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PILLS, PATENTS, AND POWER: STATE CREATION OF GRAY MARKETS AS A LIMIT ON PATENT RIGHTS

Shubha Ghosh[*]

I. INTRODUCTION

Globalization has made the world smaller and more homogeneous in terms of both culture and government policy.[1] A recent example of this convergence is the common policy response by the United States and South

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1. BENJAMIN R. BARBER, JIHAD VS. MCWORLD 4-5 (1995) (describing tendencies towards homogenization in the global economy); ROSEMARY J. COOMBE, THE CULTURAL LIFE OF INTELLECTUAL PROPERTIES: AUTHORSHIP, APPROPRIATION, AND THE LAW 3-5 (1998) (describing cultural homogenization through the proliferation of brand names and trademarks).

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African governments to a shared problem.[2] The problem is the high price of pharmaceutical products. The policy response is the creation of gray markets, or reimportation (or parallel importation) of patented products from overseas markets to create competition in the domestic pharmaceutical market. Although, ostensibly, the policy responses are the same, there are important differences which present an important case study of the relationships among patents, human rights, and competition.

The problem posed by the high price of pharmaceuticals is a familiar one.[3] The proposed solution of creating gray markets is less familiar. A gray market is an unauthorized distribution of a good or service.[4] It is different from a black market, which involves the distribution of a product or service that is illegal to distribute, such as cocaine or sexual services. In a gray market, the product or service itself is not illegal, but the means of distribution are unauthorized. The classic example of the gray market is the group of small retail outlets selling electronic goods on 42nd Street in New York City and in Chinatown of San Francisco. These outlets sell electronic products that are not illegal to sell in the United States, but the outlets are not authorized by the manufacturer. The retailers obtain the products overseas where they are sold at a price lower than that prevailing in the United States. Because of the price difference, it is profitable to purchase the goods overseas, transport them to the United States, and sell them here.

The question raised by gray marketers is whether their lack of authorization should imply illegality or should the state authorize gray markets and take affirmative steps to foster their development. In the electronic outlets example, the manufacturer typically designates certain authorized dealers through contracts. Contracts limit the number of dealers in a particular geographic market and may also limit the types of customers to whom the goods may be sold. The gray marketers for electronic products have, of course, not breached any contract terms since they are

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2. 146 CONG. REC. D 776-216 (daily ed. July 19, 2000) (amending the Federal Food, Drug, and Cosmetic Act to allow importation of covered products); Consumer Project on Technology, South Africa and Access to Pharmaceutical Drugs, *available at* http://www.cptech.org/ip/health/sa (last visited Apr. 9, 2001) (collecting materials on the debate and experience of South Africa).

3. For journalistic accounts, see Stephen S. Hall, *The Claritin Effect: Prescription for Profit*, N.Y. TIMES, Mar. 11, 2001, § 6 (Magazine), at 40-43 (reviewing the problem of prescription drug prices in the United States); Tina Rosenberg, *Look at Brazil*, N.Y. TIMES, Jan. 28, 2001, § 6 (Magazine), at 26-28 (reviewing pharmaceuticals in the AIDS crisis). For a technical discussion of the costs of drug development, see Michael Kremer, Creating Markets for New Vaccines 35-38 (May 12, 2000) (unpublished manuscript, on file with author).

4. Nancy T. Gallini & Aidan Hollis, *A Contractual Approach to the Gray Market*, 19 INT'L REV. L. & ECON. 1, 3-7 (1999); Shubha Ghosh, *An Economic Analysis of the Common Control Exception to Gray Market Exclusion*, 15 U. PA. J. INT'L BUS. L. 373, 375-85 (1994).

not in privity with the manufacturer. The authorized dealers very likely have not breached any terms of the contract with the manufacturer since the authorized dealer has not sold outside the territory designated in the contract. Furthermore, any customer restrictions in the contract most likely have not been violated, unless the authorized dealer knew that he was selling to a gray marketer. Contract law would not serve as a basis for challenging the legality of gray marketing.[5]

However, intellectual property law would provide a basis for legal challenge and has been the body of law used in legal claims against gray marketing. When the gray market products or services are branded, the trademark owner may have a strong claim of trademark infringement against the gray marketer, especially if there may be consumer confusion as to whether the manufacturer endorses the gray market sale.[6] Furthermore, the packaging of the product and the product itself, for example books and songs, may be copyrighted.[7] Distribution of products protected by copyright would constitute copyright infringement. Finally, U.S. patent law gives the patent owner the exclusive right to make, use, and sell the patented item within the United States and to enjoin the importation of the patented item into the United States from overseas.[8] If the gray market product or service incorporates patented items or is itself patented, then patent law would serve as a means to prevent the gray market.

However, there are very important limits within intellectual property that would protect gray markets. Under trademark law, the plaintiff must

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5. Even though lack of privity limits the efficacy of contract law in regulating the gray market, a combination of contract, tort, and antitrust laws could prove effective. *See* Gallini & Hollis, *supra* note 4, at 18-19.

6. *See* K Mart Corp. v. Cartier, Inc., 486 U.S. 281, 285-95 (1988) (discussing the role of the U.S. Customs Office and corporate control in the gray market); Lever Bros. Co. v. United States, 981 F. 2d 1330, 1338-39 (D.C. Cir. 1993) (discussing the role of consumer confusion and material difference).

7. Quality King Distribs., Inc. v. L'Anza Research Int'l, Inc., 523 U.S. 135, 152-54 (1998) (holding that the first sale doctrine limits copyright claims against gray marketers regardless of where the sale occurred when gray market goods originated in the United States); *see also* BMG Music v. Perez, 952 F. 2d 318, 319-20 (9th Cir. 1991) (holding that the first sale doctrine does not apply when gray market goods originated overseas).

8. "The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States." 35 U.S.C. § 261 (1994). This provision has been read to prevent contractual import bans of patented items into the United States. Becton, Dickinson & Co. v. Eisele & Co., 86 F. 2d 267, 269-70 (6th Cir. 1936). For a discussion of patent law and parallel importation in the United States, see COMPETITION POLICY AND INTELLECTUAL PROPERTY RIGHTS IN THE KNOWLEDGE-BASED ECONOMY 408-11 (Robert D. Anderson & Nancy T. Gallini eds., 1998).

show that there is a likelihood of confusion as to the source of the product. The classic trademark case is when a manufacturer makes a product and affixes a competitor's brand to the product, making it seem that the competitor produced it. Gray marketing is very different from the classic case. The gray market goods were manufactured by the trademark owner. The manufacturer distributed the product overseas through authorized channels in which they were purchased and later resold in the United States through unauthorized channels. Consequently, there cannot be any consumer confusion or deception as to the source of the product. The main qualification to this limitation is that if the products and services distributed in the foreign market are of a lower or different quality than similarly branded products in the United States, then the trademark owner would have a cause of action against the gray marketer for trademark infringement.[9]

Copyright law has similar limitations. If the gray marketer bought the product or service overseas from an authorized dealer and redistributed it within the United States and the product or service was legally created under U.S. copyright law, then the gray marketer would be protected from violating the copyright owner's right of exclusive distribution within the United States under the first sale doctrine.[10] Under this doctrine, a copyright owner cannot prevent the distribution of a copyrighted work after the owner has made the first sale of the work. The doctrine is an example of the broader principle of the exhaustion of rights, which applies potentially to all intellectual property rights. In the area of trademark law, the principle of exhaustion will limit the ability of the trademark owner to prohibit sales of the branded item after the item has been sold in the geographic market where the trademark is recognized.

The principle of exhaustion, and its specific application in the first sale doctrine, has been applied in two very important and recent gray market cases. In the United States, the U.S. Supreme Court held that the first sale doctrine barred a claim of copyright infringement against a gray marketer when the product was lawfully made under U.S. copyright law.[11] In the European Community, the European Court of Justice held that the manufacturer of trademarked sunglasses could prohibit the sale in Austria

9. *See K Mart*, 486 U.S. at 293; *see also Lever Bros.*, 981 F. 2d at 1338 (stating that "common control exception" upheld in *K Mart* does not apply when gray market goods are "physically, materially different" from goods distributed in the United States with the same trademark).

10. 17 U.S.C. § 109(a) (1994).

11. *See Quality King*, 523 U.S. at 147.

of gray market sunglasses that were obtained from a dealer in Bulgaria.[12] The sale to the dealer in Bulgaria could not exhaust the trademark owner's rights because the trademark was not registered in Bulgaria.[13] Therefore, the trademark owner had not exhausted any economic rights in the brand.[14]

Patent law offers the strongest protection against the gray market because it escapes the limitations noted for trademark and copyright protection. If the gray marketed product is patented, then, under the law of all jurisdictions, the patent owner has the right to exclude all imports and the exclusive right to distribute within the geographic boundaries of the patent jurisdiction. Because of this strong protection, the patent owner obtains strong rights to produce and market the patented item within each geographic market in which she has a patent.[15] Gray markets in the United States are extremely rare when patent law comes into play. However, gray markets are quite active in the European Union, particularly for pharmaceuticals.[16] The European Court of Justice has held that the sale of a patented pharmaceutical anywhere in the European Union, even in a jurisdiction where the patent is not registered, exhausts the rights of the patent owner.

With this background, we can now consider the pharmaceutical industry. The high prices charged for patented drugs reflect the strong protection accorded by patent law. The protection of patent law is enhanced by trademark law, which is used to obtain proprietary rights in the shape and color of the pills, even after the patent has expired. In South Africa, a market has developed to provide low cost alternatives for patented AIDS drugs through both generic manufacturers, which produce in violation of South African patent law, and through gray marketers, who import patented drugs from India into South Africa. Both activities have been challenged by Western pharmaceutical firms in a recent lawsuit filed against the South African government in a South African court.[17] In the

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12. Case C-355/96, Silhouette Int'l Schmied v. Hartlauer Handelsgesellschaft, 1998 E.C.R. I-4799.

13. *Id.*

14. *Id.*

15. The principle of exhaustion has been applied to permit the importation of gray market goods that are patent-infringing when the goods have been distributed without an express contractual restriction in the contract of sale or license. Dickerson v. Matheson, 57 F. 524, 527 (2d Cir. 1893); Holiday v. Mattheson, 24 F. 185, 185-86 (S.D.N.Y. 1885).

16. Joined Cases C-267/95 & C-268/95, Merck & Co. v. Primecrown, Ltd., 1996 E.C.R. I-6285; Merck & Co. v. Stephar BV, 1981 E.C.R. 2063.

17. Pharm. Mfrs. Ass'n v. President of the Republic of S. Afr., No. 4183/98 (Transvaal Provincial Div., filed Feb. 18, 1998), *available at* http://www.cptech.org/ip/health/sa/pharmasuit.html.

United States, Congress passed legislation in October 2000, as part of a general appropriation bill for agriculture, that authorized the reimportation of patented pharmaceutical products from Canada into the United States, subject to approval from the Department of Health and Human Services.[18] Then Secretary of Health and Human Services, Donna Shalala, refused to authorize such reimports for fear that the gray market pharmaceuticals would not meet U.S. safety standards.[19] Both her decision and its support by President Clinton were controversial, especially in light of the pharmaceutical firms' support for the President's earlier campaign. Current Secretary of Health and Human Services, Tommy Thompson, is reconsidering the measure.[20] In both instances, we see the use of the gray market to limit and regulate the rights of patent owners.

What is even more interesting about these policies is that the gray market is being commandeered to address what is essentially a human rights issue.[21] Professor Rosemary Coombe has addressed how human rights and economic rights merge in the regulation of culture, particularly with the issue of intellectual property protection for indigenous knowledge and folklore.[22] In her examples, the recognition of intellectual property rights in indigenous knowledge can further the human rights goals of cultural and identity protection.[23] With respect to the case of the pharmaceutical industry, human rights and intellectual property rights are in seemingly irreconcilable conflict. Through high prices, patent owners are denying

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18. H.R. Conf. Rep. No. 106-948, at 39 (2001) ("Making Appropriations for Agriculture Rural Development, Food and Drug Administration, and Related Agencies Programs for the Fiscal Year Ending Sept. 30, 2001, and for Other Purposes," amending 21 U.S.C. § 381).

19. Marc Kaufman, *Shalala Halts Bid to Lower Drug Costs; Reimportation Bill's 'Fatal Flaws' Cited*, WASH. POST, Dec. 27, 2000, at A1; Robert Pear, *In a Turnaround, White House Kills Drug-Import Plan*, N.Y. TIMES, Dec. 27, 2000, at A1; Alissa J. Rubin, *Plan Dropped to Reimport U.S. Made Medications*, L.A. TIMES, Dec. 27, 2000, at A1.

20. *Hearing on the Nomination of Tommy Thompson to be Sec'y of Health and Human Services Before the Senate Comm. on Health, Educ., Labor, and Pensions*, 107th Cong. 59 (2001). Transcripts of Thompson's testimony, *available at* http://www.kaisernetwork.org/health_cast/uploaded_files/day_2_Transcript_of_gov.pdf (last visited May 30, 2001).

21. For a discussion of the complexity of the meaning of human rights, see Makau Mutua, *Savages, Victims, and Saviors: The Metaphor of Human Rights*, 42 HARV. INT'L L.J. 201, 207, 244 (2001) (critiquing the notion of human rights law as a tool for saving savages and victims by imposing a Western notion of the good society as opposed to recognizing a "construction of a human rights movement that wins for all"). A discussion of the universal appeal of the U.N. Declaration of Human Rights can be found in MARY ANN GLENDON, A WORLD MADE NEW: ELEANOR ROOSEVELT AND THE UNIVERSAL DECLARATION OF HUMAN RIGHTS 232-33 (2001).

22. Rosemary J. Coombe, *Intellectual Property, Human Rights and Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity*, 6 IND. J. GLOBAL LEGAL STUD. 59, 61-62 (1998).

23. *Id.* at 80-81.

access to life-saving or pain-reducing drugs. Since patent owners are granted a very strong, if not absolute, right to exclude, the only way to grant access to the drugs is by limiting the rights of the patent owners. Sovereigns, since they grant initial patent rights, could in theory limit the rights of patent owners under some more salient principle. In fact, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) allows signatory nations to limit intellectual property rights in the case of emergency or life-threatening situations.[24] However, TRIPS also imposes procedures that must be followed in these situations.[25] The creation of a gray market seems to provide an ingenious way to use the market to create competition and resolve pressing human rights issues.

The question, of course, is whether allowing gray markets for pharmaceuticals is effective. I address this question in this Article and conclude that while the gray market solution is appropriate in South Africa, its effectiveness, as proposed, is questionable in the United States. While ideally it would be more appropriate to address the problems directly as human rights matters,[26] the solution of creating gray markets may be the most effective within the constraints of the current legal system. However, the gray market must be created in a suitable and rational fashion. I develop these points as follows. Part II presents an overview of the economics of intellectual property and gray markets, focusing specifically on the fixed cost and the public goods problems. Part III addresses the United States and South Africa's experiences with pharmaceuticals and assesses the gray

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24. "Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement." Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establish the World Trade Organization, Annex 1C, art. 8, ¶ 1, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND, vol. 31, 33 I.L.M. 83, 87 (1994) [hereinafter TRIPS].

25. Article 41 imposes the requirement that "[p]rocedures concerning the enforcement of intellectual property rights shall be fair and equitable." *Id.* art. 41 ¶ 2. Article 30 permits restrictions on exclusive patent rights that "do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." *Id.* art. 30. For restrictions that do unreasonably conflict with the right's normal exploitation or do unreasonably prejudice the legitimate interests of third parties, the requirements of Article 31 are to be complied with the requirements of the signatory states before such restrictions can be imposed. *Id.* art. 31. Provisions equivalent to Article 30 apply to trademarks and copyrights, but there are no equivalents to Article 31 for trademarks and copyrights. *Id.* arts. 13, 17.

26. Here, I mean human rights in the deeper sense used by Professor Mutua. *See* Mutua, *supra* note 21, at 201, 243 (critiquing the human rights paradigm for offering only a "script of rights" as opposed to a system that demonstrates a respect for many cultures).

market proposal in each context. Part IV focuses on the efficacy of limiting patent rights through the gray market, and Part V concludes.

II. FIXED COSTS, PUBLIC GOODS, AND INTELLECTUAL PROPERTY RIGHTS SYSTEMS

There are two poles to the debate over the protection of intellectual property, namely the strong protection position and the open access position.[27] Advocates of the strong protection position contend that the creation of intellectual property would be undermined unless the creator has complete and nearly absolute control over the uses, distribution, and marketing of her intellectual property. Absent such control, less intellectual property would be produced. At the other extreme are those who advocate open access since intellectual property is an important input for the creation of new works and involves expression that is important for the development of the marketplace for ideas. This position would advocate very weak or non-existent intellectual property rights because of democratic and communitarian values.

Intellectual property illustrates two classic economic problems: that of fixed costs and that of public goods provision. Strong protectionists and open access advocates focus on only one of these two problems, ignoring the other. A full understanding of intellectual property law entails addressing both problems. The production of intellectual property is expensive and involves large fixed costs.[28] No one would expend such costs unless there was some guarantee of a reasonable return to the investment. Normally such return would be earned by selling the item produced in the marketplace. The problem with items protected by intellectual property is that the costs of production entail very high fixed costs and low variable costs. Consequently, the marginal costs of production will be low. Since a competitive market will tend to drive prices down to marginal costs, prices in a competitive market will be driven to a point where it may not be possible to cover fixed costs, and the enterprise will be unprofitable. This classic fixed cost problem affects many large scale industries, such as railroads and utilities, and has provided the rationale for regulating such

27. For an excellent historical and economic account of this debate, see Gillian K. Hadfield, *The Economics of Copyright: An Historical Perspective*, 38 COPYRIGHT L. SYMP. (ASCAP) 1, 33-45 (1992).

28. JEAN TIROLE, THE THEORY OF INDUSTRIAL ORGANIZATION 307-08 (1988).

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industries.[29] The degree of regulation has been controversial, ranging from direct price regulation to government management of the development of facilities. Intellectual property provides another means of resolving the fixed cost problem by giving the creator a strong monopoly right in the creation, which frees the creator from the forces of competition that would otherwise make the enterprise unprofitable.

However, intellectual property evinces not only the fixed cost problem but also the public goods problem. A public good is one that is non-rival and non-excludable, meaning that consumption can be shared by a large group of individuals without depleting the supply.[30] On the other hand, ordinary consumer goods, such as cars and food, are rival and excludable. A fixed stock of these consumer goods will be depleted as consumers use the goods, and sharing is only minimally possible. Public goods, such as music, movies, news, and information, can be used by a potentially infinite number of consumers without diminishing the amount of entertainment and information. Some public goods exhibit congestion costs, which are costs associated with too many people using the good.[31] An example outside the area of intellectual property is provided by a public swimming pool. Many people can share its use, but too many people raise the costs of using the pool by increasing congestion. Such costs also arise in the context of intellectual property use. For example, trademarks are public goods, but if the trademark becomes overused it loses its value as an indicator of source and quality. Too much use imposes the equivalent of congestion costs that diminish the value of the good.[32]

The public goods aspect of intellectual property is captured by the cliché "information wants to be free." A corollary of this cliché is that information should be free since attempts to curb its use through price or other mechanisms would be futile. Information is non-rival and non-excludable, according to this argument, and therefore should be made open for all to use. The problem with this argument is that it ignores the costs of producing information.[33] Economic theory does not state that if a good is public that it should be free. Instead, economic theory suggests that such goods cannot be provided through a market mechanism alone. Either the

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29. HERBERT HOVENKAMP, ENTERPRISE AND AMERICAN LAW 1836-1937, at 308-22 (1991) (describing the fixed cost controversy).

30. RICHARD CORNES & TODD SANDLER, THE THEORY OF EXTERNALITIES, PUBLIC GOODS, AND CLUB GOODS 10-13 (1986).

31. *Id.* at 272-77.

32. ROSEMARY COOMBE, THE CULTURAL LIFE OF INTELLECTUAL PROPERTIES: AUTHORSHIP, APPROPRIATION, AND THE LAW 79-82 (1998).

33. JOHN SEELY BROWN & PAUL DUGUID, THE SOCIAL LIFE OF INFORMATION 65-66 (2000).

government provides public goods (such as roads and national defense) or the government subsidizes the market to provide these goods. In addition, economists recognize the role for non-market and non-governmental institutions, such as non-profit entities, in providing public goods.[34] The problem posed by public goods for economists and lawyers is determining what set of institutions should be adopted to produce and provide public goods in an economically rational and effective manner.

Before discussing how intellectual property law addresses the fixed cost problem, the public goods problem, and how these problems result in the development of gray markets, let me describe how economists would propose resolving the public goods problem. One way, as discussed above, is to have the government supply the public good and finance it with general tax revenues.[35] The problem with this scheme is establishing a tax structure that is both fair and efficient. A flat tax structure would result in some people paying more than their value for the good and some less. The unfairness of this is obvious, especially for those who are forced to pay for something they do not value. The scheme is also inefficient because of the separation of payment from individual valuation. An alternative is to use a system of user fees that will allow consumers to pay for the amount of the public good used. Toll roads and fees for entry into parks are examples of such user fees. The problem is that this system would work for some public goods, such as roads and parks, but not for others, such as national defense. Furthermore, determining the appropriate user fee structure imposes a cost on government that must be borne somehow.

Privatization is another possible economic solution to the problem of public goods creation and provision. Private firms could compete in the creation and provision of public goods, and the firms could develop the appropriate payment structure to cover their costs and guarantee a return. The problem is that private provision of a public good may be inefficient because of the free rider problem. If one firm provides the public good, then there is little incentive for another firm to do so, especially since public goods are non-rival and non-excludable by definition. Therefore, competition will not likely survive in private markets for public goods. Furthermore, pricing must be modified to deal with the sale of public goods. In markets for ordinary consumer goods, firms charge the same price for goods of a given quality and quantity. Setting such a price structure for public goods would cause the same problem as financing

34. KENNETH J. ARROW, THE LIMITS OF ORGANIZATION 21-23 (1974).

35. For an overview of how public goods are provided, see DENNIS C. MUELLER, PUBLIC CHOICE II 17-25 (rev. ed. 1989).

public goods through taxes: some will pay more and some less than their valuation of the public good.

The solution is to allow firms to price discriminate. Just as governments can set user fees, firms should be allowed to price discriminate in the pricing of public goods so that consumers pay according to their valuation of the good. Ideally, each consumer will be charged exactly the amount they value the good, and the firm will obtain enough revenue to recoup the costs and earn a return. This arrangement is known as perfect price discrimination, and economists recognize that perfect price discrimination as efficient.[36] The problems are the costs of a system of price setting tailored to the individual consumer and the potential that discriminatory pricing may not be perfect, which may result in inefficiencies arising from market power.[37]

The last economic solution is to have joint production and provision of public goods by both private and governmental entities. Education is a public good that is provided through this mechanism in almost all countries. Such a system has the costs of the governmental and private arrangements described above, but also has one clear benefit: the potential for competition between public and private entities. Even though the competition may be limited (there may be only one private entity and only one public entity), the mixed scheme potentially provides choices that the separate arrangements do not.

Intellectual property law resolves the fixed cost and public goods problems by granting a limited right of exclusion to the creator of intellectual property.[38] The right of exclusion gives the creator some monopoly power to recoup the fixed costs of investment without being subjected to the destructive forces of competition. The limitation of these rights through provisions such as time, duration, fair use, and permitted use, protects the public goods aspect of intellectual property. However, the law creates a baseline against which market and business forces work to produce and distribute intellectual property. The limited right to exclude gives the owner of intellectual property leeway to market intellectual property.

Technological and social methods of exclusion serve to complement the legal methods. Territorial restrictions, retailing, and the packaging of products permit the owner of intellectual property to further privatize the

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36. LOUIS PHILIPS, THE ECONOMICS OF PRICE DISCRIMINATION 12-16 (1983).

37. For an excellent critique of the theory of price discrimination as applied to copyrights, see Julie E. Cohen, *Copyright and the Perfect Curve*, 53 VAND. L. REV. 1799, 1799-1891 (2000).

38. DENNIS W. CARLTON & JEFFREY M. PERLOFF, MODERN INDUSTRIAL ORGANIZATION 502-05 (3d ed. 2000).

protected work and extract value from the consumer. Territorial restrictions are imposed, for example, in franchising or through restrictions on where and to whom intellectual property protected goods can be sold. These restrictions further limit competition and allow the intellectual property owner to extract more for the creation. Retailing goes hand-in-hand with territorial restrictions and creates another layer in the distribution of intellectual property. This creates value added through the provision of service and generation of advertising and also permits the intellectual property owner to extract value for the work. Finally, packaging serves as an advertising function and as a means of bundling products, such as music, which allows the owner of intellectual property to sell and extract value for her creation. These extra-legal mechanisms permit the intellectual property owner to recoup fixed costs and provide the incentives to create and distribute public goods.

But exclusion mechanisms are imperfect, especially when public goods are concerned. Territorial restrictions, regulated largely by contracts between the manufacturer and the distributor, can be bypassed. Alternative distribution mechanisms to retailing, such as resale by private consumers, can be created post-sale. Goods can be unpackaged and repackaged as consumers play songs for friends and create their own mixes. The exclusive right to exclude can give the intellectual property owner only limited control over the range of business and social practices that facilitate the distribution of non-rival and non-excludable goods. It is on this point that the cliché of information wanting to be free actually rings true; owners of intellectual property cannot feasibly control all dimensions of its dissemination. Gray markets, or alternate distribution mechanisms, arise to fill in the gaps in the distribution channels created by intellectual property owners.[39]

Of course, the response by intellectual property owners has been to close the gray markets through the one tool that is potentially successful: legal regulation. But the law of the gray market reflects a checkered and largely unsuccessful means of restricting the gray market.[40] I discuss this body of law elsewhere, but summarize here, the main legal tools intellectual property owners have used to prevent the gray market. Trade restrictions have been of mixed success because of the authority given to agents of the customs office in determining what gets in and what does not. Claims for trademark infringement have been of mixed success since the trademarked goods actually originate from the trademark owner, but only through a

39. Shubha Ghosh, *Turning Gray into Green: Some Observations on Napster*, HASTINGS COMM. & ENT. L.J. (forthcoming) (manuscript on file with author).

40. Ghosh, *supra* note 4, at 378-82.

different distribution mechanism. Copyright law has little weight because of the first sale doctrine. Patent law offers the strongest support for restricting the gray market because of the strong rights of exclusive distribution, granted under patent law in the entire United States. But patent law applies to a narrow set of intellectual property, namely novel, non-obvious, and useful inventions, and hence serves as a tool for only a few industries, such as pharmaceuticals. But even for those industries, patent law's power has been potentially limited by Congressional legislation allowing reimportation of certain drugs, a policy whose status is currently under debate. Gray markets cannot be so easily closed or regulated.

The economic relationships among patent law, international trade, and gray markets provide one basis for assessing the policy of reimportation. Patent law gives the patent owner exclusive rights to make, use, and sell the patented item in the domestic market. This exclusive right gives the owner some degree of monopoly power in markets where he has patent rights. In each market, the patent owner can package the patented item so as to control its dissemination through the market. For example, with pharmaceutical products, the packaging occurs through embodying the patent in pills or other items that allow control of dosage and dispensing to consumers. Table One depicts a typical monopoly market in two different situations. The quantity axis measures number of pills sold, and the price axis measures the price per pill. In each market, the patent owner can set prices to maximize profits in the two separate markets. Price differences arise because of differences in costs and demand in the two markets. The price differential creates the incentive for a gray marketer to buy in the cheaper market and resell in the more expensive market. However, under patent law the patent owner can prevent the gray marketer from engaging in such activity. The result is a price differential in two markets that results from a form of price discrimination.

The debate over pharmaceuticals follows from the inequity of this price differential, especially in the context of life-saving pharmaceuticals. Given the benefits from pharmaceutical products, it seems unfair, even if consistent with market practices, that the price for the same product should differ across markets. Furthermore, the high price in one market excludes potential beneficiaries of the drug from access. The response to these arguments is that it is difficult to correct the price differential and guarantee broader access without imposing other inequities. For example, Professor Varian has correctly pointed out that if prices were to be equalized in the two markets through some mechanism, the question remains which price would prevail, a price closer to the higher price or one closer to the lower

price.[41] If the price equalization were left to political mechanisms, then the lower price might prevail and result in loss of profits in the high price jurisdiction. On the other hand, price equalization may lead the higher price to prevail in the marketplace and cause even greater loss in access. Which result will prevail depends on the relative demands in the two countries and the mechanism for price equalization. But whichever result prevails, other inequities might result.

An obvious response to the price differential is to attack the monopoly power that makes the price discrimination possible.[42] But this solution entails challenging the vested patent rights of the patent owner and stokes the flames of the politics of intellectual property law.[43] Compulsory licensing would create competition, but would also directly challenge the exclusive rights granted to the patent owner to decide who should be given the right to make, use, or sell the patented item and on what terms.[44] State subsidies or income transfers granted to consumers of pharmaceuticals also are politically difficult to muster, introducing the politics of taxation into an intellectual property debate. Attacking anti-competitive practices through antitrust law is another possibility, but since the price differential occurs across international borders, questions of comity and jurisdiction pose impediments to enforcement.[45] Creating gray markets, it seems, is a politically feasible manner of ensuring competition and reducing prices. Although the creation of gray markets challenges the patent owner's

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41. CARL SHAPIRO & HAL R. VARIAN, INFORMATION RULES: A STRATEGIC GUIDE TO THE NETWORK ECONOMY 44-45 (1999); *see also* Hal R. Varian, *Economic Scene; A Big Factor in Prescription Drug Pricing: Location, Location, Location*, N.Y. TIMES, Sept. 21, 2000, at C2.

42. The Robinson-Patman Act, while ostensibly making price discrimination illegal, applies to differential pricing by wholesalers in selling to retailers. AMERICAN BAR ASSOCIATION SECTION OF ANTITRUST LAW, A PRIMER ON THE FEDERAL PRICE DISCRIMINATION LAWS: A GENERAL REVIEW OF THE ROBINSON-PATMAN ACT FOR BUSINESS MANAGERS 3-8 (2d ed. 2000). For a discussion of the Act from a business and economic perspective, see SHAPIRO & VARIAN, *supra* note 41, at 299-300.

Article 40 of TRIPS authorizes signatory nations to control and regulate anti-competitive uses of intellectual property rights. TRIPS, *supra* note 24, art. 40. The scope of this power has yet to be explored. *See* CHRISTOPHER ARUP, THE NEW WORLD TRADE ORGANIZATION AGREEMENTS: GLOBALIZING LAW THROUGH SERVICES AND INTELLECTUAL PROPERTY 210-11 (2000); *see also* BHAGIRATH LAL DAS, AN INTRODUCTION TO THE WTO AGREEMENTS 124 (1998).

43. *See* MICHAEL RYAN, KNOWLEDGE DIPLOMACY: GLOBAL COMPETITION AND THE POLITICS OF INTELLECTUAL PROPERTY 8-11 (1998) (documenting economic and political forces leading to TRIPS).

44. INTERNATIONAL INTELLECTUAL PROPERTY ANTHOLOGY 305-14 (Anthony D'Amato & Doris Estelle Long eds., 1996) (analyzing compulsory licensing in copyright and patent law as a government taking).

45. *See* Eleanor M. Fox, *U.S. and Global Competition and Trade–Jurisdiction and Comity*, ANTITRUST REP., Oct. 1993, at 3-4.

exclusive rights, the solution has the advantages of avoiding the politics of redistribution and the difficulties of enforcing antitrust laws globally.

Authorizing gray markets, of course, introduces additional costs as well.[46] A gray marketer will bear the cost of transportation between the two markets and will engage in gray marketing until the price differential between the two markets just equals the transportation costs. Gray marketing will tend to lower the price of the product in the high price market, which is its intended effect. But gray marketing may raise or lower the price of the product in the market from which the gray marketer is reimporting. The ambiguity of the effect in the low price country reflects the two countervailing effects of gray marketing. The first is the upward pressure on price in the low price market created by the increase in demand for the product from the gray marketer. The second is the downward pressure placed on price by global competition and the price equalization between the two markets. It is possible that the second effect dominates the first, and the price for the product will fall in both markets. It is also possible that the price will rise in the low price market while falling in the high price market. The outcome in the low price market depends on how responsive demand is to price changes in the two markets. The larger point is that while gray marketing may have the effect of lowering prices in both markets, it also raises the possibility of benefitting consumers in the high price market at the expense of consumers in the low price market. The tension between the two sets of consumers raises issues for the global politics of gray marketing.

The creation of gray markets will also affect the behavior of the patent owner. In order to prevent the gray market and capture market share from the gray marketer, the patent owner will adopt practices to reduce the price differential between the two markets. The patent owner has two possible strategic responses. The first is to alter his licensing practices by altering royalty fees and other license terms in order to reduce the price differential between the two markets. The second possibility is for the patent owner to merge the business entities in the two markets so as to be able to control the pricing policies in the two markets. The responses from the patent owner are desirable to the extent that they tend to lower the price differential that is the source of the problem. However, the result can be beneficial or harmful depending upon the direction of price movements in the two markets.

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46. The economic analysis presented below is taken from my previously published work in Ghosh, *supra* note 4, at 409-26.

For the sake of discussion, it is useful to describe four possible scenarios:

A = the gray market is prohibited;[47]
B = the gray market is allowed, but there is no response from the patent owner;[48]
C = the gray market is allowed, but the patent owner responds through licensing terms;[49]
D = the gray market is allowed, but the patent owner responds through common control of the two markets.[50]

Drawing on economic analysis from my earlier work,[51] I can make some statements about how consumers and non-gray market firms would rank these four scenarios in the high price and low price markets using a simple model of linear demand. The rankings are as follows on the next page.[52]

Each set of consumers would unambiguously prefer the gray market scenario with no response to all other scenarios. The second choice would unambiguously be the gray market scenario with common control. There would be disagreement over the rankings of a regime with no gray marketing and a regime with gray marketing controlled through licensing. Consumers in the high-price market would unambiguously choose gray

47. This scenario is analyzed under the assumption that the prohibition can occur at zero cost. This is obviously an unrealistic assumption since the gray market may still exist even if ostensibly illegal or policed. The case is considered, however, as an ideal case for the purposes of comparison.

48. Under this scenario, the patent owner does not respond, either because the gray market is legal or because the patent owner cannot control the distribution mechanisms in other countries through contract or corporate control of business entities overseas.

49. This scenario is the most subtle and needs elaboration. The patent owner will distribute his patent both domestically and overseas through licensing. The royalty terms of the license will affect the price in the two markets (in conjunction with, of course, the demand for the patented product in the two countries and the production costs). Theoretically, if the patent owner can set the royalty terms, he can affect the price of the patented product in the two markets to make gray marketing unprofitable. The effectiveness of this policy depends upon the ability of the patent owner to prevent unlicensed uses. For the sake of analysis here, I assume that unlicensed uses can be prohibited at zero cost.

50. Under this last scenario, the patent owner obtains ownership and control over the entity distributing the patented product overseas and sets the royalty structure in each market accordingly to maximize the joint profits of the entity and prevent gray marketing.

51. Ghosh, *supra* note 4, at 373-439.

52. For consumers, the rankings of the scenarios are based on the predicted price of the product under each scenario. Scenarios ranked number one, for example, would result in the lowest price. For firms, the rankings are based on predicted profits, with high-ranking scenarios yielding higher profits than low-ranking scenarios.

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Table 1. Comparing Different Gray Market Regimes with Respect to Effects on Firms and Consumers in Domestic and Overseas Markets

	High price market (destination of gray market goods)	Low price market (source of gray market goods)
Rankings of Consumers	1. B 2. D 3. C 4. A	1. B 2. D 3. A 4. C
Rankings of Non-gray Market Firm	1. A 1. A 2. D 2. C 3. B (The rankings of D and C and of B and C are ambiguous)	1. B 1. B 1. C 2. A 2. D 2. A (The rankings of A and D, of B and C, and of D and C are ambiguous)

marketing with licensing control over a regime where gray marketing is prohibited. Consumers in the low-price markets, however, would prefer no gray marketing. The reason for this discrepancy is that consumers in the high-price market will always prefer to allow gray marketing. The effect of gray marketing in the low-price market is always ambiguous. However, gray marketing controlled through licensing would tend to raise prices in the low-price market while the other forms of gray marketing would tend to lower prices in the low-price market.

The rankings of the non-gray market firm include several ambiguities. These ambiguities mean that the comparison of profits across regimes cannot be made without further information about demand curves and costs. The non-gray market firm in the high-price market (that is, the market into which gray market goods would be entering) prefers a regime where gray marketing is not allowed to all other regimes. Relative rankings among gray market regimes are difficult to make. The non-gray market firm in the high-price market would unambiguously prefer a regime where the gray market was controlled by common control compared to one in which the entities in the two markets were separate. But it is not possible to compare the scenario where control of the gray market occurs through licensing with either of the two other methods of controlling the gray market.

Finally, the non-gray market firm in the low-price country (that is, the source country for the gray market goods) would prefer gray marketing, either uncontrolled or controlled through licensing to a regime where gray marketing was prohibited. The firm would also prefer uncontrolled gray marketing to gray marketing controlled through common ownership. But it is not possible without further information to compare the regime of prohibited gray marketing with that of gray marketing controlled through common ownership in terms of the effects on the profits of the firm in the source country. It also is not possible to compare gray marketing controlled through licensing with either uncontrolled gray marketing or gray marketing controlled through common ownership.

Despite such ambiguities, the analysis of the gray market scenarios provides a basis for approaching the policies of gray marketing as proposed in the United States and as implemented in South Africa. Two lessons emerge from this analysis. First, gray marketing will result in responses from the patent owner in the manner in which distribution is controlled in both the destination country and the source country. These responses must be taken into consideration in assessing gray marketing. Second, the effects of gray marketing on various groups are mixed and in many cases are ambiguous. Nonetheless, understanding these responses and their mixed

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effects is crucial in assessing the efficacy of limiting patent rights and power through gray markets.

In this Part, I present the economics of intellectual property law and its relationship with the economics of gray marketing. Intellectual property law is designed to address both the fixed costs and the public goods problems that characterize information markets. Patent law, unlike copyright and trademark law, gives the owner an absolute right to make, use, and sell the patented item in the market that consists of the jurisdiction of the patent. In the context of international trade, patent law creates price differentials for the patented item, which provides incentives for gray marketing. If gray marketing was allowed, we would expect the patent owner to preempt gray marketing by attempting to lower the price differentials across markets. Gray marketing, therefore, will produce very complicated responses in global markets depending on how the patent owner responds and the demand and costs in all markets. With these analytical insights, I, next address the situation in the United States and South Africa.

III. COMPARING AND CONTRASTING THE PROPOSED GRAY MARKETS IN THE UNITED STATES AND SOUTH AFRICA

As described above, both the United States and the South African governments have attempted to address the issue of access to pharmaceuticals by the creation of markets through permissive reimportation or gray markets. The non-economic issues raised by this policy are addressed in Part IV. The economics of intellectual property and gray markets delineated in Part II provide an important basis for assessing these policies.

I will present an important structural difference between gray marketing in the United States and in South Africa. In both countries, the problem arises from patent owners exercising their patent rights and creating high relative prices for the pharmaceutical product. In both countries, gray markets are seen as providing effective competition that will lower prices and benefit consumers. However, gray markets are created very differently in the two cases. The following diagram illustrates the two different cases:

CASE ONE: The Round Trip
United States ➜ patented pharmaceuticals ➜ Canada
Canada ➜ gray market pharmaceuticals ➜ United States

CASE TWO:
Western Firms ➡ patented pharmaceuticals ➡ South Africa South Africa ⬅ gray market ⬅ India

In the case of the United States, the source and destination of the pharmaceuticals are the same. The drugs are manufactured in Canada under license from the U.S. patent owner or manufactured in the United States under license and exported to Canada.[53] In the case of South Africa, both source and destination are different. Western firms that import licensed drugs into South Africa face competition from gray marketed drugs produced in India either under a license or without. The different structures of gray marketing will have different implications for their efficacy. In Case One, the patent owner has more ability to control the gray market through price setting that limits the price differential in the two markets. In Case Two, the patent owner has less ability to control the gray market through reducing price differentials. This difference in structure with resulting implications for control is the basis for why, as an economic matter, the South African policy would be more effective than the one in the United States.

A. *Reimportation from Canada to the United States*

In October 2000, President Clinton signed into law an agricultural bill that contained a provision authorizing the Secretary of Health and Human Services, "after consultation with the United States Trade Representative and the Commissioner of Customs," to promulgate "regulations permitting pharmacists and wholesalers to import into the United States covered products," meaning prescription drugs other than controlled substances or biological products.[54] The statutory provision was deemed to be effective only if the Secretary demonstrated that its implementation would "pose no additional risk to the public's health and safety... and result in a significant reduction in the cost of covered products to the American consumer."[55]

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53. By way of comparison, the first scenario corresponds to what Justice Ginsburg has described as the round trip in her *Quality King* concurrence. Quality King Distrib., Inc. v. L'Anza Research Int'l, Inc., 523 U.S. 135, 154 (1998) (Ginsburg, J., concurring). In the context of exhaustion of rights under copyright law, the round trip scenario would lead to the exhaustion of rights. Most likely, the second scenario, where the goods do not make a round trip, would not lead to the exhaustion of rights. *See* BMG Music v. Perez, 952 F. 2d 318, 319 (9th Cir. 1991).

54. H.R. Conf. Rep. No. 106-948, at 39.

55. *Id.* at 43.

The statute also contained a sunset provision, which would have canceled the legal effect of the regulations five years after going into effect.[56]

In December 2000, Secretary of Health and Human Services, Donna Shalala, refused to implement the legislation, contending that there were serious risks to health from allowing reimports of pharmaceuticals into the United States from a foreign country.[57] The Secretary also expressed doubt that the reimportation would result in substantial reduction in the price of drugs.[58] President Clinton supported her decision, causing yet another controversy in the closing days of the Clinton Administration.[59] Supporters of the bill indicated suspicions about the influence of pharmaceutical firms (opponents to gray marketing) on the measure.[60] The legislation is currently in limbo; the newly appointed Secretary of Health and Human Services, Tommy Thompson, described the future of the program as "doubtful."[61]

The preamble to the legislation lists several congressional findings on price differentials in pharmaceuticals between countries and the alarming rate at which the cost of prescription drugs continues to rise in the United States.[62] Congress concluded that "Americans should be able to purchase medicines at prices that are comparable to prices for such medicines in other countries, but efforts to enable such purchases should not endanger the gold standard for safety and effectiveness that has been established and maintained in the United States."[63] The appeal of allowing reimportation was based on reports that many elderly Americans were making excursions to Canada and Mexico solely for the purposes of obtaining prescription drugs. Reimportation would permit access but place the transportation costs on gray marketers.

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56. *Id.*

57. Kaufman, *supra* note 19, at A1; Pear, *supra* note 19, at A1; Rubin, *supra* note 19, at A1. The amendment permits imports from Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and countries in the European Union or the European Economic Area if the drug is authorized for general marketing in the European Economic Area. H.R. Conf. Rep. No. 106-948, at 41 (incorporating by reference 21 U.S.C. § 382(b) in proposed section 804(f)). I will limit my discussion to potential imports from Canada since that country has been the focus of the debates and popular discussion.

58. Kaufman, *supra* note 19, at A1; Pear, *supra* note 19, at A1; Rubin, *supra* note 19, at A1.

59. Michael Kinsley, *No Free Lunch at the Pharmacy*, WASH. POST, Dec. 31, 2000, at A33; Kaufman, *supra* note 19, at A1; Pear, *supra* note 19, at A1; Rubin, *supra* note 19, at A1.

60. Kaufman, *supra* note 19, at A1; Pear, *supra* note 19, at A1; Rubin, *supra* note 19, at A1.

61. Sara Fritz, *Election Over, Prescription Law Languishes*, ST. PETERSBURG TIMES, Apr. 8, 2001, at A1; Anjetta McQueen, *Program to Reimport Drugs Likely to Get Axed*, RECORD (Bergen County, N.J.), Apr. 10, 2001, at A11.

62. H.R. Conf. Rep. No. 106-948, at 39.

63. *Id.*

Whether reimportation is an appropriate response rests largely on the sources for the price differential across markets. The assumption is that such price differences stem from degrees of protection for intellectual property in the United States and Canada. But the record suggests that there has been a convergence in the intellectual property regimes of the two countries over the past decade. While price differences in patented products may in part reflect differences in regulatory environments, intellectual property law may not be the source of the price divergence. Limiting domestic patent rights through gray marketing may not be an appropriate response. But, as I discuss below, an even more compelling case against reimportation is provided by the predicted response of U.S. patent holders to gray markets, which may harm non-U.S. consumers even as they benefit the United States.

1. United States Background

There are two regulatory forces that shape the policy of the United States toward the pharmaceutical industry: regulatory review for drug safety and patent protection. The two have developed symbiotically since the 1970s and together shape the regulatory environment in which drug marketing occurs.[64]

Regulation of the pharmaceutical industry has been the subject of debate in the United States since at least 1959, when the Kefauver Commission issued a report with supporting materials challenging pricing and other marketing practices in the pharmaceutical industry.[65] The Commission alleged monopolistic and anti-consumer practices in the industry, sparking a debate that has continued to this day on the appropriate regulation of the industry.[66] Industry representatives at the time contended that the industry was in fact competitive, citing low mark-ups and intensive competition in the area of research and development.[67] In the 1970s, the debate switched to the over-regulation of the industry and the resulting unprofitability and threats to innovation. Competitive pressures from Japan and Germany were centered on pharmaceuticals, and the burdens of the Food and Drug Administration approval process became the focus of attention.[68] The

64. William S. Comanor, *The Political Economy of the Pharmaceutical Industry*, 24 J. ECON. LIT. 1178, 1180-81 (1986).

65. *Id.* at 1181-82.

66. *Id.*

67. *Id.*

68. F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 97, 102, 108-14 (1993).

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process, in itself cumbersome and expensive, was claimed to stifle the ability of pharmaceutical firms to bring drugs to the marketplace. The process was also believed to interfere with the patent process by effectively shortening the life of a granted patent. Regulatory changes in the 1980s permitted expedited review, and reforms permitted the patent owner to take advantage of the full duration of patent life.[69]

The other issue was the availability of competition from generic, or unbranded, pharmaceutical products. For generic drug manufacturers, patent protection serves as a barrier to entry and a limitation on competition. Since generic drugs required FDA approval, the approval mechanism served as an additional barrier. Patent protection and safety review posed particularly difficult problems because submission of a review application to the FDA before the expiration of a drug patent would constitute infringement of that patent.[70] Reforms in the 1980s resolved these problems by permitting expedited FDA review for generic drugs prior to patent expiration.[71] As patent protection increased for the pharmaceutical industry, some competitive pressures were introduced through relaxation of the regulatory barriers to generic drugs.[72]

Trademarks also serve as barriers to entry for generic drug manufacturers. Often after the patent expired, pharmaceutical firms would protect the shape and color of their drugs through trademark law. The shape and color of a pill often served as a means of brand identification, easing confusion among consumers and among pharmacists filling prescriptions. Such brand identification created an additional barrier to the entry of generic drugs.[73] Pharmaceutical firms, through their exclusive rights to make, sell, and use the patented product, established brand loyalty and consumer identification with pills of a certain color and shape that

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69. *See* Comanor, *supra* note 64, at 1200-02 (describing patent reform); Patricia I. Carter, *Federal Regulation of Pharmaceuticals in the United States and Canada*, 21 LOY. L.A. INT'L & COMP. L. REV. 215, 227-34 (1999).

70. 35 U.S.C. § 271(e)(2)(a) (2000).

71. 35 U.S.C. § 271(e)(1) (2000). For a discussion of the background leading up to these developments, see Comanor, *supra* note 64, at 1202-09; *see also* Henry Grabowski & John Vernon, *Longer Patents for Lower Imitation Barriers: The 1984 Drug Act*, 76 AM. ECON. REV. 195, 196-98 (1986); Scherer, *supra* note 68, at 100-03.

72. The battle between patented pharmaceuticals and generic drugs in the United States continues today. In 2001, two courts, the U.S. District Court for the District of Columbia and the U.S. District Court in Maryland, split on allowing two different pharmaceutical firms to prevent the marketing of generic drugs by extending their protection for a patented drug through the life of the patent. Melody Peterson, *Judge Says Mylan Can Sell Generic Version of Bristol-Myers Drug*, N.Y. TIMES, Mar. 14, 2001, at C9.

73. SK&F, Co. v. Premo Pharm. Labs., Inc., 625 F. 2d 1055, 1057 (3d Cir. 1980).

made it difficult for generic drug manufacturers to establish a consumer base and differentiate their product, except through price. As of this date, the relationship between trademark protection and patent protection is still an open question.

The *Singer Manufacturing Co.* and the *Kellogg Co.* cases from 1896 and 1938, respectively, held that expiration of the patent prevented enforcement of any trademarks in the patented product.[74] However, these cases are not directly relevant to protection of the shape and color of pills because the patent and trademark protect very different dimensions of the pill. The patent protects the process by which the pill was manufactured or the composition of matter comprising the pill; the trademark protects the pill's packaging and associated goodwill. A recent Seventh Circuit decision, in fact, held that expiration of a design patent did not preempt trademark protection for the design.[75] The U.S. Supreme Court recently decided a case involving trade dress protection for an arguably functional design that had been patented.[76] The Court decided the case on grounds other than patent preemption and did not address the question of whether an expired patent negates trademark protection.[77] The legal question in the United States is still open.

Patent protection for pharmaceuticals has provided the industry with strong protection from competition. The extension of patent life to comply with regulatory approval and the protection from generic competition serve to give pharmaceutical firms a strong degree of market control. This control extends to protection against foreign imports of pharmaceuticals. Legislation in the late 1980s allowed a patent owner to enjoin the importation of a product that was manufactured overseas by a process patented in the United States, even if the product itself was not patented.[78] Furthermore, a patent owner is given exclusive rights to make, use, and sell

74. Singer Mfg. Co. v. June Mfg. Co., 163 U.S. 169, 185-200 (1896) (denying protection to the Singer trademark after expiration of patent); Kellogg Co. v. Nat'l Biscuit Co., 305 U.S. 111, 116-20 (1938).

75. Kohler Co. v. Moen, Inc., 12 F.3d 632, 636-43 (7th Cir. 1993) (holding that trademark protection for design is not an infinite patent). *But see* Vornado Air Circulation Sys., Inc. v. Duracraft Corp., 58 F.3d 1498, 1500 (10th Cir. 1995) (foreclosing trademark protection on design after a patent expires when the "product configuration is a significant inventive component of an invention covered by a utility patent.").

76. Traffix Devices, Inc. v. Mktg. Displays, Inc., No. 99-1571, 2001 U.S. LEXIS 2457, at 12-23 (Mar. 20, 2001) (holding that design is not protected as trade dress, because it is functional).

77. *Id.*

78. 35 U.S.C. § 271(g) (2000).

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the patented product within the United States.[79] Patent law provides the owner with an exclusive territory which, when combined with trademark protection for the product, gives protection to the owner from interbrand competition. With this as a background, it is easy to see how the preconditions can exist for the creation of a gray market in pharmaceuticals. A consideration of the Canadian regulatory environment explains why Canada becomes the likely source for gray marketed pharmaceuticals.

2. Canada Background

A comparison of the regulatory systems governing pharmaceuticals in the United States and Canada uncovers many similarities in design despite differences in institutional backgrounds.[80] The convergence is a recent phenomenon, as changes to patent law, beginning in 1987, attempt to mimic the U.S. system of patent protection. This mimicking was arguably not conscious and was most likely motivated by the policy goals of strengthening the pharmaceutical industry and its ties to health care.[81] As Professors Doern and Sharaput described the reforms: "Patents set the conditions of profit for the manufacturers of pharmaceuticals, and it is this which allows patents to be used to exert a structural influence over the industry."[82]

If patent law was being used to strengthen the pharmaceutical industry in 1987 and thereafter, then patent law prior to 1987 was focused on consumer protection and competition. The patent regime that existed in Canada from 1869 to 1987 was strikingly different from its U.S. counterpart and very likely set the institutional structure that permitted competition and development in the Canadian pharmaceutical industry. In the 1920s, Canada's patent law was amended to allow extensive compulsory licensing for patented items that served a public purpose and encompassed manufacture within Canada.[83] However, it was in the 1960s that the Canadian government addressed the problem of high prices and low competition in the pharmaceutical industries. Bill C-190, which was tabled in the late 1960s, was part of a larger policy package designed to bring competition to the pharmaceutical industry through lower tariffs for

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79. 35 U.S.C. § 261 (2000).

80. Carter, *supra* note 69, at 215 ("The development of [the Canadian and U.S.] drug regulatory systems has often paralleled each other.").

81. G. BRUCE DOERN & MARKUS SHARAPUT, CANADIAN INTELLECTUAL PROPERTY: THE POLITICS OF INNOVATING INSTITUTIONS AND INTERESTS 134-43 (2000).

82. *Id.* at 148-49.

83. *Id.* at 34-38.

imported pharmaceuticals and by permitting the importation of drugs into the Canadian market.[84] Canada had already provided weaker protection for pharmaceuticals than the United States by protecting pharmaceutical patents as process and not product patents. This distinction meant that patent owners' rights extended only to the process by which the product was made and not the product itself.[85] Finally, the changes in the 1960s expanded the role for compulsory licensing of manufacturing by relaxing the requirement that patents subject to the compulsory license had to be manufactured in Canada. Under the reforms, the pharmaceuticals could be manufactured overseas and the compulsory license would permit sales within Canada.[86]

The 1980s and particularly the 1990s witnessed a reversal in the weak patent protection accorded to pharmaceuticals under the legislation from the 1960s.[87] The first big change was the extension of the patent life to twenty years from the date of grant from the previous term of ten years (or seven, if the patent was manufactured from Canadian fine chemicals).[88] The other, more substantial change was the repeal of all compulsory licensing for pharmaceuticals.[89] The current system is one that accords very strong patent protection to pharmaceuticals and reverses the goals of competition and consumer access under the previous regime. But the intellectual property protection for pharmaceuticals is not completely impenetrable. In 1997, the High Court of Canada denied trademark protection to the shape and color of pills, reasoning that such markers were meant to protect pharmacists from confusion in filling prescriptions and consumers from confusion in recognizing the correct product.[90] The shape and color, the Court decided, were not designed to indicate the source of the product; trademark law's sole purpose under Canadian law is source identification.[91] This ruling provides hope for generic manufacturers in the Canadian pharmaceutical industry.

84. *Id.* at 46-48.
85. *Id.* at 50.
86. DOERN & SHARAPUT, *supra* note 81, at 47.
87. *Id.* at 134-43.
88. *Id.* at 134-35.
89. *Id.* at 135.
90. Eli Lilly & Co. v. Novopharm, Ltd., [1997] 73 C.P.R. 3d 371, 422-23.
91. *Id.* at 421.

3. Assessment

My description of the pharmaceutical industries of the United States and Canada indicates the basis for the creation of a gray market in drugs. The regulatory and intellectual property regimes create high prices in the United States and low prices in Canada. The reimportation bill is an attempt to take advantage of this price differential by authorizing a gray market.

However, the structure of the gray market is one that may not lead to the intended effects. What needs to be considered in assessing the efficacy of the gray market are the possible responses within the industry to the gray market. If the industry does not respond and the gray market is created, then the first, and best, situation would arise. As Table One in Part II indicates, both sets of consumers would prefer an uncontrolled gray market. Unfortunately, U.S. firms would least prefer an uncontrolled gray market. Therefore, we would expect U.S. firms to react either through merger, by entering into other corporate control arrangements with Canadian firms, or through licensing practices. If corporate control arrangements are entered into, such as through joint ventures, mergers between Canadian and U.S. firms, or entry of U.S. subsidiaries into the Canadian market, then the second best situation would arise. As Table One indicates, both sets of consumers would rank gray market with corporate control as their second choice. The problem is that such corporate arrangements would require consent by both U.S. and Canadian firms, and Canadian firms would prefer a separate existence to common corporate control.

Therefore, it is likely that U.S. pharmaceutical firms will exercise their control through licensing practices. While U.S. consumers would prefer gray markets controlled by licensing to no gray markets at all, Canadian consumers would prefer no gray markets to gray markets controlled through licensing. The reimportation bill would make U.S. consumers better off, but it would do so at the expense of Canadian consumers when the potential responses by U.S. and Canadian pharmaceutical industries are taken into consideration. While I do not purport to quantify the full benefits and costs of the reimportation bill here, I do conclude that the bill may not have all the desired benefits for U.S. consumers and would affect the licensing practices of U.S. firms in a way that may result in benefits to Canadian firms.

B. *The South African Experience*

In January 2001, forty pharmaceutical firms in conjunction with the Pharmaceutical Manufacturers' Association of South Africa reinstated a lawsuit against ten members of the South African government, including the Minister of Health and the Registrar of Patents, challenging the Medicines and Related Substances Control Amendment Act of 1997 (1997 Amendment).[92] The case was initiated in 1998 and dropped in 1999 due to political pressures. The 1997 Amendment permits the development of generic AIDS drugs in South Africa under compulsory licensing and permits parallel imports of cheap AIDS drugs into South Africa.[93] The source of the parallel imports is largely from India, which until recently did not recognize patents on medicine (but has enacted legislation granting patent protection that will be effective in 2005).[94] The lawsuit alleged that the 1997 Amendment grants to the Minister of Health unfettered discretion to regulate the pharmaceutical industry and "to deprive owners of intellectual property in respect of pharmaceutical products of such property" or "alternatively to expropriate such property without any provision for compensation."[95] The complaint also alleged that the 1997 Amendment violates Article 27 of TRIPS, which defines patentable subject matter and the scope of patent rights.[96] Oral hearings in the case were held in Pretoria on March 5, 2001, under a storm of protest.[97] The plaintiffs have

92. Pharm. Mfrs. Ass'n v. President of the Republic of S. Afr., No. 4183/98 (Transvaal Provincial Div., filed Feb. 18, 1998), *available at* http://www.cptech.org/ip/health/sa/pharmasuit.html (last visited Sept. 28, 2001).

93. Pat Sidley, *Experts Hammer Out Drugs Rules*, BUS. DAY (S. Afr.), Apr. 26, 2001, at 3.

94. Sara Boseley, *Legal Roadshow Rolls on to Brazil*, GUARDIAN (London), Apr. 20, 2001, at 13; Donald G. McNeil Jr., *Selling Cheap "Generic" Drugs, India's Copycats Irk Industry*, N.Y. TIMES, Dec. 1, 2000, at A1.

95. *Pharm. Mfrs. Ass'n*, No. 4183/98, § 2.3.

96. *Id.* § 2.4.

97. Robert Block, *Big Drug Firms Defend Right to Patents on AIDS Drugs in South African Court*, WALL ST. J., Mar. 6, 2001, at A3.

since dropped the suit,[98] but the South African government is still struggling with implementation of the 1997 Amendment.[99]

The policy of the South African government is in response to the AIDS crisis in South Africa (and in much of the developing world) and is in line with the policies of many other countries, including Thailand and Brazil.[100] According to the AIDS law project, access to pharmaceutical treatment is prohibitive and exacerbated by conditions in the health care infrastructure:

> The total pharmaceutical bill for South Africa during 1995 stood at R6.4 billion or U.S. $1 billion. The public sector prescription drug bill accounted for R1.6 billion (78% population). While the private sector prescription medicines counted [sic] for R3.1 billion (22% population). Medicines sold over the counter accounted for R1.7 billion or U.S. $300 million. It is clear that the private sector is particularly profitable for the pharmaceutical industry. Medicines are still the single largest item of expenditure for private medical insurance schemes. The unequal distribution of medicines and their costs ensure that the majority of South Africans are denied quality care and treatment. The attempts by the government to establish essential drug lists and to introduce generics have been resisted at every step by the pharmaceutical industry and many private sectors [sic] doctors.
>
> Even access to drugs for opportunistic infections in HIV/AIDS are increasingly limited. This includes no treatment for CMV retinitis, cryptococcal meningitis, or even serious cases of candida. In 1998, intravenous acyclovir was only available in 31% of hospitals;

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98. On Apr. 19, 2001, the pharmaceutical firms settled with the South African government and agreed to provide more affordable AIDS treatment to victims in South Africa.

> In response to resounding global denunciation of their lawsuit, 39 [pharmaceutical firms] today unconditionally dropped the case they pursued for three years against the South African government. The end of the lawsuit clears the path for the 1997 Medicines Act to go into force, allowing importation of affordable medicines and increased use of quality generic drugs.

Joint Press Release, Médecins Sans Frontières, Oxfam, Treatment Action Campaign, Pharmaceutical firms in South Africa Capitulate Under Barrage of Public Pressure: Powerful Precedent Set for Other Developing Countries (Apr. 19, 2001), *available at* http://lists.essential.org/pipermail/pharm-policy/2001-April/000944.html.

99. Sidley, *supra* note 93, at 3.

100. *See* Rosenberg, *supra* note 3, at 31 (describing policies in Brazil and Thailand).

flucanazole was available in less than 30% while ciprofloxacin was available in 73% of clinics.[101]

In post-Apartheid South Africa, concerns over economic rights and access to health care, and especially the promotion of fair opportunity and equal rights, have been the focus of government policy. Nowhere have these concerns been more salient than in the treatment and prevention of AIDS.

The response of South Africa contrasts with the responses of other countries, which have been heralded as success stories in controlling the AIDS crisis. Thailand and Brazil provide such examples. In both Thailand and Brazil, the governments responded by providing free and reduced cost treatment to AIDS sufferers and promoted the production of the AIDS drugs.[102] The Brazilian government started to manufacture generic versions of the pharmaceutical products in 1998 after the costs of importing brand-name drugs became prohibitive.[103] Although Brazil passed patent legislation in 1996 to comply with the WTO and TRIPS, the legislation exempts patent protection for "anything commercialized anywhere in the world by May 14, 1997."[104] Patent owners who sold their patented item anywhere prior to May 14, 1997 (the effective date of the 1996 Patent Act), exhausted their rights.[105] According to one report, "[t]he price of AIDS drugs with no Brazilian generic equivalent dropped 9 percent from 1996 to 2000. The price of those that compete with generics from Brazilian labs dropped 79 percent."[106]

Touted as a model for the developing world, Brazil demonstrates how competition in the pharmaceutical industry can be fostered by limits on patent rights. What is perhaps key to Brazil's success is the non-recognition of patent rights for patented items sold before the enactment of their patent law. Such a broad scope of exhaustion of rights permits competition

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101. Zackie Achmat, *We Can Use Compulsory Licensing and Parallel Imports: A South African Case Study*, *available at* http: //www.hri.ca/partners/alp/tac/license.shtml (last visited Apr. 12, 2001).

102. Rosenberg, *supra* note 3, at 28, 31; *see also* Christopher S. Mayer, *The Brazilian Pharmaceutical Industry Goes Walking From Ipanema to Prosperity: Will the New Intellectual Property Law Spur Domestic Investment?*, 12 TEMP. INT'L & COMP. L.J. 377, 377-80 (1998); Rosemary Sweeney, Comment, *The U.S. Push for Worldwide Patent Protection for Drugs Meets the AIDS Crisis in Thailand: A Devastating Collision*, 9 PAC. RIM. L. & POL'Y J. 445, 456-58 (2000) (discussing Thailand's policy).

103. Rosenberg, *supra* note 3, at 28.

104. *Id.* at 31.

105. *Id.*

106. *Id.*

without the difficulties faced by the South African government in limiting intellectual property rights. South Africa's patent law dates back to the 1960s, and therefore patent owners have some vested rights that are protected from retroactive legislation. Permitting gray market pharmaceuticals serves as a political compromise, which, although limiting the patent owner's right of exclusivity in South Africa, may be broadly protected by international principles of exhaustion.

Although South Africa may not match Brazil's success in lowering costs, a gray market strategy may nonetheless be very effective. An empirical study of gray marketing of pharmaceuticals in the United Kingdom estimated that gray markets would reduce prices for pharmaceutical products on average from between thirty-three percent and forty-one percent, depending upon the product and the base price used for comparison.[107] The study also demonstrated the wide range of prices that a gray marketer would provide depending upon the source country.[108] For example, the U.K. list price for Zerit, an AIDS drug manufactured by Bristol-Myers Squibb, was £ 171.98.[109] The equivalent price from a gray marketer ranged from £ 65.99, if supplied by a Spanish gray marketer, to £ 193.20, if supplied by a gray marketer from the United States.[110] The gray market is in itself a varied and complex distribution mechanism that reflects differences across countries in business regulation, supply costs, and tastes.

The response of the United States to the policies of South Africa portrays the politics of gray marketing and intellectual property rights. Until 1999, South Africa was on the "301 Watch List," a list of countries compiled by the U.S. Trade Representative that are in violation of international treaty obligations under the former GATT.[111] The United States's position was that South Africa was not in compliance with obligations under international law in recognizing and protecting intellectual property rights. The dropping of South Africa from the list in 1999 was influenced partly by domestic protests against pharmaceutical firms and partly by a shift in the Clinton administration, evidenced by the June 25, 1999, letter from Vice-President Al Gore to Representative James Clyburn, Chair of the Congressional Black Caucus, supporting compulsory licensing

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107. James Love, *Medicines and Related Substances Control Amendment Bill and South African Reform of Pharmaceutical Policies, available at* http://www.cptech.org/pharm/sa/sa-10-97.html (last visited Apr. 12, 2001).

108. *Id.*

109. *Id.*

110. *Id.*

111. Editions of the "301 Watch List," *available at* http://www.ustr.gov/enforcement/special.pdf (last visited June 5, 2001).

and parallel importation in South Africa.[112] President Bush, although he has not discussed the South African policy in great detail, has made statements that ostensibly support South Africa's attempt to promote competition in its pharmaceutical market.[113]

Albeit with mixed support in the United States, the use of gray markets to promote competition in the pharmaceutical industry illustrates an interesting convergence of policies in the United States and South Africa. Needless to say, the pharmaceutical industry is not a supporter of gray markets in either country. In the United States, industry opposition has been voiced through lobbying efforts, and through a lawsuit in South Africa. Furthermore, some pharmaceutical firms have attempted to respond to the crisis in South Africa by providing the drugs for free or at a reduced cost. The response by the U.S. Government has been mixed, reflecting perhaps the influence of the pharmaceutical firms on administrations in transition.

In assessing and comparing the policies, it is important to recognize how different the gray markets are in the United States and South Africa. In the United States, the proposed gray market is a scheme of reimportation under which drugs sold by U.S. firms in the Canadian market are bought and resold in the United States. In South Africa, the sources of gray market drugs are not Western pharmaceutical firms, but are manufacturers from other developing countries that resell in South Africa.[114] This difference in structure has important implications for the effectiveness of gray marketing.

Reimportation of pharmaceuticals in the United States gives the pharmaceutical firms greater control over the gray market than reimportation in South Africa. Since the source of the gray market drugs in the United States are drugs sold into Canada by U.S. pharmaceutical firms, the U.S. firms can effectively control the size of the gray market.

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112. Letter from Al Gore, Vice-President of the United States, to James E. Clyburn, U.S. House of Representatives (June 25, 1999), *available at* http://www.cptech.org/ip/health/sa/vp-feb-25-99.html.

113. Denise Gellene, *Aids Drug Pricing Controversy Opens Door to Wider Debate*, L.A. TIMES, Mar. 25, 2001, at C1; Raja Mishra, *U.S. Pursues Aids-Drug Profit Abroad*, B. GLOBE, Apr. 22, 2001, at A1.

114. "Indian firms lead the world in the manufacture of generic AIDS drugs. The managing director of Cipla, Ltd., an Indian generic manufacturer that meets international quality standards, told me in December that he could make a triple therapy for $500 per year, plus another $200 in packaging costs." Rosenberg, *supra* note 3, at 31. For an overview of the principle of exhaustion, see W.R. Cornish, *The Free Movement of Goods I: Pharmaceuticals, Patents and Parallel Trade*, and Belinda Isaac, *The Free Movement of Goods II: Pharmaceuticals, Patents and Parallel Imports*, *in* PHARMACEUTICAL MEDICINE, BIOTECHNOLOGY, AND EUROPEAN LAW 11-44 (Richard Goldberg & Julian Lonbay eds., 2000).

While such control may be desirable, as it may lead to price reductions and narrowing of the price differential between the two markets, the control over the gray market by U.S. firms can limit the effectiveness of the reimportation policy. In the South African case, on the other hand, manufacturers in other developing countries are the source of the gray market drugs. The Western pharmaceutical firms cannot control the flow of gray market drugs into South Africa. Therefore, gray market policies in South Africa will be more effective in promoting competition in the pharmaceutical industry than gray market policies in the United States.

A review of the economic analysis as summarized by Table One provides a basis for comparison. The firm in the destination country can control the gray market either through licensing practices in the destination and source country, or by merging or entering into some other type of corporate control arrangement with the firms in the source country. As discussed above, the firm in the source country would prefer to maintain its separate existence and would fight attempts to merge. The recourse for the destination country's firm would be to control gray marketing through licensing, which would be the worst outcome for consumers in the source country and would be the least desirable form of gray marketing for consumers in the destination country. Permitting reimportation into the United States may not be an effective means of lowering prices in the United States. Any benefits to U.S. consumers would come at the expense of consumers in the source country.

The South African program for creating gray markets would benefit consumers in both the source and the destination countries and also provide benefits for firms in the source country. These benefits would arise largely at the expense of Western pharmaceutical firms. Due to the structure of the gray market for pharmaceuticals in South Africa, Western pharmaceutical firms cannot control the source of the gray market goods. Consequently, the South African policy would lead to the creation of an uncontrolled gray market. As Table One indicates, consumers in both the source and the destination countries would prefer an uncontrolled gray market, as would firms in the source country. However, firms in the destination country (here, the Western pharmaceutical firms that would have exclusive rights to the South African market absent the gray market) would find the uncontrolled gray market to be the least desirable outcome. For these reasons, the gray market policies in South Africa would be more effective in regulating costs than the proposed policy in the United States.

My assessment of the gray market policies rests on the economics of gray marketing and the pharmaceutical industry. The analysis raises questions of the legality of the policy — questions raised in the South African lawsuit. If the benefits from gray marketing come at the expense of

Western pharmaceutical firms, as I conclude, does not this finding strengthen the case against the South African Government? More broadly, how is the creation of a gray market that provides competition to a patent owner to be reconciled with exclusive rights granted to a patent owner? These questions raise other issues about the efficacy of gray marketing, as well as its legality. If the goal is to provide access and establish competition, why not adopt policies other than gray marketing, such as income redistribution, the creation of more effective institutions, and infrastructure for the transfer of health care, or preventative disease policies?[115] While I cannot address all of these questions in this Article, I turn to the non-economic issues raised by gray markets in the next Part.

IV. TOWARDS AN UNDERSTANDING OF THE LIMITS OF GRAY MARKETS

What is intriguing about the use of gray markets in regulating the pharmaceutical industry is the use by sovereigns of markets to address what has been seen as, and largely is, a human rights issue. My analysis in this Article has been on the economics of gray marketing; my goal has been to fill a gap in our economic understanding of gray markets. The common perception is that gray markets serve to narrow a price gap between two markets. While this is certainly an important function of gray markets, it is important to understand how patent owners can regulate the gray market through licensing and corporate control decisions. The economics of gray marketing are more complicated than the mere arbitrage of a price differential. Instead, gray marketing occurs against a background of intellectual property rights and decisions about corporate structure and distribution.

While the economic analysis is helpful, the policy choice entailed in the creation of gray markets is not purely an economic one. Economic consequences are important to ascertain and assess in policy determination, but the economic consequences must be understood in conjunction with other non-economic values that are raised by the distribution of potentially

115. One possibility that I do not discuss in this Article, but which is worth noting, is that gray marketing policies may strategically support compulsory licensing under the Paris Convention on Industrial Property and TRIPS. If patent holders respond to gray markets in ways that violate the working requirements of the Paris Convention or through anti-competitive techniques, then the state can make a stronger case for infringing on patent rights through compulsory licensing. Note that the policy of South Africa consists of both compulsory licensing and opening up gray markets. I would like to thank Professor Jerome Reichman for raising this point with me.

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life-saving products. I address three issues in this section: (1) the question of exhaustion; (2) the tension between human rights and economic rights; and (3) issues of sovereignty and the vesting of patent owners' rights.

A. *The Principle of Exhaustion Versus the Right of Exclusion*

The principle of exhaustion limits the rights of the patent owner in controlling the distribution of the patented item in the jurisdiction granting patent protection. In the United States, the principle is recognized in the first sale doctrine, which limits the right of the patent owner to control distribution to the first sale of the patented item. However, the first sale doctrine for patent law applies only to first sales within the United States since the patent owner is also granted the exclusive right to import the patented item into the United States. Within the European Union, the exhaustion principle applies to sales of the patented item in any of the member countries, regardless of where the patent owner has received patent protection. In the case of *Merck & Co. v. Stephar, B.V.*, the owner of a patent on a drug in the Netherlands attempted to enjoin the reimportation of the patented drug from Italy where the drug was unpatented.[116] The owner had not sold the drugs in the Netherlands, but the patent owner's rights were exhausted by the sale in Italy even though the drug was not patented there.[117]

The principle of exhaustion offers a curious blend of universalism and territorialism. The first sale of a patented item relieves the patent owner of his exclusive distribution rights and makes the right of distribution fall into the public domain. But the loss of exclusivity applies only to the region within which the patent rights are recognized. Seemingly, the patented item is in the public domain but not in the public domain at the same time, a paradox that is resolved by understanding the definition of "public domain." The relevant public is defined by the geographic scope of the patent rights. In the United States, the geographic scope is the boundaries of the United States; in the European Union, the scope is the boundaries of the member countries of the Union. In effect, patent law creates two publics. The first is defined by the sovereign granting the rights; the second is everyone else. Exclusive distribution rights may be lost by the first sale to the first public, but not to the second.

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116. Case 187/80, Merck & Co. v. Stephar BV, 1981 E.C.R. 2063
117. *Id.*

Understanding the principle of exhaustion in relation to the relevant sovereignty elucidates the principle of exhaustion as it exists under TRIPS. Article 28 of TRIPS confers onto the patent owner the exclusive rights:

> (a) where the subject matter of a patent is a product, to prevent third parties not having [the owner's] consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
> (b) where the subject matter of a patent is a process, to prevent third parties not having [the owner's] consent from the act of using the process, and from the acts of: using, offering for sale, selling or importing for these purposes at least the product obtained directly by that process.[118]

These provisions are qualified by Article 6, which states that "[t]his right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6."[119] Under Article 6, "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."[120] Article 6 is subject to the requirements of national treatment and most-favored-nation treatment under Articles 3 and 4.[121] Under TRIPS, the principle of exhaustion is a matter of national law that limits the exclusive rights of the patent owner. However, the principle cannot be used in a way that discriminates against foreign nationals in violation of the requirement of national treatment. Furthermore, a TRIPS signatory cannot apply the principle of exhaustion in a way that discriminates among fellow signatories without running afoul of the requirements of most-favored-nation treatment.

Signatories to TRIPS have great discretion in how to fashion the principle of exhaustion within their jurisdictions.[122] As in the United States, the principle can be applied solely within the boundaries of the jurisdiction, or, as in the European Union, the principle can be applied to the larger trading territory without regard to differences in patent law. The question

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118. TRIPS, *supra* note 24, art. 28.
119. *Id.* art. 28 n.6.
120. *Id.* art. 6.
121. *Id.* art. 3-4.
122. *See* Sweeney, *supra* note 102, at 455-56 (discussing the ambiguous treatment of parallel imports under TRIPS). *See generally* Claude E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185 (1999).

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remains how the exhaustion principle is to be applied in developing countries with emerging patent law, like South Africa. South African patent law gives the patent owner the exclusive right to use, sell, manufacture, or import the patented item in South Africa.[123] The Act is silent on the principle of exhaustion. Gray marketed drugs in South Africa would infringe the patent owner's rights unless the principle of exhaustion extinguished the exclusive rights to distribute in South Africa. Such exhaustion would occur if the patent owner had sold the patented item before it was reimported into South Africa. However, in the context of South African policy the drugs are being produced in another developing country before being reimported into South Africa. They are not being distributed by pharmaceutical firms before being reimported. Consequently, it is doubtful that the principle of exhaustion would protect the gray market in South Africa.

The principle of exhaustion is less likely to apply when the patent owner is not selling or otherwise transacting with the potential gray marketer. If the gray marketer is not obtaining the patented item from the patent owner, but instead manufactures the patented item in a jurisdiction that does not recognize the patent or provides limitations on the patent owner's rights (such as in India), then the importation of the gray market good is not protected under the principle of exhaustion. However, if the gray marketer does purchase the item from the patent owner, and then reimports in competition with the patent owner, the gray marketing would be protected under the principle of exhaustion. The application of the principle is inconsistent with the economic analysis of controlled gray marketing. Consumers would prefer uncontrolled gray marketing to controlled gray marketing, but uncontrolled gray marketing is more likely to occur when the patent owner cannot exercise control over the gray market either through licensing practices or through corporate control. It is precisely when the patent owner cannot exercise such control that the exhaustion principle will not apply and gray marketing would be prohibited. The principle of exhaustion protects controlled gray marketing but not uncontrolled gray marketing to the detriment of consumers in both countries.

The conflict between economic analysis and legal analysis raises questions about whether the principle of exhaustion is the appropriate principle under which to protect gray marketing. As discussed in this Part, the principle works to prevent a form of gray marketing that is highly

123. Section 45 of Patents Act 57 of 1978 (S. Afr.), *available at* http://www.cptech.org/ip/health/sa/patlaw.html (last visited Sept. 28, 2001).

beneficial to consumers. If gray marketing is meant to serve consumerist ends, then it is best justified by a legal theory that protects the form of gray marketing that is the most consumer friendly. The principle of exhaustion is, in the context of gray marketing, antithetical to pro-consumer values.

B. *Human Rights and Economic Rights*

Within U.S. jurisprudence, human rights and economic rights have been viewed as distinct and often in conflict. Human rights jurisprudence in the United States has, as its domain, protection of political rights, protection of privacy (usually limited to reproductive and sexual freedom), and protection of bodily and emotional integrity from the coercive power of the state and, in some rare instances, of private individuals. Economic rights jurisprudence, in contrast, focuses on the right to private property and the right to economic sustenance and well-being. The dichotomy in U.S. thinking, however, is not shared by the rest of the world. The Universal Declaration of Human Rights recognizes economic freedom (such as freedom from want) and the right to health care, education, and sustenance, as core human rights.[124] International covenants, such as the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social, and Cultural Rights, recognize rights in culture, especially in what would be called rights in indigenous knowledge and cultural property.[125] Human rights and economic rights are more closely integrated outside the U.S. context.

Intellectual property rights challenge the dichotomy between human rights and economic rights, even in the United States. With a focus on property ownership, commerce and exchange, intellectual property rights seemingly fall into the category of economic rights. But intellectual property systems protect cultural expressions and protect access rights through fair use. In this way, intellectual property rights implicate non-economic rights as well. Within the United States, this tension is reconciled by casting intellectual property law in purely utilitarian terms, terms not protective of the author's personality or of rights protected by other bodies of law, such as the First Amendment. However, recently U.S. intellectual property law has had to face the non-economic dimensions of intellectual property and break out of its utilitarian straight jacket. Issues raised by indigenous knowledge protection in the developing world and Native

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124. *Universal Declaration of Human Rights*, G.A. Res. 217A(III), U.N. GAOR, (1948), *available at* http://www.un.org/ Overview/rights.html (last visited June 5, 2001).

125. *See* Coombe, *supra* note 22, at 59-60.

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American property in the United States stretch existing intellectual property doctrine and regimes to protect non-economic values and aspects of culture divorced from commercial uses. International treaty obligations under the Berne Convention require recognition of some form of moral or author's rights, which have been implemented, albeit narrowly, through the Visual Artists Rights Act (VARA).[126] Finally, legal claims of free speech and freedom of exercise have been raised in intellectual property infringement cases although with little success for the claimants.

The debate over pharmaceuticals is another example of the continuing confrontation between economic and non-economic (or human) rights. The solution of gray marketing, largely a political compromise, reflects an intriguing use of the market to correct a problem of distribution and access. Another example of a market means to reach human rights ends is provided by the use of competition policy in South Africa and Indonesia, as documented by Professor Eleanor Fox.[127] Professor Fox points out that competition policy has been and can be used in South Africa and Indonesia to challenge the control that ethnic majorities have over minorities.[128] While competition policy has often been seen as a means of achieving economic efficiency, or the maximization of aggregate social wealth without consideration of its distribution, Professor Fox suggests that such policy can also be used to redistribute resources from the economically powerful to those who are weaker.[129] Such redistribution occurs through leveling of the market playing field and lowering entry barriers to improve access to the marketplace.[130] Leveling the field and lowering the barriers also have the effect of promoting competition and improving aggregate wealth.

Professor Fox's argument is a very conventional process — based on understanding of redistribution and efficiency. By focusing legal regulation on the protection of market and political outsiders, competition can be fostered in market and political processes with benefits for society as a whole. Gray marketing policies, I would argue, are of a different species than process — based policies. Gray markets foster competition by creating an additional channel of access for consumers in the marketplace. They work in one dimension; the lowering of price. The market process is not necessarily corrected nor is a level playing field created. The creation of a gray market does not foreclose the possibility of incumbent firms

126. Visual Artists Rights Act, 17 U.S.C. § 106A (2001).

127. Eleanor M. Fox, *Equality, Discrimination, and Competition Law: Lessons From and For South Africa and Indonesia*, 41 HARV. INT'L L.J. 579 (2000).

128. *Id.* at 583.

129. *Id.* at 593.

130. *Id.*

controlling the gray market through licensing or corporate policies. Instead, the state has created a channel for distribution made possible by global price differences otherwise foreclosed by rights of exclusion created by intellectual property law.

Gray markets, in a certain sense, do not create new rights. They create new institutions that place some limitations on the patent owner's rights. Whether they protect or create economic or human rights is an unimportant and ultimately nebulous question. Instead, gray markets highlight that what is at stake in intellectual property systems is the relationship between ownership and control. One's views about how intellectual property systems should be structured rest on one's acceptance of the following two normative propositions:

> Proposition One: The creator of intellectual property should be its owner.
>
> Proposition Two: The owner of intellectual property should have absolute control over its distribution.[131]

If one accepts both of these propositions, then the resulting intellectual property system would be one of strong intellectual property rights. If one rejects both, then the resulting system is one of open access. Most proponents of intellectual property law reject one of these propositions. In the context of gray market policies, the debate is over the second proposition, with supporters of gray marketing contending that unauthorized distribution should not imply illegal distribution. But supporters of gray marketing also need to consider the other means of control that can be exercised by intellectual property owners through licensing and corporate control decisions.

I state the debate in terms of these two propositions, because I feel they are ultimately more helpful than thinking in dichotomies such as human and economic rights. The two propositions also are more precise than process based applications of legal doctrine to protect minority rights, whether they are categorized as human rights or economic rights. The key questions for the creation of intellectual property systems are: who should be the owner, who should be able to exercise control, and the logically prior questions of what can and cannot be owned or controlled. The gray market debate, and the economic analysis of Part II, illustrates the difficult problems in

131. Shubha Ghosh, Ownership, Control, and the Public Domain: The Case of Indigenous Knowledge Protection (unpublished manuscript, on file with author).

determining ownership and control issues when ownership can be established and control exercised in strategic, and not always predictable, ways. But recognizing the roles of ownership and control in intellectual property rights systems adds important dimensions to assessing gray marketing and potentially other intellectual property policies.

C. *Sovereignty and Patent Rights in a Global Arena*

The previous section indicated a deficiency in using the principle of exhaustion to protect gray marketing. The principle is designed to limit the control of the patent owner over the distribution of the patented item. But in the context of gray markets, the principle does not protect gray markets in the case where gray markets are the most desirable: gray markets that cannot be controlled by the patent owner. The legality of gray markets can be defended on the principle of exhaustion in many situations, but not in scenarios presented by South Africa in which the source of the gray market goods is another developing country where the goods are manufactured. The issues raised by this structure of gray marketing raises questions of sovereignty, particularly the ability of the state to fashion and refashion patent rights.

Under TRIPS, signatory nations can limit or take intellectual property rights through eminent domain in case of national emergency. South Africa, while once considering declaring its AIDS epidemic a national emergency, has declined to do so. While a state of emergency would have given the government wide latitude in altering intellectual property rights, the government still has the power to limit the exclusivity of patent rights. Furthermore, the proposal for reimportation in the United States also presents issues of violation of property rights and expropriation of the rights of the patent owner. While in South Africa and in the United States the patent owner would still have recognized patent rights, one stick in the bundle (the exclusive right to distribute in the jurisdiction) has been taken away.

The reimportation plans of both governments would most likely be protected under Article 30 of TRIPS, which states: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[132] The key is determining what is an unreasonable conflict,

132. TRIPS, *supra* note 24, art. 30.

a normal exploitation, an unreasonable prejudice, and what are legitimate interests. Arguably, the creation of an alternative distribution channel for the dissemination of a life-saving drug that allows the patent owner to retain most of the rights granted under patent law, would meet the standards of Article 30. It is important to point out that Article 30 permits the government to alter patent rights without having to pay compensation. The compensation requirement is expressed under Article 31, which applies only when Article 30 does not (that is, when modifications of rights unreasonably conflict with normal exploitation or unreasonably prejudice a legitimate interest of the patent owner).[133] The South African and U.S. Governments would have legal support for their position that creating a gray market does not infringe on the rights of the pharmaceutical firms in their patents.

The state strategy of creating gray markets creates two important issues with which I will end my comments and leave for future debate. The issues have to do with sovereignty and rights.[134] As my economic analysis described, patent owners will respond to gray markets and the response may involve more transnational control over how patented items are distributed and their sale price. Although national sovereigns can control some of this activity (for example, by limits on transnational mergers), sovereigns will have to coordinate their policies and activities to control the responses to the gray market. While the battles may play out in legislative politics (as they are in the United States), the real forum will be the marketplace. What is troubling about the gray market policies is that the hierarchy of politics and markets is reversed. Instead of sovereigns regulating market activities, the market is created to resolve political battles. Within the marketplace, national governments and patent owners (combined with manufacturers and retailers) are competing sovereigns that determine claims of access and distribution. The competition among sovereigns has become transparent as several pharmaceuticals in South Africa have ceded their claims and now offer to provide drugs for free and offer to develop infrastructure for delivery and access, activities deemed as traditional sovereign functions.

What is even more troubling about the creation of gray markets as a policy tool is that rights have seemingly vanished. Gray markets in pharmaceuticals are used to protect rights without recognizing them. Pragmatically, the distinction might not matter. If the goal is to provide health care to the indigent and gray marketing does provide the necessary

133. *Id.* art. 31(h).

134. *See* Coombe, *supra* note 22, at 89 (commenting on the centrality of state sovereignty in the human rights arena).

access as presumed, then what difference does it make that the policy was not based on an institutional recognition of rights?[135] But looking purely at results and not means ignores certain values, such as a sovereign's commitment to obligations, particularly the obligations to its citizens, especially the most indigent.

Stressing my earlier point, this lack of commitment reinforces the ceding of sovereignty. Even if the policies make some firms provide the drugs more cheaply or for free or invest in infrastructure, the question remains about what is the long-term benefit. In *The Age of Access*, commentator Jeremy Rifkin laments that in the information age governed by intellectual property law, fewer and fewer people actually own anything except for a right to access.[136] Information, knowledge, and innovative products are not bought and sold, but licensed and loaned.[137] Gray markets for pharmaceuticals reinforce this type of society where rights of access are granted to life-saving pharmaceuticals without recognizing a right to a certain quality of life or standard of living. While, in the short run, gray markets are beneficial and are, perhaps, even a practical and politically available instrument in the long run, the appeal of gray markets should not blind policy and law makers to commitments to institutions that protect and respect individuals.[138]

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135. The point could be made that the policy of South Africa of promoting gray markets has worked to lower prices. Several of the pharmaceutical firms doing business in South Africa, relenting to political pressures and perhaps to the economic pressures from the gray market, have agreed to lower the prices for AIDS drugs in South Africa. The question is whether these changes are short or long-term and how they will change the system of health care delivery and access in South Africa and other countries. *See* Carol Bellamy, *How to Distribute AIDS Drugs*, N.Y. TIMES, Mar. 26, 2001, at A19.

136. JEREMY RIFKIN, THE AGE OF ACCESS: THE NEW CULTURE OF HYPERCAPITALISM WHERE ALL OF LIFE IS A PAID-FOR EXPERIENCE 4-5 (2000).

137. The role of leasing in extending the market power of a monopolist has been studied extensively by economists. The seminal article is written by R.H. Coase, *Durability and Monopoly*, 15 J.L. & ECON. 143 (1972) (demonstrating why a monopolist selling durable goods would prefer to lease rather than sell the good). *See also* John Shepard Wiley Jr. et al., *The Leasing Monopolist*, 37 UCLA L. REV. 693, 695-97 (1990) (discussing Coase's 1972 article and its applications to antitrust law).

138. I have in mind here the conception of human rights that expressly recognizes power, political relationships, and economic relationships, as opposed to the ethnocentric notion, discussed by Professor Mutua. *See* Mutua, *supra* note 21, at 207 (critiquing the human rights paradigm for ignoring power).

V. SUMMARY

In two different jurisdictions, gray markets have been appealed to as a way to protect interests that may be viewed solely as a matter of human rights. In the United States, gray marketing was chosen largely out of political feasibility. In South Africa, the solution was part of creating a market for generic pharmaceuticals in conjunction with compulsory licensing. In this Article, I have presented an economic analysis of gray marketing and have demonstrated that its effectiveness rests on how the patent owner responds to the creation of gray markets through his licensing and corporate control practices. I conclude that the economic effect of gray marketing will depend upon how the gray market is structured. Since the United States and South African policies structure gray markets very differently, the policies will have quite different effects, with greater effectiveness in South Africa than in the United States.

While a large part of this Article has been devoted to the economics of gray marketing, I conclude the Article by considering the legal issues surrounding gray marketing, particularly the tension between economic and human rights, the application of the principle of exhaustion, and the question of vested rights and expropriation. There are strong legal arguments to defend gray marketing, but the form of gray marketing—uncontrolled or controlled—can be affected by the interpretation of particular legal doctrines, specifically the principle of exhaustion. I conclude that ultimately the question of gray marketing is one of the scope of sovereignty in defining and altering intellectual property rights, a scope that I contend is relatively broad under TRIPS. Gray marketing, whether applied to pharmaceuticals or other industries, offers a rich case study through which to understand sovereignty, intellectual property policy, and the ownership and control structure imposed by intellectual property law.