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# COMPETITION POLICY AND THE STIMULATION OF INNOVATION: TRIPS AND THE INTERFACE BETWEEN COMPETITION AND PATENT PROTECTION IN THE PHARMACEUTICAL INDUSTRY

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## I. INTRODUCTION

The expiration of the January 2000 deadline that has exempted many developing countries from creating legislation to enact a regime more friendly to intellectual property rights (“IPRs”) under the TRIPS Agreement, calls for a renewal of emphasis on patent protection in the developing world; specifically on its effects to the pharmaceutical industry.<sup>1</sup> The fundamental question that faces the pharmaceutical world today is how best to provide drugs to the general population and how to do so cheaply. The ability of drug manufacturers in the developed world to cure diseases and create increased global social welfare is under attack by the effects of weak intellectual property regimes in some developing world countries. When economic agents free ride on the intellectual innovation of other economic agents, irrespective of legality, the owners of the intellectual property refer to the free riders as “pirates” or “copycats.”<sup>2</sup> As this article will show, the ability of so-called copycat firms to thrive in a system of little or no patent protection causes significant net social loss. Only a strong intellectu-

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1. Even though the TRIPS Agreement improved the level of patent protection in many countries, it is an imperfect system based on a compromise between the developing and developed worlds. As this paper will show, the developing world, in diluting the TRIPS Agreement, acted against their own long term best interest.

2. WOLFGANG E. SIEBECK, STRENGTHENING PROTECTION OF INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES: A SURVEY OF THE LITERATURE 77 (Robert E. Everson et al. eds., 1990).

al property system can best serve the needs of people around the world. Such a system would promote greater competition because it would allow market forces to set prices and, as part of a larger competition policy, would create a better functioning system with significant social economic gains. Though a number of articles have described the TRIPS Agreement and outlined some of its more salient features, few of them have looked at the implication of the TRIPS Agreement upon developing countries. Even fewer have cited any of the empirical data gathered by economists and applied it to their theoretical arguments. This article seeks to use existing empirical research to prove how a strong patent protection regime has a net global social gain, as well as a net social gain to developing countries.

As many developing countries embrace competition policies and enact competition laws, the patent system itself has come under attack. Many countries may seek to use competition law to attack what they see as an unfair patent monopoly. This article asks whether the patent is indeed a monopoly right as defined by competition policy, and what attitude competition policy should have towards innovation-enhancing patents. The article asks how effective some antitrust remedies, such as compulsory licensing, are likely to be in the case of pharmaceutical patents, and further considers other issues which lie on the intellectual property/antitrust nexus. Finally, the article offers some recommendations to improve the system, but which do not damage the patent system (which the author recognizes as the key for spurring innovation and global economic growth).

The need to protect innovation and to incentivize technological development is not a new one. Aristotle wrote about such protection in *The Politics*.<sup>3</sup> Though ideas on the protection of intellectual property stem from ancient times, government protection of intellectual property has been traced back to the early Italian Renaissance, particularly to 13th century Venice, where patents were given for particular types of glassmaking. Patents were used primarily as tools for technology transfer until the 18th century, at which point patents

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3. ARISTOTLE, *THE POLITICS*, Book II, at 72 (C. Lord trans., University of Chicago Press 1984).

became engines of innovation in Europe and the American colonies.<sup>4</sup> The right to patent was viewed with such importance that the only time the word “right” is mentioned in the U.S. Constitution is in this context. Article I, Section 8 of the Constitution states, “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>5</sup> The economic theory behind patent protection echoes the belief of the founders for the protection of this right. Patents provide important public goods.<sup>6</sup> Goods that result from patents can be consumed by multiple economic actors, at a very low marginal cost, because the cost of replication of the creation of an invention is significantly smaller than the cost of invention of a new product. A patent introduces a static distortion in the form of knowledge being sold at above its marginal cost. This distortion, however, is a necessary way to foster the dynamic benefits associated with innovation.<sup>7</sup> If pricing were to occur at the marginal cost to maximize consumer welfare, there would be a chilling effect on innovation since the incentives to create would be diminished by economic actors who would free ride on the efforts of others given that the marginal cost of reproducing the innovation is far below that of the average total cost. As Frank Easterbrook notes, “Curtailed the top returns, and the whole structure of rewards changes for the worse.”<sup>8</sup> Therefore, by granting temporary exclusive rights to new inventions, patent law allows the inventor to recoup the cost of investment for the innovation.

One way to understand the patent system is through an analogy to the mineral rights claims of the nineteenth century American West.<sup>9</sup> During this period, the U.S. government had two competing objectives: to retain government ownership of

4. See SIEBECK, *supra* note 2.

5. U.S. CONST. art. 1, §8.

6. See Kenneth W. Dam, *Economic Underpinnings of Patent Law*, 23 J. STUD. 247 (1994).

7. Seminal work in this area was conducted by Kenneth Arrow. See generally Kenneth W. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in THE RATE AND DIRECTION OF INVENTIVE ACTIVITIES: ECONOMIC AND SOCIAL FACTORS, NBER (1962).

8. Frank Easterbrook, *Technological Innovation and Tradition: Enduring Principles for Changing Times*, 4 TEX. REV. L. & POL. 103, 106 (1999).

9. See Edmund Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977).

public land, and to make it possible for private firms to find and extract minerals contained in that land.<sup>10</sup> In the mineral claim system, priority was given to those who were the first to discover, stake and file a claim. The claimant had the exclusive right to mine a particular piece of land. As in the patent system, the mineral claim system required claimants to strictly limit their claims both in what they sought and how it differed from the public domain. One of the functions of the mineral claim system was to create incentives for the prospectors (inventors) to search for minerals (innovations). If the risk in research and development is high, then the reward for discovery must compensate for the high level of risk. In the mineral case, it is easy to see the potential for output-increasing effects (as opposed to output restriction). It is the same with the patent system.

A patent increases the efficiency with which investment in innovation can be managed. The patent owner is incentivised to coordinate the search for technological and market enhancement of the patent's value which allows information to be exchanged among searchers and ensures that duplicative investments are not made. It facilitates the channeling of development into the most efficient invention for achieving a goal. ("A" can also coordinate work on the production of product, "P" avoiding wasteful expenditure on product, "Q," which is a substitute for "P," which must be independently invented and developed). These efficiency-creating, output-expanding aspects of the patent system counteract part or all of the output-restricting consequences of creating an exclusive property right. The patent owner also has an incentive to make investments to maximize the value of the patent, without fear that this effort will lead to unpatentable information; which may be directly appropriated by competitors. Incentivization is needed to achieve a more efficient allocation of incentives. Strong patent rights reduce the risk to investors to create new projects. As one economist suggests, "In this context, patents can be understood as a second-best solution to the problems created by the public-good characteristics of knowledge. In theory, the term of patent protection could be set such that it would stimulate the development of new products and production

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10. *See id.*

processes at a socially optimal rate . . . ."<sup>11</sup> Thus, a lack of patent protection leads to sub-optimal behavior. Some take a particularly stark view of the deleterious effect of patent copying. Deputy U.S. Trade Representative Richard Fisher has stated that, "The result of [copying] would be the erosion of America's comparative advantage in high technology; and ultimately loss of the benefits of new advances in health, public safety, education, defense and freedom of information for the entire world."<sup>12</sup> Fisher likens intellectual property to a warehouse of ideas and the unauthorized copying of such patents as analogous to theft of goods from a warehouse.

Another effect of the patent right is its promotion of innovation both within the same field, because advances from innovation can be extended, and to other areas in which innovators can apply for patents of their own, thereby "inventing around" the patent. Moreover, because of patent rights, inventors have an incentive to disclose knowledge to the public that they might otherwise try to keep secret. This dissemination of information has the effect of accelerating the research and development ("R&D") of others. As information from patents is disclosed in patent applications, information about new technologies becomes more readily available to other inventors as an input into their own R&D.

One can increase the efficiency of the production of new drugs through a patent system because a patent right allows for contracting between two firms. The innovative firm can sub-contract parts of the development and manufacturing work to other firms at a lower cost if its right to its innovation is protected.<sup>13</sup> As one study notes, the movement of knowledge through the contracting for the transfer of information associated with innovations plays an important role for developing country firms.<sup>14</sup> Moreover, the opportunity to compete in the

11. See Carlos Primo Braga et al., *Intellectual Property Rights and Economic Development*, 412 WORLD BANK DISCUSSION PAPER 40 (March 2000).

12. *Violations of Intellectual Property Rights: How Do We Protect American Ingenuity?: Hearings Before the Subcommittee on International Economic Policy and Trade*, 106th Cong. (1999) (testimony of Hon. Richard Fisher, Deputy U.S. Trade Representative).

13. See Jean O. Lanjouw and Iain Cockburn, *Do Patents Matter?: Empirical Evidence After GATT*, 7495 NAT'L. BUREAU OF ECON. RES. WORKING PAPER 5 (January 2000).

14. See Ashish Arora, *Contracting for Tacit Knowledge: The Provision of Tech-*

market with a strong patent regime remains. Just because one company has produced a cancer treatment medication does not mean that other companies cannot create better cancer fighting medications. Stated differently, therapeutic alternatives create pressure to keep the price of patented drugs down. The year after Recombinate was released to treat hemophilia, Kogenate was introduced onto the market to treat the same symptoms. Similarly, in the case of Invirase, a protease inhibitor for AIDS/HIV, Norvir was introduced just three months later.<sup>15</sup> Thus, the possibility that patent holders would use their exclusive right to engage in monopolistic practices is limited, because the patent holder does not in fact possess power over price. One writer points to the fact that statistical studies prove that in the overwhelming number of patents, there is very little monopoly power.<sup>16</sup> Competition laws that prevent predatory pricing and other monopolistic practices also serve to keep any monopolistic impulse by patent holders in check.

## II. IS THE PATENT A MONOPOLY RIGHT OR A PROPERTY RIGHT?

The patent system is designed to strike a balance between granting a complete and absolute monopoly to an inventor for a particular innovation (which would discourage other inventors to engage in further research within the field covered by the monopoly), and giving the inventor exclusive rights for so short a period of time that they could not possibly recoup their initial investment serving as a disincentive for invention. It is important to point out that, from an economics perspective, it is difficult if not impossible to make a judgement as to where the balance is properly drawn. Anything done is at best merely an estimate. It is true that it is possible for patent protection to overcompensate inventors. The size of the monopoly profit has more to do with elasticity of demand and marginal cost of production than it does with amounts invested in research and development. However, it remains the best method that we

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*nical Services in Technology Licensing Contracts*, J. OF DEV. ECON. (1996).

15. See Claude E. Barfield & Mark A. Groomberg, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185, 203 (1999).

16. See F.M. Scherer, *The Value of Patents and Other Legally Protected Commercial Rights: Panel Discussion*, 53 ANTITRUST L.J. 535, 547 (1985).

currently know of for incentivising research and development. The benefit of the exclusive right is that it allows a limited free market to operate for the licensing of the right, and it avoids having a government institution or a court decide what the royalty rate should be; thereby creating this "second best" solution. In this context, it is important to draw a distinction between the monopoly right in the product, which is itself the subject of the patent right, and a monopoly in the treatment of a particular disease in the case of pharmaceutical product patents. In the case of patent protection for a particular pharmaceutical product, there is no monopoly conferred for the treatment which that drug is intended to provide, as a substitute could be found which does not operate in the same way that the patented product operates in treating the same disease.

Whether the patent is regarded as a monopoly right or a property right will determine its role in the context of competition policy. It is a fundamental question, and one that too often has been glossed over. And like all antitrust analysis, the starting point is to determine the size of the relevant market. In the case of drugs, or more accurately treatments, the key question is, "What is the product market?" Is it, for example, all drugs that treat a particular disease? Or is it one particular drug for the treatment of that disease which is protected by patent? Patents protect particular drugs or processes, not the treatment itself. Hence, if the relevant market is the drug itself, then the patent cannot confer monopoly power in the antitrust sense because it does not confer power over price. The price of the drug may be lowered by other therapeutic substitutes.<sup>17</sup> Zantac and Tagamet are both patented pharmaceuticals that can be substituted for each other for the treatment of ulcers. Because of substitutes, the price of ulcer medication is lower than it would be if there was only one such drug for ulcers. Only in such cases where there are no substitutes can the potential power over price be found.<sup>18</sup> Even so, the calculation is identical to the first fact pattern. In neither case does the monopoly itself give the patentee power over price.

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17. See Lanjouw, *supra* note 13, at 10.

18. See *id.*



The question posed above is answered in antitrust analysis by posing a further question. We assume the smallest possible market - that of only one patented drug - and ask would, if the price of that drug increased, consumers shift to cheaper substitutes. The answer is of course yes, as long as such substitutes exist. In other words, the relevant product market only will be the single patented drug *where no other products are substitutable*. So, the monopoly issue is only relevant when there is only one treatment for a particular disease. Indeed, not only are there different chemical entities which can treat a disease, these different chemical entities actually can be delivered by different brands, and the prescribing doctor has a choice of chemical entities and brands (such as in the case where there is a patented brand and a series of generics). The choices possible equals the number of chemical entities multiplied by the number of brands, which rapidly becomes a large array of possibilities. Each of these permutations offers competition to the patented product, and the possibility of independently reducing its price through competition. To put it simply, the presence of other available or potentially available substitutes is a price discipline on the behavior of the patentee. The greater the cross-elasticity of demand, the greater the effect of price substitution. However, studies suggest that this is not a constant. In some cases, a smaller number of brands may sometimes lead to a smaller price increase in a post-patent world, where the cross-elasticity of substitution between chemical entities actually exceeds the overall cross-elasticity of demand. Hence, stronger therapeutic competition does not necessarily lessen the profit-maximizing potential of patentees. Frequently, as patent protection raises price, as is so under more intense therapeutic competition, all of the competitors increase price too, weakening the disciplining effect of competition. The key criterion appears to be the number and weight of off-patent chemical entities. If this is high, then a high degree of therapeutic competition will lead to lower profits (and hence prices). On the other hand, where elasticity is low, greater competition will have less of an effect on profits and price. In this context it should be borne in mind that elasticity will increase the less developed a country actually is, as price factors will become more important to a poorer population. Hence, the disciplining effect on pharmaceutical profits is actually greatest in countries with the poorest people. It is also impor-

tant to note that in antitrust, market power alone is not enough to violate antitrust laws. It is only when a company with market power uses its power unreasonably with respect to its patent right that antitrust laws may be triggered; such as when a merger in a field risks harm to competing new goods and services.

In its Antitrust Guidelines for the Licensing of Intellectual Property (promulgated by the DOJ and FTC in April 1995),<sup>19</sup> the agencies determine that intellectual property does not necessarily create market power in the antitrust context. The Guidelines make the point that although the patent right may confer the power to exclude with respect to a specific product or process, there will often be sufficient actual or potential close substitutes for such products, processes, or works to prevent the exercise of market power.<sup>20</sup>

Defining the market is critical in evaluating whether patentees actually have market power in relevant antitrust markets, and not solely over a particular patented product. One of the most significant questions in determining the relevant market is, "What are the potential substitutes?" Traditionally, legal antitrust analysis has focused exclusively on product and geographic market definitions. One important aspect of the market is time; which is often considered in potential competition theory. Is there a separate technology or innovation market for certain pharmaceutical products? Potential competition theory has been recently "resurrected" to deal with the issue of technology.<sup>21</sup> Broadly, potential competition theory was formerly used to challenge mergers or acquisitions where the acquiror might have entered the market independently (so that the acquisition removed the future benefits of new entry), or that the perceived new entry by the acquiror may have disciplined the behavior of those already in the market. The FTC began to rely on the doctrine once again in the early nineties, after it had laid largely dormant during the Reagan-

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19. U.S. Dep't of Just. and the Fed. Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property (Apr. 6, 1995), at <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm>.

20. *Id.* at 2.

21. See Mark Whitener, *Potential Competition Theory - Forgotten But Not Gone*, 5 ANTITRUST 17 (1991).

era.<sup>22</sup> Since then, the doctrine has shed its antique name, and re-emerged as the modern-sounding theory of "innovation markets."<sup>23</sup> It is likely that this theory has broader application where dynamic rather than static market concerns are pre-eminent.

Many of the cases in which the potential competition theory resurfaced were mergers involving pharmaceutical companies. For example, in Roche's acquisition of Genentech, the FTC alleged that the acquisition would lessen competition in the research, development, production and marketing of three broad product areas (Vitamin C, Human Growth Hormone and treatments for HGH deficiency, and CD4-based AIDS/HIV therapeutics).<sup>24</sup> The FTC order clearly evidences the FTC's consideration of the effect on research and development spending in those distinct product markets if the merger were allowed to proceed. Thus, innovation market theory was developed. However, in a market where there are significant barriers to entry, the likelihood of potential competitors being foreclosed by exclusive agreements or by unilateral action by a monopolist is much less than in markets where barriers to entry are low. It, therefore, would be arguable that innovation market theory should be less important in the area of pharmaceutical innovation, because of the significant barriers to entry for new drug development.

### III. PATENTS, INNOVATION AND GROWTH

There exists an important relationship between a strong patent regime and Research and Development (R&D). R&D plays an important role in the world economy. The amount spent on R&D in the developed world slightly exceeds 2% of GDP.<sup>25</sup> The United States spends an even greater percentage of its GDP on R&D, 2.8%, or approximately \$167 billion.<sup>26</sup> This is to be expected given the U.S. preeminence in advanced research in the world. Not surprisingly, R&D is particularly important in the pharmaceutical sector. Firms in the pharma-

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22. *Id.*

23. *See id.*

24. *See* File No. 901-0072, proposed consent order, 55 Fed. Reg. 38,153 (1990), final order accepted, 55 Fed. Reg. 53,191 (1990).

25. *See* Braga, *supra* note 11, at 24.

26. *See id.*

ceutical industry typically invest, at the very least, 10% of their sales into R&D. In the United States, this percentage is even higher and is estimated to be between 16% and 20.8% of revenue.<sup>27</sup> This makes the cost of research for the discovery of a single drug exceptionally high. Drug research in particular is risky, time-consuming and expensive. Only five out of every 4,000 chemical compounds that pharmaceutical research discovers demonstrate a level of effectiveness sufficient to warrant trial testing on humans.<sup>28</sup> In all, only one of 4,000 new chemical compounds discovered in the laboratory is ever marketed.<sup>29</sup> A recent study estimated the cost of a single new drug to be \$500 million.<sup>30</sup> Therefore, the need for patent protection in the pharmaceutical industry is significantly higher than in other industries spending far less on such costs. A 1994 study by Grabowski and Vernon found that only 30% of drug products introduced from 1980 to 1984 generated returns higher than their average after-tax R&D costs.<sup>31</sup> Their work revealed that the 20% of products with the highest revenues generated 70% of returns during this time period.<sup>32</sup> Another study found that 55% of industry profits came from just 10% of drugs.<sup>33</sup> As one study notes, "Patent protection of pharmaceutical and chemical products and processes is critical to justify high R&D expenditure in these sectors."<sup>34</sup> Thus, given the high costs and risks associated with drug research, companies must rely on a

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27. See Pharmaceutical Industry Profile (Phrma), at <http://www.phrma.org/publications/industry/pro-file00/chap8nf.html> (last visited Sept. 13, 2000). See also Julio Noguez, *Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries*, 502 WORLD BANK WPS PAPER 18 (Sept. 1990).

28. See Alan M. Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 JURIMETRICS J. 295, 302-03 (1994).

29. See *id.* at 303.

30. See Boston Consulting Group, *Sustaining Innovation*, in U.S. PHARMACEUTICALS: INTELLECTUAL PROPERTY PROTECTION AND THE ROLE OF PATENTS (1996). An earlier study by the Office of Technology Assessment estimated that cost of a new drug was \$359 million in pretax 1990 dollars for drugs that first entered human testing in the period 1970-1982, when drugs were less complex than they are today. See *Pharmaceutical R&D: Costs, Risks, Rewards*, Office of Technology Assessment (Feb. 1993).

31. H. Grabowski & J. Vernon, *Returns to R&D on New Drug Introductions in the 1980s*, 13 J. HEALTH ECON. 238 (1994).

32. *Id.*

33. F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 86, 97 (1993).

34. See SIEBECK, *supra* note 2, at 103.

limited number of highly successful products to finance their continuing R&D.<sup>35</sup>

Copycat pharmaceutical companies threaten the future ability of innovative pharmaceutical firms to undertake R&D for new drugs. If companies can easily copy the products of drug research, the economic incentive to conduct new drug research is greatly diminished. One study suggests that 65% of medicines would not have been commercially introduced or developed if patent protection was not available; a much higher percentage than in other industries.<sup>36</sup> The implication is clear. Without strong patent protection in developing countries, we risk making future research into life saving drugs financially unattractive. The loss of a possible AIDS vaccine or drug that would ameliorate the effects of malaria seems unconscionable. Yet, this very possibility results from making drug research unviable due to overly high costs that cannot be recouped without sufficient patent protection.<sup>37</sup>

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35. See Grabowski & Vernon, *supra* note 31. Earlier studies show how the pharmaceutical industry is particularly dependent on the protection of patent rights. See also C.T. TAYLOR & Z.A. SILBERSTON, *THE ECONOMIC IMPACT OF THE PATENT SYSTEM* (Cambridge University Press 1973); F.M. Scherer, *The Economic Effect of Compulsory Patent Licensing*, in *FINANCE AND ECONOMICS*, (NYU Press 1977); Edwin Mansfield, *Patents and Innovation: An Empirical Study*, *MGMT. SCI.* 173-81 (Feb. 1986); R. C. Levin et al., *Appropriating the Returns from Industrial R&D*, 3 *BROOKINGS PAPERS ON ECON. ACTIVITY* 783 (1987). See generally M. Baily, *Research and Development Costs and Returns: The U.S. Pharmaceutical Industry*, 6 *J. POL. ECON.* 232 (Feb. 1972). Baily was among the first to show the relationship that the profit of pharmaceutical companies was linked to the number of patents issued to it because of the correlation between the returns on profits based on the patented drugs.

36. See Mansfield, *supra* note 35. Mansfield used a random sample of 100 firms from 12 industries in the United States, and reports that 65% of the innovations generated by pharmaceutical firms from 1981 to 1983 would not have been marketed, and 60% would not have been developed, if patent protection had not been available. The corresponding figures for companies in the next two highest industries were considerably lower. In the chemical industry 30% of the innovations would not have been marketed and 38% would not have been developed. The petroleum industry ranked a distant third with 18% and 25%, respectively.

37. A McKinsey study on the pharmaceutical industry in India notes that multinational corporations limited their involvement in the Indian drug market after the adoption of the weak patent system in 1970. Some stopped selling drugs that were priced too low, while many multinationals limited the portfolio of products they sold in India to only patent expired products. See Rajesh Garg et al., *Four Opportunities in India's Pharmaceutical Market*, 4 *MCKINSEY Q.* 132 (1996).

#### IV. A STRONG INTELLECTUAL PROPERTY REGIME LEADS TO GREATER PROSPERITY.

Linkage between intellectual property protection to economic growth has been longstanding, at least in the developed world. Robert Solow's seminal work over forty years ago on the relationship between technology to growth demonstrated that 87.5% of the growth of American economic output between 1904 and 1949 was related to technological factors.<sup>38</sup> Other studies also have shown the strong correlation that the injection of new technology into the economy produces, and the resulting significant expansion of public wealth and social welfare that it achieves. Charles Jones argues that in the period between 1965 and 1990, over 40% of U.S. growth can be attributed to the rise in research intensity.<sup>39</sup> A strong intellectual property system allows for the growth of new technologies. Industrial studies suggest evidence that the social returns to R&D exceed private returns, i.e., that countries benefit more from R&D undertaken than the companies that pursue the R&D.<sup>40</sup>

Though less research exists in the impact of R&D in the developing world, Edwin Mansfield's work illustrates that the intellectual property protection afforded by a country directly relates to the amount of technical development and transfer into the developing country.<sup>41</sup> This factor significantly influences the composition of Foreign Direct Investment ("FDI"). Countries with strong intellectual property protection tend to experience a continuing flow of new high technology firms entering the industrial base. One World Bank study concludes that patent protection is an important ingredient in any package to support domestic R&D.<sup>42</sup> The higher the intellectual

38. Robert Solow, *Technical Change and the Aggregate Production Function*, 39 REV. ECON. & STAT. 312 (1957).

39. Charles Jones, *Sources of U.S. Growth in a World of Ideas*, STAN. FAC. WORKSHOP PAPER (Sept. 1999).

40. See SIEBECK, *supra* note 2, at 56.

41. Edwin Mansfield, *Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer*, INT'L FIN. CORP. OF THE WORLD BANK GROUP DISCUSSION PAPER 19 (1994) [hereinafter Mansfield, *Foreign Direct Investment*]; Edwin Mansfield, *Intellectual Property Protection, Direct Investment, and Technology Transfer: Germany, Japan and the United States*, INT'L FIN. CORP. OF THE WORLD BANK GROUP DISCUSSION PAPER 27 (1995).

42. See SIEBECK, *supra* note 2, at 103.

property protection the greater amount of investment. This investment in technology has important secondary effects on the economy of a developing country. Because of the competition, older firms adapt to the new technology. As more FDI penetrates the economy, the benefits permeate to human capital investment since workers need to be trained in the new technologies. As the amount of high technology investment grows - once the development reaches a certain threshold level - remaining in the country to pursue high technology work, rather than moving to the United States or Europe, becomes an option for developing highly educated workers. Once there are more high skilled workers that remain in a developing country as a result of stronger intellectual property laws, private capital investment, such as venture capital, increases because of the increased investment opportunities. This in turn creates more employment opportunities as more technology businesses are developed, thereby creating a net social economic gain for the developing country.

Another area in which developing countries benefit from the impact of greater patent protection is FDI in technology. Significant FDI occurs in countries with stronger patent regimes since a legal regime that protects intellectual property is one of the factors that foreign investors use in order to decide where to place their investments. FDI is an important way for knowledge to be diffused from one country to another as a multinational firm will externalize proprietary knowledge with its local partners. Even in the case of wholly owned local subsidiaries of multinationals, knowledge is still transferred because local employees are hired by and receive training from the multinationals. The relationships of these subsidiaries also produce an externalization of knowledge with the local firms with which it has business relationships.<sup>43</sup> Evidence shows that U.S. firms that invest in foreign production in developing countries are more R&D intensive than similar U.S. firms that invest in developed countries.<sup>44</sup>

Surveys have found the strength of the intellectual proper-

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43. See F. Stewart, *Technology Transfer for Development*, in SCIENCE AND TECHNOLOGY: LESSONS FOR DEVELOPMENT POLICY (R.E. Evenson & G. Ranis eds., Westview 1990); R.E. Lipsey et al., *R&D by Multinational Firms and Host Country Exports*, in SCIENCE AND TECHNOLOGY: LESSONS FOR DEVELOPMENT POLICY (1990).

44. See Stewart, *supra* note 43.

ty rights regime of a country to be of particular importance to firms making R&D decisions regarding investment in the manufacturing stage of development, and in licensing of technology to unrelated firms.<sup>45</sup> It follows that the stronger the intellectual property regime, the stronger the patent protection will be (and the greater the FDI will be). This is particularly true in the case of the pharmaceutical industry sensitive to patent protection. In an examination of the Indian pharmaceutical market, Lanjouw argues that there may be economic reasons why an intellectual property regime matters in decisions regarding the location of an R&D facility in a country.<sup>46</sup> This may have spillover effects of R&D into neighboring firms. Just as important, a country's level of intellectual property protection may be used as a signaling mechanism for investors indicating the general business climate in a particular country: Where the stronger the intellectual property regime, the more favorable the general business climate. The effect of trade barriers on technology transfers is linked to FDI when based on the level of intellectual property rights. Parente and Prescott argue that the extent of barriers to trade play a key role in per capita income across countries since trade may affect growth by lowering the barriers to technology adoption.<sup>47</sup> Therefore, as free trade increases, so too will the impact of FDI on increasing per capita income. These findings are supported by Gould and Gruben's work in which they determine the importance of patent protection is a key determinant of economic growth. Moreover, they note that there is a stronger effect from a robust patent system in open economies than in closed economies.<sup>48</sup> Augmenting this point is a recent study

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45. See Mansfield, *Foreign Direct Investment*, *supra* note 41. The study bases evidence on surveys of American, Japanese and German multinational corporations suggests that intellectual property protection affects FDI decisions. See also Kamal Saggi, *Trade Foreign Investment, and International Technology Transfer: A Survey*, in MICROFOUNDATIONS OF INTERNATIONAL TECHNOLOGY DIFFUSION (1999).

46. Lanjouw, *supra* note 13, at 7.

47. Stephen L. Parente & Edward C. Prescott, *Barriers to Technology Adoption and Development*, 102 J. POL. ECON. 298 (1994).

48. David M. Gould & William C. Gruben, *The Role of Intellectual Property Rights in Economic Growth*, 48 J. DEV. ECON. 323 (1996). An open economy also has significant general benefits. Developing countries' open economies grew on average at 4.5% per year in the 1970s-80s while those with closed economies grew by only .07%. See Jeffrey Sachs & Andrew M. Warner, *Economic Reform and the Process of Global Integration*, BROOKINGS PAPERS ON ECON. ACTIVITY, No. 1 (1995).



that suggests that weak patent protection is itself a barrier to trade.<sup>49</sup>

Increased patent rights stimulate investors and businesses inside and outside of a country to undertake activity beneficial to the country.<sup>50</sup> Because patents protect innovation, even smaller developing countries can benefit from a strong patent regime since such a regime will help to establish a pro-invention culture in the domestic industry of such a country.<sup>51</sup> A study of developing countries on the higher end of the development spectrum, such as the Philippines, Argentina and Turkey, suggests that such countries must protect intellectual property in order to encourage the rapid development of long-term innovative abilities.<sup>52</sup> In the thirteen years since the publication of the study, the countries in the surveyed group that have seen the greatest technological innovation are the very ones that created strong patent systems; for example, Mexico and South Korea.<sup>53</sup>

In contrast with a strong patent system, a weak patent system, or one that fails to protect patents at all, will have a chilling effect on local scientific and technological capabilities. Scientists and engineers may abandon their home countries in search of stronger intellectual property systems so as to pursue their innovations in more hospitable settings. There is no incentive to innovate in countries where innovators cannot protect their work product from copycats. Copycat companies keep these countries from developing a robust technology related sector in their country. One author notes that highly educated graduates in developing countries often do not have technologically sophisticated businesses, universities or other research institutes in which to continue innovative high technology

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49. See E.J. Smith, *Are Weak Patent Rights a Barrier to U.S. Exports?*, Dep't of Econ., U. of Del., (unpublished mimeo 1997) (cited in Barfield, *supra* note 15, at 219).

50. See Robert M. Sherwood, *Intellectual Property Systems and Investment Stimulation: The Ratings of Systems in Eighteen Developing Countries*, 37 IDEA 261, 275 (1997).

51. See *id.* at 276.

52. See J. Davidson Frame, *National Commitment to Intellectual Property Protection: An Empirical Investigation*, 2 J.L. & TECH. 209, 217 (1987).

53. The volume of applications following the adoption of Mexico's strong patent regime was a 46% increase and steady increases thereafter. See Robert M. Sherwood, *The TRIPS Agreement: Implications For Developing Countries*, 37 IDEA 491, 526-27 (1997).

work that one can more easily find in the developed world.<sup>54</sup> Establishing such institutions is costly.<sup>55</sup> Perhaps a quicker means to establishing such institutions is to attract high technology firms to a developing country. Since the only way that a high technology company will share its technology with a developing country is if a strong intellectual property (and particularly patent) system is in place, this will affect the business decision to transfer technology to the country.<sup>56</sup> Moreover, a weak patent system has a chilling effect on the return of technologically skilled nationals who have studied or worked abroad in the developed world.<sup>57</sup> Information from India suggests that despite the fact that about 2-3% of the world total of scientific papers originate in India, the number of scientists engaged in industrial research there is low and did not increase between 1977 and 1982 - a period when industrial research was expanding globally.<sup>58</sup>

Another benefit of heightened patent protection is the incentive it provides to public-private partnerships in university-based research. Private companies tend only to invest the sums needed to spur research in universities when they can gain the exclusive rights to the research. This insight has been borne out in practice in the United States.<sup>59</sup> By 1992, some \$3-\$5 billion of US GDP originated from university licensed products. Canada, Europe and Japan also have shown that a more robust patent system increases the number of technology transfers from universities to private companies that exploit the research to the benefit of national economies.<sup>60</sup> In contrast, too often in developing countries, potentially useful research contributes only to the university library and not to the economy of the country.<sup>61</sup> The key to facilitating this type of technology transfer is, again, a robust patent protection system.

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54. See Edmund W. Kitch, *Policy Consideration: The Patent Policy of Developing Countries*, 13 UCLA PAC. BASIN. L.J. 166, 173-75 (1994).

55. See *id.*

56. See *id.* at 175.

57. See Frame, *supra* note 52, at 224.

58. See UNESCO, *1986 Statistical Yearbook* at V-37 (1986).

59. See Sherwood, *supra* note 53, at 509.

60. See *id.*

61. See *id.*

## V. CREATION OF VENTURE CAPITAL OPPORTUNITIES

Venture capital is an area that is encouraged by a strong patent regime. Venture capital is financing that comes from firms that invest in young and rapidly growing companies. Venture capitalism is particularly important as a source of funding for start-up companies.<sup>62</sup> In the United States, private equity funds, which include firms specializing in venture capital, have expanded from \$50 billion in 1980, to roughly \$200 billion in 1999. Private equity has also increased tremendously in Europe where the size of funds raised has increased by 40% or more annually over the last few years.<sup>63</sup> In the United States, venture capital alone accounted for \$46.55 billion of private equity in 1999, up from \$3.94 billion in 1993.<sup>64</sup>

In the developing world, the amount of venture capital available is smaller. In part, this is a result of a weak intellectual property system. A strong intellectual property system is crucial to the success of venture capital and encourages the creation of venture capital investment in fledgling technology industries. Venture capital fills a void that larger institutions cannot fill, as it serves as an intermediary between investors searching for high returns and entrepreneurs seeking funding. Consequently, venture capitalists require a higher return than other investments because of the more risky nature of the endeavor. Venture capitalists therefore structure their deals to minimize risk and maximize returns.<sup>65</sup> Private funds only will seek out new technologies and innovations if the risk of that creation being copied is very low. Otherwise, the risk on a return will be too great to make the venture viable given that many enterprises can list their innovation as their only significant asset. If the innovation cannot be protected, there is little

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62. In the first quarter of 2000, 85.2 percent of all venture capital investments went to companies in the early or expansion stage. This is in contrast to 64.8 percent in the first quarter just a year ago. See National Venture Capital Association, *Venture Capital Investments Increase 266% to 22.7 Billion in Q1 2000*, at [http://www.nvca.org/Vepress/5\\_04\\_00.htm](http://www.nvca.org/Vepress/5_04_00.htm) (last visited Oct. 11, 2000).

63. See *Venture Capital and Private Equity*, Venture Capital and Private Equity Statistics, at <http://www.entrepreneurship.hbs.edu/VCPE.htm> (last visited Oct. 14, 2000).

64. See National Venture Capital Association Web site, at [http://www.nvca.org/Vepress03\\_27\\_00.htm](http://www.nvca.org/Vepress03_27_00.htm) (last visited Oct. 15, 2000).

65. See, e.g., Bob Zider, *How Venture Capital Works*, HARV. BUS. REV., (Nov. 1, 1998) at 132-133.

chance that a venture capital firm would incur the risk of investment since the collateral for the investment could be easily copied, and thereby rendered worthless. The theory is born out in figures from countries that have stronger intellectual property regimes. For example, there are roughly 5,500 venture companies in South Korea and 174 venture capital funds have invested capital of 1.18 trillion won (\$1.53 billion).<sup>66</sup>

## VI. THE CASE FOR A STRONG PATENT REGIME IN DEVELOPING COUNTRIES

Developing countries have traditionally argued in favor of a weak patent regime.<sup>67</sup> Previously, one could explain the level of patent protection in relation to the economic development of a country. The greater the level of economic development, the higher the protection a country afforded to its patent regime.<sup>68</sup> However, since the early 1980s this traditional understanding has not held up as patent protection in the aggregate has increased worldwide, even with regard to developing countries.<sup>69</sup> Moreover, the TRIPS agreement, when put into effect, will raise the level of patent protection in many developing countries.<sup>70</sup> Perhaps it is therefore not surprising that since the 1980s intellectual property rights have grown with regards to a country's output in international transactions of goods and services. Between 1980 and 1994, the amount of knowledge intensive or high technology products as a percentage of the trade in goods worldwide has doubled from 12% to 24%.<sup>71</sup> As patent rights increase the range of traded goods through innovation, this may stimulate the development of technological capabilities in developing countries.<sup>72</sup> One recent study finds

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66. See Samuel Len, *Seoul to Set Up Venture Support Center in U.S.*, KOREA HERALD (Mar. 20, 2000).

67. See Braga, *supra* note 11, at 19.

68. See *id.*

69. See *id.*

70. One area of concern is that developing countries will see the TRIPS Agreement as an upper limit to patent protection rather than as a minimum threshold. Since the TRIPS Agreement is a compromise agreement, a country must create stronger patent protection than merely under TRIPS to maximize the effect of a strong patent system.

71. See Braga, *supra* note 11, at 28.

72. See *id.* at 44.

that the impact of patent protection enhances growth the more open a country is to trade.<sup>73</sup> Therefore, developing countries removing their trade barriers and creating stronger patent regimes generate greater economic growth.

Some developing countries have argued that strong patent regimes only have helped developed countries because foreign companies displace domestic producers of pharmaceuticals. The evidence does not seem to support this position. In 1978, Italy adopted a system of full patent protection, replacing a system without any patent protection. A study undertaken ten years later revealed that local manufacturers actually increased their market share by 5%.<sup>74</sup> One factor that changed in Italy, however, was the size of the surviving local firms. Thirty percent of the companies that existed in 1978 had disappeared by 1988. Interestingly, while employment in the rest of the industry declined, employment within the pharmaceutical sector rose by 2.7%. This increase could be traced to the significant growth within R&D during this period equaling 22.8% of revenue, an almost 20% growth annually in real terms.<sup>75</sup> This data suggests a strong correlation that the new robust patent regime played a vital role in the growth of the pharmaceutical sector. Further, anecdotal evidence from South Korea and Mexico supports the conclusion that stronger patent systems lead to greater local R&D and greater growth within the pharmaceutical sector.<sup>76</sup> In Mexico, U.S. R&D into the Mexican pharmaceutical market has doubled since the adoption of a strong Mexican patent law.<sup>77</sup>

One recent study by Lanjouw and Cockburn sheds light on some of the empirical issues in this debate.<sup>78</sup> They suggest that more important than legal change itself, is whether or not

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73. See Carlos A. Primo Braga & Carsten Fink, *International Transaction in Intellectual Property and Developing Countries*, J. INT'L TECH. MGMT. (forthcoming 1999).

74. See G. Jori, *The Impact of Pharmaceutical Patents - The Italian Experience*, (1988) (cited in *Fundacion de Investigaciones Economicas Latinoamericanas (FIEL)*, in PROTECTION OF INTELLECTUAL PROPERTY RIGHTS: THE CASE OF THE PHARMACEUTICAL INDUSTRY IN ARGENTINA 62 (Buenos Aires: FIEL 1990).

75. See *id.*

76. See Sherwood, *supra* note 50, at 357-358; Sherwood, *supra* note 53, at 497. See also PHARMA Web site, at <http://www.phrma.org/publications/industry/profile00/chap8.html> (last visited Sept. 13, 2000).

77. Sherwood, *supra* note 53.

78. See Lanjouw, *supra* note 13.

firms believe that legal changes will be implemented and how effective the new system will be.<sup>79</sup> In this way, some international investment into countries with low patent rights can be explained as a belief by firms that these countries were serious about the future enforcement of laws they were in the process of enacting. They offer India as an example of where patent applications doubled in 1995; the year before the TRIPS Agreement was signed, strengthening protections there.<sup>80</sup>

## VII. INVESTMENT AND TECHNOLOGY IN THE DEVELOPING WORLD

Local capital seems even more dependent than foreign capital on a strong intellectual property system because of the greater mobility of foreign capital to invest in projects that have a higher return and less risk. As one study notes, local capital has fewer options than its foreign counterpart especially in areas where R&D is necessary for originating its products or services; either through local R&D or through the acquisition of foreign R&D.<sup>81</sup> Certain types of diseases are less profitable for drug manufacturers to research because they affect either a smaller group of people or the group cannot afford the drug even if it were to go on the market. Many of such drugs would combat tropical diseases which disproportionately affect the developing world.

These diseases could be treated by so-called orphan drugs,<sup>82</sup> but only if there is an incentive to innovate and develop these drugs. In the United States, the incentives for companies to develop these drugs were increased by passage of the Orphan Drug Act.<sup>83</sup> Before 1983, there were only ten drugs for rare diseases approved by the U.S. FDA. In the decade after passage of the Orphan Drug Act, 99 drugs were approved, and 189 were reported to be under clinical testing.<sup>84</sup> The Orphan Drug Act allowed seven years of market exclusivi-

79. *Id.* at 7.

80. *Id.* at 9.

81. See Sherwood, *supra* note 50.

82. See The Orphan Drug Act, Pub. L. 97-414 (1983).

83. See *id.*

84. See Jean O. Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering?"* 6366 NAT'L. BUREAU OF ECON. RES. WORKING PAPER 6366 (1998).

ty for drugs where the target population was fewer than two hundred thousand patients.<sup>85</sup> Perhaps the most well known drug that would not have been developed for market but for the Orphan Drug Act is the anti-AIDS treatment AZT.<sup>86</sup>

If drug manufacturers have no economic incentive to work on the R&D of tropical disease remedies, then it is the poor of the developing world who will suffer. The weak intellectual property regime that creates disincentives for R&D further creates an important negative externality upon world health.<sup>87</sup> Lanjouw notes that the strengthening of intellectual property rights appeared to be stimulating domestic R&D in countries that previously had weak protections.<sup>88</sup> Lanjouw demonstrates the belief that TRIPS would be taken seriously led firms to take greater interest in tropical disease research.<sup>89</sup> This was a departure from previous firm practice of doing very little research into tropical diseases because, in India for example, the weak patent system would not have allowed firms to recoup the cost of their investments.<sup>90</sup> As the study concludes in the case of malaria research, "[i]t is hard to avoid the conclusion that the historical absence of IPRs played an important role in retarding the development for this important disease."<sup>91</sup>

In the past, many in developing countries have argued that a weak patent regime was necessary to create and increase the size of domestic pharmaceutical firms.<sup>92</sup> This policy may have worked in some countries such as Argentina and India.<sup>93</sup> In Brazil, the absence of controls was not in itself sufficient to boost the market share of Brazilian pharmaceutical

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85. *See id.*

86. *See id.*

87. *See* Keith E. Maskus, *Regulatory Standards in the WTO: Comparing Intellectual Property Rights with Competition Policy, Environmental Protection and Core Labor Standards*, 00-1 INST. FOR INT'L. ECON. WORKING PAPER 5 (2000).

88. Lanjouw, *supra* note 13, at 20.

89. *Id.*

90. *Id.*

91. *Id.* at 29

92. *See* F. Grynszpan, *Case Studies in Brazilian Intellectual Property Rights*, in *INTELLECTUAL PROPERTY RIGHTS IN SCIENCE, TECHNOLOGY, AND ECONOMIC PERFORMANCE: INTERNATIONAL COMPARISON* (F.W. Rushing & C.G. Brown eds., Westview Press, 1990); C. R. Frischtak, *The Protection of Intellectual Property Rights and Industrial Technology Development in Brazil*, WORLD BANK INDUSTRY SERIES PAPER 13 (1989).

93. *See* Frischtak, *supra* note 92, at 13.

companies.<sup>94</sup> Even if in general this is true, there are two important responses. First, the growth of domestic industries did not necessarily help consumers, which will be addressed later in the paper.<sup>95</sup> Second, even if it helped infant industries in the past, these domestic industries are strong enough to compete in the world today and many do so by exporting abroad. India and Argentina provide examples. At their current stage of development, in the long-term, both companies and their home countries in the developing world will be hurt by programs that protect these industries since they retard high technology growth in the home country. If anything, intellectual property rights should be seen as a tool for development in countries because of the increase in the technology base from funding, local research and the introduction of technology that produces economic growth.<sup>96</sup> Copying the work of others makes it more difficult for firms to innovate on their own since they too will merely copy the work of others. This means they are generally not first movers in science and technology. Should technology become more difficult to copy as it gets more complex, it would further set back the domestic industry from the world leaders. Jeffrey Sachs notes, "In the poorest countries, it is possible to have economic growth without much innovation because they can borrow or import technology. However in a country like Argentina, that has a high level of revenues, progress really requires a much larger community of innovation."<sup>97</sup> In countries where innovation could lead to great results because of an educated workforce, a lack of patent protection is therefore particularly damaging.

#### VIII. DRUG PRICES UNDER A PATENT PROTECTION REGIME

Drug prices will not necessarily increase if countries shift to a patent enforcing system.<sup>98</sup> New patents only will apply to new products unless pipeline protection is available; not to those that already exist. Hence, there will be no effect on price

94. *See id.*

95. *See id.*

96. *See* Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and Reality*, 33 *IDEA* 349, 360 (1993).

97. Margalit Edelman, *Treading on Toes in US-Argentine Trade Tango*, 21 *J. ECON. COM.* 419 (June 29, 1999).

98. *See* Sherwood, *supra* note 53, at 498.



and any future effect on new products will take some time to percolate through to the market. A number of critics of a strong patent regime argue that prices will increase if patent rights are recognized. This is not necessarily true. In Italy, price increases were lower than the general increase in prices after the patent regime was strengthened.<sup>99</sup> Additionally, prices eventually go down after the patent expires. Numerous studies conclude that generic competition after the expiration of a patent brings prices of a drug close to its marginal production cost.<sup>100</sup> The market thereby makes the pricing more competitive as competition from other pharmaceutical companies forces the original holder of the patent to reduce price or accept a loss of market share.<sup>101</sup> Another common argument is that the price of drugs will rise because of the displacement of copycat firms from the market because of patent protection. The displacement of copycat firms does not lead to a net social loss. A study by MacLaughlin, Richard and Kenny notes, "[the] transfer of sales or royalty payments to other nationals would represent merely a transfer of income from one member of society to another and therefore, from the nation's perspective, would represent no net loss at all."<sup>102</sup> Likewise, much is made by critics of patent protection regarding the payment of royalties for patented products that copycat companies had previously utilized without such payment. Yet, a developing country that purchases technology is not disadvantaged by the purchase. Over the long term, it will result in gain due to the incentive to build up its own imitative R&D capacity for when the drug patent expires.<sup>103</sup> The payment for patented technology has an offset that can prove to be advantageous. Japan saw its high technology sector increase as the flow of new technologies stimulated domestic technological growth.<sup>104</sup>

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99. See Jori, *supra* note 74, at 62.

100. See Noguez, *supra* note 27. See also TAYLOR & SILBERSTON, *supra* note 35; H. Grabowski & J. Vernon, *Longer Patents for Lower Imitation Barriers: The 1984 Drug Act*, 2 AM. ECON. REV. 76, 195-198 (1986) (examining the U.S. drug market).

101. See Noguez, *supra* note 27.

102. See J.H. MacLaughlin et al., *The Economic Significance of Piracy*, in INTELLECTUAL PROPERTY RIGHTS: GLOBAL CONSENSUS, GLOBAL CONFLICT? (R.M. Gadshaw & T.J. Richards eds., Westview Press 1988).

103. See SIEBECK, *supra* note 2, at 56.

104. See Guntram Rahn, *The Role of Industrial Property in Economic Development: The Japanese Experience*, Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, 14 INT'L REV. OF IND. PROP. AND COPY-

At the consumer level, the introduction of strong patent protection will not have a large effect on consumer welfare. If the new rate of product innovation is stable over time, the introduction of new patented drugs will be matched by those going off patent. While Lanjouw's study on the Indian market was inconclusive as to whether introducing a stronger patent regime would speed up or slow down the availability of drugs to Indian customers, Lanjouw notes that if the domestic market is already competitive, as in India, then the ability of the drug innovator to extract higher prices from consumers is limited.<sup>105</sup> The availability of other drug therapies that are off patent also reduce the price of drugs under a strong patent system because firms will compete in price for sales; thereby reducing price to a level slightly above that of marginal cost.<sup>106</sup> By the end of 1996, only eight of the drugs on the World Health Organization's 7th Model List of Essential Drugs were still under patent in Europe.<sup>107</sup> This suggests that switching to lower priced alternative drugs is an available option for all but 10% of drugs on the WHO list.<sup>108</sup> The availability of therapeutic substitutes serves to restrain prices and limit the amount of welfare loss that consumers would suffer.

Another reason that patent protection will not affect the welfare of most consumers is a sad but true fact. Many people are priced out of drugs once the price of drugs reaches a certain level. It does not matter if the cost of a drug is \$100 or \$180 a year if the average salary in a particular country is \$560 a year. Both drugs are equally unaffordable. As Lanjouw notes, "for the 70% or so of the population who currently do not have access to pharmaceuticals, the introduction of patent protection, and any price effects that may follow are irrelevant."<sup>109</sup>

Weak patent regimes, on the other hand, encourage anti-competitive and exclusionary behavior that permits the abuse of monopoly power in defending home markets or in penetrating foreign markets. This manifests itself in a number of differ-

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RIGHT L. 449-92 (1983).

105. Lanjouw, *supra* note 84, at 9.

106. *See id.*

107. *See id.*

108. *See id.* at 10.

109. *See id.* at 30.

ent ways: export cartels, predatory dumping in the export of copied drugs, and collusive agreements among firms to divide markets in the internal sale and distribution of copied drugs.<sup>110</sup> Such firms may behave in an oligopolistic manner in which each copycat firm is assigned a particular part of the domestic market. The firms could then enforce their pricing scheme through the threat of disciplining a member of the oligopoly through predatory pricing that would attempt to increase its market share.<sup>111</sup>

#### IX. DO COPYCATS COMPETE?

An important element of overall drug pricing is the extent to which copycat industry is competitive. Copycats frequently collude to fix prices and engage in other forms of anti-competitive conduct which leads to higher, and not lower, prices. Indeed the evidence from Argentina, where the average imitation product is actually more expensive than the patented product, strongly suggests price-fixing or other anti-competitive behavior by copycat firms.<sup>112</sup> Why else would the products be *more* expensive? If there is a lack of competition in the market for copied products as evidence suggests, then weakening the patent system will serve only to enrich the copycats at the expense of local consumers (who do not see material price reduction), the patentees (whose potential R&D investment is significantly diminished), and global welfare generally, measured by fewer new drugs being developed.

The off-patent market where generics are still 30 - 40% less than branded drugs is interesting for comparison purposes.<sup>113</sup> The reason could be a perception of higher quality among branded products. This price difference cannot be explained by the patent system.

R&D costs are not, though they should be, calculated by many critics into the price of drugs since the R&D costs make

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110. See Maskus, *supra* note 87, at 5. See also Sherwood, *supra* note 53, at 500 (noting that copycat drug companies have been known to fix prices among themselves).

111. On the destructive potential of oligopolies, see George Stigler, *A Theory of Oligopoly*, in THE ORGANIZATION OF INDUSTRY 39 (George J. Stigler, ed., 1968).

112. See Alan M. Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 JURIMETRICS J. 295 (1994).

113. See *id.*

up a significant portion of the price that pharmaceutical firms charge for products. As a result, those scholars that have noted lower costs in some countries that have low patent protection have flawed analyses since they never factor into consideration the lost drugs that companies do not produce because of the increased development costs from copying.<sup>114</sup> The overall loss in terms of the increased cost of R&D and the loss to companies in revenue because of copying explains how the extra cost of R&D makes some drugs untenable. When this is factored into the cost of the purchase of a copied drug, the cost of that drug rises. The cost of the copied drug also fails to take into consideration the cost of non-tariff barrier and higher distribution costs that affect only imported, legitimate drugs.

#### X. THE ROLE OF DISTRIBUTION LAWS IN INFLATING PROFIT MARGINS

Many countries maintain distribution laws which are uncompetitive and provide large protection for local distributors at the expense of foreign suppliers (but not local suppliers). These laws, known as dealer protection laws, are leftovers from days of import substitution and usually provide for very high termination indemnities which must be paid by foreign suppliers upon terminating local distributors. Such indemnities do not arise for purely local relationships. Hence, these laws certainly violate GATS article XVII, and arguably also GATT article III.4 (the GATT provisions on non-discrimination between foreign and local entities).<sup>115</sup> The result is that, for products which are distributed by foreign suppliers, distributors can, without fear of recourse, extract very high profit margins from local suppliers. In some cases these can be as much as 80%. Clearly this represents a substantial part, if not all the difference between foreign pharmaceuticals prices for pat-

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114. See, e.g., Robert Weissman, *A Long, Strange Trips: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069 (1996); A. Samuel Oddi, *TRIPS—Natural Rights and a "Polite Form of Economic Imperialism,"* 29 VAND. J. TRANSNAT'L L. 415 (1996).

115. See General Agreement on Trade in Services, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Legal Instruments - Results of the Uruguay Round, vol. 31:33 I.L.M. 81 (1994), art. 17 [hereinafter GATS Agreement]. See also General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, art. 3, para. 4 [hereinafter GATT Agreement].

ented products and those of copycats in some markets.

At present, in the Latin American and Caribbean region alone, these laws apply in the Dominican Republic, Costa Rica, Honduras, Guatemala, El Salvador, Haiti, and to a lesser extent, in Brazil and Colombia.

#### XI. COMPULSORY LICENSING: CONVERGENCE OR CLASH BETWEEN ANTITRUST AND PATENT PROTECTION

A compulsory license arrangement is one in which a government mandates that a patent holder release her patented right to a government institution or licensee in return for a set fee. Put differently, "[a] compulsory license is an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state."<sup>116</sup> Compulsory licensing is a particularly damaging way that some countries use to weaken patent rights; even if patent rights are recognized in that country. Developing countries fear that without compulsory licenses they will not get the drugs needed by their populations. They also believe the licenses prevent overpricing of drugs by multinationals. Yet, compulsory licensing serves to make the patent right less secure because it allows for the free-riding of other companies that, after the expensive R&D is completed by the innovative firm, can apply for a license to sell the drug and make considerable profit from doing so.<sup>117</sup> As Robert Sherwood explains, "A compulsory licensing system is a policy contradiction. In effect, the state, having bestowed an exclusive property right for an innovation in order to serve the public good, then exercises its discretion to reduce the value of that right through compelled sharing of the property right under defined circumstances, also to serve a public good."<sup>118</sup> In fact, compulsory licenses do not necessarily lead to significantly lower prices in developing countries. Copied products through compulsory licenses often sell at high prices even though the R&D costs are minimal.<sup>119</sup> Prices, therefore, should be even

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116. P. Gorecki, *Regulating the Price of Prescription Drugs in Canada: Compulsory Licensing, Product Selection, and Governmental Reimbursement Programs*, (Economic Council of Canada, 1981) cited in Julian-Arnold, *supra* note 96, at 349.

117. See Julian-Arnold, *supra* note 96, at 357

118. See Sherwood, *supra* note 50, at 276-77.

119. See Julian-Arnold, *supra* note 96, at 364. See also Juan Aznarez, *Los medicamentos nacionales, más caros*, LA NACION (Argentina), (May 28, 1999) (offer-

lower than they tend to be in the developing world.

As a result, a high social rate of return is sacrificed in favor of a high private rate of return to the few beneficiaries of compulsory licenses.<sup>120</sup> Since compulsory licensing weakens the patent right, it diminishes foreign investment into a country's economy. This, in turn, limits the opportunity for increased growth.<sup>121</sup> Canada, for example, repealed significant portions of its compulsory licensing statute because of the near demise of the Canadian R&D based pharmaceutical industry.<sup>122</sup> Compulsory licensing is anti-competitive because it encourages free-riding, thereby increasing societal economic cost. Further, it destroys the "prospect function" of a patent right, as analogized earlier in this article,<sup>123</sup> because the patent owner loses the ability to control who uses the patent.<sup>124</sup> Third parties can find ways of increasing the value of the patent and then force the owner to license the patent at a regulated rate. There are also serious questions as to who regulates the rate for a compulsory license and what basis the regulator uses for doing so. It is very difficult to measure the putative future value of a given patent and a government may do a poor job in estimating such value.

In the developing world, compulsory licenses have been identified as a way to increase competition and reduce prices for poor consumers. Manot Tshabalala-Msimang, South African Minister of Health, stated that he believes compulsory licensing to be a crucial tool to make HIV/AIDS drugs more widely available.<sup>125</sup> Many non-governmental organizations ("NGOs") have also stated that compulsory licensing holds the key to the world's health problems.<sup>126</sup> Many of those that support com-

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ing evidence that copied products in Argentina sell at a higher price than even the products of the multinational pharmaceutical firms that have patented the product elsewhere).

120. See Julian-Arnold, *supra* note 96, at 362.

121. See *id.* at 363.

122. See U.S. Int'l Trade Comm'n Pub. No. 332-302, *Global Competitiveness of U.S. Advanced Technology Manufacturing Industries: Pharmaceuticals* 3-15 (1991) (cited in Fisch, *supra* note 28, at 315).

123. *Id.*

124. *Id.*

125. See Press release from Medecins Sans Frontieres Web site, at <http://www.msf.org/advocacy/accessmed/reports/2000/06/pr-pfizer.htm> (last visited Oct. 14, 2000).

126. See Joelle Tanguy, *Treating AIDS*, N.Y. TIMES at A24.

pulsory licensing do so based on the possibility of greater access to generic products. Joelle Tanguy, Executive Director of the NGO Doctors Without Borders, has advocated that long-term strategies, such as "generic production," be undertaken to make medicines affordable to the developing world.<sup>127</sup> In fact, Tanguy does not mean generic production as it is commonly known—production of drugs by companies after the patent right has expired.<sup>128</sup> Rather, Tanguy, and many NGOs conflate the practice of producing generics, which involves respecting a system of patent rights and rewarding innovation on the one hand, with the use of copied drugs through a system of compulsory licensing and parallel trading that weakens the ability of firms to innovate on the other hand. This misguided conflation becomes more apparent in the HIV/AIDS Pricing Report that Doctors Without Borders produced in connection with the 13th International AIDS Conference in July 2000.<sup>129</sup> In its report, Doctors Without Borders explicitly states that compulsory licensing and parallel trading are ways to mitigate the "negative consequences" of patent rights.<sup>130</sup>

A review of recent publications by Doctors Without Borders sheds light on why the group, as representative of a number of NGOs, takes this view. In one document, the group states, "Millions of poor people die every year from infectious diseases because medicines that could cure them are too expensive. For other diseases there is no treatment: no effective medicine exists and nobody is looking for a cure."<sup>131</sup> Surprisingly, the group never asks why it is that pharmaceutical companies do not research diseases for which there are no effective treatments. In order for companies to do so, there needs to be an economic incentive to pay for the process of innovation. As noted earlier, this innovation can only occur in countries which protect the patent right. The fact that anti-malarial medications in India are only now being developed is due to the fact that the developing world did not respect patent rights and

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127. *See id.*

128. *Id.*

129. *See* C. PEREZ-CASAS ET AL., HIV/AIDS MEDICINES PRICING REPORT, SETTING OBJECTIVES: IS THERE A POLITICAL WILL (2000).

130. *Id.*

131. Doctors Without Borders, *1999 Activities Report*, at [http://www.msf.org/publications/activ\\_rep/1999/access.htm](http://www.msf.org/publications/activ_rep/1999/access.htm) (last visited Oct. 14, 2000).

thereby removed the incentives to create such a drug.<sup>132</sup> In an attempt to lower prices for drugs through a weak patent system, developing countries actually served to increase the price for new drug development to a level that made R&D into these drugs economically unfeasible. Doctors Without Borders therefore seriously underestimates the disincentivising effect that a compulsory licensing and parallel trading system would have on the world's ability to come up with new treatments for diseases, and by doing so undermines the position of its own constituency.

Another problem that Doctors Without Borders notes in its publications is the prohibitive cost of medicines in developing countries that spend as much as half of their total health budgets on medicines.<sup>133</sup> The answer here lies not so much in the hands of innovative companies, but rather in the use of procurement methods which can dramatically reduce the cost of healthcare on a nation's budget. This means that many countries need to create better programs in which procurement problems can be mitigated through mass purchases of medicines through transparent agencies. As one World Bank report notes, "Experience has demonstrated that when procurement is executed well . . . significant savings are possible—resulting in the maximization of pharmaceutical budgets."<sup>134</sup> These savings can be significant and immediate. For example, Nicaragua spent \$21 million of its health budget, 17% of the total health budget, on pharmaceutical procurement.<sup>135</sup> Nicaragua established a transparent procurement agency and accompanied the creation of this agency with the implementation of an essential drug list.<sup>136</sup> Within one year, the pharmaceutical budget shrank to \$13 million.<sup>137</sup>

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132. See Lanjouw, *supra* note 13, at 29.

133. Doctors Without Borders, *1999 Activities Report*, at [http://www.msf.org/publications/activ\\_rep/1999/access.htm](http://www.msf.org/publications/activ_rep/1999/access.htm) (last visited Oct. 14, 2000).

134. Jillian Clare Cohen, *The LAC Pharmaceutical Sector* (2000), at <http://www.worldbank.org>.

135. See *id.*

136. See *id.*

137. See *id.* A more in depth study of the type of policies that will reduce costs through better administration and procurement can be found in Jillian Claire Cohen, *Public Policies in the Pharmaceutical Sector: A Case Study of Brazil*, World Bank, LCSHD PAPER 54, (Jan. 2000).



## XII. THE DEMISE OF COMPULSORY LICENSING AS AN ANTITRUST REMEDY

Proponents of strong compulsory licensing statutes argue that they are a solution to the problem of patent exclusivity because they are a remedy that is sometimes used in patent cases under U.S. law. In order for compulsory licensing to be a remedy, there must be some right that is violated; it is in antitrust cases that these remedies are most often fashioned. The basis of antitrust jurisprudence is to distinguish between lawful and unlawful acquisition and maintenance of monopoly power in order to promote greater competition, yield an efficient allocation of resources, and benefit consumers.<sup>138</sup> When a patented product represents one of many products that compete in the market, few antitrust problems will arise. In the case where a patented product is so successful that it either evolves into its own market or engulfs a large percentage of the preexisting market, there is potential for tension between the antitrust and patent law.<sup>139</sup> However, the U.S. Supreme Court has found that, "Compulsory licensing is a rarity in our patent system . . ."<sup>140</sup> The types of cases in which compulsory licenses have been granted are a small group in which the, "intellectual property has been wrongfully acquired or pooled and cross-licensed with competitors and only if one of these acts is accompanied by other predatory conduct."<sup>141</sup> As a major treatise on antitrust notes, compulsory licensing may be used as a remedy for certain antitrust violations involving

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138. See Wynne S. Carvill & Douglas D. Leeds, *Antitrust Issues in Management of Intellectual Property*, 483 PLI/Pat 59.

139. See *SCM Corp. v. Xerox Corp.*, 645 F2d 1195, 1203 (2d Cir. 1981); *Eastman Kodak v. Image Tech. Svcs., Inc.*, 504 U.S. 451 (1992).

140. *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980).

141. James B. Koback, Jr., *Antitrust Treatment of Refusals to License Intellectual Property*, 566 PLI/Pat 517, 533. As the Court stated in *Eastman Kodak Co. v. Image Technical Services, Inc.*, 504 U.S. 451, 479 (1992), "The Court has held many times that power gained through some natural and legal advantage such as a patent, copyright, or business acumen can give rise to liability if 'a seller exploits his dominant position in one market to expand his empire into the next.'" (citing *Times-Picayune Publ'g Co. v. U.S.*, 345 U.S. 594, 611 (1953)). It is important to note that on its own, dominating a market is not punishable. In fact, it is rewarded. See *U.S. v. Grinnell Corp.* 384 US 563, 570 (1966) (noting that it is not unlawful for a competitor to become a monopolist by virtue of a superior product, business acumen or historical accident).

patents, but "it must be used sparingly."<sup>142</sup>

Even where there has been an antitrust violation, compulsory licensing is not favored as a remedy because any advantages are outweighed by administrative difficulties. The courts would have to supervise it and there is no way of determining what a "reasonable" royalty rate would be. The royalty rate will depend on the value of the patent, but value is almost impossible to determine until the product has been in the market for some time.<sup>143</sup> In the United States, compulsory licensing has not been adopted as a statutory requirement but is part of the relief which petitioners may receive if there has been a demonstrated patent misuse or antitrust violation. Nevertheless, in the United States there are very few cases where the use of compulsory licensing as a remedy resulted from the non-use of a patent.<sup>144</sup> Importantly, compulsory licensing as a remedy for non-use is inapplicable to the pharmaceutical sector in which companies would want to bring new drugs to market to earn back the high cost of R&D.

### XIII. COMPULSORY LICENSING AND THE PATENT MISUSE DOCTRINE

Arguments that support compulsory licensing are also sometimes based on some variant of the patent misuse doctrine. The U.S. Federal Circuit has construed the patent misuse precedent narrowly.<sup>145</sup> As a general rule, the patent misuse doctrine has a broader scope than that of antitrust laws; though there is a large amount of overlap between the two as long as antitrust concerns such as market structure, intent and anticompetitive effect can be met.<sup>146</sup> "All that a successful defense of patent misuse means is that a court of equity will not lend its support to enforcement of a mis-user's patent."<sup>147</sup> The patent misuse doctrine is a court made doctrine that is intend-

142. AREEDA AND HOVENKAMP, *ANTITRUST LAW*, Vol. III, §705 (Rev. 1996).

143. *See id.* Vol. III, §704.

144. *See* Jack Kaufmann, *Symposium: Antitrust and the Suppression of Technology in the United States and Europe: Is There a Remedy?*, 66 *ANTITRUST L.J.* 527, 529 (1998).

145. *See* Patricia A Martone et al., *The Patent Misuse Defense - Does it Still have Vitality?*, 566 *PLIPat* 547, 552 (1999).

146. *See* Wynne S. Carvill & Douglas D. Leeds, *Antitrust Issues in Management of Intellectual Property*, 483 *PLIPat* 59, 89 (1997).

147. *Senga-Gel Corp. v. Seiffhart*, 803 F.2d 661, 668 (Fed. Cir. 1986).

ed to prevent a patent holder from extending the power of the patent beyond the grant defined by the patent statute.<sup>148</sup> The doctrine is most frequently raised as a defense in infringement suits and breach of contract actions to pay royalties.<sup>149</sup> If a patent holder is found guilty under the misuse doctrine, the patent is rendered unenforceable until the patent holder remedies the misuse.<sup>150</sup> However, patent misuse may limit the validity of a patent for behavior that does not rise to the level of an antitrust violation. With the exception of non-economic reasons why the doctrine should apply (e.g. fraud on the patent office), this represents a serious flaw in the doctrine itself.

The lack of enforceability of a patent has the same *de facto* effect as a compulsory license. The patent misuse doctrine differs from antitrust violations. The U.S. Supreme Court has noted that a patentee's act may constitute patent misuse without rising to the level of an antitrust violation.<sup>151</sup>

The patent misuse doctrine applies the "clean hands" equitable doctrine as a vehicle for enforcing good faith requirements.<sup>152</sup> Unclean hands alone will not render a patent right unenforceable; as the unclean conduct must have a relation to the patent in question.<sup>153</sup> Yet, the doctrine has been applied to cases in which the patent holder has attempted to "tie" the sale of goods not covered by the patent.<sup>154</sup> The test the Federal Circuit uses in its patent misuse jurisprudence examines whether, "the patentee has impermissibly broadened the 'physical or temporal scope' of the patent with anti-competitive effect."<sup>155</sup> A patent holder's behavior can be a misuse on its face in the case of *per se* antitrust violations such as a tie-in (in which the purchase of two products are tied together) or price fixing.<sup>156</sup> The rule of reason serves as the basis for judging the legality of a potential anti-competitive effect. In *Mallinckrodt, Inc. v. Medipart, Inc.*, the Federal Circuit held

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148. See Carvill & Leeds, *supra* note 146, at 88.

149. See *id.*

150. See *id.*

151. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 140 (1969).

152. See Martone, *supra* note 145, at 554.

153. See *id.*

154. See *id.* at 555.

155. *Windsurfing Int'l Inc. v. AMF, Inc.*, 782 F.2d 995, 1001-02 (Fed. Cir. 1986).

156. See *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992).

that, "where an anticompetitive effect is asserted, the rule of reason under 35 USCA § 154 is the basis of determining the legality of the provision."<sup>157</sup> If, under the rule of reason, there has been a violation, then the misuse doctrine will apply. The patent misuse doctrine seems ill equipped as a remedy in the pharmaceutical setting. The patent right makes it possible for pharmaceutical firms to get out products, which they are incentivized to do. Others are equally incentivized to come up with therapeutic alternatives if a large market exists for the drug. If there were *per se* violations, then the patent misuse doctrine as well as antitrust legislation would apply. However, these types of *per se* violations are not common in the drug industry. Problems in the pharmaceutical industry are those of pricing - a result of copycats.<sup>158</sup> It is not a patent misuse problem. It is a problem of the use of patented property without the right to do so.

#### XIV. HOW MUST A PATENTEE TREAT RIVALS?

The patentee's obligation with respect to how it treats rivals is a significant issue, and one that is becoming more serious for patentees every day. Many reports quoted elsewhere in this article have suggested that patentees might be deemed to have some kind of obligation to deal with others. The apparent basis for this suggestion is public concern with the monopoly nature of the patent right. There appears to be a view that, since the patent confers a monopoly on the patentee, then one has to be very concerned about the behavior of the monopolist. Furthermore, on occasion, it may be appropriate to use government intervention to force a monopolist to license his products. However, this characterisation is deeply misleading. Firstly, patentees are not necessarily monopolists. Whether they are or not depends on the range of substitutable products available to treat a particular disease. Secondly, even if the patentee is a monopolist, forcing the patentee to license his product may not necessarily lead to positive results for consumers for reasons detailed below. However, requiring a firm with market power to deal with rivals could have significant deterrent effects on innovation, and could lead to a decline in

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157. *Id.* at 706.

158. *See* discussion, *infra* Section IX.

overall research and development spent by innovators. Some have also sought to use the patent misuse doctrine to discipline the patentees decision to license or not license his patented product.

The U.S experience is instructive here also. In the United States, refusal to licence is not a basis for the patent misuse doctrine.<sup>159</sup> According to the Xerox litigation, it will not be grounds for any kind of antitrust violation either if the patentee is merely exercising his right under the patent. Monopolists may not refuse to deal in certain circumstances, because they have market power and their actions may lead to foreclosure of the market to competitors. The key question for pharmaceutical patent holders is whether they have market power in a relevant antitrust market. This question will turn on the availability of substitutes. Generally, a monopolist cannot change its pattern of dealing, or may be precluded from refusing to deal, if it controls an "essential facility," or it uses its monopoly power in one market to attempt to gain a monopoly in the second ("monopoly leveraging doctrine").<sup>160</sup> There is a defense for the refusal to deal only if the monopolist has a legitimate business reason for the refusal to deal.<sup>161</sup>

#### XV. COMPULSORY LICENSING AS A REMEDY FOR REFUSALS TO DEAL

Compulsory licensing has had changing fortune in United States litigation, principally as a remedy for antitrust violations, such as refusal to deal. However, recent U.S. learning in this area is very important. The increasing protection of patent rights in the U.S. in recent history has done much to boost innovation, and provides a model for other countries intent on building economic growth.

The compulsory licensing doctrine has not been significantly relied upon in the U.S. It has only substantively been applied where intellectual property has been wrongfully acquired or pooled and cross-licensed with competitors, and only if one of these acts is accompanied by some predatory conduct.<sup>162</sup>

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159. See Patent Reform Act, 1988 S271(d); *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322 (Fed. Cir. 2000) (hereinafter Xerox litigation).

160. *Id.*

161. See *id.*

162. See *S. Pac. Communications Co. v. AT&T Co.*, 740 F.2d 980 (D.C. Cir.

The use has been more typically limited to consent decrees in merger cases. There is now a rebuttable presumption that a monopolist's desire to exclude others from its protected work is a preemptively valid legal business justification for any immediate harm to consumers.<sup>163</sup> Originally a copyright test, this has now been extended to patents also.<sup>164</sup> In the *Image Technical* case, the court held this presumption could be rebutted by evidence of pretext.<sup>165</sup> The Xerox litigation makes it clear that the courts will not inquire into the subjective motivation for exercising statutory rights granted under the patent laws, "even though [the] refusal to sell or license [a] patented invention may have an anti-competitive effect, so long as the anti-competitive effect is not illegally extended beyond the statutory patent grant."<sup>166</sup>

#### XVI. RECENT FTC ENFORCEMENT ACTION

In *Intergraph Corp. v. Intel Corp.*,<sup>167</sup> the district court imposed significant obligations on Intel by imposing an affirmative duty to continue to deal with a competitor. The court so held even though Intel was effectively being asked to reveal its trade secrets to one of its rivals.<sup>168</sup> The decision caused some consternation among antitrust practitioners. Intergraph was a manufacturer of graphical interface workstations, and had acquired the Clipper computer technology but abandoned it in favor of a relationship with Intel. Intergraph threatened to sue Intel for patent violations relating to its chip technology. In response, Intel demanded that it enter into a cross license agreement.<sup>169</sup> When Intergraph refused, Intel allegedly retaliated by denying access to chips and technical product development information which it had previously furnished to Intergraph.<sup>170</sup> The district enjoined Intel from refusing to

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1984).

163. See *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 36 F.3d 1147 (1st Cir. 1994).

164. See *Image Technical Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997).

165. *Id.*

166. Xerox Litigation, *supra* note 159.

167. *Intergraph Corp. v. Intel Corp.*, 3 F. Supp. 2d 1255 (N.D. Ala. 1998).

168. *Id.* at 1289.

169. *Id.* at 1267.

170. *Id.* at 1267-8.

deal with Intergraph.<sup>171</sup> The Federal Circuit, however, rejected the district court's assertion that Intel's microprocessor technology was an essential facility, with respect to which Intel had "affirmative duties to refrain from acting in a manner that unreasonably harms competition."<sup>172</sup> Indeed, the Federal Circuit was careful to make sure that the essential facility doctrine was confined to competition with the controller of the essential facility, and not to competition in derivative markets. The Federal Circuit stated that:

[the] courts have well understood that the essential facility theory is not an invitation to demand access to the property or privileges of another, on pain of antitrust penalties and compulsion; thus the courts have required anti-competitive action by a monopolist that is intended to 'eliminate competition in the downstream market'.<sup>173</sup>

#### XVII. THE EXCEPTION TO THE RIGHT TO REFUSE TO DEAL: ESSENTIAL FACILITIES DOCTRINE

The seminal definition of the essential facilities doctrine can be found in *MCI Communications Corp. v. American Tel. and Tel. Co.*, in which the Court held "A monopolist's refusal to deal under these circumstances is governed by the so-called essential facilities doctrine. Such a refusal may be unlawful because a monopolist's control of an essential facility (sometimes called a 'bottleneck') can extend monopoly power from one stage of production to another, and from one market into another. Thus, the antitrust laws have imposed on firms controlling an essential facility the obligation to make the facility available on non-discriminatory terms."<sup>174</sup> Under *MCI*, four elements must be met to establish liability under the essential facilities doctrine: (1) control of the essential facility by a monopolist; (2) a competitor's inability practically or reasonably to duplicate the essential facility; (3) the denial of the use of the facility to a competitor; and (4) the feasibility of providing the

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171. *Id.* at 1259.

172. *Id.* at 1277.

173. *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1358 (9th Cir. 1999).

174. *MCI Communications Corp. v. Am. Tel. and Tel. Co.*, 708 F.2d 1081, 1132 (7th Cir. 1983).

facility.<sup>175</sup> In the pharmaceutical setting, the patented drug itself does not create a bottleneck. Indeed it could be regarded as the opposite of a bottleneck since new innovations can be derived as a result of the patented product. To the extent that there are bottlenecks in the pharmaceutical sector in the developing world, they are distribution bottlenecks. Solving these bottleneck problems would only lower prices because it would reduce vertical monopolistic restraints on price imposed by a number of the copycat producers.

#### XVIII. COMPULSORY LICENSING UNDER TRIPS

The TRIPS Agreement allows for compulsory licensing under Articles 27(1), 31 and 65(4), but limits these circumstances to cases of antitrust violation, national emergency, and public noncommercial use.<sup>176</sup> The damaging effect of compulsory licenses was recognized by the WTO, and hence, where WTO Members insist on maintaining such provisions, the WTO rules strictly regulate what can be used as a basis for compulsory licensing. Indeed, laws can be TRIPS compliant with no provision for compulsory licensing at all. TRIPS Article 31 states that, "Where the law of a Member allows for [compulsory licensing] . . . the following provisions shall be respected."<sup>177</sup> In other words, even if Members have compulsory licensing provisions, they must respect certain basic provisions.<sup>178</sup>

Article 31 of TRIPS lists, conjunctively, the criteria which must be met before a compulsory licensing regime is deemed to be TRIPS compliant. These include:

- a) each case must be considered on its merits;
- b) the grant is conditional on the purported licensee having attempted to obtain authorization by the patentee on commercial terms, and failure to achieve it in a reasonable period of time;

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175. *Id.* at 1132-33.

176. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex IC, LEGAL INSTRUMENTS - RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

177. *Id.* art. 31.

178. *See id.* art. 31(a)-(l).



- c) the use of compulsory licensing is limited to the purpose for which it was initially authorised;
- d) the license may not be exclusive;
- e) the license cannot be assigned;
- f) that license should be predominantly (note earlier drafts stated "solely" or "exclusively" for domestic market use;
- g) compulsory licensing is allowed only during the time that the circumstances which gave rise to the license still prevail, and provided that a competent authority has the power to review the continuation of the license;
- h) requires proper compensation to the patent holder;
- i) provides that the procedure in deciding compensation;
- j) provides that the decision itself must be subject to higher judicial review; and
- k) enables countries to bypass (b) through (h) in cases of anti-competitive actions by patentees.<sup>179</sup>

Although much has been made of the fact that Article 31 of TRIPS is ambiguous, this should not cloud those aspects of the article which are clear and unambiguous. Compulsory licensing is subject to very strict conditions, which must all apply (except in cases of anti-competitive conduct by the patentee). The references to a reason behind the need for the license grant, and the fact that the license only will be granted while that reason prevails, is strongly suggestive that the compulsory licensing regime should be used as a remedy for some form of market failure only, and, therefore, should not be universally applicable. The foregoing addresses what constitutes anti-competitive behavior, and what might further constitute patent misuse. However, many countries' submissions to the WTO trade and competition group help to further clarify this issue.

Applying TRIPS, anti-competitive practices must be strictly construed. Article 40 of TRIPS gives a clue as to what

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179. *Id.* art. 31.

should be considered anti-competitive for these purposes.<sup>180</sup> Article 40 provides that some licensing practices “may have adverse effects on trade and may impede the transfer and dissemination of technology.”<sup>181</sup> Article 40(2) gives examples of how abuses of intellectual property rights which might have an adverse effect on the market can be corrected.<sup>182</sup>

In its submission to the WTO Trade and Competition group, the European Union offers useful examples of what may or may not constitute anti-competitive practices, possibly justifying the imposition of a compulsory license:

“The core rationale for their [IPR] protection is that they tend to create a dynamic efficiency that is pro-competitive and outweighs any short term allocative efficiency gains that might exist in the absence of such protection . . . .”<sup>183</sup> The EU notes that the exclusive right given to the patentee will, in and of itself, not give rise to an abuse of market power. This depends on the availability and market share of substitutable products. The practices that might give grounds for anti-competitive abuse of a monopoly right are:

1. If competitors grant licenses to each other for the purposes of dividing up markets, then there may be a market division problem. But transfers in and of themselves do not present a problem. Competition problems only arise if the transfer is the subject, the means, or the consequence, of an anti-competitive arrangement.
2. The patentee may not try and impose a fixed margin on licensees. If he does so, that may constitute a competitive problem.
3. The exclusive right conferred by the patent is not in and of itself sufficient to determine the existence of a dominant position. The price of goods is not necessarily an abuse of dominant position. Indeed the EU submission states that “only in exceptional circumstances,

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180. *Id.* art. 40.

181. *Id.*

182. *Id.* art. 40, para. 2.

183. See *EU Submission on the Relationship Between the Trade-Related Aspects of Intellectual Property Rights and Competition Policy, and between Investment and Competition Policy*, WT/WGTCP/W/99 (Sept. 15, 1998).

should abnormally high prices be considered as an abuse in themselves."<sup>184</sup>

4. A refusal to grant a license, even for a reasonable royalty, does not in itself constitute an abuse of a dominant position. Additional requirements are required, such as where the patentee is not working the patent itself, withholding important technical information from the public against the public's interests, engaging in unfair sales prices, or engaging in discriminatory sales practices (e.g. unfairly refusing to supply certain parts of the market).<sup>185</sup>

All of these points are directed towards practices by patentees which tend to impede trade and prevent the invention being fully exploited in the domestic market. Many of the U.S. cases also illustrate the type of anti-competitive practices, which are outside the limited antitrust immunity that the patent itself provides. In *Twin Labs, Inc v. Weider Health & Fitness*,<sup>186</sup> the Second Circuit relied on the authority of the leading antitrust treatise, stating that "facilities that are natural monopoly, facilities whose duplication is forbidden by law, and perhaps those that are publicly subsidized and thus could not practicably be built privately."<sup>187</sup> It is clear from the case law and commentary that patent owners risk compulsory licensing of their property only if they are a monopolist for a particular treatment, have some intent to foreclose competitors from that particular treatment, or are otherwise engaging in anti-competitive activity. Generally, the patent right itself will be a legitimate business justification for refusing to licence a patent in the absence of other anti-competitive factors as set out above. As if further clarification was necessary, the IP Guidelines state that the agencies will not require a patent owner to create competition in its own technology.

The FTC Action against Intel considered the issue of an patent holder's duty to license to customers who were not direct competitors with Intel (the OEMs).<sup>188</sup> The FTC's case al-

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184. *Id.*

185. *Id.*

186. *Twin Labs, Inc. v. Weider Health & Fitness*, 900 F.2d 566 (2d Cir. 1990).

187. *See Areeda and Hovencamp*, ANTITRUST LAW, s736.2 (Supp. 1988).

188. *See In re Indep. Serv. Orgs. Antitrust Litig.*, 99-1323, 2000 U.S. App., Lexis 9987.

leged Intel's practices stifled competition in micro-processor related technology.<sup>189</sup> But even in this case, the consent order permits Intel to restrict use of its advanced technical information to the production of computer systems that incorporate the microprocessor to which the information applies, not to the creation of rival microprocessors.<sup>190</sup> Bill Baer, former director of the FTC's Bureau of Competition said:

A . . . concern some have expressed is that the Commission's action seeks to force compulsory licensing of Intel's patents to its competitors. Even a cursory reading of the Commission's complaint and proposed order shows that suggestion to be seriously misleading . . . Where however, Intel had a legitimate business reason - such as evidence of misuse or misappropriation of its inventions, the company would be free to protect its rights.<sup>191</sup>

By analogy, where pharmaceutical patent holders know that their property is being misused or misappropriated, as in the case of copycats, there is simply no antitrust issue in their refusal to license, and no antitrust remedy (such as compulsory licensing) is appropriate. Any other approach could lead to serious economic erosion of the very fabric of the patent right itself.

In the words of one commentator, "allowing competition policy to trump property rights is, in all but the most egregious of situations, an extraordinary result."<sup>192</sup> The essential facility doctrine applies more in the area of regulated utilities, such as the *MCI* case itself.<sup>193</sup> It is a departure to try to apply such a doctrine to the ordinary business of patent holders where such considerations do not apply. The Xerox litigation and the *Intergraph* case seem to finally put out of court the suggestion that patent property ever can be subject to the essential facility doctrine. Indeed, the freedom to license or not

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189. *See id.*

190. *See id.*

191. Baer, *Antitrust Enforcement and High Technology Markets*, Remarks before the American Bar Association Sections of Business Law, Litigation, and Tort and Insurance Practice, San Francisco, California (Nov. 12, 1998).

192. Robert P. Taylor, *Intellectual Property As "Essential Facility,"* Address at the American Bar Association Practicing Law Institute Seminar on Intellectual Property and Antitrust, San Francisco, California (July 20-21, 2000).

193. 708 F.2d 1081, at 1132.

license is one of those integral bundle of rights conferred by the patent system itself.<sup>194</sup>

#### XIX. THE EFFECT OF COMPULSORY LICENSING ON PHARMACEUTICAL COMPANIES

Compulsory licensing could have dramatic effects on pharmaceutical companies. The compulsory license will lead to a reduction of price for patented products. That loss will have to be somehow absorbed by pharmaceutical companies. There are various possibilities:

1. *Raising revenue by increasing other products' price.* This cannot occur where drugs are sold in a competitive environment and may be capped by countries which have price controls. In other words, prices of the non-compulsory licensed patented drugs would likely increase in more competitive, non-price controlled markets, such as the United States, which would be politically unpalatable.

2. *Reduction of expenditure.* The major expense that pharmaceutical companies incur is the cost of research and development. Other expenses include advertising and returns on investment. If returns on investment are lowered, share price could decline, and might lead to further consolidation in the industry. Lowering advertising revenues would have little impact on the losses that would result from compulsory licensing. The most significant reductions would have to come from R&D budgets. Companies might elect to engage in lower risk activity, such as generic production. In any event, a lower R&D budget will lead to fewer new pharmaceutical products being developed.

3. *Reduce costs by merging with rivals.* Pharmaceutical companies may be faced with no other alternative but to merge with rivals in order to reduce costs. The result of this could be an overall reduction in innovation as competition in innovation is reduced and the incentive to invest substantially in research and development declines.

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194. See *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980).

## XX. PARALLEL TRADING

Parallel trading in the pharmaceutical setting occurs when a product in one market is exported to another country. Parallel traders seek to take advantage of the arbitrage possibilities available in the pricing of drugs due to different economic and regulatory practices between countries.<sup>195</sup> The practice has attracted international attention because of the perception that use of parallel importation regimes results in cheaper drug prices in the developing world.

Although empirical evidence on the implications of parallel trading are scant, a number of theoretical works show the negative implications of a parallel trading system.<sup>196</sup> Parallel trading undermines the patent right and therefore creates an economic loss to both innovators and consumers; thereby creating an anti-competitive practice. Barfield and Groombridge note four types of market settings in which parallel trade has particularly pernicious effects to the pharmaceutical industry.<sup>197</sup> Such settings include:

1. where parallel imports would inhibit the ability of pharmaceutical firms to recoup R&D and other fixed costs and chill further innovation;
2. where price discrimination would enhance welfare by facilitating entry of pharmaceutical firms into new, low-priced markets and thus expanding output;
3. where government created monopolies creates price distortions and drives price down below marginal cost of the production of a pharmaceutical product; and
4. where parallel imports could freeze out authorized distributors through lower prices.<sup>198</sup>

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195. See Barfield, *supra* note 15, at 185.

196. See *id.* See also National Economic Research Associates, *The Economic Consequences of the Choice of Regime of Exhaustion in the Area of Trademarks*, (Feb. 8, 1999).

197. Barfield, *supra* note 15, at 187.

198. *Id.*

To extract the lowest possible price for pharmaceutical products consumers need a strong competition policy that encourages trade liberalization, protection against monopolization power, and the encouragement of FDI, rather than a system of parallel trading. This strong competition policy will let the market determine a pareto-enhancing allocation of resources in the economy. It also will create proper regulatory supervision to prevent monopolization or exploitation of market power, since businessmen have an incentive to pursue anti-competitive behavior. This will prevent any abuse of the patent right.

In contrast to the appeals made on behalf of parallel trading, the economics of such trading does not significantly help consumers. Burstall and Senior note, "Doctors and patients may not profit from parallel trade but the distributors - the wholesalers, the dispensers in the high street or in hospitals, and, of course, the traders themselves - very definitely do."<sup>199</sup> Likewise, the National Economic Research Associates found similarly that, "the major beneficiaries of parallel trade are the parallel traders who, on average, claim about 70 percent of the price difference between a parallel import product and the local price. Other direct beneficiaries are pharmacists and, to a much lesser extent, payors. The consumer hardly benefits at all."<sup>200</sup> Such studies prove that parallel trading serves to benefit a few private individuals at the expense of society at large. It raises R&D costs and makes financially infeasible R&D into some necessary drugs.

Advocates of parallel trading often claim that parallel trading is in reality no different than the doctrine of international exhaustion of rights. Exhaustion occurs when a patent holder, or other intellectual property rights holder, has sold a product and can thereafter not prevent its authorized entry into a different market. The patent holder cannot prohibit the subsequent resale of the product because their rights to a particular item have been exhausted by the act of selling it. Such a definition requires a particular geographic area. For example, once a product enters the U.S. market it is exhausted

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199. Burstall & Senior M.L., *Burstall and I.S.T. Senior, Undermining Innovation: Parallel Trade in Prescription Medicines* 22 (1992), cited in Barfield and Groomfield, *supra* note 15, at 250.

200. National Economic Research Associates (NERA), *Survey of Parallel Trade*, 25 (May 1997), cited in Barfield, *supra* note 15, at 250.

anywhere within the U.S. market.<sup>201</sup> This is quite different from international exhaustion of rights, which is what parallel traders seek. A study by the National Economic Research Association on the consequences of an international exhaustion regime on trademarks in Europe extends this theory to other intellectual property rights, such as patents.<sup>202</sup> It notes that an international exhaustion of rights doctrine would have significant negative economic consequences.<sup>203</sup> The report argues against an international exhaustion of rights system noting that pareto-efficient outcomes will occur when patent holders are allowed the freedom to exploit their rights through price discrimination in different national markets.<sup>204</sup> Exploitation of the property right creates incentives to innovate and develop new products. International exhaustion of rights disadvantages consumers by making patents less effective in protecting the consumer by maintaining quality through safety or technical standards and identifying the origin of a product.<sup>205</sup> It also would make it difficult for the patent holder to control the distribution chain and conditions under which products are sold.<sup>206</sup> In the absence of a strong competition policy, an exhaustion doctrine and exclusive distributorship agreements would have a detrimental effect on welfare, since domestic brands may be part of a single *de facto* cartel that would conspire to keep prices high through the exclusive distributor relationships—vertical arrangements between upstream and downstream sellers. This type of vertical restraint was deemed untenable in the United States sixty years ago.<sup>207</sup> National

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201. *U.S. v. Univis Lens Co.*, 316 U.S. 241, 249 (1942) (noting, “[b]ut merely because the licensee takes the final step in the manufacture of the patented product, by doing work on the blank which he has purchased from the patentee’s licensee, it does not follow that the patentee can control the price at which the finished lens is sold.”).

202. National Economic Research Associates, *The Economic Consequences of the Choice of Regime in the Area of Trademarks*, (Feb. 8, 1999) Executive Summary at 3.

203. *Id.*

204. *Id.*

205. See National Economic Research Associates, *The Economic Consequences of the Choice of Regime in the Area of Trademarks*, (Feb. 8, 1999) Executive Summary at 6-7. The problem of counterfeit and poor quality medicines that Doctors Without Borders notes, is only exacerbated by parallel trading.

206. See *id.*

207. See *Ethyl Gasoline Corp. v. U.S.*, 309 U.S. 436 (1940).



exhaustion, in contrast, is permissible since traders are given the right to move goods within a national border, in the case of the United States, or regional borders, in the case of the European Union. The situation of international exhaustion where one country allows for parallel imports from another unrelated country does not fit within this national exhaustion policy. The only reason why the doctrine might have some vitality in Europe is because of the drive towards a single European market. It has no application in free trade areas or among countries where market conditions are significantly different. Moreover, in Europe, the doctrine of exhaustion of rights is a bifurcated one. Recognizing the drive to retain and develop Europe's single market, exhaustion of rights applies to trademarks in Europe, but outside Europe the doctrine has no application.<sup>208</sup> However, even in Europe there are significant problems with the application of the doctrine in the case of pharmaceutical products where price controls exist in some countries, but not in others, and where pricing is not set in a uniform manner.

Some who believe in parallel trading and an international exhaustion system argue that such a system favors free trade, whereas systems that limit parallel trading reduce free trade and are thereby anti-competitive. This reveals a certain confusion. Followed to its logical conclusion, it would eliminate all forms of intellectual property, because it fails to recognize that the intellectual property right is not merely tolerated by competition law, but encouraged.<sup>209</sup> In addition, it also fails to take into account that efficient pricing may depend on a certain level of international price discrimination as described above. This is because the world is not yet a single, uniform market and different prices have to be charged for different products. If companies cannot rely on the integrity of their pricing structures (because parallel traders are arbitraging the price differences), this efficiency would be lost. Further, the argument for parallel trading does not take into account the fact that patents restrict market forces for a period of time in order for the patent holder to recoup the cost of innovation. This is based upon the assumption that the dynamic effects of the patent right will produce greater societal economic welfare

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208. See *Silhouette International Schmied GmbH & Co v. Harlauer Handelsgesellschaft mbH*, Case C-355/96.

209. See *Barfield*, *supra* note 15, at 191-93.

gains than would occur without the patent right. The exhaustion doctrine is not so much a question of free trade as much as it is one of which form of patent policy to pursue. As one scholar notes, there are two serious problems with the exhaustion as free trade argument rather than as one of patent policy. "First, the conditions surround parallel trade do not fit into the assumptions on which standard static trade models supporting the case for laissez-faire trade are built. Second, a static analysis with regard to IPRs . . . would require the removal of all rights to intellectual property."<sup>210</sup>

The economic reality is that price discrimination in the setting of drug prices in different markets, through market segmentation, can have significant positive effects for both producers and consumers. Because of the possibility of arbitrage, parallel importation also has a disciplining effect on the ability of companies to offer discounts for drugs in poorer countries' markets. Any discounted drug simply would be the subject of an arbitrage action by a parallel trader, which would treat the drug like a discounted foreign currency. This would lead to dampened innovation and less of a likelihood that companies will lower price in less developed nations' markets.

Under Ramsey pricing, companies base pricing on how much a particular consumer will be willing to pay for a particular good, above the marginal cost of producing such a good, because of different price elasticities for pharmaceuticals.<sup>211</sup> The ability to discriminate based on price is a common and economically justified practice.<sup>212</sup> Examples include offering volume discounts or discounts to initial customers.<sup>213</sup> Price discrimination is permitted in the case of movie tickets, where matinees and evenings shows are priced differently, as are tickets for youth and senior citizens, or advanced purchases over the phone, or prices for a large group.<sup>214</sup> Price discrimination has ill effects when it is used to gain or enhance monopoly power. Without a differentiation of markets, pharmaceuti-

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210. *Id.* at 193 (citing Carsten Fink, *Does National Exhaustion of Intellectual Property Contradict the Principle of Free Trade?* 3-4, Draft Paper for Conference on Exhaustion of Intellectual Property rights and Parallel Importation in World Trade, Geneva, Switzerland (Nov. 6-7, 1998)).

211. See Barfield, *supra* note 15, at 224.

212. See *id.*

213. See *id.*

214. See *id.*

cal companies will not be able to recoup the cost of innovation during the life of their patent right.

Another significant problem with allowing parallel trading is that the arbitrage it offers is a significant incentive for traders to cartelize their operations, and even for patentees to collude on price. This erosion of the incentive to charge a national market-based price will ultimately lead to problems in efficient allocation of resources.

Within the borders of the United States price discrimination is permitted in some circumstances, although § 2(a) of the Robinson-Patman Act and § 2 of the Sherman Act prohibit price discrimination in other circumstances.<sup>215</sup> The standards for each Act differ slightly. Price discrimination violates the Robinson-Patman Act if it involves: (1) two sales to different person; (2) in interstate commerce; of (3) goods that are of like grade and quality; (3) at different prices; (4) where the effect of the discrimination may be to lessen competition substantially among the sellers of the product (primary-line injury), the buyers of the product (secondary-line injury) or the customers of the buyers (third-line injury).<sup>216</sup> The *prima facie* case can be rebutted with several defenses, such as meeting competition or volume discount.<sup>217</sup>

The Sherman Act §2 offense of monopolization has two elements: (1) the possession of monopoly power in the relevant market, and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.<sup>218</sup> The essence of a §2 monopolization or attempted monopolization claim is that a single firm with market power has engaged in conduct designed to exclude and foreclose competition in a relevant market. It may be the market in which the party already has market power or the market into which it would like to extend that market power.

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215. Robinson-Patman Act, 15 U.S.C. §§13a, 13b, 21a; Sherman Act, 15 U.S.C. §§1-6, 6a, 7.

216. Robinson-Patman Act, 15 U.S.C. §§13a, 13b, 21a.

217. *See id.*

218. Sherman Act, 15 U.S.C. §2.

## XXI. TRIPS-BASED SOLUTIONS FOR DEVELOPING COUNTRIES?

A modern patent law would allow for compulsory licensing only in very specific cases, as specified in the TRIPS agreement itself. The law would be focused on sound patent protection (including enforcement of patent rights) that would stimulate innovation in the country. Adherence to TRIPS should be seen as a minimum requirement but should not be seen as the maximum amount of patent protection. The law should give patentees the right to discipline parallel traders by enforcing their patent rights against them.

However, provisions also need to be made for procurement of patented drugs. International financial institutions could contribute to procurement programs based on competitive bidding, not dissimilar to the programs which already exist in the World Bank for the procurement of generic drugs.<sup>219</sup> In order to avail itself of such a program, the country concerned would have to demonstrate TRIPS compliance and show that compulsory licensing and parallel trading regimes were not present in its law and that proper enforcement steps were being taken against violators. For patented drugs, any bidder, if not the actual patentee, would have to be licensed by them.

Given the key, and often understated role that distribution difficulties play in these countries in ensuring that drugs are delivered throughout the country, distribution issues also should be a central element in the certification process. Indeed, countries that maintain distribution laws of the type described herein should not be eligible for these new procedures because of the significant profit margins that local distributors could charge and effectively block proper distribution of the drugs once purchased.

## XXII. CONCLUSION

Countries must create patent friendly regimes as part of a larger legal and political infrastructure. As one recent book notes, developing countries often fail to enforce already existing laws against violators of patent rights.<sup>220</sup> Often, enforcement mechanisms are weak at best. Moreover, even if patent

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219. *See id.*

220. *See* INTELLECTUAL PROPERTY RIGHTS IN EMERGING MARKETS (Clarisa Long ed., AEI Press, 2000).

protection exists, compulsory licensing systems, or a system of parallel imports, undercut these laws.<sup>221</sup> Therefore, a dynamic and robust system of patent protection is needed. Without a dynamic integrated legal framework and the associated enforcement, the gains made with the TRIPS agreement and corresponding domestic legislation could disappear as countries attempt to circumvent their TRIPS obligations. This will lead to a net global social loss. Equally important, reforms must be geared toward maximizing the benefits from a robust intellectual property system; not merely from creating the minimum system possible to avoid WTO complaints.<sup>222</sup>

Such reforms include strengthened antitrust and competition laws, the addition of more staff in patent offices, greater transparency from government and business, and a greater will on the part of the developing world for better enforcement of laws. This recognizes the fact that the objectives of competition policy and intellectual property policy are in fact the same: to stimulate and encourage innovation. The key is innovation, and its importance is summed up in a comment by two FTC commentators:

An antitrust policy that reduced prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovation lowers the costs of production would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses.<sup>223</sup>

This remark recognizes the critical role of innovation in our society and, consequently, the importance of securing dynamic efficiency over static efficiency. Hence, linked to increased patent protection is the use of competition policy to maximize the effect of the patent right system. As the U.S. Antitrust Guidelines for Licensing of Intellectual Property states, "the intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare."<sup>224</sup> A strong competition policy

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221. *See id.*

222. *See Braga, supra* note 11, at 53. Sherwood notes the problem of creating a well administered patent office in the developing world. *See Robert M. Sherwood et al., Promotion of Inventiveness in Developing Countries Through a More Advanced Patent Administration*, 39 *IDEA* 473 (1997).

223. Willard K. Tom & Joshua Newberg, *Antitrust and Intellectual Property: From Separate Spheres to Unified Field*, 66 *ANTITRUST L.J.* 167 (1997).

224. U.S. DEP'T OF JUSTICE AND THE FED. TRADE COMM'N, *ANTITRUST GUIDE-*

would lower the cost of drugs in developing countries by ensuring that distribution channels are more competitive. These are often arcane and add substantially to the cost of drugs for consumers.<sup>225</sup> Many developing countries maintain laws that give local distributors enormous amounts of protection when they distribute the products of foreign suppliers. These laws serve to make the distribution system itself uncompetitive and increase price. Distributors can charge very high profit margins, sometimes close to 100%. Unless these laws are changed it will remain difficult for pharmaceutical and other supplier firms to make the most of their opportunities in different markets, thereby reducing prices for consumers. Without a change in these anti-competitive distribution laws, it is difficult for consumers in the developing world to see the real benefits that import competition can bring in terms of reduced prices and greater consumer choice.

If firms are to find cures for new diseases or those that affect developing country populations, they must be incentivised to engage in the necessary research. Without this incentivisation, new drugs will not be developed. Without a strong and enforced patent system, it is unlikely that the developing world's health problems will be solved, nor will the new and complex diseases which afflict the world, such as HIV/AIDS, be treated. Indeed, the kind of patent regime that many activists crave is one which would freeze innovation, lead to no new drugs being developed, and the world's health problems continuing to visit human suffering and misery on millions of people. The misguided belief that innovation will always be with us and does not need to be incentivised could lead to needless tragedy at a time when new innovations and genetic discoveries hold such rich promise for humanity.

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LINES FOR THE LICENSING OF INTELLECTUAL PROPERTY, April 6, 1995. On the similarities between the two regimes, see also *Atari Games Corp. v. Nintendo of Am., Inc.*, 897 F.2d 1572, 1576 (Fed Cir. 1990).

225. *Latin American Pharmaceuticals*, BUSINESS LATIN AMERICA, Aug. 2 1999, available at 1999 WL 10528970.

