The Global Debate on Intellectual Property, Trade and Development: Past, Present and Future

A Conference in Honour of Pedro Roffe

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Session One: Intellectual Property Governance and the Rise of the Regulatory State: Intersections with Trade, Investment, Health and Development

A Never-ending Tale: IP governance, the (captured) regulatory state and the world of second bests

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Pedro and I discussed this yesterday, and neither of us can remember precisely when we first met, though we agree it was in 2001. Since then, we have worked together on many projects.

I can say without doubt that Pedro was the first person who suggested to me that developing countries would begin to change their perspective on the TRIPS Agreement and understand that it provides affirmative protections, notwithstanding its imposition of substantive obligations. Today this is conventional wisdom with much discussion of preserving TRIPS flexibilities.

Pedro has been insistent on seeking a more objective approach to analysis of IP issues, initiating studies under the auspices of ICTSD of the impact of FTA-mandated standards on medicines prices and access. As UN climate change negotiations proceeded and demands arose regarding modifications to the TRIPS Agreement to encourage transfer of technology, Pedro insisted that the horse be placed before the cart and that studies be undertaken to determine whether patents and other forms of IP would indeed impede developing country use of climate change mitigation technologies. If a protracted political battle was unlikely to make a concrete difference, he believed that developing countries might well preserve their negotiating capital.

It is Pedro's balanced approach to critical issues that has created confidence among so many of his peers in Geneva and elsewhere. He is also good company, which doesn't hurt.

Part I

Intellectual property is policy instrument that can be used to accomplish defined objectives. Whether you think that IP policy and governance are succeeding may well depend upon how you define the objectives.

If we define the objectives of health policy in terms of universal health coverage,[1] or more narrowly in terms of universal access to medicines, accompanied by patient-centric technological innovation, we

[1]SDG 3: Ensure healthy lives and promote well-being for all at all ages, including "Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all." Many national governments share this objective, though notably not that of the United States, which in fact appears at the moment to be moving

may well conclude that patent policy and its governance are failing.[2] Public health budgets throughout the world are strained beyond capacity, new medicines are priced to extract the largest possible payment from patients,[3] investments are foregone where innovation will not yield significant profits, the industry is engaged in myriad abusive practices in connection with drug promotion, and there remain critical gaps in developing new treatments.

What accounts for this failure of governance? Universal health coverage can be understood as a public good, or as a human right. In either case, it is something that citizens of a country, or of the world community, can and should expect government to provide.

The patent system effectively privatizes the provision of medicines, that is, privatizes the provision of this important public good. There is -- to be clear -- nothing inherently wrong with private contracting to achieve public aims. However, if that approach is used, there is an essential corollary: effective government regulation or control. And, here is where the present arrangements are failing. The problem is not the rise of the regulatory state. To the contrary. The problem is capture of the regulatory state -- or at least substantial parts of it -- by the regulated. There remain some resistance points, particularly constitutionally protected judges and independent prosecutors, but this resistance is largely defensive, a matter to which I will revert.

The problem of regulatory capture is not limited to high income countries where the major subjects of regulation are based. The capture has taken place, or is taking place, in countries around the world. The pernicious role of heavily funded corporate lobbying of legislatures and executive officials -- often through lawyers -- is on display nearly everywhere. At the international governance level, this is a phenomenon that is well-documented by my fellow panelist, Susan Sell. This is not a novel discovery or observation.

Regrettably, pointing to a persistent systemic feature of global governance discounts from the novelty factor. But, the fact that regulatory capture plays a tremendous role in international IP and health governance is too important to leave out of today's dialogue. It goes a long way toward explaining the failure of the international patent system in respect to public health.

The international community needs new financial and legal mechanisms for the development of medicines and their distribution. Alternatively, we need to dramatically reform the way the current system is regulated. But new funding mechanisms and systemic reform are fought at virtually every stage. It is a never-ending story.[4]

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precisely backward from that goal. I share the perspective of the WHO DG that has declared universal health coverage fundamental to legitimate governance.

[2] If we define the objectives of health policy in terms of creating a basket of wealth for a group of investors, with secondary benefits of discovering treatments for patients, we might think that patent policy and its governance are succeeding. There has been a considerable aggregation of capital and wealth in the form of large multinational pharmaceutical enterprises, the executives of those enterprises are paid well, dividends are paid to shareholders, and new pharmaceutical products are introduced with some regularity, although most typically in the form of modifications of existing treatments.

[3] With six-figure annual pricing for new medicines increasingly common.

[4] The world trading system is a modest part of the governance problem, which is more deeply rooted at the national government level around the world. National legislatures, executives and judges have the power to shift

Part II

In the absence of systemic reform, we are left with a world of second-best solutions, essentially rear-guard defenses against private sector excess. Even these defensive measures require the exercise of governmental authority. We depend on the independence of judges and prosecutors and must continuously promote and guard this independence.

The use of competition law to constrain abuses of market dominance through excessive pricing, patent and regulatory abuse, and collusive undertakings is an increasingly important element of these defensive measures. My own work over the past several years, largely under the auspices of UNDP, has been focusing in this area-- though indeed I have been working on this for a long time. My work has especially focused on the potential use of excessive pricing doctrine to constrain monopoly power. Investigations into pharmaceutical industry anticompetitive abusive practices are gaining traction. The South African Competition Commission on June 13, 2017 announced initiation of a major investigation into several major pharmaceutical companies with respect to excessive pricing of cancer treatments, among others. The EU Competition Directorate previously undertook a broad inquiry into abuse of patents in the pharmaceutical sector. Following the lead of the British CMA's levying of fines against Pfizer for excessive pricing, the EU Competition Directorate has also launched an investigation into excessive pricing.[5]

The recent trend toward more robust pharmaceutical-related action by competition authorities, including in emerging markets like China, India and Africa, is suddenly met with suggestions from multinational trade groups that perhaps new multilateral competition rules are needed. These proposals should be treated with caution as they are intended to constrain the power of competition authorities, not expand them.[6]

The enforcement of competition law relies on independent prosecutorial authorities with adequate power to accomplish their jobs. Those authorities rely on independent judges to assess their actions. This may sound like it can be taken for granted, but interference in the work of competition authorities, and gaps in investigative powers, are a substantial issue in a number of countries. It is important to support the independence of these authorities.

Of course, the more commonly discussed defensive measures involve the use of TRIPS flexibilities, including those related to patentability criteria, exceptions and compulsory licensing. As emphasized by the UN Secretary General's High Level Panel on Access to Medicines, the use of these flexibilities remains severely constrained by diplomatic and economic threats. These assertions of power are reflective of regulatory capture of trade and financial negotiators. These are not problems easily solved. We have been discussing them here in Geneva for many years.

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focus from profit maximization to universal health coverage, and generally do not exercise that power. That is not something that decisions in the TRIPS Council, or at WHO, can fix.

[5] Patents are the basis on which excessive prices are generally founded. The more recent European investigations are not so far addressing patented drugs, but this is just a matter of time.

[6] A second avenue for enforcement of competition law is through private causes of action. Private competition law enforcement is an important complement to government enforcement, though it is limited in most countries because of expense and difficulties in obtaining evidence. Here the idea of triple damages used in the United States as an encouragement to undertake private enforcement might be more widely considered.

Rather than going into further details here, I would refer to recommendations of the High Level Panel in terms of redressing political pressures, allowing the use of TRIPS flexibilities, and in strongly encouraging what I will call "deep transparency" in the sense of requiring disclosure of financial information, including granular R&D data, from industry.

Part III

Finally, a few words about two recent decisions of the US Supreme Court. The most important the decision of May 30, 2017, in *Impression Products v. Lexmark International*, in which the Court adopted or reaffirmed international exhaustion of patents for the United States. In doing so, the Supreme Court reversed an unfortunate precedent of the Federal Circuit dating back to 2001, the *Jazz Photo* decision.

I expect that everyone in this room is familiar with the subject of exhaustion. Indeed, recounting the history of this subject matter, including its relevance to medicines and public health could keep us here all day. As happy as I would be about that, perhaps for another time.

In *Impression Products* the Supreme Court placed a sharp limit on downstream control by patent owners. It held that a patent gives its owner only the authority to place its good on the market, a first sale, somewhere in the world. There is no possibility to initiate an infringement action based on importation or other movement of the goods following the first sale. The Court emphasized that the patent owner does not have a right to obtain any particular price, such as one based on geography. The patent owner decides about where to place its good on the market and lives with the consequences of that decision.

The US Patent Act does not expressly address the issue of exhaustion -- a subject on which all parties agreed – and the Court based its decision largely on the antipathy of the common law toward restraints on alienation.

It is a pro-development decision. If a multinational business based in a high income country raises prices in a developing country to prevent parallel exports, this will provide an opportunity for developing country manufacturers to supply substitute lower-priced products there. Developing country manufacturers are today capable of supplying high quality innovative products.

The US pharmaceutical market is now open to parallel imports in the sense that patents may not be used to block them. It is not as simple as that since FDA regulations remain applicable. As these regulations stand, they should allow parallel imports of pharmaceutical products approved for commercial marketing in the United States and manufactured in FDA-inspected and approved facilities abroad. Proposals for legislation to expand the range of allowable imports has been introduced in the Congress.

My hope is that the major parallel importers like Costco and Walmart will take advantage of the Supreme Court decision, and that a host of other procurement possibilities will open up. This is early days and I am fairly certain that pharmaceutical industry lobbyists are already in the halls of Congress seeking to protect their pricing power. This will be a very important test of the regulatory state. How will the legislature react? Will the lobbying be resisted? I will not offer a prediction.

On June 12, the Supreme Court in *Sandoz v. Amgen* rendered another decision reversing the Federal Circuit, and limiting the scope of regulatory market exclusivity for biologic medicines. The Federal Circuit

had interpreted relevant statutory language to grant an additional six months' market exclusivity following the licensing of a biosimilar medicine. The Supreme Court said that the Federal Circuit got it wrong, that this six month delay in favor of the exclusivity holder is not built in to the statutory scheme. Once again, the Supreme Court cut back on the scope of an exclusive right for the pharmaceutical industry. It is a less philosophically important decision than *Impression Products* because it is heavily reliant on statutory interpretation, but nonetheless moves toward limitation of exclusive rights.

These decisions highlight the critical role of a constitutionally protected independent judiciary in looking after the public interest in the field of IP governance. These decisions do not involve a systemic reform of the way in which medicines are developed or distributed, but are rather defensive in nature, introducing competition where it may otherwise be restricted. They are second-best alternatives, but nevertheless important to promote and preserve.