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PHARMACEUTICALS AND INTELLECTUAL PROPERTY: MEETING NEEDS THROUGHOUT THE WORLD

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INTRODUCTION

To the extent that most people think about patents and other forms of intellectual property at all, they tend to be aware that the owners of such property may have the legal capacity to limit market entry-- without fully appreciating the extent to which products or processes that can be easily copied might otherwise be unavailable. [n.1] Focusing on their function in recouping risk capital, this article will survey the types and functions of intellectual property. Then it will attend to the situation in developing countries, particularly the role of intellectual property in meeting their needs for medical products.

Pharmaceuticals are especially expensive to develop and test. [n.2] At least in the United States, it seems to be widely recognized that the amount of innovation in a particular technology is largely a function of the *4 degree to which intellectual property is protected. If this is true, to the extent that recognition, as well as speedy and inexpensive enforcement, varies among countries, development costs are disproportionately absorbed by countries which have strong intellectual property laws. Moreover, to the extent that the need for certain products is greater in countries with weaker intellectual property protection, it is likely that the availability of those products is less than desirable and less than would be the case if protection were stronger.

WHAT IS "INTELLECTUAL PROPERTY"?

Patents and trademarks are most likely to come to mind when intellectual property for pharmaceuticals is considered. However, trade secrets, as well as kinds of protection which are more similar to copyright may play a role.

Of the four types of intellectual property, trademarks are most distinct. [n.3] Because products with strong brand names tend to be more expensive, this kind of protection has generated considerable controversy. [n.4] Yet critics have tended to ignore the need of consumers to search out low cost and reliable products as well as the role of trademarks in furthering that end. Antitrust law rests in part on the idea that competition in the marketplace encourages firms to produce the highest quality products or services at the lowest possible price. Before this can occur, assuming that there is, in fact, competition with regard to a particular product, consumers, directly or indirectly, [n.5] must be able to

obtain accurate information [n.6] and to distinguish producers. The latter goal is served by trademarks. [n.7]

*5 While brand name drugs are often more expensive, it is difficult to imagine how a competitive market could function without source indications -- even so-called "generics" are likely to have trademarks! To the extent that higher prices do not reflect expenses needed by the producer to maintain hard- won consumer goodwill or other increased costs, measures may need be taken, e.g., to better educate physicians or consumers, but it would make little sense to do away with trademarks. [n.8] Particularly in countries without extensive consumer safety regulation, a trademark owner's investment in goodwill may provide the most reliable assurance of safe product design and assurance of quality in manufacturing and distribution. [n.9] In any case, given the small likelihood that the maker of a superior product would ever be inclined to adopt a mark similar to that of an inferior product, no one should be eager to purchase from a firm that feels compelled to trade on the goodwill of another.

In contrast with trademarks which provide indeterminate protection against source confusion and no legal barrier whatsoever to honest market entry, [n.10] a patent [n.11] may be used to prevent another from making, using, or selling [n.12] protected technology for the duration of its term. [n.13] *6 The protected technology is specified within a patent's "claims." [n.14] Those claims are the subject of intense scrutiny in an examination process [n.15] designed, for example, to assure that the applicant can explain how to practice the invention [n.16] and to assure that the protected subject matter is objectively novel. [n.17] Thus, even if the applicant for a patent is unaware of a prior teaching or use by another, claims covering that subject matter will be rejected during the examination or open to subsequent invalidation during infringement litigation. [n.18]

Indeed, the applicant is usually barred from claiming subject matter which s/he has previously disclosed or exploited commercially. [n.19] Usually, too, the inventor will be required to demonstrate that the claimed invention is more than facially novel. In the United States, for example, patentable claims cannot cover subject matter "obvious" to those who are skilled in the technology in question. [n.20]

Historically, the requirement which has caused major difficulty for pharmaceutical innovators -- even in countries with an otherwise strong patent system -- is that the claims fall within technical subject matter which can be covered by a patent. While most other kinds of products are patentable, chemical products, or pharmaceuticals more specifically, *7 are often excluded from coverage, irrespective of their novelty, unobviousness, or other characteristics. [n.21]

Concerns which give rise to such exclusions may include the fear that an inventor who has discovered a method of making a new composition should not be able to block those who later discover other, and possibly superior, methods for making the same thing. [n.22] However, whatever the concern, it is difficult to understand how chemical products would differ, for example, from lasers, transistors, or the printing press.

Indeed, the majority of the U.S. Supreme Court recently adopted an interpretation which extended U.S. patent protection to new organisms notwithstanding a number of more compelling arguments. [n.23] In doing so, it recognized that the capacity to exclude is not the capacity to make, use, or sell -- and, more importantly, recognized that potentially valuable innovations would not otherwise come into existence. [n.24] The last point, of course, disposes of arguments that pharmaceuticals, specifically, are too important to protect. On the contrary, they are too important not to protect.

That process patents, alone, are deficient in enabling recoupment of the costs of pharmaceutical innovation is easily demonstrated. Consider, for example, a situation where an active ingredient is either naturally occurring or is otherwise lacking in novelty. Assuming that the innovator cannot claim a new and unobvious composition -- for example, one which is purer than what might appear in nature or one which is a combination of ingredients [n.25] -- process claims are all that remain. These fall into two broad categories.

*8 On the one hand, one might be able to claim a process of making a product, whether through synthesis or purification. However, unless that is the only economically viable process, the patent will, at best, be difficult to police. The bare fact that another firm is making an unpatented product, alone, should be inadequate to justify that firm's having to show that it is not using a patented process. [n.26] Moreover, even when the other firm is using the same process, if it is doing so in a country where the process is not patented, a patentee has serious difficulty in keeping the product of the process out of countries where the process is patented. [n.27]

On the other hand, one might be able to claim a process of using the product to treat a disease. If that is possible, the patentee may nevertheless have serious problems. If, as already posited, the composition is not patentable, users may be able to avoid contributing to the costs of innovation by substituting another firm's product -- one sure to be cheaper by virtue of its not having to reflect the costs of discovering and documenting a new use for an old product. [n.28] In such circumstances, unless the other firm is affirmatively aiding infringement, the patent will be useless.

When those and similar circumstances arise, trade secret or knowhow protection may provide an alternative for recouping costs. However, that protection is quite limited because it does not stand in the way of another firm's independently creating or "reverse engineering" a product which can be found in the market place. [n.29]

In the United States, trade secret protection arises under state rather than federal law, and important variations may occur among jurisdictions. [n.30] International variations may be even more extreme -- if for no other reason than that ratified conventions do not cover this important *9 body of intellectual property law. [n.31] Nevertheless, to the extent that a jurisdiction forbids the use of information obtained in violation of a confidential relationship [n.32] or through practices which might be loosely denominated as "industrial espionage," [n.33] it can be said to protect trade secrets.

Generally trade secret protection does not depend on a showing of objective novelty, much less unobviousness, or require any formalities (other than those needed to establish a confidential relationship or to preserve secrecy). Also, unlike patents, trade secrets have a potentially perpetual term. Yet the inability to prevent independent origination or reverse engineering may result in their duration being quite short. [n.34]

Nevertheless, trade secrets once played a significant role under U.S. law in enabling recovery of the quite high cost of collecting clinical or other data necessary to obtain regulatory approval for new pharmaceuticals. [n.35] In the case of a new combination of well known ingredients, for example, the Patent and Trademark Office would take the position that each active or inactive ingredient would be predicted *10 (by those "skilled in the art") to retain its uncombined characteristics and would reject an application failing to claim an unexpected result. [n.36]

Meanwhile, the Food and Drug Administration would require the innovator to bear the cost of collecting clinical or other data to prove precisely what would be the basis for a patent rejection. [n.37] Until recently, firms marketing pharmaceuticals within the United States were able to protect such data as trade secrets. However, there was widespread criticism of a situation where each manufacturer of an unpatented product would be required to collect new evidence of risk and efficacy, regardless of the length of time that a product had been on the market. [n.38] Still, for unpatentable products, there had to be some provision for the innovator to recoup the high cost of clinical trials. The upshot was the creation of a very short term, copyright-- like protection [n.39] for data needed for premarket approval. [n.40]

*11 Copyrights have not traditionally been thought of as appropriate for new technological works. [n.41] However, as just mentioned, that situation is changing, and some discussion of copyright law is therefore warranted. [n.42] This form of intellectual property prohibits the reproduction [n.43] of a work but cannot be used to prevent the making, using or selling of an identical work by an independent originator. [n.44] Like trade secrets, and unlike patents, copyrights are usually subject to few, if any, formalities, much less the need to draft claims which are then subjected to an examination. [n.45]

Copyright protection requires only that appropriate subject matter be subjectively novel or original. Yet its term may run for the life of an author and fifty years beyond. [n.46] In these ways, too, copyright protection is more similar to trade secret protection than to patents. However, copyrights are superior to trade secrets in that the innovator need only show access [n.47] and copying, not improper access and copying. Moreover, in the case of well known works, the access needed to support copyright infringement is usually presumed. [n.48] Hence, aside from their possibly *12 excessive duration and their limitations with regard to subject matter, copyrights furnish almost ideal protection from free riders. [n.49]

Thus, as mentioned above, free rider protection for clinical data in the United States is akin to copyright in that another firm would not be prevented from independently collecting and using very similar or essentially identical data -- although for a much

shorter time. Further, of course, should that term prove inadequate to support the desired level of innovation, it can be expanded. [n.50]

*13 INTELLECTUAL PROPERTY AND PRIVATE RISK CAPITAL

Thirty years ago, George Frost argued that: [n.51]

[T]he patent system encourages competitive effort of a kind that would not otherwise take place. The television industry, for example, was for all practical purposes nonexistent a decade ago -- now it dwarfs the radio industry.... Yet the industry is characterized by huge research expenditures... -- over $65 million in color television already and the return is yet to come. These expenditures have been made in anticipation of monetary return through patent license royalties. The antibiotics industry, limited to penicillin a decade ago, is now the scene of the most intense competition....

It is therefore difficult to imagine why any nation would deliberately inhibit innovation in pesticides, healthcare products, or devices to reduce environmental pollution. [n.52] Yet even the United States has occasionally run the risk of stifling domestically important areas of potential innovation by failing to correct for common judicial attitudes toward intellectual property [n.53] and by legislative actions taken to address concerns about the cost and availability of those and other goods.

*14 Many purposes have been suggested for intellectual property. [n.54] However, the emerging consensus, at least in the United States, is that it primarily enables the recoupment of risk capital invested in the creation of works which can otherwise be copied by persons who do not have to either contribute to or duplicate the research and development. [n.55] If governmental or charitable risk funds are available to meet the entire need for new or improved goods or services, private risk capital and, thus, intellectual property are unnecessary. Rarely is that the case. [n.56]

Even countries where most or all of the means of production are "owned" by the government find it necessary to induce especially capable, creative individuals to perform at their best or to focus their efforts to socially desirable ends by some sort of reward system. Often, too, such countries will need to import works from abroad. To the extent that needed technology cannot be easily copied, the exporter will need to recover out-of-pocket costs as well as a fair share of research and development costs -- particularly if the latter has required an extraordinary *15 investment. [n.57] To the extent that any given country provides inducements for its citizens or others to create works that can be cheaply copied or to disclose information that might be otherwise withheld, an intellectual property system, however informal, exists. [n.58]

Where the source of innovation is a private, for-profit firm, the need for intellectual property protection is critical. [n.59] David Schwartzman has said. [n.60]

The conclusion . . . that strong patent protection did not encourage discovery was based on the fact that a large number of drugs were discovered in Western Europe, especially Switzerland, where inventions were less generously protected by patents than

in the United States. But U.S. patents protect these products of foreign-based companies sold in the United States as much as they do the products of domestic companies, and the United States is by far the largest single national market for drugs.

Thus, a firm which contemplates investing a large fraction of its resources in research and development leading to a particular product will be concerned with the economic viability of the venture. Firm managers who lack that concern or appear to be ignorant of the fact that consumers ultimately bear the costs of developing and manufacturing *16 successful products will, sooner or later, be forced out of business because of an inability to borrow or to attract investors. [n.61]

Managers of large, established firms with the capital and human resources necessary to engage in important innovative activity are not apt to be so naive. On the contrary, they are likely to be quite sophisticated in minimizing the risk of loss from a potential innovation. In deciding whether to pursue one of several avenues of research or even to invest its money in other kinds of ventures, the firm is going to look first at the maximum potential income from a successful effort. Against that, its management will attempt to weigh the minimum necessary research and development costs. If the maximum potential income is less than the minimum cost of innovation, including a reasonable return on capital, the project will be unlikely to be started. If at any point during the innovation process a similar prognosis begins to emerge, for example, because the product is not performing as expected, the project is likely to be scrapped.

Because of this reality, the United States, in 1982, belatedly enacted "orphan drug" legislation [n.62] to encourage private firms to attempt development of cures for serious, but relatively rare, domestic diseases which are defined as: [n.63]

> any disease or condition which (A) affects less than 200,000 persons in the United States or (B) affects more than 200,000 persons in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such a disease or condition will be recovered from sales in the United States of such a drug.

While the legislation, of course, could do nothing about the size of the affected population, it was nevertheless possible, for example, to offer various inducements toward the development of treatments. [n.64] Whether *17 these measures will sufficiently reduce the costs of taking a significant number of those products to market remains to be seen. [n.65]

In any case, this legislation again demonstrates the widely-held belief that private innovation will not occur if a product is projected to cost more to develop, manufacture, and market than customers are willing or able to pay (in the aggregate). Nor is it likely to occur where the product is projected to cost more than customers are willing or able to pay in view of therapeutic alternatives which may be found more efficacious, less risky, or cheaper. [n.66] Indeed, even a public entity aware of opportunity costs is not likely to fund a particular line of research where other afflicted populations could be more cost-effectively served with the same resources. [n.67]

Of more significance to the present discussion, however, are circumstances in which the benefits of a successful private project can be realized by consumers who can avoid contributing to the cost of research and development. [n.68] The larger the likelihood that this can occur in any given market, geographical or otherwise, the smaller the potential for recovering the costs associated with having a new or improved product to deliver to the marketplace.

In such circumstances, if innovation is to occur at all, the risk capital must come from governmental or charitable sources which are not overly *18 concerned about potential nonconstituent beneficiaries. For example, basic advances in scientific understanding are usually funded with public risk capital [n.69] because the cost of making those advances ordinarily cannot be recouped by the sale of products. [n.70] Although attempts could be made to restrict access to that kind of information, it tends to be freely disseminated throughout the world. [n.71] Innovations in agricultural or surgical methods are similar: Because those methods probably do not fall within the subject matter of any major intellectual property schemes, and rights in them would be difficult to enforce in any case, private firms play a fairly small direct role.

Even where a given innovation falls within patent subject matter, it may be difficult or impossible to recoup private risk capital. Thus, while new uses for old substances are protected under the U.S. patent law, the value of pharmaceutical patents for second or subsequent indications is seriously undercut when final users can make generic substitutions which do not reflect the cost of demonstrating the extended efficacy of the product.

Commonly, attempts to predict a firm's ability to recoup the costs of any given venture are vastly more complex. First, for any of a myriad of possible reasons, a given research venture may prove unsuccessful. [n.72] *19 Second, even if the research is successful, the product may present risks which did not become apparent until late in the clinical investigations or, worse, after the product had been marketed and used by considerably larger populations. [n.73] In the last situation, the innovator may lose not only research and development costs but also suffer major litigation expense and liability. [n.74] Further, as mentioned earlier, the product may not prove as attractive as its therapeutic equivalents. [n.75] Indeed, because of these and other risks, even the very large firms with the necessary resources to undertake pharmaceutical research and development ventures may be reluctant to risk marketing a product which has been researched and almost fully developed with public funds. [n.76]

In any event, a private firm is apt to need to recoup more risk capital than that which was necessary to have gotten to market with a specific product. Anyone failing to appreciate this fact may have a mistaken notion of what constitutes a "reasonable" price, and this has sometimes led to various kinds of regulatory schemes layered on top of basic intellectual property provisions: One of the most common of those is compulsory licensing. However, if the regulator fails to appreciate the existence of indirect costs, royalties not only will fall short of enabling full recoupment of risk capital but also will

fail to provide a reasonable rate of return thereon. [n.77] Consequently, licensees will enjoy an advantage, albeit one less than that enjoyed by a total free rider.

Whether they are only perceived or are real, projected shortfalls in the recoupment of risk capital tend to discourage innovating firms. Moreover, to the extent that shortfalls do, in fact, exist in some markets, the innovating firm must be able to charge higher prices in remaining markets. Lacking that option, because of elasticity of demand for *20 example, the firm will need a longer period of recoupment in markets which permit it.

Anyone who interferes, for whatever reason, with a firm's ability to recapture its costs across all markets should consider at least two consequences of their choice. [n.78] First, remaining markets may serve as only a modest inducement for research in particular diseases. As mentioned earlier, in extreme situations it is possible that no innovation will occur. However, short of that, the incidence of a given disease in some market populations, for example those in rural or tropical areas, may warrant the use of more resources than would be attracted elsewhere, for example markets in urban or temperate areas. [n.79] Second, if fortuitously there are markets within which firms have the ability to support research and development adequate to the needs of all subsets of the world population, purchasers in those markets will be forced to carry the entire cost of innovation.

Where submarkets correspond to the boundaries of nations, it would seem particularly difficult for the leaders of countries which are well beyond the challenge of feeding their citizens -- much less those which have otherwise sophisticated intellectual property systems -- to justify, ethically, pursuing any path which forces the citizens of other countries, *21 via hidden costs, to absorb a disproportionate share of the expense of developing socially important products. [n.80] Further, particularly where pharmaceuticals and related products are involved, the costs often include those which are carried by individuals who participate in clinical trials. [n.81] While subjects in such trials may be happy to know that their participation benefits people throughout the world, ultimate consumers concerned about their cost of health care may be less enthusiastic.

MINIMIZING ADMINISTRATIVE COSTS

Government officials who want to encourage private pharmaceutical innovation must take closer look at their intellectual property options. Yet persons doing so for the first time often have legitimate concerns about what implementation would entail. For example, visitors from smaller countries, after touring the U.S. Patent and Trademark Office, frequently express apprehension about the administrative costs which a full blown patent system would impose on their economy. [n.82] They are especially apprehensive when predicting relatively few filings, with a *22 large fraction of those potentially or actually originating from abroad. [n.83] Such concerns cannot be ignored.

Of the four main types of intellectual property, patents will likely cost the most to administer. [n.84] An examination system is especia lly expensive partly because of the

need to have a staff of experts available to evaluate the claims of applications. Still there are a number of ways to cut such costs, including restricting the examination to only matters of form [n.85] or excluding obviousness from substantive examination. Further, costs can be reduced through the use of part-time employees or consultants, the recognition of foreign patents, the formation of regional patent offices, or the use of worldwide search facilities. [n.86]

*23 While maintenance of a prior art data base can also be very expensive, advances in computer and communications technology (assuming that there is a level of intellectual property protection adequate to support the necessary innovation in those technologies) should soon make it possible for persons in quite remote locations to gain instantaneous access to virtually all of the world's published knowledge, including for example search reports. Advances in software may also soon remove any language barriers which might otherwise have to be overcome. While some technologies are proving to be difficult to search with computers, chemicals are not among them. [n.87] Thus, pharmaceuticals should be among the first products for which worldwide searches will be possible from almost anywhere.

A particular country might also consider a patent registration system, with or without publication for opposition. However, its officials should consider the tradeoffs between the costs of examination, on the one hand, and the costs of opposition or other means for challenging arguably invalid patents, on the other. They should consider, too, that even invalid patents may serve as a potent practical barrier to entry by firms lacking the resources to challenge them. Such considerations have probably playeda major role in the worldwide movement from registration to examination systems. [n.88]

Governments need also to attend to the cost and availability of means for enforcing intellectual property rights. Having survived an examination conducted by a person knowledgeable about the technology and the legal requirements for issuance of a patent, claims ought to be presumed to be valid so as to facilitate enforcement. [n.89] Also, the speed and cost of litigation may be reduced by the use of specialized courts [n.90] or, perhaps, as is done in Europe, the segregation of validity and infringement issues. [n.91]

*24 The nature of the problems can be illustrated with trade secrets and copyrights. Because neither kind of right depends on an examination to determine the proper scope of the protection which is afforded, questions of scope must be addressed in litigation. While expert tribunals might reduce the time and cost associated with such a chore, as far as this writer is aware, no nation has seen fit to establish such tribunals. In the United States at least, non-expert judges are therefore left to wrestle with such matters as the difference between an employer's trade secret, which may not be taken by a former employee, and an employee's job skill, which is not the property of a former employer [n.92] -- or the difference between an idea, which is not protected by copyright, and the manner of expressing that idea, which is protected. [n.93]

In any event, while expenses may be minimized, the need for efficient administration cannot be avoided. If patent or other rights cannot be cost- effectively obtained and

enforced, they may as well not exist. While the system may function for a while, eventually the costs and risks inherent in the system will become apparent to its users -- competitors and consumers as well as innovators.

The ledger must be balanced. If it is too difficult to avoid unwarranted liability for using a particular work long after the innovating firm has recouped its risk capital, the system will be subject to attack. Not only will other firms be improperly denied the right to compete, but more importantly consumers will be paying unreasonable prices. Yet, if the *25 capacity to recoup is a hollow one, [n.94] would-be competitors will have nothing to copy, and consumers will be deprived of new goods and services or be otherwise shortchanged. [n.95]

SUMMARY AND CONCLUSIONS

Focusing particularly on pharmaceuticals, this paper has tried to explain why worldwide imposition of extensive limitations on -- or, worse, outright rejection of -- intellectual property protection for particular categories of products or processes may have effects which are detrimental to social welfare. To that end, it has tried to show that private resources may contribute significantly to the solution of important social problems and that, in the absence of private firms' being able to recoup their direct and indirect costs, innovation will not occur. Where the yield from such innovation is new and improved pharmaceuticals, the consequences are particularly serious.

Further, this paper has tried to show that unwanted domestic consequences may flow from a country's attempts to rely solely on foreign inducements to innovation. Indeed, unless the need for new and improved *26 pharmaceuticals of unique local importance can be met with public or charitable funds, the rejection or stringent limitation of intellectual property will result in unnecessary human suffering. [n.96] At best, those needs will have to be satisfied via hidden costs imposed on foreign consumers.

Intellectual property furnishes an almost infinite range of options for promoting innovation. With appropriate attention to administrative costs, few countries are likely to be small or poor enough to justify contributing nothing toward the cost of developing important new pharmaceuticals.

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[n.1] Even among lawyers there is very little understanding of intellectual property; see, e.g., P. GOLDSTEIN, COPYRIGHT, PATENT, TRADEMARK AND RELATED STATE DOCTRINES, Preface (2d Ed. 1981). In part, the cause of misunderstanding is

the failure to treat the subject in legal curricula, but there has been some improvement in the number of U.S. law schools offering courses in intellectual property over the past ten years; see, e.g., Field, Brief Survey... of the Options in Patent, Trademark, Copyright and Related Law, 26 IDEA 57, 57-58 (1985). There is no cause to believe that the situation would be materially different elsewhere.

[n.2] See, e.g., Hansen, The Pharmaceutical Development Process: Estimates of the Development Costs and Times and the Effects of Proposed Regulatory Changes, in ISSUES IN PHARMACEUTICAL ECONOMICS 151 (R. Chien, ed. 1979). See also, $125 Million Question: What do Drugs Cost? Wall St. J., Jan. 29, 1990, at B1, col. 2.

[n.3] For the most part, this discussion will cite to U.S. law specifically. However, except for the requirement that a mark be used prior to registration, the U.S. law generally conforms to that which is in effect elsewhere. See generally Frayne, History and Analysis of the TRT, 63 TMK. REP. 422 (1973).

[n.4] See, e.g., R. BOND & D. LEAN, SALES PROMOTION AND PRODUCT DIFFERENTIATION IN TWO PRESCRIPTION DRUG MARKETS -- ECONOMIC REPORT (U.S. Federal Trade Comm. 1977). See also, e.g., Pharmaceutical Society of N.Y. v. Lefkowitz, 586 F.2d 953 (2d Cir. 1978).

[n.5] In the U.S., for example, most information concerning prescription pharmaceuticals is provided through physicians rather than directly to consumers.

[n.6] This idea was at the heart of, e.g., Virginia State Bd. Pharm. v. Va. Citizens Consumer Council, 425 U.S. 748 (1976), a leading case permitting pharmacists to advertise the prices of their products.

Although U.S. law, until recently, tended to discourage head-to-head comparisons of products, this too has changed. See, e.g., the Federal Trade Commission policy statement on comparative advertising, 16 C.F.R. § 14.15 (adopted in 1979).

[n.7] See generally, e.g., Blair, Understanding Patents, Trademarks, and Other Proprietary Assets... The Practical View 1 (1978). This pamphlet is available from Franklin Pierce Law Center. See also Field, supra note 1, at 60- 67.

[n.8] See, e.g., Liebeler, The Deregulation of Industry: How Far Should We Go?, 51 IND. L.J. 735, 739-45, particularly fns. 14 & 15 (1976).

[n.9] Id. Indeed Liebeler's general thesis is that drugs are "credence" goods, i.e., they have qualities which a reasonably well informed consumer cannot judge either before or after purchase; hence the producer's investment in a good reputation furnishes a kind of collateral against misconduct. While his conclusion, i.e., that the Food and Drug Administration could be abolished, is extreme, the underlying point is nevertheless well taken.

[n.10] On the contrary, a mark which is or becomes incapable of distinguishing the goods of a particular producer (or family of producers) is worthless. See, e.g., 15 U.S.C. § § 1052 and 1064(3).

[n.11] See, e.g., Field, supra note 1, at 67, for a brief discussion of three kinds of patent. What is usually meant when the term, "patent," is used is a so-called utility patent, as contrasted with a design or plant patent; that is how the term will be used here.

Because patent laws vary a great deal, generalities are dangerous. By and large, this discussion will focus on the U.S. law. It will also cite to WORLD INTELLECTUAL PROPERTY ORGANIZATION, WIPO MODEL LAW FOR DEVELOPING COUNTRIES ON INVENTIONS: PATENTS (1980) -- hereinafter, e.g., 1 WIPO. Where there are known exceptions to both of those, at least one additional example will be given.

[n.12] 35 U.S.C. § 271; 1 WIPO § 135 (2)(a)(i).

[n.13] 35 U.S.C. § 154; 1 WIPO § 38 (1). The former expires 17 years after it is granted, while the latter expires 15 years after it is filed. The longer an application may take to issue, the bigger the difference would be between the two terms.

35 U.S.C. § 271 provides no exception for independent originators. See Field, supra note 1, at 90-93. But see 1 WIPO § 137.

[n.14] 35 U.S.C. § 112 2.1 WIPO § 123 (4).

[n.15] 35 U.S.C. § 111.1 WIPO § 130 (form), § 131 (substance). [The administration of intellectual property systems will be discussed in the last part of this paper.]

[n.16] 35 U.S.C. § 112.1 WIPO § 123 (3).

[n.17] 35 U.S.C. § 102.1 WIPO § 114.

[n.18] An exception may occur when the prior use was secret; see W.L. Gore & Assoc. v. Garlock, 721 F.2d 1540, 1549-50 (Fed. Cir. 1983). See also Field, supra note 1, at 90. A more straightforward exception concerning prior inventors appears in 1 WIPO § 137.

[n.19] 35 U.S.C. § 102(b) and 1 WIPO § 114 both permit a one year grace period. However, European systems do not; see, e.g., Winner, Practical Effects of the Patent Cooperation Treaty and the European Patent Convention on Domestic Technology Management and Patent Practice, 62 J.P.O.S. 419, 421 (1980). See also Dickson, A Push for European Patent Reform, 227 SCIENCE 926 (1985).

[n.20] 35 U.S.C. § 103. 1 WIPO § 115.

This is probably the most difficult area in patent law, but such a rule is necessary to avoid giving a patent to an inventor who has made but a trivial advance in the technology. In the United States, the rule is even more difficult to apply by virtue of validity and infringement issues being tried before juries; see, e.g., Field, Law and Fact in Patent Litigation: Form Versus Function, 27 IDEA 153 (1987).

[n.21] Such an exclusion appears neither in 35 U.S.C. § 101 nor in 1 WIPO § 112. However, only recently was it abolished in Europe or Japan. See, e.g., Briner, Protection of Chemical Inventions in Foreign Countries, 2(1) CHINA PATS. & TMKS. 55 (1986). See also Haertel, The Munich Diplomatic Conference on European Patent Law, 4 IIC 271 (1973). It is not surprising that newly emerging countries are reluctant to provide such coverage; see, e.g., Shen, Patent Protection of Chemical Inventions in China, 1(2) CHINA PATS. & TMKS. 17 (1985).

[n.22] See, e.g., Briner, supra, at 57.

Another legitimate concern may be that a patent could issue without the patentee having demonstrated a significant use for the compound; see Marquis, An Economic Analysis of the Patentability of Chemical Compounds, 63 J.P.O.S. 3, 39 (1981). However, at least in the United States, that problem seems to be adequately addressed by Brenner v. Manson, 383 U.S. 519 (1966). Compare Kitch, The Nature and Function of the Patent System, 20 J. LAW & ECON. 265 (1977).

[n.23] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[n.24] Id., at 307.

[n.25] In either case the composition would be novel, but whether it would be unobvious is another matter altogether. See supra note 20.

[n.26] Because of that and an inability of would-be competitors to derive the process from an examination of the product alone, a firm might well consider not to get a patent. As discussed below, relying on trade secrecy would subject the inventor only to the risk that another might independently invent the same process. For further discussion of this matter in the United States, see Leuzzi, Process Inventions: Trade Secret or Patent Protection?, 66 J.P.O.S. 159 (1985).

[n.27] Only recently was the U.S. law amended to permit such an exclusion. See 35 U.S.C. § 271(g), added by Title IX of P.L. 100-418 (1988).

[n.28] Where the product is a pharmaceutical, this is particularly expensive; see, e.g., supra note 2.

[n.29] To "reverse engineer" is to duplicate a product or process by using only what can be learned from an inspection of goods acquired in the marketplace.

[n.30] See generally, Field, supra note 1, at 83-85.

[n.31] But see 2 WIPO Model Law, supra note 11, covering know-how. "Know- how," is defined in § 201(i) as "technical information, data, or knowledge resulting from experience or skills which are applicable in practice, particularly in industry."

In 4 RESTATEMENT OF TORTS § 757, comment b (1939) "trade secret" is defined as "any formula, pattern, device or compilation which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." Because a "compilation" is further described as including customer lists, the U.S. law may be broader.

For a discussion of this area of law in the United Kingdom, see Coleman, Protection of Innovation under the Common Law and in Equity, in PATENTS IN PERSPECTIVE 18 (Phillips, ed. 1985).

[n.32] This is basically contract law, but the obligation may be implied from the facts or arise from operation of law as well as from a written document, see e.g., Coleman, supra, at 21.

[n.33] This is basically tort law and requires no formal dealings between the parties -- or that they even know one another prior to occurence of the tort. Obtaining another's secrets by theft, bribery or otherwise tortious or criminal acts is clearly an "improper" taking and forbidden in the U.S. However, whether other means short of independent origination or reverse engineering (duplication from a product acquired in the marketplace) are "improper" is an open question. See, e.g., Field, supra note 1, at 83.

[n.34] See Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1976), where these distinctions were found adequate to avoid a conflict between the U.S. federal patent law and the state trade secret laws. However, the formula for Coca-Cola is a well known example of a trade secret which has been maintained for a very long time.

[n.35] See, e.g., W. CASEY et al., ENTREPRENEURSHIP, PRODUCTIVITY, AND THE FREEDOM OF INFORMATION ACT 165 (1983).

[n.36] One of the ways to demonstrate "nonobviousness," see supra note 20, is to show that the result obtained by the invention is not what those skilled in the art would expect. See, e.g., U.S. v. Adams, 383 U.S. 39, 51 (1966).

[n.37] U.S. v. Generix Drug Co., 460 U.S. 453 (1983).

[n.38] See, e.g., REVIEW PANEL ON NEW DRUG REGULATION, FINAL REPORT, 33 (U.S. Dept. Health, Ed. & Welfare 1977). In fact, in Public Citizen Health Research Group v. Food and Drug Administration, 704 F.2d 1280, 1286-89 (D.C. Cir. 1983), the Restatement definition of trade secret was rejected in favor of one more akin to the WIPO definition of "know-how", supra note 33, for purposes of applying the U.S. Freedom of Information Act. Nevertheless, the court left open whether the data might be protected from disclosure as "commercial information," 704 F.2d, at 1290; see also Casey et al., supra note 38.

[n.39] Compilations of data, e.g., phone or other directories, have been long protected under U.S. copyright law, even though rights in the data themselves are quite limited. See, e.g., Patry, Copyright in Collections of Facts: A Reply, 6 J. COMM. AND THE LAW 11, 31 (1984).

[n.40] Drug Price Competition and Patent Term Restoration Act, Pub. L. 98- 417, 98 Stat. 1585 (1984). In lieu of indefinite trade secret protection for clinical data, Title I provides that the Food and Drug Administration (FDA), cannot use the data of a pioneer FDA licensee with an unpatented drug, as the basis for approval of a subsequent licensee until

four years have elapsed. Nevertheless, a subsequent FDA applicant for a drug marketing license apparently can collect original data as well as await the lapse of the period of exclusivity. Independent origin being a defense makes this more like copyright than patent protection.

In the case of a patented drug, however, there appears to be no period of exclusivity other than that afforded by the patent. However, Title II, subject to various conditions, offers the quite limited possibility of a patent being extended to make up for delay occurring during the approval process.

For an interesting illustration of the problems which can arise, see Nat. Ass'n. of Pharmaceutical Mfrs. v. Ayerst Fab., 830 F.2d (2d Cir. 1988).

[n.41] See generally, Field, supra note 1, at 76. Except as noted below, U.S. copyright law generally conforms to that in other countries which recognize copyright.

For an interesting argument that the United States has long protected nontraditional works with copyright, see Bernstein, Is a Plant a Form of Copyright?, 27 IDEA 31 (1986). See also the House of Lords decision in British Leyland Motor Corp. Ltd. v. Armstrong Patents Co. Ltd., 2 W.L.R. 400 (1986), reversing earlier decisions which had held that, e.g., an automobile muffler could be protected from duplication via copyright in the engineering drawings -- in the absence of evidence of access to those drawings themselves.

[n.42] If nothing else, the potential for use of software in medical applications would warrant some discussion. See, e.g., MICROCOMPUTERS IN PATIENT CARE (Eden and Eden, eds. 1981), suggesting that such technology could, at 47, help decentralize the practice of medicine or, at 49, help patients understand how to use pharmaceuticals.

[n.43] Depending on the work, performance or display may also be forbidden; see 17 U.S.C. § 106.

[n.44] See 17 U.S.C. § 102(b).

[n.45] But see 17 U.S.C. § § 409 and 410.

[n.46] 17 U.S.C. § 302(a). Exceptions are made when the author is not an individual or is unknown; see § 302(c).

[n.47] Access to a work must be shown where independent creation is asserted. See generally, Patry, supra note 39, at 202.

[n.48] But see Benson v. Coca-Cola, 795 F.2d 973 (11th Cir. 1986). See generally Patry, note 49, supra, at 203.

[n.49] A "free rider" is someone who gets the benefits of another's efforts without having to contribute thereto. Thus an independent creator is not a free rider. This writer has elsewhere argued that the patent law may go too far by stopping independent originators as well as free riders; see Field supra note 1, at 89.

See also Vaitsos, Patents Revisited: Their Function in Developing Countries in SCIENCE, TECHNOLOGY AND DEVELOPMENT: THE POLITICAL ECONOMY OF TECHNICAL ADVANCE IN UNDERDEVELOPED COUNTRIES 71, 86 (C. Cooper ed. 1973), at 88. Compare Kitch, supra note 22.

Unfortunately, Vaitsos offers no alternative mechanism for recovering risk capital. Also, copyrights suffer from a deficiency which would not, without modification going well beyond the shortening of term, make them appropriate for situations other than those presented by regulatory compliance data.

[n.50] Such numbers (four years in this case) represent nothing short of crude guess work or political "horse trading."

In a somewhat related vein, Fritz Machlup has observed:

> If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, itwould be irresponsible, on the basis of our present knowledge to recommend abolishing it. The last statement applies to a country such as the United States of America -- not to a small country and not to a predominantly nonindustrial country, where a different weight of argument might well suggest another conclusion. [An Economic Review of the Patent System, at 80, Study No. 15 of the Senate Subcomm. on Patents, Trademarks, and Copyrights of the Comm. on the Judiciary, 85th Cong., 2d Sess. (1958).]

Compare the observation of Frank Press that: "For twenty-five years the question of innovation and America's ability to innovate has been . . . around; it's been studied to death;" Industrial Innovation: Joint Hearings Before the Senate Comm. on Commerce, Science and Transportation, and Select Comm. on Small Business, and House Comms. on Science and Technology, and Small Business, at 40 (part 2), 96th Cong., 1st Sess. (1979) [hereinafter Carter hearings].

It seems that Machlup suggests ignorance than warranted, and Press suggests less; there is yet a great deal to be done to fine-tune intellectual property systems. For a somewhat more pragmatic view, see D.P. O'Brien, Patents: An Economist's View, in PATENTS IN PERSPECTIVE, supra note 31, at 32.

[n.51] The Patent System and the Modern Economy, at 76, Study No. 2 of the Senate Subcomm. on Patents, Trademarks, and Copyrights of the Comm. on the Judiciary (1957). In all, there were 28 such studies commissioned. In addition to the Machlup study

quoted, supra, others of possible interest include: No. 1, V. Bush, Proposals for Improving the Patent System (1956) and No. 26, V. Abramson, The Patent System: Its Economic and Social Basis (1960).

[n.52] See 42 U.S.C. § 7608; this section was added by § 308 of the Clean Air Amendments of 1970, Pub. L. 91-604, 84 Stat. 1676. See also, Conference Report No. 91-1783, at 17 reprinted in 1970 U.S. CODE CONG. & ADM. NEWS, 5356, 5390. The main difference between this and the scheme discussed in note 74, supra, is that it provides for the license being sought directly in a court instead of through an arbitral/regulatory process which is then subject to court review. In neither case do the statutes give any indication of how a "reasonable" license is to be calculated.

[n.53] See Carter Hearings, supra note 50, at 3 (part 1), comparing growth figures for Japan, West Germany, the United States of America and the United Kingdom. Those hearings focused on the relatively poor showing of the United States -- particularly the extent to which flaws in the patent and antitrust laws might have played a role. The result has been a number of legislative changes designed to encourage innovation.

As mentioned supra note 50, it would be impossible objectively to justify any one of them. Nevertheless, it is widely believed that the climate for innovation in the United States has materially improved. Within fairly broad limits, such perceptions are apt to be self-fulfilling. Given the lag time between predictions and results, and the difficulty of isolating economic variables for empirical research, one must assume that specific investments are made on the basis of perceived, not actual, ability to recoup risk capital. See also, Field supra note 1, at 75 -- especially fns. 105-107.

[n.54] Machlup, supra note 50, at 21, lists four reasons for granting such protection: It (1) enables one to obtain the fruits of his or her labor to which they are entitled under "natural law," (2) provides a reward for socially desirable work by granting a monopoly, (3) provides a profit incentive for inventors and their capitalist backers, and (4) encourages inventors to disclose secrets which they might otherwise withhold.

It should be mentioned, however, that no reward will be forthcoming if there is no market for the new work -- irrespective of anything which the law might provide. See, e.g., Field, supra note 1, at 69 -- particularly fns. 64 and 65. Unfortunately, the typical U.S. citizen, and apparently others as well, assumes that a patent will, of itself, generate income.

[n.55] Supra note 23. Nevertheless there is an occasional need to rank the rationale set forth by Machlup, supra. For example, in Kewanee, supra note 34, the U.S. Supreme Court rejected an argument that trade secrets (or "know- how") should be accorded no protection in view of their failure to serve the last of those purposes. In doing so, the Court recognized that not all useful innovations would qualify for a patent and that failure to recognize trade secrets might encourage inventors to be more aggressive in seeking

protection for trivial inventions. It thus ranked disclosure as less important than enabling the recoupment of risk capital -- particularly where increased pressure to patent unqualified inventions might do more harm than secrecy in inhibiting innovation.

[n.56] See, e.g., van Ravenswaay, Government Patents and the Public Interest, 19 IDEA 331 (1978). The proposition was then highly debatable, but some of the ambiguity has been resolved by subsequent legislation; see Pub. L. 96-517, 94 Stat. 3019 (1980). That law, with subsequent amendments, appears in 35 U.S.Code. Ch. 18 permits, inter alia, the granting of exclusive licenses, subject to various restrictions, in government owned patents.

[n.57] For an assertion to the contrary, see Gorodissky, Terms and Forms of Transfer of Soviet Technology and Know-how to Developing Countries, WORLD INTELLECTUAL PROPERTY ORGANIZATION, THE IMPORTANCE OF THE PATENT SYSTEM TO DEVELOPING COUNTRIES 175 (1977) -- hereinafter WIPO Symposium.

[n.58] Even a system of public recognition would qualify. For some activities, particularly those requiring a large amount of individual effort, recognition and the income which it, in turn, could generate, might be ample to secure the desired result. Thus, for example, new surgical procedures have been developed even though none of the more formal mechanisms discussed earlier were available.

[n.59] It can be helpful, too, in a socialist system. With regard to the Hungarian system, see, e.g., Horvath, Patent Protection as an Efficient Means for Establishing and Developing a National Pharmaceutical Industry, in WIPO Symposium, supra note 57, at 175. However, O'Brien, supra note 50, at 38, argues that the Soviet system furnishes inadequate incentives.

[n.60] THE EXPECTED RETURN FROM PHARMACEUTICAL RESEARCH, 11 (1975).

See also, Calonius, European Drug Companies, Their Own Markets Stagnating, Are Pressing for Growth in the U.S., Wall St. J., April 12 1985, at 32. Apparently even though U.S. drug firms' annual profit growth has fallen in the past few years, the U.S. market is very attractive because of the lack of price controls.

[n.61] For a refutation of the "better mousetrap myth," see A. KELLEY et al., VENTURE CAPITAL 12 (1973).

[n.62] Pub. L. 97-414, 96 Stat. 2049 (1982). See generally, Orphan Drug Act, House Report No. 97-840, reprinted in 1982 U.S. CODE CONG. & ADM. NEWS 3577. See also ORPHAN DRUGS AND ORPHAN DISEASES: CLINICAL REALITIES AND PUBLIC POLICY (G. Brewer, ed. 1983).

[n.63] 21 U.S.C. § 360bb (a)(2); emphasis added.

[n.64] Among others, § 360cc provides that a second manufacturer may not be licensed to sell an orphan drug within seven years of the first approval. Also 96 Stat. 2065 amended the patent law to add § 155, providing the possibility of a patent term extension.

[n.65] In 1985, Congress, citing the success of the legislation, nevertheless felt obligated to amend the statute. See House Report No. 99-153, at 3, reprinted in 1985 U.S. CODE CONG. & ADM. NEWS 301, 303. Originally § 360cc made the exclusive period available only to unpatented drugs; see 96 Stat. 2050. However, as an added inducement, Pub. L. 99-91, 99 Stat. 387 expanded its coverage to patented drugs. Why this was needed in view of 35 U.S.C. § 155 is unclear.

More recently, it appears that the inducements may be larger than necessary. See Noah, Rare-Illness Drug Rivals Get a Boost, Wall St. J., April 27, 1990, at B1, col. 6.

[n.66] Distinct chemical compounds to the extent that they accomplish the same result are therapeutic equivalents. Even in the United States, the first inventor of an analgesic would not be able to claim a process of analgesia, thereby preventing others from selling different drugs to accomplish the same result. One cannot patent a result as such; see, e.g., Steinfur Patents Corp. v. William Beyer, 62 F.2d 238, 241 (2d Cir. 1932).

Generic equivalents are copies of the same product. Thus, depending on the patentability of pharmaceuticals, as such, a patent could prevent others from selling copies during its term.

[n.67] Indeed, at least part of the motivation for the U.S. orphan drug law, supra note 62, was the thought that private innovation would be more efficient. See House Report, supra note 65, at 6. Nevertheless, § 360ee appropriates $4 million for each of the years 1986-88, with the subsidies being available to profit as well as to nonprofit entities.

[n.68] As discussed earlier, this can arise because the innovation is unprotected or because the protection is unenforceable.

[n.69] But see, NARIN et al., THE QUEST FOR KNOWLEDGE: CONTRIBUTIONS OF U.S. PHARMACEUTICAL INDUSTRY SCIENTISTS 34 (PMA 1986). There, based on the costs per published research paper funded by the National Institutes of Health, the authors estimate the value of industrially funded papers at $150 million per year in 1982 dollars. See also, Waldoz, Pharmaceutical Firms Prepare to Introduce New Wonder Drugs, Wall St. J., Jan. 22, 1981, at p. 1, col. 1.

[n.70] Under U.S. law there is a requirement that the invention be applied to a useful end. See, e.g., Brenner, supra note 22. However, 1 WIPO § 112 explicitly excludes such subject matter.

[n.71] Except for military secrets, efforts to restrict access by foreign nationals are generally regarded as counterproductive and likely to inhibit local innovation. However, it is sometimes difficult to draw a line; see, e.g., Athanasion, Encryption Technology, Privacy, and National Security, Technology Review, Aug./Sept. 1986, at 57.

[n.72] See also WIPO Symposium, supra note 57, at 179. There Horvath relates the situation in Hungary in 1977:

It is incontestable that the difficulty of finding a new and potent drug is constantly increasing. Some 20 years ago, from 3,000 new compounds synthesized and pharmacologically and clinically tested only one could be introduced as medicine in therapy. Nowadays, this ratio has changed to between 8,000 and 10,000 to 1. In view of the thalidomide (CONTERGAN) catastrophe, the regulations of drug safety became extremely severe, resulting in the prolongation of the time needed for testing and arise in expenses. Today, a successfully accomplished drug research campaign takes some 6 to 10 years and expenses amount to between 10 and 15 million US dollars for each new drug.

[n.73] Id., particularly the discussion of thalidomide. See also, OFFICE OF TECHNOLOGY ASSESSMENT, POSTMARKETING SURVEILLANCE OF PRESCRIPTION DRUGS (1982), pointing out the difficulty of detecting long term effects from clinical trials alone.

[n.74] See, e.g., Gelardin and Swiatek, The Oraflex Story, Indianapolis Star, Aug. 7, 1983, at p. 1F.

[n.75] See, e.g., Holland-Rantos Co. v. U.S. Dept. H. Ed. & Welfare, 587 F.2d 1173 (D.C. Cir. 1978).

[n.76] See generally, e.g., Kitch, The Vaccine Dilemma, 2 ISSUES SCI. & TECH. 108 (1986). At 115-17, he discusses the swine flue debacle.

[n.77] Horvath, supra note 72, at 181, provides some interesting data concerning France. With 1960 = 100, he shows the price index for various sectors of the French economy in 1975. Whereas wages have an index of 522; the average of the economy, 232; cleaning articles, 241; drugs are at 135. It is difficult to imagine how prices could have been kept so low and yet permit a reasonable return on investment except as explained by Schwartzman, supra note 60.

[n.78] See, e.g., Kirim, Reconsidering Patents and Economic Development: A Case Study of the Turkish Pharmaceutical Industry, 13 WORLD DEVMT. 219 (1985). At 220, he mentions that Turkey, in 1961, became the first of several countries to abolish all patent protection for pharmaceuticals in order to increase technology transfer, competition and local research and development.

The third objective is most central here. It seems that Turkish research and development of pharmaceuticals would have halted except for two other matters. First, as above, trade secret or know-how protection may play a role in supporting innovation. Second, not only is there a great deal of literature which is available everywhere (including expired patents), but also every patent in the world is free to be practiced in any jurisdiction where it is not in effect. Nevertheless, at 232-3, Kirim concludes that the abolition, over the past 25 years or so, at best, did not accomplish its ends.

[n.79] See, e.g., Brody, Taiwan: From Imitation to Innovation, High Technology, Nov. 1986, 24 -- one of a series of articles under the general title, "Four Tigers of the Orient." At 27, Brody quotes Wang Chi-Wu, vice- chairman of the National Science Council, "Hepatitis is our national disease. The carrier rate is 10-12%, making it 100 times as prevalent as in the United States."

Where there is such disparity in incidence between countries which do and do not have strong patent protection for pharmaceuticals, one can be sure that the private resources devoted to addressing the disease will be suboptimal from the standpoint of the country with the higher incidence of disease and the lower level of intellectual property protection. In some circumstances, measures such as the U.S. orphan drug law may help; see notes 62-67 and discussion, supra. However, the level of innovation may still be quite low as a function of incidence elsewhere.

[n.80] Schwartzman, supra note 60, at 12, put it succintly:

The policies of other governments toward the drug industry can be seen as restricting returns to R&D. As a result, foreign R&D would decline were it not for the returns available in the United States. This may seem to impose an unduly large share of the costs of drug R&D on U.S. consumers and taxpayers. The remedy, however, is not to reduce U.S.drug prices to the low levels prevalent elsewhere and thereby further reduce

the profitability of research. In fact,... the current expected rate of return. . . is already well below the level necessary to attract continued investment. If this were generally known, other governments might be more cautious in adopting policies which tend to reduce the industry's investment. . . . [Emphasis added.]

[n.81] See, e.g., Final Report, supra note 38, at 70-82.

[n.82] Over the past several years, this writer has had occasion to discuss these problems with a number of such persons who visited the Law Center under the sponsorship of WIPO.

[n.83] See generally, e.g., Grundmann, Foreign Patent Monopolies in Developing Countries: An Empirical Analysis, 12 J. DVMT. STUDIES 186 (1976) or Tumwine-Mukubwa, Patents and Technology Transfer to Underdeveloped Countries, 7-9 ZAMBIA LAW J. 1 (1975-77).

For an explanation of the low number (in absolute terms) of foreign filings, see also, e.g., Blair, supra note 7, at 2: His currently low estimate was that it would cost a U.S. company $50,000 to file the average five patents needed to protect a single new product in only ten of the then- available 160 countries.

Pharmaceuticals, as discussed earlier, present a more complex situation. Patent protection may be unavailable or subject to various restrictions which make the grant essentially valueless. Such factors are probably related to the fact that U.S. pharmaceutical manufacturers derived less than half of their income from foreign sales; see PHARMACEUTICAL MANUFACTURERS ASSOCIATION, 1983-1985 ANNUAL SURVEY REPORT 9 [data for 1982 and 1983].

[n.84] See, e.g., OFFICE OF MANAGEMENT & BUDGET, BUDGET OF THE UNITED STATES, APPENDIX (Fiscal Year 1987). At I-A13, the 1986 estimated budget for the Copyright Office is about $17 million, with approximately $14.5 million offset by fees and the value of deposited works. At I-F29, the 1986 estimated budget for the Patent and Trademark Office, which is not easily separated for patents and trademarks, is about $228.2 million, with $119.5 million being offset with fees.

[n.85] This, however, as explained below is essentially a "registration system."

[n.86] All of these are presently used to some extent. With reference to the recognition of foreign patents, see, e.g., Vaitsos, supra note 49, at 89.

Vaitsos makes much of the fact that many U.S. patents had been invalidated by its courts 30 years earlier -- for more recent data and discussion of its significance, see Field, supra note 1, at 75 -- but this should be cause to rejoice. Insofar as the outcome of such

litigation is filed with the U.S. Patent and Trademark Office under 35 U.S.C. § 290, it should be easy to avoid invalid U.S. patents, in any case, being foisted upon other countries.

When all is said and done, however, the major inhibitor to developing countries' recognizing foreign patents -- e.g., subject to various potential local restrictions on the length of term -- is probably that it smacks of colonialism. However, that should not be a hindrance to countries' recognizing the results of an international novelty search.

Indeed, the whole purpose of the Patent Cooperation Treaty was to make worldwide patent systems more efficient. No country is so wealthy that it or its citizens can afford to waste money. See, e.g., Bartels, The Advantages of the Patent Cooperation Treaty (PCT) for American Applicants, 65 J.P.O.S. 387 (1983). Compare Winner, supra note 19.

[n.87] The difficulty arises in the mechanical arts where drawings are more important than the words used to describe them. In contrast, words are easily searched by computer. The chemical arts have the further advantage of standardized terminology.

[n.88] See, e.g., Haertel, The Draft Conventions for a European System for the Grant of Patents and for the European Patent for the Common Market, 1 IIC 289, 290-91 (1970).

[n.89] 35 U.S.C. § 282. Compare 1 WIPO § 158 which makes no mention of a presumption.

[n.90] See, e.g., Pakuscher, Centralized Jurisdiction in Patent, Utility Model and Trademark Matters in the Federal Republic of Germany, 10 IIC 671 (1979). See also ARBITRATION OF PATENT AND OTHER TECHNOLOGICAL DISPUTES (Field, ed. 1977), published as 18(4) IDEA, and Field, Patent Arbitration: Past, Present and Future, 24 IDEA 235 (1984).

[n.91] See, e.g., Stauder, The Future of Patent Infringement Proceedings in Europe, 6 IIC 168, 171 (1975). However, as pointed out there, only recently has attention turned from the granting of patents to the efficient enforcement of them.

[n.92] See, e.g., Kitch, The Law and Economics of Valuable Information, 9 J. LEGAL STUDIES 638 (1980).

[n.93] Compare Landsberg v. Scrabble Crossword Players, Inc., 736 F.2d 485, 488 (9th Cir. 1984) with Whelan Associates, Inc. v. Jaslow Dental Laboratory, Inc., 797 F.2d 1222, 1234 (3d Cir. 1986).

[n.94] See, e.g., Means, India on the Move, Mass High Tech, Sept. 29-Oct. 12, 1986, at 1. In an otherwise favorable review of the potential for investment in India, Means nevertheless observes, at 18:

Probably one of the most troubling features of doing business in India has been the fact that, while it is possible to develop contracts protecting patents and copyrights, such agreements are virtually unenforceable in Indian courts. Because of that it is important to be sure that selected joint venture partners or distributors have a strong reputation for ethical business practices by U.S. standards.

While India apparently is not as much of a problem as other developed and developing countries, such a reputation, earned or not, is likely to have an effect on innovation.

Moreover, India clearly fails to offer much protection for pharmaceutical innovation; see, e.g., NARAYANYAN, PATENT LAW 65 and 66 (Eastern Law House: Calcutta 2d Ed. 1985). This probably accounts for a fraction of U.S. sales sufficiently miniscule that India's at least 100 million "middle class" citizens are not mentioned in the PMA Report, note 83, supra.

Finally, with regard to this and the following note, I certainly do not intend to suggest that either India or Thailand are unique. On the contrary, there is reason to believe that a number of other countries are similar, perhaps offering even less protection for intellectual property.

[n.95] See, e.g., White, Thailand's Drug Copying Companies Keep Prices Down, Upset Foreign Firms, Wall St. J., December 1, 1986, at 25. There it is reported that, because of failure to allow patent protection for pharmaceuticals, local consumers may be able to purchase copies of Tagamet (R) (ulcer treatment) for a small fraction of SmithKline's price. It is also mentioned that those copies may lack any active ingredient!

[n.96] I have been unable to locate information concerning the number of diseases which exist in, e.g., Thailand, or India. Whereas individual governments might not have the resources needed to devise treatments, it seems likely that there are conditions which private firms could address if several countries with similar populations and climates were combined.

Indeed, even without such protection, it is possible that U.S. pharmaceutical firms will be able to help; see supra notes 62-67 and discussion. This follows from the fact that an "orphan" disease in the United States may well be far more common in other climates or populations.