers may market the same drug under a different brand name, and there is an international nomenclature system (INNs) that provides a generic identifier that is open to everyone for use. National and subnational jurisdictions adopt "generic substitution" laws to control the market power of pharmaceutical brand name owners. Pharmaceutical industry copyright owners can protect unique forms of designing or explaining their products, but the "science" in medical literature, including drug information leaflets, is not protected against third-party use. Regulatory data protection may preclude registration by a generic company of the same drug for a limited term, but when the term expires the generic producer may rely on the originator regulatory submission, at least in the sense of seeking approval for a "bioequivalent" drug.

As recognized in the preamble of the WTO TRIPS Agreement, intellectual property rights are "private rights". They are granted to a person (including, in most cases, a corporation). It is the responsibility of that person to enforce its IPRs through action in the civil courts or before appropriate administrative authorities. The process of enforcing an IPR in the civil courts typically results in a defense by an alleged infringer. This allows the judge or administrative authority to study the evidence and balance the interests of the parties. In the case of civil enforcement of patent rights by pharmaceutical originators, it is not uncommon for the originator's patent to be found "invalid", i.e., it should not have been granted in the first place. With respect to each form of IPR, there is a legal contest between the person asserting

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exclusive rights and the person against whom those rights are invoked. The results of the contest are judicially determined based on evidence.

There were both "mercantile", that is, business profit-oriented, interests and objectives for negotiation of the WTO TRIPS Agreement and, in the pharmaceutical area, public health interests and objectives. The results of the TRIPS Agreement negotiations were transformative in the sense of requiring developing countries to adopt and implement essentially the same levels of IPRs protection present in the developed countries, including for the pharmaceutical sector. The TRIPS Agreement was also transformative in that it introduced a new type of "border regulation" into the trading system, one in which private IP right holders would be entitled to prevent entry of certain IP-protected goods into free circulation by initiating procedures with customs authorities. "Mandatory" border measures proceedings were limited to "trademark counterfeit" and "copyright pirated" goods. The TRIPS Agreement authorized each WTO Member to apply its own doctrine of exhaustion, including to allow parallel importation of drugs.

It is important to recognize the fundamentally different characteristic of IPRs regulation from that of trade regulation that was embodied in the former GATT system. When a customs agent applies tariff rates to an imported good, or limits importation based on a quota, he or she is acting on behalf of the government, and with a governmental interest. Assuming the absence of corruption, the tariff rate that is applied to imports is relatively transparent and fixed by law. The quota it is a matter of internal customs administration.

IPRs are different. They are invoked by private right holders, including for our purposes pharmaceutical originator companies. When the pharmaceutical originator company lodges a complaint based on an IPR with the customs authority, that customs authority has limited capability to determine whether or not the IPR is valid and should be enforced. The customs authority is typically acting on the basis of a piece of paper showing local registration of an IPR, or some reference to an IPR registration number, along with a description of the covered pharmaceutical products. Although the WTO TRIPS Agreement says that there must be evidence sufficient to satisfy the customs authority of the IPR, customs authorities do not have the time, training or capability of investigating an IPR claim on which a request to act is made.

Significant implications flow from the way the border measures system is designed to operate. It is relatively easy for an originator IPRs holder to block the importation of pharmaceutical products, at least temporarily, and to shift the financial and administrative burden on to a generic drug importer to challenge the blocking action before a court or administrative authority. IPRs holders have a power to control the importation of products of potential competitors that is not present for those without IPRs.

But there is a problem with the protection of pharmaceutical products by intellectual property, and this problem is traces back to the very inception of the TRIPS Agreement. In addition to serving as instruments of industrial policy and public health promotion, IPRs serve as strategic mercantile tools in the hands of their holders.

The pharmaceutical industry, like most industries, is highly competitive. The actors with the power to do so fairly consistently demonstrate the willingness to use IPRs to obtain commercial advantage beyond the "legitimate scope" of their rights. At the macro level, shortly following entry into force of the TRIPS Agreement a large group of originator companies banded together to sue Nelson Mandela's new government in South Africa for authorizing parallel importation of medicines, a practice which every genuine expert in the field of TRIPS -- including at the WTO Secretariat -- opined was permissible. Developing country governments are routinely threatened with trade sanctions or withdrawal of investment when they exercise, or threaten to exercise, rights to grant compulsory licenses clearly allowed under the TRIPS Agreement. The government of India was sued for violating the TRIPS Agreement in amending its Patent Act when it was apparent to any knowledgeable observer that a suit based on the TRIPS Agreement could not be pursued as a matter of the Indian constitutional treatment of treaties. These are the "macro" problems that receive attention at the international level. But, they are only a part of the present reason for concern in the area of "anti-counterfeiting" legislation based on IPRs.

As pharmaceutical originator companies face key patent expirations over the next several years, and have not yet found replacements for their new drug pipelines, they are aggressively pursuing market share in the generics sector where they have previously been willing to cede ground to developing country producers. A recent study by the European Commission Competition Directorate found what had previously been found by the Federal Trade Commission in the United States: that pharmaceutical originator companies are routinely using strategies involving "weak" patents to artificially block generics companies from entering the European market, just as such strategies were used in the United States. Much more attention is being paid to emerging markets where incomes are rising rapidly, and attention is being paid in Africa where markets are evolving. The aggressive pharmaceutical originator companies are using marketing strategies that include casting doubt on the quality of the drugs being offered by developing country producers, both manufactured locally and imported from countries such as India. This use of negative marketing strategies is not a secret. A year ago at the annual meeting of the International Generic Pharmaceutical Association in Montréal, this was among the most consistent concerns expressed by generics producers, large and small: that is, the problem of negative marketing campaigns coming from the major originator actors.

Strategic misuse of IPRs for the purpose of mercantile advantage flared again recently as originator patent holders began to demand the seizure of medicines shipments in transit through an airport in the Netherlands.<sup>1</sup> Members of the IPRs policy community interested in preserving the integrity of the international patent system reacted strongly to this misuse. And, at least one of the companies that initiated the seizures attributed this activity to inadequately supervised outside counsel who had acted without proper corporate oversight. To the credit of the originator companies in this case, they acknowledged this was not a use of the patent system which they supported. India and Brazil have initiated consultations with the EU in order to find a sound legal mechanism to ultimately resolve this problem. The European Commission through statements in Brussels by Commissioner De Gucht has

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<sup>1</sup> The author noted in presenting this section that he is advising the Indian government in dispute settlement consultations with the EU on this matter, and thus is not a "disinterested observer".

attributed the seizures to a single member state which does not have the support of the EU in this matter in so far as medicines are concerned. Finally, at last reading, patents have been taken out of the border measure provisions of the draft ACTA. So the system is rebalancing itself. But, only because the policy community interested in access to medicines was vigilant in defending the integrity of the balance.

Measures to address drug counterfeiting at the multilateral and national level must be understood in this context. Without doubt the problem of substandard or falsified drugs must be seriously addressed. But, it must be addressed as a public health problem, and not as a problem of mercantile competition based on IPRs.

Why is there controversy about use of the term "counterfeiting" to address the problem of substandard drugs? It is not because the term "counterfeiting" understood in its traditional sense as the use of an identical trademark to that of a right holder without legal authority or consent on identical or substantially identical products is wrong. It is instead because the originator industry has been strongly pursuing efforts to expand the meaning and scope of "counterfeiting" in an IPRs sense in ways that take it far beyond its traditional meaning, and risk impeding public access to legitimate generic drugs. At the plurilateral level, the draft ACTA is not limited to counterfeiting, it is an IPRs enforcement agreement substantially broader than that. I do not propose to go into the details in this short time allotted, but there remain provisions of the ACTA with significant implications for trade in legitimate generics, including those dealing with labeling which may affect the practice of parallel importation. Moreover, it is important to consider that laws in developed countries like the United States make special provision for fair use of pharmaceutical brand names in the context of generic substitution laws. Finally, but not exhaustively, the ACTA will substantially increase the *ex officio* activity of customs authorities in enforcing IPRs, meaning that the public will be paying more for enforcement of originator pharmaceutical industry IPRs. This represents a substantial transformation from the original concept of enforcement under the TRIPS Agreement.

Sisule Musungu I expect will address the specific legislative proposals or statutes recently considered and/or adopted in Africa. I do not propose to go into the details, but these statutes under the rubric of "counterfeiting" would reorder international IPRs law as we know it, and substantially inhibit possibilities for marketing of legitimate generic drugs in a number of African countries.

So we now face a challenge with respect to semantics. Public health specialists are not part of the struggle for mercantile advantage that is being played out with IPRs. Public health specialists should be and are concerned with protecting the public against substandard or falsified drugs.

Addressing the substandard drugs problem as a public health problem will require efforts to approve capacity and oversight by drug regulatory authorities in developing countries. It will require cooperation between national drug regulatory authorities and local police authorities. Ideally, it will involve cooperation among national, regional and international drug regulatory authorities. There is a substantial role for the WHO in supporting these efforts, but it is different than a role of supporting attempts to extend the concept of counterfeiting to cover legitimate generic trade.

It may seem tempting to simply turn drug regulatory issues over to the well-capitalized originator pharmaceutical companies, in this case allowing them to cooperate with customs authorities to prevent the importation and sale of products alleged to infringe IPRs. But the long-term consequences will be unattractive from an access to medicines and public health standpoint. Placing originator pharmaceutical companies in the role of policing the quality and safety of generic drugs in developing countries based on their IPRs holdings is ceding an essential role of public health authorities, and government more generally. It is putting the regulated companies in charge of regulation, a rather problematic turn. A coordinated effort among drug regulatory authorities to police quality and safety is more difficult to accomplish, and requires adequate funding. But improving the capacity of drug regulatory authorities around the world is a worthy objective that would improve public health in various ways. It seems a task worth taking on.