

## **PROMOTING CHECKS AND BALANCES IN A WORLD OF STRENGTHENING INTELLECTUAL PROPERTY POLICIES (DRAFT)<sup>1</sup>**

Over the past decades, developing countries have substantially widened and deepened the protection of intellectual property rights (IPRs). This move was largely brought about by external pressure—intellectual property producing interests in rich countries lobbying their governments to demand stronger IPRs protection as a matter of enhanced market access. The conclusion of the Uruguay Round of trade negotiations in 1994 thus established the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as one of three pillar agreements framing the multilateral trading rules of the World Trade Organization (WTO). Since then, so-called TRIPS-plus disciplines have been created in bilateral free trade agreements (FTAs)—notably those of the United States. In addition, international treaties that would foresee a strengthening of certain aspects of the intellectual property system are being considered at the World Intellectual Property Organization (WIPO).

The context in which developing countries adopt new IPRs policies differs from how these policies have evolved in developed countries. Even though the interests of IPRs owners have always played a key role in norm-setting in developed nations, IPRs policies have been embedded in a broader institutional framework providing certain checks and balances to the exclusive rights of IPRs holders. These checks and balances are not well-developed in many developed countries. This short note points to selected checks and balances and asks, specifically, how the adoption of competition laws can be promoted in developing countries.

### **Selected checks and balances**

The set of complementary policies that can provide checks and balances is large. Intellectual property rights are multifaceted and affect sectors that differ markedly in how innovation takes place, how firms compete, and how new products or technologies are used. To be concrete, this note will need to be selective. It focuses on the role of competition law—as a key “horizontal” complementary policy—and, as an illustration of sector-specific policies, on the role of price and advertising regulations in the pharmaceutical sector.

#### *Competition law*

From an economic perspective, the role of competition law in the presence of IPRs can generally be seen as countering the abuse of exclusive rights beyond the purpose that

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<sup>1</sup> This draft “think piece” was written by Carsten Fink, Senior Economist at the World Bank Institute. The views expressed here are the author’s own and should not be attributed to the World Bank.

IPRs intend to serve. One can broadly distinguish between two key types of IPRs-related business practices that may result in anti-competitive behavior:

- Any practice that may be considered an *abuse of a dominant position*. Such practices may include below-cost pricing, above-cost pricing, refusal to license, restricting access to essential facilities, or otherwise excluding entry by competing firms.
- *Restrictive vertical licensing practices*, such as exclusive dealing, tying arrangements, and territorial market restraints.

Mainstream economic thinking holds that business practices along these lines may or may not have harmful effects. A “rule of reason” inquiry is required to resolve each case, taking into account the nature of the market, the degree of market power exercised by the right holder, incentives for innovation, the effects of business practices on consumption and follow-on innovation, and other factors. In this context, there are marked differences in the application of competition laws across national jurisdictions. For example, jurisprudence in the European Union appears to have taken a more expansive view of the circumstances in which a refusal to license may be considered harmful than jurisprudence in the United States has done.<sup>2</sup> Attitudes of competition authorities have also changed substantively over time. For example, in the United States, early antitrust policy provided for strict prohibition of certain vertical licensing practices, which has been replaced by a case-by-case approach.

The application of competition law to IPRs-related business practices has largely been confined to developed countries. Some legal observers have argued that competition (antitrust) law in the European Union and in the United States has not been successful in limiting excessive exploitation of IPRs.<sup>3</sup> In addition, some observers have warned that competition law is increasingly seen as subordinate to intellectual property policies.<sup>4</sup> Even if true, this does not imply that competition law in developing countries cannot take a different direction. In particular, a “rule-of-reason” approach in a developing country jurisdiction may well come to different conclusions about the effects of certain business practices. In particular, different technological needs and innovation capacities can lead competition authorities to opt for a different balance between incentives for innovation and competitive access to new technologies. The 2003 ruling by the South African

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<sup>2</sup> See the recent decision by the European Court of Justice in *IMS Health GmbH & Co. OHG v. NDC Health GmbH & Co. KG*.

<sup>3</sup> See Eleanor M. Fox. (2005). “Can Antitrust Policy Protect the Global Commons from the Excess of IPRs?” In Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime*. (Cambridge Press).

<sup>4</sup> See Hanns Ullrich, “Expansionist Intellectual Property Protection and Reductionist Competition Rules: A TRIPS Perspective.” In Keith E. Maskus and Jerome H. Reichman (eds), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime*. (Cambridge Press).

Competition Commission against two research-based pharmaceutical companies seems to be a case in point.<sup>5</sup>

The TRIPS Agreement affords WTO member countries substantial leeway in addressing abusive IPRs-related practices through competition law. In particular, under the Agreements' general provisions and basic principles, Article 8.2 of TRIPS sets out that:

“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 right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”

Section 8 of TRIPS addresses the control of anti-competitive practices in contractual licenses. Article 40.1, expressly acknowledges that:

“[...] some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.”

Article 40.3 provides for a consultation mechanism between WTO members, where anti-competitive cross national boundaries. Important flexibilities are also provided for in Article 31 dealing with the use of patented subject matter without authorization of the right holder. In particular, Article 31(k) waives certain requirements on the use of compulsory licenses or government use licenses,

“[...] where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.”

Finally, it is worth pointing out for what the TRIPS Agreement does not provide. The Agreement neither defines an exhaustive list of IPRs-related business practices that may be potentially abusive, nor does it set any explicit standards according to which a particular practice may be considered abusive.<sup>6</sup>

### *Certain complementary policies in the pharmaceutical sector*

As an illustration of sector-specific checks and balances, consider the role of price and advertising regulations in the pharmaceutical sector.

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<sup>5</sup> The South African Competition Commission ruled that GlaxoSmithKline and Boehringer Ingelheim had engaged in the following restrictive practices: denied a competitor access to an essential facility; excessive pricing; and engaged in an exclusionary act.

<sup>6</sup> The treatment of IPRs-related abusive practices in US FTAs differs from agreement to agreement. I am not aware of any comprehensive study that has explored to what extent these agreements may have reduced the flexibilities of the TRIPS Agreement in this respect.

First, price regulations can be grounded in terms of economic efficiency. Taking the length of patent protection as a given, efficient recovery of fixed research and development (R&D) expenditure calls for so-called Ramsey pricing structures (prices which minimize the consumption distortion of above-marginal cost pricing). Ramsey prices are set according to consumers' elasticity of demand, but they are generally lower than market prices set by a profit-maximizing monopolist. Under plausible assumptions, Ramsey prices in poor country markets would be lower than the ones set in rich country markets. Unregulated pricing by monopolists leads to additional distortions when pharmaceutical companies price uniformly across market, for fear of parallel importation or other forms of price leakage.

These considerations are relevant to actual drug pricing in developing countries. While research-based pharmaceutical companies have extended price discounts for certain drugs purchased under public health programs, these discounts may not apply to developing country retail markets.<sup>7</sup> Yet most drug purchases in developing countries are paid for out of pocket. In contrast to most developed countries, public or private health insurance co-financing drug expenses is confined to a small minority of the population.

Second, the regulation of drug advertising can have an important effect on pharmaceutical pricing and incentives for innovation. Pharmaceutical markets are characterized by asymmetric information. Most patients do not possess the medical knowledge to choose the drug that offers the best treatment value for money. Doctors generally are in a better position to make this judgment. But knowing that the consumer is asymmetrically informed and a significant portion of the drug expenses may be picked up by insurance, they are susceptible to the promotional activities of pharmaceutical companies. From the viewpoint of pharmaceutical companies, there is a strong incentive to heavily market patent protected drugs. Since prices are above marginal production costs, additional sales generate sufficient rents to finance large marketing investments (and those investments can be fully appropriated by the patent holding firm).

The end result is that the promotional activities of pharmaceutical companies serve to enlarge their pricing hold. That, in turn, creates a distortion in the incentive to invest in pharmaceutical R&D. Companies may not necessarily invest in drugs for which society's true willingness to pay is highest, but which can be most effectively marketed to large population segments. There is thus a role for governments to regulate the advertising activities of pharmaceutical companies and to promote rational choices about which drugs to prescribe, in light of available alternatives. These considerations are still more relevant to developed country markets. Indeed, questions about which promotional activities by pharmaceutical companies should be permitted are heavily debated in those

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<sup>7</sup> For example, early evidence on the pricing of antiretroviral drugs suggested no correlation between drug prices and countries' per-capita income. See F.M. Scherer and Jayashree Watal. (2002). "Post-TRIPS Options for Access to Patented Medicines in Developing Nations." *Journal of International Economic Law*, Vol. 5, No. 4.

countries. But the introduction of pharmaceutical patents in developing countries will likely require a rethinking of drug advertising regulations in these countries as well.

As a final point, nothing in the TRIPS Agreement (or in other WTO Agreements) prevents countries from regulating drug prices or the promotional activities of pharmaceutical companies. However, national price regulation systems have become the subject of bilateral trade relations—most recently, in the context of the Australia-US FTA.

### **How can the adoption of competition laws be promoted in developing countries?**

The TRIPS Agreement's flexibilities in the area of competition law are generally considered as under-utilized. At the same time, one has to keep in mind that competition institutions in many developing countries are still relatively young. Twenty-seven developing countries adopted a competition law in the 1990s. The total number of jurisdictions with a competition law is estimated to be above 80.<sup>8</sup> However, not all competition laws address the kind of abusive practices most commonly associated with IPRs ownership. Some laws only establish rules against cartels. It is unclear how many developing countries actually deal with abusive dominance and restrictive vertical licensing practices.

In addition, the existence of a competition law is only a necessary but not sufficient condition for effective competition enforcement. Competition authorities need to have the necessary financial and human resources and legal powers to pursue anti-competitive practices. Some large middle income countries (e.g., Brazil, India, and South Africa) have developed some investigative capacity, whereas this capacity remains underdeveloped in many other countries.

#### *Do we need a multilateral agreement on competition policy?*

Given that there are a number of multilateral agreements on IPRs—notably TRIPS—and no “offsetting” agreement on competition policy, it is tempting to answer that question with ‘yes’. Indeed, one could argue that a multilateral framework would spur the adoption and development of competition policies in developing countries. In some countries, it may also help overcome political economy interests that may oppose greater disciplines on competitive behavior.

However, the international IPRs system does leave ample flexibility for national competition laws and one does not need a multilateral agreement to proceed at the national level. Indeed, a multilateral agreement may end up limiting existing flexibilities

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<sup>8</sup> See Clarke, Julian L. and Simon J. Evenett. (2003) “A Multilateral Framework for Competition Policy?” Chapter II of *The Singapore Issues and The World Trading System: The Road to Cancun and Beyond*. (World Trade Institute and the Swiss State Secretariat of Economic Affairs).

and it is difficult to make the case for harmonized international standards on the type of abusive practices commonly associated with IPRs ownership. Moreover, which country or group of countries would advance such an initiative and willing to pay a political price for it (e.g., at the WTO)?

*What else can be done at the international level?*

The development community could play a useful role in assembling international experience on how competition law could counterbalance the strengthening of IPRs in developing countries. This could take the form of formulating key principles that developing countries may wish to incorporate into their competition laws, along with the dissemination of best (and possibly worst) practices on how these principles can be given effect in the application of laws.

*How can the development of national competition laws be promoted?*

This is probably the greatest priority. The development of effective enforcement institutions entails several elements:

- Developing the laws needed to discipline anti-competitive behavior, as outlined above.
- Creating a competition authority with the necessary legal powers to investigate anti-competitive behavior.
- Defining the institutional status of the competition agency. Greater autonomy from the Government can help insulate the agency from political pressures.
- Equipping competition agencies with adequate financial and human resources to investigate anti-competitive behavior.
- Develop the competition agency's advocacy role to lobby for competition concerns to be taken into account in the development of national IPRs policies. In addition, competition advocacy involves reviewing the state of competition in different sectors and those reviews could devote specific attention to IPRs-related business practices.

Development assistance can play a useful role in some of these areas—notably, legal assistance in drafting laws, training of staff, financing, and the sharing of best practices and investigation methodologies.

Two additional points. First, for small developing countries, it may be unrealistic and possibly wasteful to create a fully fledged competition authority and it may be worthwhile to consider regional approaches. Second, in some countries, the analytical capacity of competition agencies will likely be constrained—for example, due to political constraints. In those cases, it could be worthwhile to support independent entities—especially consumer groups—to review IPRs-related business practices, which could trigger fully fledged competition investigations.