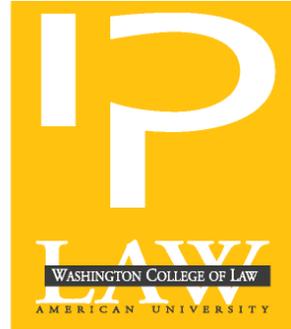




Program on Information Justice  
and Intellectual Property



## USING COMPETITION LAW TO PROMOTE ACCESS TO MEDICINES

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## I. INTRODUCTION

In September 2002, the access to medicines movement took a decisive turn when the Treatment Action Campaign shifted the site of its political advocacy to open access to key first line AIDS drug patents to the South African Competition Commission. A complaint filed with the Commission alleged that the use of the patents by multinational pharmaceutical companies to demand prices that only a sliver of South Africa's population could afford was an illegal "abuse of dominance" prohibited by South Africa's new competition law. A year later, the South African Competition Commission found that the companies were in violation of the Act, and announced that it would seek a judicial order "authorising any person to exploit the patents to market generic versions of the respondents patented medicines or fixed dose combinations that require these patents, in return for the payment of a reasonable royalty."

Two other competition complaints were filed by treatment activists in South Africa against multinational medicines suppliers in subsequent years, including a complaint against Merck filed in November of 2007 alleging anticompetitive refusals to license patents on the AIDS drug efavirenz. In February 2007, Knowledge Ecology International, a leading northern NGO, filed a complaint in the U.S. Federal Trade Commission alleging that Gilead Science Inc. was illegally using restrictive licensing policies to inhibit competition in the supply of active pharmaceutical products in developing countries. And also in 2007, after Abbot Laboratories pulled registration applications in Thailand for new drugs in response to lawful compulsory licenses issued by the Thai government, treatment activists filed a complaint with Thai authorities alleging that Abbott's move violated a prohibition against dominant firms "suspending, reducing or restricting services . . . without justifiable reasons."<sup>1</sup>

The use of competition laws to promote more equitable and open access to IP protected goods is not new, nor confined to the global south, nor confined to the access to medicines wing of the A2K movement. Tens of thousands of patents have been subject to compulsory licensing through antimonopoly (aka "antitrust") cases in the U.S., including General Electric's incandescent lamp patents, Kodak's color film patents, Xerox's copy machine patents and a large number of pharmaceutical product patents.<sup>2</sup> Competition law strategies were used successfully to open access to Microsoft's application programming interfaces for internet browsers,

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<sup>1</sup> Background and materials for all of these cases can be found on PIJIP's Competition Project website, <http://www.wcl.american.edu/pijip/competitionpolicyproject.cfm>.

<sup>2</sup> F. M. SCHERER AND JAYSHREE WATAL, POST-TRIPS OPTIONS FOR ACCESS TO PATENTED MEDICINES IN DEVELOPING COUNTRIES, CMH WORKING PAPER SERIES, PAPER NO. WG4:1, 16-17 (June 2001).

and competition complaints have been filed to open access to the digital rights management software used to prevent iTunes music from being played on competing players.

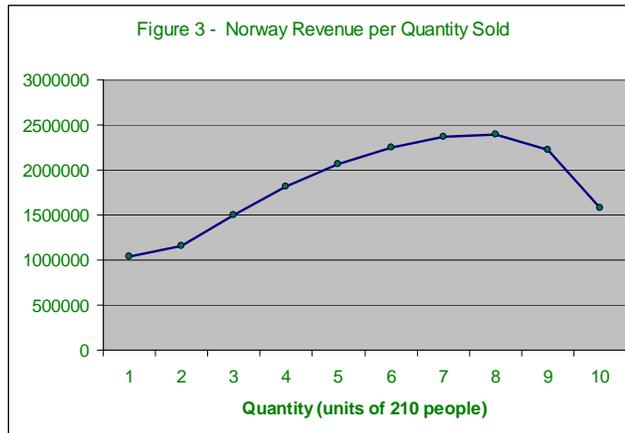
This chapter discusses some of the policy and political background animating competition strategies to open access to essential medicine patents. The chapter begins with an examination of the economics of exclusive rights and why such rights on the production and distribution of essential goods in developing countries have such odious effects. It then discusses the political and economic advantages and doctrinal and institutional receptiveness that animate the turn to competition law strategies to promote access to medicines. The concluding comments of the chapter include reflections on evaluating the potential risks and rewards of these strategies.

## II. ECONOMICS OF EXCLUSION

When intellectual property gives an exclusive right to produce and distribute an item of essential value to society – such as a key medicine without sufficient substitutes or a canonical learning text – it creates an especially powerful form of monopoly. All monopolies maximize profits by serving a smaller segment of the consumer population (limiting output) at a higher price than would be the case under a competitive market. Absent some form of government price regulation or threat of entry by competitors, the only restraint on the monopoly's pricing will be a function of the demand curve. A monopoly will continue raising prices above its costs until consumer refusals to purchase the product, or shifts to a substitute, are so numerous as to make further price increases unprofitable. It will keep raising prices, in other words, until the additional profit per unit from the price increase is negated by the lower sales volume at the higher price.

Economists illustrate the effect of consumer demand choices on monopolist pricing behavior through the shape and slope of a demand curve. A flat horizontal demand curve (with price on the vertical axis and quantity on the horizontal axis) would indicate that the seller has no discretion to raise price, referred to as an elastic market. A small price increase would lead to all consumers foregoing purchases. A vertical demand curve would yield no restraint on prices at all, referred to as an inelastic market. Consumers will purchase the amount of good they require regardless of the price set. Real demand markets are normally somewhere in between with the rule holding that more steep/vertical curves lead to less price restraint on the monopolist.

Real demand curves have a shape as well as a slope. The shape of the curve is affected by how different consumers react to a price increase. If there are a large number of consumers that are very price sensitive and



The lesson is this: the more unequal the distribution of income is in a country the larger the deadweight loss will be when a monopoly practices profit maximizing pricing strategies for an essential good. At the same time, because sales in such a country are likely to be so few (making sales only to the very top income earners), the monopoly does not enjoy very high levels of overall profits in these countries. In other words, in countries with high income inequality, unrestrained monopoly pricing of essential goods is very likely to cause large social harms and comparatively small incentives to invest in innovative activities.

### III. TURN TO COMPETITION

Economic analysis normally identifies two main government policy responses to remedy the inefficiencies caused by excessive monopoly pricing and associated deadweight losses. One strategy is to impose price controls on the monopolist. The other is to introduce or threaten competition. In either case, the government intervention can force the firm(s) to increase output and lower prices to the benefit of consumers.

For a variety of reasons, both practical and ideological, the access to medicines movement has been more committed to competition-based remedies to intellectual property market power than to price controls. In particular, the most discussed policy tool for the promotion of access to patented medicine has been the public interest compulsory license. Under this tool, which is available to most patent authorities and some public health authorities in the developing world, a government may authorize others to use the subject matter of a patent upon determining that the patent holder has failed to meet a broad public interest standard, such as that the patent holder is not meeting local demand on “reasonable terms.”<sup>3</sup>

<sup>3</sup> Ghana Patent Act, Section 45(1)(b) (1992). *See also* Section 49(1)(b) of the Malaysian Patent Act (1993) (authorizing a compulsory license when the patented article is

Certainly the problem of monopoly pricing causing extreme market segmentation, excluding the overwhelming majority of consumers from access to the product, would be adequate justification for evoking most public interest compulsory license standards in developing countries. But the same facts may also justify using competition laws as a basis for authorizing compulsory licenses, and there are important political and economic advantages to using competition laws for promoting access to medicines.

*A. Advantages of Competition Law Strategies*

1. Establishing Precedent

As shown above, the problem caused by patents on medicines and other essential goods is systemic. The World Trade Organization agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) does not place any substantive restrictions on the use of general public interest grounds for compulsory licenses. But TRIPS requires that compulsory licenses be addressed on a case by case basis and generally requires negotiation with the patent holder prior to the grant of a compulsory license. The time and effort required to address industry-wide monopoly pricing issues on a case by case basis may overwhelm many government offices and is an inefficient way to deal with a problem that is not confined to a few outlier cases. Although these problems can be overcome by establishing administrative guidelines and protocols that speed along the grant of compulsory licenses for needed medicines, competition laws provide an important alternative for compulsory licensing that can establish lasting precedents both to guide subsequent proceedings and to create strong incentives for firms to engage in voluntary licensing.

Section 8 of TRIPS specifically recognizes the authority of countries to address the “control of anticompetitive practices in contractual licenses” and powers of “specifying in their legislation licensing practices or conditions that may in particular cases constitute abuse of intellectual property rights having an adverse effect on competition in the market.”<sup>4</sup> Although competition based licenses must, like other compulsory licenses, be granted on a case by case basis, TRIPS exempts competition cases from the requirement of prior negotiation before the grant of a license. In addition, competition authorities normally establish precedent to be followed in later cases and often have the ability to levy fines and other penalties on firms that fail to follow such precedent. When a competition authority declares, for example, that a refusal to license essential patents on

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“sold at unreasonably high prices or do not meet the public demand without any legitimate reason”).

<sup>4</sup> TRIPS Article 40(2).

reasonable commercial terms is a violation of the law, other firms may begin issuing voluntary licenses in the market to avoid exposure to liability and penalties in subsequent enforcement actions.

Compare, for example, the industry responses to recent general public interest licenses in Thailand versus competition-based licenses in South Africa. In each case, licenses were demanded by competent government authorities based on the high prices of drugs combined with the refusal of the patent holders to grant licenses authorizing generic competition. Thailand issued general public interest licenses for two AIDS drugs and a leading heart disease medication through its department of health. The licenses were limited to use in public purchasing programs. South Africa, as described above, issued an order through its Competition Commission finding that refusals of AIDS drug suppliers to license competitors while maintaining extraordinarily high prices were illegal abuses of dominance under its competition law. In addition to the demand for licenses, the South African Competition Commission threatened to seek a financial penalty from the firms equal to 10% of their gross revenues in South Africa over the preceding year.

In Thailand, the licenses were met with defiance. One company, Abbott Laboratories, removed the registration applications for several new products awaiting marketing approval. More importantly, Thailand's expression of interest in granting similar licenses for several other products has not been met with any increase in voluntary licensing.

The experience in South Africa has been very different. Soon after the Competition Commission ruling, treatment activists targeted another AIDS drug supplier, Bristol Myers Squib, with a complaint about an important antifungal medicine used to treat opportunistic infections in people with AIDS. Ten weeks after the activists informed the company of their complaint, and before a formal filing was presented to the Competition Commission, the company dropped the South African price of the drug by 85 percent.<sup>5</sup> Other AIDS drug suppliers have lowered prices and issued voluntary licenses to local manufacturers to produce competing versions of their products.

Many of the voluntary licenses issued by AIDS drug companies in South Africa are unduly restrictive. There are no voluntary open licenses authorizing full competition for any AIDS drug in South Africa. Treatment activists recently filed a complaint against Merck and its subsidiaries alleging that the licenses granted for generic production of the AIDS drug efavirenz are insufficient because they do not license the lowest cost

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<sup>5</sup> See TENU AVAFIA, JONATHAN BERGER AND TRUDI HARTZENBERG, *THE ABILITY OF SELECT SUB-SAHARAN AFRICAN COUNTRIES TO UTILIZE TRIPS FLEXIBILITIES AND COMPETITION LAW TO ENSURE A SUSTAINABLE SUPPLY OF ESSENTIAL MEDICINES: A STUDY OF PRODUCING AND IMPORTING COUNTRIES*, sec. 5.2.2 (2006)

suppliers and they do not allow the production of co-formulated products combining efavirenz with other medications in a single pill format.<sup>6</sup> But the recent Merck complaint is a sign that the rules of the game have shifted in South Africa. The legal debate is now about the extent of AIDS drug suppliers' obligations to license rather than whether the obligation exists in the first instance.

## 2. Authorizing exports

TRIPS generally requires that compulsory licenses authorize use predominantly for the local market. In most developing countries, the local market will be too small to achieve the economies of scale required to invest in new production capacity and compete effectively with the incumbent firm. For older drugs (such as the first generation of AIDS drugs) that were being made in countries like India before TRIPS required the implementation of pharmaceutical patents, this may not be a serious problem. Countries granting compulsory licenses for older drugs may obtain supplies through imports from companies that have already achieved economies of scale and offer very low prices. But as we move toward the new order where India and other possible producers will themselves have patents on drugs, the restriction of compulsory licenses to predominantly local use may become a huge barrier to finding efficient sources of supply.

The problem of finding adequate sources of supply was recognized in Paragraph 6 of the Doha Agreement on TRIPS and Public Health, and in a later amendment to the TRIPS agreement, authorizing a procedure for issuing compulsory licenses by potential exporting countries to serve importing countries with little or no manufacturing capacity. But the procedure created, which requires WTO approval of specific contracts and amounts of intended purchases, has been widely criticized as being procedurally burdensome and contrary to economic realities.

Using competition grounds for compulsory licenses enables an important end run around the TRIPS restrictions on exporting. Section 31(k) of TRIPS waives the requirement that compulsory licenses be restricted to predominant use in the licensing country where the license is issued to remedy an anticompetitive practice. In practice this means that if a competition ground is used to authorize a compulsory license, local supplies may be exported to any country where there either is no patent on the product or that has itself issued a compulsory license. The authorization of unlimited exports allows the license holder to serve a larger range of markets, which may provide the economies of scale necessary to meaningfully compete with the patent holder. For countries that have

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<sup>6</sup> See Sean Flynn, *Summary of the South African Competition Complaint Against Merck*, <http://www.wcl.american.edu/pijip/documents/pijip11062007.pdf?rd=1>, (November 6, 2007).

ambitions to create or maintain competitive generic industries, the ability to authorize exports through competition licenses is one of the most important flexibilities in the TRIPS agreement.

### 3. Heightening Public Advocacy

According to one of the South Africa Treatment Action Campaign's attorneys, the use of a competition law strategy was selected in part because of a perceived "need to revive the public debate about patent abuse and profiteering," particularly in the face of strategic price decreases by patent holders designed to distract public attention.<sup>7</sup> The competition law strategy in South Africa allowed treatment activists to shift the public narrative from stories about the drug companies voluntarily lowering their prices to South Africans to one about a public investigation about whether the companies were acting illegally by pricing their products out of the reach of the majority while blocking competition.

Competition law procedures differ from general public interest licensing procedures in that competition laws are punitive. Using competition laws shifts the inquiry from whether the government should use its discretion to limit patent rents to whether the company was acting illegally to the detriment of social welfare. In the battle for public support for government action, this rhetorical re-framing of the debate can be advantageous.

Competition proceedings may provide a calendar of events to guide a public advocacy campaign on the effects of patents on medicine prices. Unlike for public interest licenses, which often lack set procedures or precedent, competition procedures are normally defined by regulations with set points for decision and input. The filing of a complaint, the filing of a response by the companies, a public hearing, the decision by the agency, a formal complaint or appeal to a tribunal, etc., all become moments where public attention can be brought to bear on the complaint and focused on the story of illegal action and patent abuse told by activists. The proceedings may also produce documents and statements through the investigation that can be obtained through freedom of information laws and used in subsequent campaigns to explain industry dealings in the country.

#### *B. Potential for Legal Movements*

Many aspects of access to medicines and other A2K movements are at their heart legal in that they are working within the medium of national and international legal doctrines and principles to promote rule choices that promote access goals. The combination of the radical indeterminacy of competition law in most developing countries and the rich history of

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<sup>7</sup> Jonathan Michael Berger, *Litigation Strategies to Gain Access to Treatment for HIV/AIDS: The Case of South Africa's Treatment Action Campaign* 20 Wis. Int'l L.J. 595, 609 (2002).

progressive legal concepts and principles in competition law of the global north make the doctrine an especially attractive medium for access advocates to work within.

1. Globalization of Competition Law

Competition laws in most developing countries are extremely new. Only a handful of developing countries had such laws before 1990. In the decade between 1990 and 2000, the same decade that witnessed the globalization of substantive intellectual property laws through the TRIPS agreement (1994), 50 countries (most of them developing) added competition laws to their books.

## GLOBALIZATION OF COMPETITION STATUTES

Before 1990	1990s
<p><b>1900-1969</b></p> <ul style="list-style-type: none"> <li>• Germany - 1909 (Many substantial changes since)</li> <li>• Brunei* (1930 - Monopolies Act)</li> <li>• Mexico* (1934 - monopolies, substantially amended since)</li> <li>• Brazil* (1945 - Unfair Competition Law, modified substantially since)</li> <li>• Japan* (1947 - additional statutes since)</li> <li>• Liechtenstein (1946)</li> <li>• Holland (1956 - amended numerous times, most recently in 1997)</li> <li>• Israel (1959 - since replaced)</li> <li>• Chile* (1963 - antimonopolization)</li> <li>• Colombia (1962)</li> <li>• Haiti (1964)</li> <li>• India (1969 - amended since)</li> <li>• Lebanon (1967 - Pricing and monopolies)</li> </ul> <p><b>1970s</b></p> <ul style="list-style-type: none"> <li>• Australia* (1974 - Trade Practices Act)</li> <li>• Austria (1972)</li> <li>• Bahrain (1970)</li> <li>• Cote D' Ivoire (1979)</li> <li>• El Salvador (1970 - Unfair competition)</li> <li>• France* (1977 - Monopolies and Abusive practices)</li> <li>• Great Britain (1973 - Fair Trading Act)</li> <li>• Greece (1977)</li> <li>• Mauritius (1979)</li> <li>• Pakistan (1970 - Restrictive trade practices)</li> <li>• Argentina (1980 - replaced earlier law from 1946)</li> </ul> <p><b>1980s</b></p> <ul style="list-style-type: none"> <li>• Canada (1986)</li> <li>• Gabon (1989)</li> <li>• Korea (1986)</li> <li>• Kuwait* (1980)</li> <li>• Luxembourg (1986)</li> <li>• Malawi (1987 - Trade Descriptions Act)</li> <li>• Mali (1986)</li> <li>• New Zealand (1985)</li> <li>• Spain (1989)</li> <li>• Sri Lanka (1987)</li> </ul>	<ul style="list-style-type: none"> <li>• Albania (1995)</li> <li>• Algeria (1995)</li> <li>• Belarus (1992)</li> <li>• British Virgin Islands* (1990 - Distribution and Price of Goods Act)</li> <li>• Bulgaria (1998)</li> <li>• Burkina Faso (1994)</li> <li>• Cameroon* (1990 - Commercial activity)</li> <li>• China (1993)</li> <li>• Costa Rica (1994)</li> <li>• Croatia (1997)</li> <li>• Cyprus (1999)</li> <li>• Czech Republic (1991)</li> <li>• Denmark (1997)</li> <li>• Estonia (1998)</li> <li>• Finland (1992)</li> <li>• Hungary (1996)</li> <li>• Indonesia (1993)</li> <li>• Ireland (1991 - though predated by Mergers Act of 1978)</li> <li>• Jamaica (1993)</li> <li>• Kazakhstan (1991)</li> <li>• Kenya (1990)</li> <li>• Latvia (1997)</li> <li>• Lithuania (1999)</li> <li>• Malaysia (1991)</li> <li>• Malta (1994)</li> <li>• Mauritania* (1991)</li> <li>• Norway (1993 - with numerous earlier statutes)</li> <li>• Oman* (1990)</li> <li>• Panama (1996)</li> <li>• Peru (1992)</li> <li>• Poland (1993 - unfair competition abrogating earlier law)</li> <li>• Romania (1996)</li> <li>• Russia (1991)</li> <li>• Slovak Republic (1991)</li> <li>• Slovenia (1993)</li> <li>• South Africa (1998)</li> <li>• St. Vincent and the Grenadines (1999)</li> <li>• Sweden (1993 - replaced earlier laws)</li> <li>• Switzerland (1995 - added to earlier laws)</li> <li>• Taiwan (1992)</li> <li>• Thailand (1999)</li> <li>• Trinidad and Tobago (1996)</li> <li>• Tunisia (1991)</li> <li>• Turkey (1994 - generally adheres to EU law)</li> <li>• Ukraine (1996 - unfair competition)</li> <li>• Uzbekistan (1996 - monopolies)</li> <li>• Venezuela (1996)</li> <li>• Vietnam (1996)</li> <li>• Zambia (1994)</li> </ul>

Noticeably absent from the history of the development of competition laws in the global south are any binding international legal standards for the

substance of such laws. Unlike in intellectual property, where binding minimum standards are established by the TRIPS agreement, developing countries remain largely free from any obligation to draft, interpret and enforce competition law in any particular manner. Indeed, although U.S. and E.U. laws are the obvious models for the substantive doctrines contained in most of the world's competition statutes, there are very noteworthy differences in the interpretive norms and policies that animate the laws of many developing countries.

Competition laws in developing countries have often explicitly incorporated developmental objectives that can be evoked to support pro-access interpretations and enforcement priorities. For example, the South African Competition Act expresses the intent to create a competitive economic environment “focussed on development;”<sup>8</sup> “to . . . advance the social and economic welfare;”<sup>9</sup> “to correct structural imbalances and past economic injustices;”<sup>10</sup> and “to reduce the uneven development, inequality and absolute poverty which is so prevalent in South Africa.”<sup>11</sup> Such norms would appear to counsel against adopting a rigidly economic interpretation of the Act's injunctions focusing only on the objective of promoting efficiency, and instead prod enforcement agencies to include equity objectives (such as ensuring broad access to essential goods and services) within their considerations.<sup>12</sup>

Injunctions to consider equity objectives in competition law interpretation and enforcement may be heightened in countries that have adopted social and economic rights in their constitutions. To take South Africa again as an example, the constitution obligates the state to “promote the achievement of equality”<sup>13</sup> and “take reasonable legislative and other means” to realize the rights of everyone to access to health care.<sup>14</sup> The constitution specifically delineates one key means of promoting these rights, enjoining every court and agency to “promote the spirit, purport and objects of the Bill of Rights” whenever “interpreting any legislation, and when developing the common law.”<sup>15</sup> In the context of structural market problems that create incentives for essential goods providers to exclude the

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<sup>8</sup> Competition Act, Preamble.

<sup>9</sup> Competition Act, Section 2.

<sup>10</sup> *Proposed Guidelines for Competition Policy: A Framework for Competition, Competitiveness and Development*, Department of Trade and Industry 2.4.11 (27 November 1997).

<sup>11</sup> *Proposed Guidelines for Competition Policy: A Framework for Competition, Competitiveness and Development*, Department of Trade and Industry 10.1 (27 November 1997).

<sup>12</sup> See Eleanor Fox, *Equality, Discrimination, and Competition Law: Lessons from and for South Africa and Indonesia*, 41 Harv. Int'l L.J. 579 (2000).

<sup>13</sup> Sec. 9(2).

<sup>14</sup> Sec. 27.

<sup>15</sup> Sec. 39(2).

majority of people in need from their products, promotion of the right to access to health care and the achievement of equality counsels for pro-access interpretations of competition law as applied to intellectual property rights.

## 2. Engaging Advocacy Agencies

One of the very helpful attributes of northern competition laws that has been exported to many developing countries is the competition advocacy agency. The role of these agencies is to receive complaints from competitors and consumers about potentially illegal practices, to investigate them using professional staffs and special legal authority (such as subpoena power) and then, if necessary, to litigate the complaints on behalf of the complainant or the state, often in a specialized tribunal.

In many countries, these agencies are well funded. Aid programs from the U.S. and Europe support the institutional capacity of competition authorities as part of packages aimed at promoting the liberalization of economies. The agencies often have the capacity to hire top lawyers, economists and other professionals. And because the laws themselves are often relatively new, frequently these staffs are not too overburdened with work to do a professional job in their investigations.

The availability of an advocacy agency may enable an access campaign to mount a highly technical legal campaign against a well resourced IP owner without the kind of legal war chest that such a battle would require on their own. Resources must still be spent on convincing the agency to act and educating the agency about medical and IP topics with which it may not be familiar. Political resources may also be necessary to convince leaders with influence over the agency to prod it to act with sufficient determination. But where competition authorities are inclined to act in the greater public interest, their professional lawyers and staff can be extremely valuable additions to the resources of an access movement.

## 3. Favorable Doctrinal Standards

Most competition laws around the world have a provision that can be interpreted to ban refusals of an intellectual property owner to grant licenses on reasonable commercial terms to competitors where such licensing is necessary to promote broad concepts of consumer and social welfare. These doctrines, which may ban refusals to give access to “essential facilities” or refusals to deal with competitors without reasonable justifications, derive from a long line of cases from the U.S. and E.U. that have ordered the owners of physical and informational infrastructure to share with others on reasonable terms.

### a) Early Origins

Competition doctrines ordering access to property trace some of their

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earliest roots to British common law norms in the 13<sup>th</sup> and 14<sup>th</sup> centuries applicable to the holders of government granted franchises to operate essential services. During this time, the crown granted franchises – known as “letters patent” – extending the right to be the only supplier of certain essential services that involve substantial capital investments. Franchises were commonly granted, for instance, the owners of a grinding mill or to the operator of a ferry across a river to ensure there was stability of demand to justify the investment and ensure that the service would continue. These franchises were granted with a common law duty of “reasonable use.” The reasonable use duty required the franchise holder to serve the entire public on reasonable and non-discriminatory terms or forfeit the franchise to the crown.<sup>16</sup>

b) United States

In the early 1900s, a famous U.S. case brought under the Sherman Antitrust Act required the owner of the only bridge across a river to share access to the resource with all competitors “upon such just and reasonable terms and regulations as will . . . place every such company upon as nearly an equal plane as may be.”<sup>17</sup> The case thus established in clear terms that the right to exclude which lies at the core of property rights may be tempered by the public policy aims of the U.S. antitrust law. Sharing of property may be required by the anti-monopoly law, the court explained, where such a duty would promote “the greatest public utility” and “public advantage.”<sup>18</sup>

Duties to share physical property are quite common in U.S. antitrust cases, and their enforcement has led to radical changes in important essential service industries. The enforcement of a duty to share access to electricity transmission lines with competing generators<sup>19</sup> has permitted isolated towns to bypass local generation monopolies and purchase power from preferred sources transmitted over the local monopoly’s lines. And the enforcement of the duty to share telephone transmission lines<sup>20</sup> led to the creation of a vibrant competitive telephone service industry in the U.S. that has lowered prices and improved consumer choices dramatically.

In each case, courts were confronted with arguments by property holders that duties to share are contrary to the essence of the property right and therefore should be rejected. And in each case the courts rejected that argument, holding that property rights, as others, are legitimately qualified by valid regulatory purposes. The Supreme Court explained in one case

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<sup>16</sup> See CHARLES M. HAAR AND DANIEL W. FESSLER, *THE WRONG SIDE OF THE TRACKS: REVOLUTIONARY REDISCOVERY OF THE COMMON LAW TRADITION OF FAIRNESS IN THE STRUGGLE AGAINST INEQUALITY* (New York: Simon And Schuster, 1986).

<sup>17</sup> *United States v. Terminal Railroad Association*, 224 U.S. 383, 411 (1912).

<sup>18</sup> *Id.* at 409-410.

<sup>19</sup> *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973).

<sup>20</sup> *MCI Communications Corp. v. AT&T*, 708 F.2d 1081 (7th Cir. 1982).

that the right to exclude and to refuse to deal with others “is neither absolute nor exempt from regulation. Its exercise as a purposeful means of monopolizing interstate commerce is prohibited by the Sherman Act.”<sup>21</sup>

The central doctrine in U.S. law requiring property owners to share access with competitors became known in the 1970s as the “essential facility” doctrine. In a case holding that the antimonopoly law could require a stadium owner to promote “equitable sharing of the stadium by potential competitors,” the court explained:

The essential facility doctrine, also called the ‘bottleneck principle,’ states that ‘where facilities cannot practicably be duplicated by would be competitors, those in possession of them must allow them to be shared on fair terms. It is an illegal restraint of trade to foreclose the scarce facility.’ . . . To be “essential” a facility need not be indispensable; it is sufficient if duplication of the facility would be economically infeasible and if denial of its use inflicts a severe handicap on potential market entrants. Necessarily, this principle must be carefully delimited: the antitrust laws do not require that an essential facility be shared if such sharing would be impractical or would inhibit the defendant’s ability to serve its customers adequately.<sup>22</sup>

The application of the essential facility doctrine to intellectual property holders in the U.S. is unclear and contested. A small number of courts and commentators have endorsed its application, arguing that U.S. antitrust law can and should impose antitrust liability for a monopolist’s refusal to licence intellectual property “as with any other kind of property, tangible or intangible...shown to constitute an essential facility.”<sup>23</sup> Courts in the U.S. are a long way off from clearly endorsing that position, however.

#### c) Canada

For over two decades, Canada’s Patent Act contained a provision requiring its patent commissioner to grant any application for a compulsory license for a pharmaceutical product “except such, if any, of those things in respect of which he sees good reason not to grant such a licence.” The law required that the Commissioner set a royalty with “regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention and for such other factors as may be prescribed.”<sup>24</sup>

<sup>21</sup> *Lorain Journal Co. v. United States*, 342 U.S. 143, 155 (1951).

<sup>22</sup> *Hecht v. Pro Football, Inc.*, 570 F.2d 982, 992-93 (D.C. Cir. 1977).

<sup>23</sup> Robert Pitofsky, Donna Patterson, Jonathan Hooks, *The Essential Facilities Doctrine Under U.S. Antitrust Law*, 70 *Antitrust L. J.* 443, 461-62 (2002); *Data General v. Grumman Sys.*, 36 F.3d 1147, 1187 (1st.Cir. 1994) (holding that refusal to license copyright may violate antitrust law where the refusal does not sufficiently serve the purposes of the copyright act).

<sup>24</sup> Canada Patent Act (1969) Section 41(4).

Canada's general public interest licensing provision was repealed in the wake of its signing of the North American Free Trade Agreement and was replaced, in part, by a new provision of its competition law. Section 32 of the Canadian Competition Act authorizes the Attorney General of Canada to apply to the Federal Court for a compulsory license for intellectual property that "unduly" prevents or lessens competition. The Canadian Competition Bureau's Intellectual Property Enforcement Guidelines (2000) explain that it believes that the Competition Act requires agencies and courts to "balance the interests of the system of protection for IP (and the incentives created by it) against the public interest in greater competition in the particular market under consideration."<sup>25</sup>

d) Europe

In the European Union, there is a fairly well developed case law directly applying essential facility standards to intellectual property. Many of the cases decided in the E.U. offer helpful doctrines and principles for access to medicines cases in developing countries.

In one lead case, often referred to as the *Magill* decision, the European Commission held that compulsory licensing of an intellectual property right were demanded under the European competition law where a refusal to license IP prevents "the appearance of a new product . . . which the appellants did not offer and for which there was a potential consumer demand."<sup>26</sup> In that case, the Commission ordered the licensing of the television listings of a broadcaster to a potential competitor that desired to create a combination television listing magazine. The case offers an especially compelling precedent for forcing the licensing of medicines to permit "fixed dose combinations" of multiple medicines in easier to administer one-pill formats. For example, for many years the only companies making three-in-one pill AIDS drug cocktails were generic firms in India that were not bound by the originator product patents. The originator companies themselves did not produce the format because the three drugs needed for the cocktail were produced by different companies that refused to cross-license each other. Reliance on the *Magill* precedent is one of the arguments currently before the South African Competition Commission in the case against Merck for refusing to allow co-formulations of efavirez with other medicines in its licenses to generic firms.<sup>27</sup>

In another case, the E.C. held that the pharmaceutical sales information firm IMS, Inc., was required to share a copyrighted business tool it used to track prescription drug sales without violating E.U. privacy laws. The court

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<sup>25</sup> Canadian Competition Bureau, *Intellectual Property Enforcement Guidelines* at 3.

<sup>26</sup> *Radio Telefis Eireann v Commission of the E.C.* [1995] E.C.R. I-743, Para 54.

<sup>27</sup> See Sean Flynn, *Summary of the South African Competition Complaint Against Merck*, <http://www.wcl.american.edu/pijip/documents/pijip11062007.pdf?rd=1>, (November 6, 2007).

held that the copyrighted tool was an essential facility because a license to its use was “indispensable to compete” in the same market, thus justifying a duty to license under the same standards applied to other forms of property.<sup>28</sup> This case offers a much broader grounds for using essential facility arguments to open access to essential IP. Extending its reasoning to its logical conclusion would suggest that competition law could be used to force licensing of IP whenever exclusive rights would prohibit all competition in the relevant market because there are no adequate substitutes.

Even if so applied, the doctrine would not render every IP right subject to open licensing. An IP right would only meet the elements of an essential facility if it truly blocked all competition in the relevant market because it was not reasonably possible to use substitutes for the protected product. Most drug patents do not fall into this category. According to one study, between 1980 and 1992 only 47 of 255 new prescription drug patents had a “significant therapeutic gain” compared to already existing medications on the market.<sup>29</sup> But in some special cases, including for AIDS, existing drugs on the market are not substitutable for many patients. An AIDS patient often can only use one possible combination of drugs on the market because others are no longer effective for the patient or because their side effects will be harmful to the patient’s health. In such circumstances, there really is an acute problem of lack of substitutes and the patents may be considered essential facilities under a reasonable construction of the *IMS* precedent.

A third European precedent that may be especially helpful in access to medicines cases was recently issued by Italy’s competition authority. In that case, Merck had refused to issue a license for the production of a drug in Italy, where a valid patent existed, for export to other European countries where no patents were in effect.<sup>30</sup> The Italian case presents a rule choice that would greatly assist the ability of producing countries to export their products to markets with compulsory licenses or that lack patents. Adoption of a rule that it violates competition law to refuse to license for export to countries without patents in effect would permit producing countries to supply countries without local production capacity without engaging the complicated “Paragraph 6” system to grant compulsory licenses for exports.

Ultimately, the experiences of each of the countries surveyed above shows that courts and agencies can and do use competition law to help

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<sup>28</sup> *NDC Health and IMS Health Comp* D3/38.044 (3 July 2001).

<sup>29</sup> F. M. SCHERER AND JAYSHREE WATAL, POST-TRIPS OPTIONS FOR ACCESS TO PATENTED MEDICINES IN DEVELOPING COUNTRIES, CMH WORKING PAPER SERIES, PAPER No. WG4:1, 12 (June 2001).

<sup>30</sup> See [http://www.agcm.it/agcm\\_eng/COSTAMPA/E\\_PRESS.NSF/92e82eb9012a8bc6c125652a00287fbd/4d1b5a8692226567c125702800540161?OpenDocument&Highlight=2,patent](http://www.agcm.it/agcm_eng/COSTAMPA/E_PRESS.NSF/92e82eb9012a8bc6c125652a00287fbd/4d1b5a8692226567c125702800540161?OpenDocument&Highlight=2,patent)

strike the balance between the aims of intellectual property laws to promote investment and innovation and competition law goals to maximize consumer welfare through competitive markets and lower prices. Where a developing country chooses to strike this balance may – and should – differ markedly from how the balance is struck in the global north. The economic analysis above suggests that rules should be drawn to much more heavily favor open access to IP on essential goods and services where the welfare implications of allowing exclusive dealing appear enormous.

#### IV. CONCLUDING THOUGHTS ON THE RISKS AND BENEFITS OF COMPETITION STRATEGIES

No strategy is without risks, and there are significant risks to pursuing competition law strategies to open access to intellectual property. Many of the risks involved with competition law strategies are the flip side of the benefits. The fact that competition strategies can create legal precedents that will affect later cases means that losses in this forum can have lasting negative repercussions. The indeterminacy of law that provides opportunities for progressive legal movements also provides a fluid medium within which industry lawyers can work. The institutional structure of the dominant model of competition law, with a well resourced advocacy agency as a gatekeeper to courts, may be a barrier to progressive use of the law if it is staffed with conservative bureaucrats. Indeed, U.S. aid programs spend substantial resources facilitating staff exchanges and other programs to help harmonize interpretation and enforcement toward the U.S. model, which may be directly counter to access advocate interests in access to medicines cases. Finally, the opportunities for relying on northern precedent should not be overstated: no northern court has held that essential drug patents are subject to open licensing duties.

The political history of the first access to medicines competition complaint in South Africa is instructive of the efforts required to win in this forum. The complaint was filed in the Competition Commission in part because the formal independence of the commission provided an alternative forum for advocacy in the face of intransigence in the Department of Health and other agencies. But treatment activists did not take for granted that the agency would act without regard to political considerations. They mounted public advocacy and education campaigns to affect the outcome of the agency and those with influence on it.

The availability of an advocacy agency did not displace the need to invest substantial resources in the case. The treatment activists filed a substantial complaint with multiple appendices, totaling hundreds of pages. The activists used both the highly skilled lawyers at the non-profit AIDS Law Project as well as a private competition specialist lawyer hired as outside counsel. The activist also organized international displays of

support for the petition, including numerous submissions by prominent experts in the field on the law and policy supporting the action they requested.

The South African Competition Commission is staffed by many progressive officers whose political background is rooted in the struggle for democracy in the country. But it is also staffed by traditional economists and lawyers with little experience in IP and a reflective position that IP and competition law are strange bedfellows. The Commission also had on staff several advisors from U.S. enforcement agencies, although it is not known to what degree they played a role in the internal discussions. A long internal debate ensued within the Commission. Toward the end of the investigation period the Commission hired a consultant to give a full evaluation of the case, which fortunately for treatment activists was a non-profit organization predisposed in favor of access to medicines remedies.<sup>31</sup> The decision to finally move forward on the complaint with a finding that the companies had violated the law by refusing to license competitors and by engaging in excessive pricing was never foreordained and was made at the highest levels of the Commission.

Ultimately, the experience in South Africa and other countries are showing that competition agencies can be valuable sites for political struggle over how IP will be regulated. The site offers many advantages for access communities and should certainly be seriously considered in any access campaign. But as with any site of struggle, the likelihood of success will depend on contextual circumstances: who will make the decision, what leverage do movements have over the decision maker, how successfully are tactics executed to leverage ideological and political power toward a favorable result.

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<sup>31</sup> The Commission contracted with the Consumer Project on Technology. The author served on the consulting team.