INNOVATION AND ACCESS: THE ROLE OF COMPULSORY LICENSING IN THE DEVELOPMENT AND DISTRIBUTION OF HIV/AIDS DRUGS

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There is currently a détente in the trade dispute between the governments of the United States and South Africa regarding South African citizens' access to HIV/AIDS drugs. This international quarrel revolves around the inherent tension in patent law as applied to life-saving pharmaceuticals. On one side is society's interest in stimulating research and development of these drugs; on the other, the interest in making the benefits of such discoveries available to all those in need. The former interest is served by strong patent law protections while the latter may be served by restrictions on the exclusivity of patent rights, such as the compulsory licensing of patented drugs. Each interest is thwarted in turn by the vehicle that best enables the other. If the proper balance is not struck, a great number of lives may be unnecessarily lost. This Note analyzes the economic effect of compulsory licensing laws on pharmaceutical research and development and concludes that compulsory licensing of HIV/AIDS drugs in developing countries contributes to a socially optimal balance between discovery and distribution and suggests measures that could further enhance that balance. Compulsory licensing is not the only measure that developing nations can take to improve the balance between innovation and access. Partitioning the global market into separate developing and developed nation markets also serves to increase the supply of these drugs at lower prices. Yet, successful partitioning requires that obstacles be erected to prohibit the movement of lower-priced products from developing nation markets to developed nation markets. The practice of directly observed therapy ("DOT"), previously employed to ensure patient compliance with infectious-disease treatment, may provide the solution by ensuring that HIV/AIDS drugs are consumed at the point and time of administration to each patient.

I. INTRODUCTION

On September 17, 1999, South Africa and the United States stepped down from the brink of a potential trade dispute concerning a 1997 South African law that enabled the production or importation of low-cost, generic forms of HIV/AIDS drugs; it is a law intended to improve the
access of South African citizens to such drugs. This event was preceded by the Pharmaceuticals Research and Manufacturers of America ("PhRMA"), an organization of United States pharmaceutical companies, stepping down from its two-year confrontation with South Africa over the same legislation by suspending a lawsuit it had brought against South Africa in an attempt to block enforcement of the law. This relaxation in the postures of the two nations and the pharmaceutical industry may be fleeting, a temporary calm following South African Health Minister Mantombazana Tshabalala-Msimang's announcement that the law would be amended. The calm may end if the change in the South African law does not satisfy the United States or the pharmaceutical industry. It is quite possible that this trade dispute will flare up again. The sides in this controversy remain separated by conflicting interests and significant ideological differences concerning the importance of strong international intellectual property protection and the proper level of protection to be given to HIV/AIDS drugs through patent law. The significance of this dispute over international pharmaceutical intellectual property protection rests on the significance of the social interests that are in tension in pharmaceutical patent law: the interest in stimulating research and development within the pharmaceutical industry that can lead to the discovery of new, breakthrough drugs, and the interest in making the benefits of such discoveries available to all people in need of them. The former interest is served by strong patent law protections which reward discovery with grants of exclusive rights in the discovery. The latter interest may be served by qualifications or restrictions on the exclusivity of patent rights allowing compulsory licensing by which the government licenses other manufacturers to produce generic and low-cost forms of the drugs. While the award of exclusive rights encourages innovation and discovery, it also restricts the subsequent distribution of benefits arising from discovery by creating a monopoly in that discovery. Monopolies in discovered goods can lead the monopoly-bearing firms to over-price and under-supply those goods. Weakening the exclusivity of the patent, while possibly enhancing access to already-discovered drugs may reduce the financial incentive to undertake the high-risk enterprise of researching and developing drugs and may block or delay the discovery of important and otherwise-discoverable drugs.

3. Id.
4. Id.
The problem faced in this dispute between South Africa and the United States is one of striking the proper and socially optimal balance between the social goods of innovation and access in the development and distribution of HIV/AIDS drugs. It is a problem of profound and pressing importance because of the number of lives that may be unnecessarily lost if the balance is struck too far to one side or the other. If the balance is struck too far in the direction of relaxing patent protections on new drugs, lives may be lost when private investment abandons research. If the balance is struck too far in the direction of strengthening new drug patent protection, lives may be lost through unnecessarily restricted access to discovered drugs that would be financially available if not for the monopoly effect created by patent law. This Note analyzes the underlying and ongoing basis of this dispute between South Africa and the United States, and examines the factual, doctrinal, and economic dimensions of the dispute. The Note examines the economic justifications for patent law protection of pharmaceuticals and the economic effect of creating monopolies in newly discovered drugs through patent law. This Note analyzes the economic effect of compulsory licensing laws on pharmaceutical research and development. The Note concludes with the finding that compulsory licensing of HIV/AIDS drugs in developing countries contributes to a socially optimal balance between discovery and distribution, and suggests measures that could further enhance that balance.

II. BACKGROUND

A. The Epidemic: HIV/AIDS in South Africa

At the heart of the recent dispute between South Africa, on the one side, and the United States and PhRMA, on the other, is the South African Medicines and Related Substances Control Amendment Act, which enables the compulsory licensing of HIV/AIDS drugs. It allows the South African Minister of Health to grant a license to a domestic pharmaceutical manufacturer to produce these drugs despite any patents on them that would otherwise confer exclusive rights on the patent holders for the manufacture and use of the patented drugs. This law was enacted in response to the enormity of the HIV/AIDS epidemic in South Africa and to the financial unavailability of existing HIV/AIDS drugs to most South African citizens. South Africa is in the midst of an enormous epidemic with an estimated 19.94% of its 21 million adult

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7. Mutume, supra note 2.
8. Id.
citizens, approximately 4.1 million people, infected with HIV. The epidemic has not restricted itself to the adult population of South Africa. An estimated 95,000 of South Africa’s 19 million children are also infected with HIV. HIV/AIDS is already taking a devastating toll on human life, with an estimated 250,000 AIDS-related deaths occurring in 1999 alone. More alarming is the fact that the epidemic is growing at an estimated rate of 1,500 new cases per day. Future projections from the present state of the epidemic indicate that “by 2005-2010, 21 years of life expectancy at birth will be lost to AIDS: the level of life expectancy is expected to be just 45 years against 66 years in the absence of AIDS.” The impact of the epidemic is and will be magnified by the financial inaccessibility of effective treatment: a triple cocktail of protease inhibitors and AZT can cost more than $750 each month, placing it well out of reach of most people in South Africa, where the annual per capita income is only $6000. South Africa is not unique among developing nations. HIV/AIDS is concentrated in the developing nations of the world, with 90% of the 33 million worldwide cases of HIV/AIDS located in Africa, South America, and Asia. Most developing nations are also like South Africa in their inability to afford effective treatment for the vast majority of people. The average country in Africa spends $10 per year per person on health care, but a year’s supply of the triple cocktail may cost as much as $12,000 per year.

B. HIV/AIDS Drugs: Development and Distribution

HIV/AIDS drugs, such as AZT and various protease inhibitors, are the focus of a particularly intense research and development program within the pharmaceutical industry. In 1991 sixty-four different firms were working on developing eighty-eight different HIV/AIDS drugs. PhRMA describes the development of these drugs as an extremely expensive process, with the pharmaceutical industry investing approximately $19 billion a year in research and development. This current level of investment is the result of a continual and remarkable

11. Id.
12. Id.
15. Mabry, supra note 9.
16. Id.
17. Mutume, supra note 2.
19. See Mutume, supra note 2.
increase in research and development expenditures which has taken place throughout the pharmaceutical industry over the last twenty years, with the amount spent on research and development increasing from $2 billion in 1980, to $8.2 billion in 1990, to its present level of $19 billion.20

The cost of developing each new drug is itself extremely expensive, with a 1987 estimate of $231 million.21 The pharmaceutical industry attributes the high cost of individual drug development to the high-risk research and development process required to successfully bring a drug to market. Only one out of every four thousand drugs investigated and developed eventually wins government approval and can be marketed.22 The cost of each drug that reaches the market thus includes not only the direct cost spent on developing that particular drug, but also includes the cost of researching the other 3,999 drugs that had to be investigated to find that one marketable drug.23

The 1962 amendments to the federal Food, Drug, and Cosmetic Act,24 which created a rigorous approval process for new drugs, are another source of expense in the development of HIV/AIDS drugs.25 Approval of a new drug requires successful completion of multiple clinical trials that demonstrate safety and efficacy, a process that can take ten to twelve years and cost more than $231 million.26 Just as the true cost of researching and developing successful new drugs includes the cost of researching drugs that ultimately prove unmarketable, the true cost of satisfying the approval process requirements for a successful new drug includes the cost of putting the many drugs that ultimately fail to win approval through the process as well.27 In 1987, the basic approval process yielded to the HIV/AIDS epidemic's severity with the creation of a new, accelerated approval process that allows drugs that make strong showings in the early stages of the approval process to be made available to people outside the clinical trials at a much earlier point in the approval process than was previously permitted.28 The United States government has further facilitated the development of HIV/AIDS drugs by conducting some of the initial testing of these drugs itself and by providing resources to support clinical trials.29

Pharmaceutical companies have been able to successfully obtain patents for HIV/AIDS drugs that they have developed and have been

20. Griffin, supra note 18, at 385.
22. Id.
23. Id. at 303-04.
25. Griffin, supra note 18, at 382.
26. Fisch, supra note 21, at 303.
27. Id.
28. Griffin, supra note 18, at 378-82.
29. Id. at 388-89.
able to achieve tremendous sales and profits from these drugs. For instance, Burroughs-Wellcome successfully obtained a patent on AZT in 1988 and consequently gained exclusive rights to AZT as a treatment for HIV/AIDS until 2005. Burroughs-Wellcome, which had been marketing AZT before the patent was ultimately approved, enjoyed sales of $158 million from AZT in 1988, with a one-year supply of AZT for one person selling in the range of $10,000 to $12,000. The price has been reduced somewhat since then, with a one-year supply of AZT falling to a price range of $4,000 to $6,000 and with the total sales of AZT increasing from $158 million to $540 million. AZT sells for one and a half dollars per dose even though the cost of production is estimated at forty cents per dose. Prices of HIV/AIDS drugs are not uniform across all markets. Pharmaceutical companies have segmented the global market for HIV/AIDS drugs into a number of sub-markets and have set different prices within these sub-markets. Pharmaceutical companies charge a great deal more for their drugs within the United States domestic market than they do within foreign markets. Glaxo-Wellcome, the present holder of the AZT patent, has offered AZT to South Africa’s public health service at 70% below the world average price.

C. The Legal Conflict: The WTO’s TRIPS Agreement and South Africa’s Medicines Act

International intellectual property protection generally, and patents of pharmaceutical products specifically, are dependent on the particular national laws of each country within which protection is sought. This creates a “problem with regard to international trade of intellectual property... that products put into the international market lose the patent protection provided by the original granting nation. This forces the patentee to seek protection from those nations to which the products are being sold.” This problem is significant because the substance and scope of protection offered by the patent laws of various countries vary greatly from country to country, with some countries providing only minimal legal protection and with others providing very stringent protection. This extreme variability in intellectual property protection is seen in the way in which different nations treat the patentability of

30. Id. at 393-94.
31. Id. at 394.
32. Id. at 395.
33. Id. at 394-95.
34. Mabry, supra note 9.
35. Id.
38. Id. at 72.
pharmaceutical products. A number of countries have refused to grant any patent protection for new pharmaceutical products. Other countries have chosen to grant only very limited forms of patent protection to pharmaceutical products, with compulsory licensing provisions being a common form of limitation on patent protection.

In addition to the laws of individual countries, a number of international treaties and agreements regarding intellectual property protection have served to create some uniformity between the intellectual property laws of participating nations. There are two major international agreements that provide the basic framework for the international treatment of intellectual property. The first of these is the Paris Convention for the Protection of Industrial Property. The Paris Convention provides limited international regulation of intellectual property with its major requirement being merely that member nations provide the same intellectual property protections to foreign patent holders that they provide to domestic patent holders. Such a requirement does not require the provision of any particular level of intellectual property protection, only equal protection. Under the Paris Convention, a member nation may well choose not to allow the patenting of pharmaceuticals products, as long as those laws meet the minimum requirement of equal treatment. Although placing no requirements on member nations as to which classes of inventions must be protected by patent law, the Paris Convention does place some limited restrictions on the abilities of member nations to impose compulsory licensing on inventions to which they have granted patent protection. The Paris Convention allows member nations to impose compulsory licensing on patented products, but only after the passage of three years from the grant of the patent or four years from the application for the patent, thus guaranteeing some minimum period of exclusive rights to patent holders.

Some consider the protections offered under the Paris Convention to be inadequate. In 1989 this concern led to the consideration of intellectual property protection in the Uruguay round of General Agreement on Tariffs & Trade ("GATT") negotiation, a round of negotiation in which the Trade Related Aspects of Intellectual Property

39. Id.
40. Id.
41. Id.
42. Id. at 71-74.
44. Id. at art. II(1); Corn, supra note 37, at 72.
45. Corn, supra note 37, at 72.
46. Id. at 73.
47. Paris Convention, supra note 43, art. 5(A); Corn, supra note 37, at 72-73.
48. Paris Convention, supra note 43, art. 5(A); Corn, supra note 37, at 73.
49. Corn, supra note 37, at 83.
Rights ("TRIPS") agreement was adopted as part of the World Trade Organization ("WTO") and GATT. Surpassing the protections mandated under the Paris Convention, the TRIPS agreement provided more substantial minimum standards for international intellectual property protection, as well as dispute settlement mechanisms and enforcement procedures.

The TRIPS agreement, like the Paris Convention, allows compulsory licensing but only under a restricted set of conditions. TRIPS allows WTO member nations to compulsorily license a patented product or process in only two situations:

(i) in national emergency or some other extreme urgency or for public non-commercial use,

(ii) in other cases, if the proposed user has made efforts to get authorization from the owner on reasonable commercial terms and conditions and not been able to get the authorization within a reasonable period of time.

In situations in which the WTO would allow a member nation to compulsorily license a patented product or process, several requirements must be observed:

(i) the owner will be paid adequate remuneration,

(ii) the authorization of such use will be mainly for the supply to the domestic market,

(iii) the scope and duration of such use will be limited to the purpose for which it is used.

The TRIPS agreement limitations on compulsory licensing are at the heart of the United States and PhRMA challenge to the South African Medicines and Related Substances Control Amendment Act. The law was challenged as violating the TRIPS agreement on the grounds that it was overly broad in the powers granted to the South African Minister of Health to provide compulsory licenses. Specifically, the minister was allowed to grant licenses under conditions not permitted by the TRIPS agreement. The particular provision of the law being challenged is Section 15(c), which creates the power to issue compulsory licenses by allowing the Minister of Health to "prescribe conditions for supply of more affordable medicines in certain circumstances so as to protect the health of the public . . . notwithstanding anything contrary
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contained in the Patent’s Act.” Section 15(c) does not explicitly restrict the Minister of Health’s discretion in granting compulsory licenses to the conditions set forth in the TRIPS agreement and, thus, enables the Minister of Health to legally grant compulsory licenses under conditions not allowed under the TRIPS agreement. Thus, the passage of the South African Medicines and Related Substances Control Amendment Act arguably puts South Africa in the position of failing to meet the minimum level of patent protection required under the TRIPS agreement. The legal challenge to the language of 15(c) has been suspended in response to the South African Health Minister Dr. Manto Tshabalala-Msimang’s assurances that the law would be redrafted to comply with the requirements of the TRIPS agreement. However, if Dr. Ian Roberts, an adviser to the South African Health Minister, is correct in saying that this “dispute is really about a different interpretation of TRIPS,” then the new draft of the South African law, reflecting the South African government’s understanding of the TRIPS requirements, may be found by the United States and PhRMA to still violate TRIPS as they understand it.

The dispute legally hinges on different interpretations of the limits that TRIPS places on the ability of member nations to grant compulsory licenses for such things as pharmaceutical products. The dispute regarding the proper interpretation of TRIPS is merely the present expression of a more fundamental, theoretical dispute pitting South Africa and other developing nations against the United States and the pharmaceutical industry. This underlying dispute is over the social value of compulsory licensing, whether such a qualification on the exclusivity of a patent holder’s rights is more beneficial to society than it is costly. This conflict of perspectives about intellectual property protection would not have been resolved by the continuation and resolution of the challenge to the South African Medicines and Related Substances Control Amendment Act in court since that would only determine what the governing law, the TRIPS agreement, actually requires of member nations. Rather, this conflict of perspectives is about what the law ought to be and what system of international intellectual property protection would be socially optimal. This, in turn, reflects a disagreement about the relative value of extensive research and development versus broad access to existing technology as well as disagreement about how changes in the level of one of these goods either causes or requires changes in the level of the other good. This Note turns next to a consideration of these fundamental problems by looking at the balance of costs and benefits created by grants of exclusive patent rights on pharmaceutical products.

58. Mabry, supra note 9.
60. Mabry, supra note 9.
61. See generally Julian-Arnold, supra note 5.
and the change in this balance caused by qualifying the exclusivity of those rights through compulsory licensing.

III. THE PROBLEM

The conflict of perspectives on the social value of compulsory licensing is rooted in significant part in the complex economic effects of patent rights. A patent grants the inventor an exclusive right to exclude others from the use, manufacture, and sale of an invention if that invention is useful, novel, non-obvious, and of appropriate subject matter. Robert Cooter and Thomas Ulen argue that the “granting of a patent creates a monopoly,” since only the patent holder is legally allowed to market the new invention. The patent holder may of course “elect to license some or all of the rights embodied by the patent—essentially ‘waiving the right to sue’ for redress of infringing conduct,” but such licensing, if a result of voluntary bargaining on the part of the patent holder, will often secure for the patent holder much of the monopolistic value of the patent right. The creation of monopolies in newly-invented materials has both an incentive effect on the discovery of new inventions since “monopolists earn profits that exceed the ordinary rate of return on an investment” and an effect on the pricing and provision of the patented product whereby “too little of the monopolized good is produced and the price is too high.” This Note will look at the economic basis of each of these effects in turn.

A. Patents as an Incentive to Invent

“In areas of new technology where research and development costs may be high and the success rate relatively low, the promise of a truly exclusive right to the invention may be needed to justify spending large sums in start-up costs.” The risk associated with research and development in the pharmaceutical industry is particularly high, with only one of every four thousand newly discovered drugs ultimately being marketed and development costs are similarly high, estimated at greater than $231 million. These numbers are significant in assessing the expected monetary value (“EMV”) for engaging in the research and development of pharmaceutical products. Economic theory generally assumes that “business organizations are risk neutral,” and that as such, they will seek to maximize their EMV. A firm will consider various

62. See Fisch, supra note 21, at 298-99.
63. COOTER & ULEN, supra note 6, at 128.
64. See Fisch, supra note 21, at 300.
65. COOTER & ULEN, supra note 6, at 128.
66. See Corn, supra note 37, at 79.
67. See Fisch, supra note 21, at 303.
68. COOTER & ULEN, supra note 6, at 47.
coursess of action with differing EMVs and will pursue the course of action that offers the highest EMV.

The EMV is a function of both the values of possible outcomes and the probabilities of those outcomes. In contemplating the research and development of a particular drug, there are two outcomes that a firm must consider. The drug may be found to be unmarketable for any of a number of reasons; in which case the value of that outcome is negative and equal to the amount of money spent on researching the drug. The loss of research costs is referred to as -RC, which may be a considerable expense. The other possible outcome is that the drug successfully makes it through the research and development process and enters the market. This outcome value is equal to the profit, P, that the drug will make on the market less the value of research costs, -RC. The other component of the EMV of research is the probability of the two possible outcomes. Using the figures given above, the first outcome, research failure, has odds of 3,999/4,000 and the second outcome, research success, has odds of only 1/4,000. Using Cooter and Ulen's equation, the EMV of researching a drug is: \[ \text{EMV} = \frac{3,999}{4,000}(-RC) + \frac{1}{4,000}(P-RC). \]

Given the disparity in probability between the two outcomes, the EMV of research will be negative and approximately equal to the loss of research costs except where the profit from the drug is several orders of magnitude greater than the research costs. In fact the EMV will only rise to zero at the point where the profit from the drug is four thousand times greater than the research costs. Even this break-even point is not significant to the firm seeking to pursue the course of action that has the greatest EMV because there will be alternatives that offer much higher EMVs. For research into pharmaceutical products to take place, the EMV of the research must be higher than that of other alternative courses of actions with high EMVs, and this means that the profits from drugs reaching the market must be significantly higher than even four thousand times the research costs. They must be significantly higher because it takes an increase of $4,000 in expected profits from a successful drug to raise the EMV of research even a single dollar.

The high costs and risks of pharmaceutical research create a strong disincentive for firms to engage in the research and development of new pharmaceutical products that are only offset by the possibility of extremely high profits from successful discovery. However, there are factors intrinsic to the nature of intellectual property that make it extremely difficult to obtain large profits from pharmaceutical research in the absence of government intervention in the form of patent rights. Discoveries such as new pharmaceutical formulas can be copied or duplicated endlessly at relatively little cost to the copying firms, and

69. Id. at 45.
70. See id.
71. Id. at 126.
these firms can sell the copied drug at nearly the cost of production, a
price at which production costs can be recouped, but at which the
original developing firm will not be able to recoup research costs. The
profits that a firm contemplating research into new pharmaceutical
products can anticipate from a successful discovery are diminished by the
possibility of competition with firms that are "able to charge very little
and achieve high return because they do not expend the millions
previously invested by the patent owner in research, development, and
testing." Such firms bear almost only production costs for entry into the
market. The developing firm would be forced to sell in a competitive
market in which the prevailing price would only reflect these production
costs.

Patent law corrects for these disincentives to research and
development of pharmaceutical products by increasing the profits that
can be obtained from a successful drug discovery and thus increasing the
EMV of research and development. It does this by granting exclusive
rights in the invented drug to the inventor, creating a monopoly. Under
the monopoly, the inventor does not have to share the market with firms
producing lower cost versions of the drug. In addition, the inventor does
not have to simply take the prevailing price set by competing firms
bearing only production, and not research costs. As a monopolist, the
inventor can charge a great deal more for the drug because potential
buyers who would be willing to pay more than would be asked for the
drug in a competitive market will be forced into a monopolistic market
because the lower price alternatives are not available. This "enables the
recoupment of risk capital invested in the creation of works that could
otherwise be copied by persons who do not have to either contribute to
or duplicate the research and development."

The difference between a monopolistic and a competitive market
can have a profound effect on the price of a drug, as evidenced by the
drastic drop in price that occurs when patent protection for drugs cease. For
eexample, the cost of Librium, an early version of Valium, dropped
from fifteen dollars to one dollar when its patent expired. The
difference can also be seen in the context of HIV/AIDS drugs that are
still under patent by comparing production costs to price charged. In
1991, a single capsule of AZT cost only forty cents to produce, but costs
one and a half dollars to buy.

72. Id.
73. Fisch, supra note 21, at 306 n.65.
74. See Cooter & Ulen, supra note 6, at 31-33.
75. Thomas G. Field, Jr., Pharmaceuticals and Intellectual Property: Meeting Needs Throughout
76. See Cooter & Ulen, supra note 6, at 132.
77. Id.
78. Griffin, supra note 18, at 394-95.
B. Monopolies and the Restriction of Supply

A monopoly allows a firm to sell at higher prices than it would otherwise be able to within a competitive market. This is because there is no alternate supplier of that good and because consumer demand for pharmaceuticals is somewhat inelastic, meaning that some consumers will be willing to buy even at prices well above the prices they would find in a competitive market. The firm with a monopoly on a pharmaceutical will not behave the same as a firm selling the drug in a competitive market. Any increase in volume sold by a monopolist will decrease the marginal revenue from each unit sold, whereas a seller in a competitive market receives the same revenue from each unit regardless of the number he sells. As a monopolist firm expands the number of units sold, it must lower the price on all other units sold in that same market, meaning that some of the marginal revenue that would have been gained in selling an additional unit is lost due to the reduction in price on all other units that it would have been able to sell without lowering the price slightly to increase sales volume. This cost is greater for each additional unit sold because for each additional unit there is an increasing number of units that would sell at a higher price and, thus, the incremental reduction in price necessary to sell that additional unit must be taken off an increasing number of units. Because the cost of providing each additional unit is higher for the firm in a monopolistic market than for the firm in a competitive market at any volume of sales, the firm in the monopolistic market will reach the point at which the marginal cost for selling an additional unit is greater than the marginal revenue from that unit at a lower volume of sales. A pharmaceutical firm with a patented product will not maximize its revenue by selling the same volume that would be revenue maximizing in a competitive market and will, therefore, sell a reduced volume while it maintains a monopoly.

The result of granting a monopoly is that firms will provide discovered pharmaceuticals in lesser quantity and at higher prices than they would in a competitive market. People who may only be able to purchase the drug at competitive market prices may be unable to purchase the drug while it is patented. This is of profound significance with HIV/AIDS drugs because 90% of all people with HIV/AIDS are located in developing nations that cannot afford the same level of health care costs because such expenditures encroach on essential spending for even more basic needs than health care, needs such as food, clothing, and shelter. One should expect the demand curve for HIV/AIDS drugs in such nations to be extremely elastic, such that small changes in the price at which these drugs are offered would create great changes in the

79. COOTER & ULEN, supra note 6, at 25.
80. Id. at 32.
81. Id.
82. See Mabry, supra note 9.
quantity demanded. This is because the typical consumer in these nations may have to forego purchasing basic necessities to cover slight increases in drug prices. If a consumer faces this decision, then raising the price of HIV/AIDS drugs effectively raises the price of basic necessities. Purchasing basic necessities now involves a greater opportunity cost, specifically the cost of having to restrict, or even give up, purchasing HIV/AIDS drugs. One should expect basic necessities to have an extremely inelastic demand curve because consumers will generally be unwilling to go without such goods, even if they have to give up greater and greater levels of other less essential goods, such as HIV/AIDS drugs, to keep them. Consumers in developing nations will incur the greater price on basic necessities that a price increase on HIV/AIDS drugs creates and purchase the same level of basic necessities by reducing their consumption of HIV/AIDS drugs. The expected elasticity of demand for HIV/AIDS drugs in developing nations is due to the inelasticity of demand for basic necessities.

One might expect this high elasticity of demand for HIV/AIDS drugs to offset the patent-created incentives for firms to over-price and under-supply these drugs. This expectation appears reasonable because a perfectly elastic demand curve acts like a competitive market. In a competitive market, with many producers, the effect of competition is to create a prevailing market price, a price that each producer must accept through "price-taking behavior." Firms in such a competitive market cannot attempt to sell at higher prices because consumers will simply buy at the lower, prevailing price from other competing producers. Slight increases in price under such conditions do not cause a slight decrease in the volume sold by that one firm but rather a catastrophic drop as the volume sold drops to virtually zero.

In circumstances of perfectly elastic demand, a firm is confronted with a similar dynamic. A perfectly elastic demand curve is horizontal, signifying that any increase in price above the price level of the demand curve will result in quantity demanded dropping to zero. Everyone who will buy will do so at or below the price of the demand curve, but no one will buy at a higher price. A firm may sell at the price level set by the demand curve but will be unable to sell any volume at a higher price. A firm must, in effect, take the price set by the totally elastic demand curve, in a manner analogous to price-taking in a competitive market. The difference between the two cases is the source of this constraint on the pricing behavior of the firm. In competitive markets, the constraint arises from the behavior of competing producers and thus this constraint does not exist for firms enjoying a monopoly in a particular good. In the case of perfectly elastic demand, the constraint depends on consumer characteristics; therefore, monopolistic firms are subject to this kind of restraint. The over-pricing and under-supplying of goods by a
monopolistic firm depends on its ability to raise its price such that the additional revenues from the higher priced units that it continues to sell offset any revenues lost by the reduction in units sold due to the price increase. This in turn depends, trivially, on its ability to continue to sell units as it increases its price. This condition is not met in circumstances in which the demand curve is perfectly elastic. The monopolistic firm cannot increase revenue by increasing price because it cannot sell any units above the price set by the demand curve. Selling at that price, the firm does not face the characteristic monopolist cost of losing an opportunity to sell some of those units at a higher price because there is no such opportunity. Since this cost alone is what induces monopolistic firms to engage in the characteristic pattern of over-pricing and undersupplying, the absence of this cost under these special circumstances will lead the firm to provide the good at a non-monopolistic price and quantity.

Given the effect of elasticity of demand on the behavior of a monopolistic firm and the reasons for expecting the demand for HIV/AIDS drugs in developing nations to be highly elastic, one might expect the behavior of pharmaceutical firms with patent-based monopolies in HIV/AIDS drugs to approximate the behavior of non-monopolistic firms by providing these drugs at nearly socially optimal quantities and prices. Indeed, one finds pharmaceutical firms, like Glaxo-Welcome, offering HIV/AIDS drugs at prices up to 70% below the world average price. This does not mean that pharmaceutical firms are in fact operating as non-monopolists in the developing nation market. If this were the case, then the volume of sales would also come up to non-monopolistic levels and there would be no pressure on countries like South Africa to compulsorily license HIV/AIDS drugs because a competitive market of multiple producers of generic versions would provide no further advantages in either price or quantity. South Africa did pursue this course of action, however, suggesting there is still a disparity between the supply behavior of monopoly-holding pharmaceutical firms and the supply behavior one would expect in a competitive market. This disparity could be either in pricing or in quantity provided. It is possible to determine the source of the disparity by analyzing Glaxo-Welcome's supply behavior in South Africa.

As stated above, Glaxo-Welcome is providing AZT to the South African public health service at 70% below the world price average. The price of a single dose of AZT in the United States, which along with other developed nations is a major component of the world market, is approximately one and a half dollars while the cost of production is forty cents. A 70% reduction from the United States price of one and a half

84. Mabry, supra note 9.
85. Id.
86. Griffin, supra note 18, at 394-95.
dollars gives a price of forty-five cents per dose. Using the United States price as an approximation of the world average price, one finds that Glaxo-Welcome's discounted price approximates the production cost of AZT and thus approximates the price at which a competitive market would supply the drug. It would appear that the disparity between actual pharmaceutical firm behavior and that of firms in perfectly competitive markets is not reflected in the prices at which the drugs are being offered but in the quantity of drugs being offered at those prices.

South Africa's attempt to compulsorily license HIV/AIDS drugs indicates that pharmaceutical firm supply behavior does not fully approximate the behavior one would expect of competitive firms supplying these drugs despite the expected demand for those drugs being highly elastic. One possibility is that the assumption of high elasticity, argued for above, is in fact wrong. However, if South Africa itself offered pharmaceutical firms a market with intermediately elastic demand for HIV/AIDS drugs, one would expect the behavior of such firms to be wholly monopolistic and unlike the actual behavior of Glaxo-Welcome, since conditions of intermediate elasticity are precisely those in which monopoly-bearing firms maximize profits by over-pricing and under-supplying. The behavior of pharmaceutical firms can be best understood as resulting from the relationship between the developing nation drug market and the developed nation drug market. This relationship is intermediate between the two markets being a single market and being two completely segregated and partitioned markets. In the case of a single market, drugs sold in "one" of the markets could freely move into the "other" market. In the case of partitioned markets, drugs sold in one market could not leave one market and enter the other market. In the former case, pharmaceutical firms would not be able to "price discriminate" by setting different prices for different consumers because consumers charged the higher of the two prices would have free access to purchase drugs sold to consumers offered the lower of the two prices. The consumers in the lower price group would compete against the firm for sales to the higher price group and would be able to under-price the firm and to sell as low as the price at which the firm sold to them. Confronted with the possibility of such an arrangement, known as arbitrage, the monopoly-bearing firm will only be able to sell at a single price to all consumers. In the case of two completely partitioned markets, a monopolist can operate in a more complex manner. The monopolist in a single market is forced to over-price the drug even though lowering the price would increase the volume of sales. This is because the monopolist in a single market can set only a single price and the price reduction that expands volume actually reduces profits by

87. Id. at 395; See Mutume, supra note 2.
88. See Cooter & Ulen, supra note 6, at 32.
reducing the price on all units that could be sold at a higher price. The monopolist faced with partitioned markets can set a lower price for one market without having to reduce the price in the other market. The profit maximizing price and quantity in one market is independent of the profit maximizing price and quantity in the other market.

Given the assumption that the demand for HIV/AIDS drugs is highly elastic, if the market in South Africa for HIV/AIDS drugs was completely segmented from the developed nation market, pharmaceutical firms would provide the drugs at prices and quantities comparable to what firms in a competitive market would provide. They would provide the drugs at these prices and levels even though they would be drastically far below the prices and quantities at which those firms could maximize their profits in the developed nation market. The firms would be able to do this because this price reduction would not affect the prices they could charge in developed nations because the lower priced drugs could not enter those markets and compete with the higher priced drugs. However, pharmaceutical firms do not behave in this manner; they do not provide competitive-market quantities of competitive-market priced drugs even though the conditions of developing nation markets, taken in isolation, would make such a behavior optimal and profit-maximizing if those markets really were partitioned. Nor do they behave in the manner one would expect if the developed nation market and the developing nation market actually formed only a single market, where price discrimination would be impossible. Pharmaceutical firms do in fact offer reduced prices for HIV/AIDS drugs that would not be profit-maximizing behavior if developed and developing markets formed a single market system. The relationship between the markets falls between these two possibilities. The pharmaceutical firms still have an incentive to provide drugs to developing nations on monopolistic terms, albeit with some moderation, due to this structure of the markets. Although profit maximizing for the individual firm, these monopolistic terms lead to reduced access to HIV/AIDS drugs for consumers in developing nations through being under-supplied at prices near the cost of production. Presumably, the drugs are readily available in South Africa at world average prices, but such “availability” is of little import to most South Africans. Maximal effective access to HIV/AIDS drugs depends on adequate supply at near-production-cost prices which arguably are not, and will not, be provided by pharmaceutical firms bearing patent-based monopolies in these drugs because such behavior would not maximize profits for these firms.

Having analyzed the economic basis of the need for patent protection of HIV/AIDS drugs as a stimulant for their development as well as the economic basis for these laws posing a serious obstacle to achieving adequate distribution of these drugs, this Note will now analyze the potential effects of compulsory licensing laws in resolving the
tension between discovery and distribution that is inherent in patent law and striking a socially optimal balance between these two social goods.

III. ANALYSIS OF THE EFFECTS OF COMPULSORY LICENSING

The most common argument introduced against the idea of compulsory licensing as a means of increasing access to a patented product is that compulsory licensing, insofar as it weakens patent protection, weakens the incentive that firms have to invest in research and development. This weakening of incentives may induce firms to shift their resources into sectors of the pharmaceutical industry other than research, or even induce a shift of resources out of the pharmaceutical industry and into other industries. Alan M. Fisch describes this potential impact of compulsory licensing laws:

In assessing return on investment, pharmaceutical companies will note the high likelihood that developing a breakthrough pharmaceutical would result in a net loss via compulsory licensing. Accordingly, reducing research, development, and testing expenditures would most likely result in the reduction, and possibly the elimination, of the creation of breakthrough pharmaceuticals.89 Fisch’s suggestion that these are the probable effects of compulsory licensing can be criticized on several fronts.

An implicit assumption in Fisch’s prediction and judgment of the effects of compulsory licensing, which he presents in the context of a critique of compulsory licensing and a defense of strong patent protection, is that a reduction in the current levels of research and development activity would entail net social costs. On the basis of this assumption, it would then follow that if compulsory licensing results in a reduction in the quantity of research and development behavior, then it produces a net social cost and should be avoided. This assumption may appear relatively unproblematic since reductions in research behavior seem to threaten the possibility that breakthrough pharmaceuticals will go undiscovered, a possibility that clearly appears to involve net social costs. However, there are good reasons to find this particular possibility of non-discovery insufficient to settle the question of the undesirability of compulsory licensing and to remain agnostic about the desirability of the present levels of research given the conditions under which the present level of research is taking place. For the sake of argument, this Note will assume that compulsory licensing will result in the non-discovery of certain drugs. The fact of this consequence cannot settle the question of whether there is net social cost associated with such a possibility becoming reality. Fisch’s assessment proceeds from a one-sided appreciation of the benefits of pharmaceutical research and development. But, as Cooter and Ulen argue, the socially optimal amount of any good

89. Fisch, supra note 21, at 313.
or service may be less than the maximum amount of that good or service.\textsuperscript{90} The possibility of appreciating the opportunity costs required to provide a particular quantity of a good or service requires adopting a broader perspective than one that attends only to the quantity of benefit provided. Therefore, one-sided appreciation of the benefits of a particular service, here pharmaceutical research, conflates the level of that beneficial service with the level of net social benefit, such that higher quantities of that service always appear to be of greater social value than lower quantities. All things being equal, this is in fact true, but all things are not equal when providing different levels of a particular good or service because there are greater costs, both explicit costs and opportunity costs, in providing a higher level of a good or service over providing a lower level. The socially optimal level of a particular good is the level at which the marginal benefit of providing another unit is equal to the marginal cost of providing that additional unit. Pointing to the fact that compulsory licensing will lead to a less-than-maximal level of research and development is not dispositive because the social cost of providing those additional units of research may outweigh their social utility. The specific social cost that must be considered is the patent-created lack of effective access to HIV/AIDS drugs on the part of potential consumers who would be able to afford these drugs if they were available in a competitive market but who can not afford them at patent-created monopoly prices. This is the deadweight loss that is typically associated with monopolistic pricing.

Given the political circumstances in which the current level of research is occurring, there is no reason to assume that the present level of research activity is in fact the socially optimal level. In economics, one can trust present allocations of resources to be efficient only when they are produced through free market interactions in the absence of sources of market failure.\textsuperscript{91} Research activity and its products are subject to market failure because of the non-appropriability of information-based goods.\textsuperscript{92} Moreover, the present level of research activity takes place in the context of significant artificial inducement of this activity through government involvement and regulation, primarily in the form of patent law protections. While some government intervention is necessary to achieve the socially optimal levels of goods that are subject to market failure, any particular government intervention in the market cannot be presumed to achieve an efficient distribution of society's resources and may in fact lead to worse allocative inefficiencies than the market failures to which these interventions are addressed. This is not to say that such interventions cannot promote or create efficient allocations of social resources, only that such interventions do not necessarily do so and thus

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\textsuperscript{90} See COOTER & ULEN, supra note 6, at 22-23.
\textsuperscript{91} See id. at 40.
\textsuperscript{92} See id. at 126.
\end{flushleft}
distributions achieved in virtue of such interventions, specifically the present level of pharmaceutical research, can not be presumed, *a priori*, to be efficient and socially optimal.

Pankaj Tandon's work on the economics of compulsory licensing and socially optimal patent policy goes further than this cautious agnosticism about the socially optimal level of research activity. He argues that the socially optimal patent is a patent of indefinite duration that allows for compulsory licensing and, by implication, that the socially optimal level of research activity is one that arises under a system of patent protection that allows for compulsory licensing. Tandon argues that such a system of patent protection achieves the optimal trade off between research levels and consumer access to patented products and processes. Although compulsory licensing would reduce the level of research activity, that cost is shown to be more than made up for by the ensuing increases in consumer surplus created by increasing the financial accessibility to patented products and processes. It follows from Tandon's argument that compulsory licensing is, in theory, a key component of the socially optimal patent policy where the socially optimal level of research activity will be the level of research activity that occurs under a scheme of patent protection with compulsory licensing.

Tandon analyzes the welfare effects of compulsory licensing under a static model of innovation, a model in which there is only a single potentially innovating firm, rather than a dynamic model of innovation in which there are two or more potentially innovating firms competing to achieve the innovation first. The dynamic model captures the "more common and important situation in which there is rivalry to innovate," the situation that holds in the pharmaceutical industry. It is the situation of so-called "patent races." The incentives to innovate are different under these two models, a difference that may, in turn, modify the effects that compulsory licensing has on innovation and welfare in each of the two models. Potentially innovating firms within the dynamic model are confronted with the possibility that a particular innovation may be achieved by another firm. This raises two opposing considerations for firms confronted with this situation.

94. See id. at 472, 484.
95. See id. at 470-71, 484.
96. See id.
97. See id. at 484-88.
98. *See Michael L. Katz & Carl Shapiro, R&D Rivalry with Licensing or Imitation, 77 AM. ECON. REV. 402, 402 (1987) (outlining these two models of innovation without the static/dynamic terminology and without reference to Tandon's work).*
99. *Id.*
101. *See Katz & Shapiro, supra note 98, at 402 (indicating that different incentives exist under the two models).*
First, it makes the expected outcome of research and development activity dependent on the intensity of research and development activity relative to competing firms. It is not, as it would be under a static model, simply a function of the absolute level of research and development activity. Under a dynamic model, "[t]he greater is firm B's expenditure rate on R&D, the more firm A will find it optimal to spend on its research programme [sic]...[i]t implies that R&D expenditures under competitive conditions exceed the collusive rates that maximize joint profits." It creates the possibility of a socially inefficient race to innovate in which "resources will be spent on R&D at a socially excessive rate." Under the dynamic model, the total expenditure and research activity of competing firms may proceed beyond the threshold point at which the marginal social cost of further research is less than the marginal social benefit of further research. The reason for this is that social utility is a function of the overall likelihood of innovation, which is a function of the absolute level of research activity. However, the individual utility of a firm in a competitive context is a function not only of the likelihood of innovation, but also, critically, of the likelihood that that firm will be the first one to achieve the innovation, which is a function of the relative level of research activity rather than the absolute level. Competing firms will engage in absolute levels of research activity beyond the point at which such activity contributes positively to social utility, to the overall likelihood of innovation, because such research activity may still continue to contribute positively to individual firm utility by increasing the likelihood of being the firm that first makes the innovation. At such levels, the competing firms are engaged in research activity that is purely distributional in objective and contributes nothing to social utility. Social utility is not affected by which firm develops a particular innovation so research activity and social resources consumed for such solely distributional objectives is socially inefficient and excessive.

Secondly, under a dynamic model, relaxation in patent protection, such as through licensing, may make it worthwhile for a competing or potentially competing firm to refrain from competition in research and development and allow another firm to develop the innovation itself. It becomes "a possibility that a firm benefits from innovation by its rival." This can have the effect of inhibiting or reducing research activity by all competing or potentially competing firms and thus slowing the innovation process. However, firms are not necessarily equally positioned within the process of innovation, a factor analyzed by Gene

102. See Grossman & Shapiro, supra note 100, at 374-75.
103. Id. at 375.
104. Id. at 375, n.7.
105. Katz & Shapiro, supra note 98, at 402-03.
106. Id. at 403.
107. Id. at 419.
M. Grossman and Carl Shapiro, and the impact of reducing the incentive to innovate may have different effects on firms in different places within the process.\textsuperscript{108} We should not expect uniform responses to changes in the parameters of competition from firms that are positioned differently.\textsuperscript{109} Diminishing the incentive to innovate through weakening patent protection may selectively remove trailing competitors. While this may reduce the absolute level of research activity along a particular line of innovation, this reduction may in fact be socially optimal since competitive developmental processes may engender socially wasteful levels of research activity in the race to be the first to innovate and reap the attendant awards.

The above arguments assumed that compulsory licensing laws enacted in developing nations would significantly diminish research activity. This assumption itself is subject to challenge. In his critique of compulsory licensing, Fisch suggests that compulsory licensing will significantly and negatively impact the present level of investment in pharmaceutical research and lead to the non-discovery of otherwise discoverable drugs by creating a "high likelihood that developing a breakthrough pharmaceutical would result in a net loss."\textsuperscript{110} This suggests that the incentive effect created by strong patent laws is just sufficient to shift resources from other industries into the pharmaceutical industry and to shift resources within the pharmaceutical industry from non-research activities into research and development activity. Fisch portrays the incentive effect as precarious, such that any reduction in it, for example through compulsory licensing laws, will reduce the EMV of research activity below the EMV of other lines of action and lead to a significant shift in resources away from research and development within the pharmaceutical industry and perhaps even a shift of resources out of pharmaceuticals and into other industries. This portrayal of the level of incentive created by strong patent protection is grossly inconsistent with basic data about the pharmaceutical industry. To assess the possibility that resources will be shifted away from the pharmaceutical industry generally, one must look at the profits earned in the pharmaceutical industry compared to the average profits achieved across all industries. "When profits being earned in a particular industry exceed the average profit rate for industry as a whole, firms will enter the industry, assuming there are no barriers to entry."\textsuperscript{111} As a corollary to this, firms in industries in which the profits are below the industry-wide average will seek to enter industries with higher rates of return. For firms in the pharmaceutical industry to be poised to shift resources out of pharmaceuticals and into other industries as a result of any diminishment

\textsuperscript{108} See Grossman & Shapiro, supra note 100, at 373-78.
\textsuperscript{109} See id.
\textsuperscript{110} See Fisch, supra note 21, at 313.
\textsuperscript{111} See COOTER & ULEN, supra note 6, at 28.
in their expected profits, the profit rate for the pharmaceutical industry would have to be at or just slightly above the profit rate for industry as a whole. On the contrary, the pharmaceutical industry currently "accumulate[s] above average profit levels." The industry is committing a significantly increasing percentage of its sales, 16.7% in 1991, up from 12.3% in 1988, to self-financing its research and development programs, indicating the profitability this line of investment offers to pharmaceutical firms. The amount of investment in research has increased from $2 billion in 1980 to $8.2 billion in 1990 to a present level of approximately $19 billion. This is evidence of an incredibly strong impetus for firms to shift resources into research and development and that a weakening of the patent protection of pharmaceuticals through compulsory licensing would likely only lead to a slowing in the increase in investment in research and development. The movement of investments into this sector would have to slow down and stop before there would be a reversal in the direction of investments. A disincentive equally as strong as the current forces driving investments into research would be required just to stabilize investments at their present level. The weakness of the arguments against compulsory licensing and other qualifications of patent protection is that they treat patent protection as all or nothing and make no attempt to quantify that protection or its economic effects. Compulsory licensing is not an absence of patent protection but merely a lessening of that protection. While compulsory licensing may weaken the incentives to invest in pharmaceutical research, the trend of rapid and significant increases in investment in pharmaceutical research demonstrates that the present incentives to invest are so strong that they would have to be weakened considerably before there would be any reduction in the amount of pharmaceutical research. This trend exists even though a large number of countries presently allow compulsory licensing under their national intellectual property laws.

IV. CONCLUSION AND RECOMMENDATION

As indicated above, one of the principle reasons given as an argument against developing nations imposing compulsory licensing on

112. Griffin, supra note 18, at 367.
113. See id. at 368.
114. See id.
115. See Thiru Balasubramaniam & Andrew Goldman, Selected Compulsory Licensing, Government Use, and Patent Exceptions in Various Countries, at http://www.cptech.org/ip/health/cl/examples2.html (last modified Aug. 8, 2000). Balasubramaniam and Goldman offer an extensive list of countries that employ compulsory licensing, in one form or another, and the conditionalities those countries observe in granting compulsory licenses; the countries that employ compulsory licensing include: Argentina, Australia, Austria, Barbados, Belgium, Brazil, Bulgaria, Chile, China, Hong Kong, Denmark, France, Germany, Ghana, Iceland, Italy, Japan, Malaysia, Mexico, Netherlands, Norway, Philippines, Poland, Russia, South Africa, Spain, Switzerland, United Kingdom, United States of America, and Vietnam. Id.
pharmaceutical products, such as HIV/AIDS drugs, is that any such weakening in the patent protection offered to those products will reduce the incentives that firms have for investing in research on such products. In turn, this will lead to a reduction in investments and possibly to the non-discovery of future blockbuster drugs. The preceding section of this Note has challenged this characterization and evaluation of the probable economic impact of a policy of compulsory licensing on both theoretical and empirical grounds. While compulsory licensing laws may in fact weaken the incentive that firms have to invest in research, it does not follow that such a reduction in incentives will lead to a significant reduction from present levels of research or even that such a reduction would be socially undesirable. The current level of investment in pharmaceutical research is at an all-time high, the result of decades of rapid growth in this sector, growth that indicates the presence of a strong impetus to increase investments in research. Given this present trend of rapidly increasing investment in research, a reduction in the incentive for investment in research through implementing a policy of compulsory licensing of pharmaceutical products in developing nations will by no means necessarily lead to a reduction in research activity relative to present levels as it may simply slow the present rate of increase in research investments.

Moreover, it is by no means necessarily the case that a slowing in the rate of increase in research investments or even an actual reduction in levels of investment in research activity would involve a net social cost. The present level of investment may be well above the socially optimal level of investment. The level of research activity has historically been much lower, and large numbers of important drugs were discovered and developed with far less investment. Increasing the level of investment does not, after a certain point, produce benefits commensurate with the costs of such investment, and the pharmaceutical industry may have crossed this point as a result of the artificial incentives created by overly strong patent protection. If the pharmaceutical industry is well beyond the threshold of diminishing return on its research investment dollars, then weakening patent protection through compulsory licensing will not only produce social benefits through increasing access to much needed medication, such as HIV/AIDS drugs, but may also reduce a socially wasteful level of expenditure on the part of the pharmaceutical industry. Tandon has argued that compulsory licensing is a component of socially optimal patent policy and by implication that the socially optimal balance between research levels and access to patented products will be the balance that arises under such a scheme of patent protection that involves compulsory licensing. Strong patent protection without compulsory licensing may serve the distributive interests of firms in the pharmaceutical industry, but, according to Tandon’s analysis, their gains under such a scheme of patent protection would be outweighed by the
social costs that such a scheme would impose on consumers in the form of deadweight losses due to monopolistic pricing.

It appears from the proceeding arguments and analysis that a policy of compulsory licensing of HIV/AIDS drugs in developing nations, such as the policy that South Africa pursued in passing the South African Medicines and Related Substances Control Amendment Act, should be allowed and encouraged as a means of striking a socially optimal balance between innovation and access. However, compulsory licensing is not the only measure that developing nations can take to improve the balance between innovation and access. In discussing the potential social benefits of compulsory licensing, Tandon acknowledges that there is an impractical but, theoretically first, best measure to efficiently eliminate the deadweight losses arising from monopolistic over-pricing and under-provision: price discrimination. As discussed in the preceding section on monopolies and the restriction of supply, an increase in volume sold by a monopolist will typically decrease the marginal revenue from each unit sold because the monopolist must typically reduce the price on all units sold, including units that could have been sold without a price reduction, to increase sales volume. If a monopolist firm can price discriminate then it can expand its sales volume by reducing the price on additional units to be sold without having to reduce the price on all other units that it could sell at higher prices. As argued above, if the developed and developing nation markets for HIV/AIDS drugs were fully partitioned such that they operated as two separate markets, then firms in the pharmaceutical industry would be able to price discriminate between, although not within, these two markets.

While the developed and developing nation markets for HIV/AIDS drugs are not fully partitioned at present, it may be possible to achieve such partitioning through the implementation of directly observed therapy ("DOT") programs in developing nations. "Directly observed therapy (DOT) is a compliance enhancing strategy in which each dose of medication is observed by a health care or public health professional." Since health care or public health personnel administer and observe each dose, they can ensure that each patient is taking the required drugs on the required schedule. DOT has been primarily implemented in the context of tuberculosis control programs, to ensure compliance with and completion of the requisite drug regimen on the part of patients with active, infectious tuberculosis. The concerns behind the use of DOT in tuberculosis control programs are that some patients will remain infectious to the public by not following their prescribed drug regimen and that imperfect compliance with such

116. See Tandon, supra note 93, at 472.
118. See id.
regimens will promote the emergence of drug-resistant strains.\textsuperscript{119} DOT has been shown to be effective in addressing both of these public health concerns, achieving "treatment completion rates of over ninety percent of patients on DOT," and "dramatically reduc[ing] the rates of primary drug resistance, acquired drug resistance, and relapse."\textsuperscript{120} The implementation of DOT in the context of HIV/AIDS control programs in developing nations would address a different concern, a concern regarding the fate of HIV/AIDS drugs after production and distribution. By channeling the flow of HIV/AIDS drugs through DOT programs, in which the administration of these drugs would be carefully monitored, developing nations could ensure that these drugs are consumed at the point and time of administration to each patient. In addition, the drugs are prevented from moving from the developing nation market into the developed nation market. DOT, therefore, offers a means by which developing nations could fully partition their HIV/AIDS drug markets from those of developed nations and enable pharmaceutical firms to treat them as discrete markets rather than as parts of a single global market. Under such conditions, pharmaceutical firms would be able to price discriminate between the markets of developing and developed nations and thereby reduce the price and expand the volume of HIV/AIDS drugs sold in developing nations. The adaptation of DOT programs from the context of tuberculosis control to the context of controlling HIV/AIDS drug administration would not only serve the purpose of partitioning the developing nation markets and expanding access, but would also reduce the rate of acquired drug resistance, a problem with the HIV virus no less than with tuberculosis and one that gives added reason for developing nations to establish and maintain DOT programs for HIV/AIDS treatment.

The recent trade dispute over the South African Medicines and Related Substances Control Amendment Act is a reminder of the ongoing challenges that the world's governments face in attempting to fashion policies that will strike a socially optimal balance between the social goods of innovation and access in the development and distribution of HIV/AIDS drugs. It is the conclusion of this Note that the implementation of both compulsory licensing and DOT programs in developing nations can contribute to improving the balance between the development and distribution of HIV/AIDS drugs.

\textsuperscript{119} See id.

\textsuperscript{120} Id.