Biotechnology Patents and Indigenous Peoples

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ABSTRACT

How do biotech patent systems affect indigenous peoples, particularly in relation to health products? This question raises two distinct issues. First, the question of biopiracy—to what extent do patent systems necessarily exploit traditional indigenous knowledge to produce valuable medicinal products? Second, the question of patenting gene-sequence and gene-product information taken from living organisms, especially human beings—how can we justify patenting naturally occurring substances? And how should we negotiate the myriad ethical issues that arise from doing so? This chapter argues that the core of the biopiracy problem is not the availability of patents based on traditional indigenous information but rather the unfair acquisition of knowledge and the inequitable sharing of profits derived from developing such information into a valuable product. Solving this problem requires ensuring that traditional information is fairly acquired and that fair compensation is paid to the group from which the information derives. In regards to patenting gene-sequence and gene-product information, this chapter concludes that such issues equally affect indigenous and nonindigenous populations and that the best way to address them is by making policy changes.

1. INTRODUCTION

Much has been written on the general subject of how modern systems of intellectual property do, can, and should affect the lives and welfare of indigenous peoples.[1] When the focus is on biotechnology, however, copyright does not play much of a role in protecting functional inventions,[2] and while trade secret is important, no biotechnology issues specific to the interests of indigenous peoples are apparent.[3] This paper therefore tries to bring to light some of the issues involving patent rights in biotechnology that have become the legitimate concerns of indigenous peoples.

Two issues, in particular, dominate the literature about biotech patents in the context of globalization and indigenous peoples' rights. The first is the use of traditional indigenous knowledge as a starting point for producing a valuable product, such as a medicine. The second is the patentability of gene-sequence and gene-product information taken from living organisms, especially human beings. While the two are perhaps related (when, for example, the genetic information is taken from an indigenous group), it may be helpful to attempt at least a conceptual separation between the two issues in order to clarify the analysis. The first issue raises questions of so-called *biopiracy* of indigenous information by developed countries. As such, the issue directly implicates the rights of indigenous peoples, even though, as discussed below, most problems can be resolved when a few basic principles of patent law are brought to the fore. The second issue, especially when information concerning the human genome is involved, necessitates important ethical inquiries and poses fundamental questions for patent law and patent policy. Most of these problems, however, are

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not specific to biotech patents as they impact indigenous peoples, and indeed many of them impact everybody, whether they live in a developing or a developed country. Parts 2 and 3 of this chapter develop these arguments.

Having set aside patents as an important cause of biopiracy and having shown that gene and gene-product patents do not pose indigenous-peoples-specific problems, Part 4 attempts to outline the real problems that the world patent system poses for developing countries. Part 4 concludes that, while it is difficult to make the case that adopting a modern patent system directly benefits developing countries, the worldwide patent system also has little direct adverse effect. The problem is not so much that the existence of patents prevents the diffusion of biotechnological advances in developing countries but that there is a danger of *leakage* through the parallel importation of patented products from developing countries back to developed countries with strong patent systems. Too much leakage can impair incentives for innovation even within the developed world, and that is not good for anybody.

This last conclusion rests upon a basic assumption that underlies the entire paper. It remains a matter of serious debate whether and to what degree patent law in general serves as an incentive to innovate or commercialize innovations. Is patent law too strong or too weak? Is the period of patent protection too long or too short? We do not know very much about how the incentives of our IP systems, especially patent and copyright, work in practice.[4] This paper does not aim to undertake a fundamental analysis of the patent system generally. It therefore assumes that the patent system in developed countries, somehow or another, generally achieves its basic goal of stimulating innovation by providing a period of exclusive rights to those whose intellectual creations qualify for patents.[5]

2. BIOPIRACY AND PATENTS

2.1 *The basic problem*

The biopiracy problem is exemplified by the taking of indigenous peoples' information about the medicinal effects of a plant or other natural substance and the developing of that substance into a patented and popular drug by a large pharmaceutical company.[6] The fundamental question is whether or to what degree it is fair for outsiders to use, and especially to profit from, knowledge of this type. Paterson and Karjala have considered this problem from the point of view of indigenous rights outside of the traditional patent and copyright regimes, concluding that a statute based on traditional principles of contract and unfair competition law could address and likely resolve this problem without raising the fundamental difficulties that would result from using traditional IP rights under patent or copyright to achieve the desired goal.[7] This paper addresses the problem from the other side: What, if anything, about patent law creates or exacerbates the problem of biopiracy?[8]

2.2 *Physical vs. informational resources*

In considering the problem of biopiracy, it is vital to distinguish between the use of a physical resource and the use of an informational resource. Physical resources are depletable, and what one person uses is no longer available for another. Informational resources are nondepletable (infinitely multipliable) in that one person's use of information does not prevent another from making the same or a different use of it.[9] In one of the strongest condemnations of *biocolonialism* that I have seen, Professor Whitt states, "*By allowing access to and exportation of data, biocolonialism concentrates knowledge about a people and their environment in the hands of an imperial power*."[10] This is simply wrong. Publicly available knowledge cannot be "concentrated" in the hands of anyone. Perhaps Professor Whitt intended to say that the *use* of some indigenous knowledge is concentrated under the patent system in outsiders who obtain foreign patents based on some of the exported data. But even that would not be correct if the implication is that the source peoples can no longer use their traditional knowledge in their traditional ways.

On the other hand, it is also incorrect to say, in general, that a patent owner is not harmed by the sale of unauthorized copies of the patented

product, on the ground that the patent owner remains free to sell any amount of the product he chooses. There is absence of harm only if the purchase of the pirated product is not a substitute for purchase of the patented product. While this is often the case because some purchasers of pirated products would wholly forego use of the product rather than pay the higher price for an authorized version, there are likely to be at least a few people who would pay the higher price if less expensive versions were unavailable. Moreover, if pirated drugs sold at a low price in poorer countries do not reach patients unable to afford the authorized version, and these drugs find their way back to developed countries, they may displace further sales and thereby reduce the patentee's profits.

IP is thus fundamentally different from tangible property, which is why the legal rules relating to IP must also be different. This point is obvious, indeed almost trite, to IP scholars, but it seems to be often overlooked in the literature on biopiracy. Nondepletability of informational resources implies that, once the information is publicly available, it is economically inefficient to afford exclusive rights in it.[11] We grudgingly accept the limited-term exclusive rights of patent and copyright, notwithstanding the ex post economic inefficiency, because we believe that they serve as an incentive to the creation of desirable works. In other words, we accept the immediate economic inefficiency for the duration of the rights in the belief that in the long run we will have more and more desirable works overall. Calls for exclusive rights in information outside the patent and copyright regimes, especially for rights in information that is already publicly known, cannot be justified by a similar creation incentive. Some other justification is necessary.

I will note only in passing that the *other justification* will be difficult to find in so-called "natural rights" theory. Natural rights theory ("*I made it so it's mine*.") carries no limitation on the duration of protection, nor does it distinguish between the rights afforded by patent and copyright for works that are equally intellectually creative. Some of the most creative works of human history, like Newton's theory of gravity or Einstein's theories of relativity, get no protection anywhere under either the patent or the copyright regime, which is difficult to explain if natural rights to one's creative ideas and discoveries are the basis for exclusive rights. In the case of indigenous populations who assert natural-rights based exclusive rights in information they have developed or discovered, mutuality demands a similar recognition of rights in information developed elsewhere. Such recognition, however, would surely cost any given group much more than it gains.

2.2.1 *Depletion of physical resources*

To the extent that criticism of biopiracy focuses on the depletion of a physical resource, the problem may be controlled under the environmental regulation of the source country.[12] In other words, this is not an IP rights question but a tangible property question. There is no significant debate today about whether taking such resources without authority (theft) or by fraud should be unlawful. But a patent elsewhere on the active ingredient of a plant simply has nothing to do with the problem of environmental depletion with regard to the plant. If the patentee can manufacture the active ingredient synthetically, that activity does not contribute to further depletion. If the patentee needs the plant itself but can grow it away from its original source, again there is no contribution to depletion in the source country. And if the plant grows only in the source country, the existence of a patent abroad or even in the source country itself gives no right to take the physical plant in order to manufacture the patented product. Although a patent on the active ingredient, if recognized in the source country, would give the patentee the legal right to prevent others from taking the physical plant for the purpose of extracting the active ingredient, exercise of that right would likely mean *less* depletion of the physical resource, because it would no longer be in anyone's economic interest to take more of it than whatever is required by traditional uses. The patent thus may add a little something to the source country's power

to regulate depletion, but it cannot exacerbate the depletion if the source country chooses to prohibit the patentee's taking of the plant.

2.2.2 *Depletion of informational resources*

Where the complaint is that the source country's people are not rewarded for supplying the information leading to the invention, several points should be borne in mind. First, if the information is obtained legally and results in a patented invention, that patent cannot cover any prior use that the source country's people made of the original resource.[13] Indeed, if the end product is a naturally occurring substance, that country may be in a position to refuse a patent altogether. Even U.S. patent law denied patents on naturally occurring substances until relatively recently, regardless of whether they had been isolated and purified.[14] Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires member states to have patent laws that protect inventions that are *"new, involve an inventive step, and are capable of industrial application*,"[15] but TRIPS nowhere defines what *new* means. Any member state is therefore free to deny patents covering naturally occurring substances or traditionally used methods of treatment on the ground that they are not *new*. According to TRIPS Article 27(3)(a), a member state can also deny method patents covering the use of naturally occurring substances, purified or not, for therapeutic or diagnostic purposes. Moreover, following traditional U.S. law, a member state could find that isolating and purifying such substances lacks *invention* and therefore does not involve an *inventive step*.

Second, where the end product is a substantial modification of the original source[16] and constitutes a true invention that has, let us assume, greater therapeutic value than the original source, a patent in the source country will indeed have the effect of allowing the patentee to charge, for the period of the patent, a monopoly price in that country for use of the new drug (assuming there is no effective substitute that could hold down the price). If people in the source country cannot afford the new drug, their position is no different from that with respect to any other new drug, whether or not patented, or indeed any other product, that they cannot afford. They have not lost anything that they previously had. They can continue to use the original source as they always did, and they now have, in addition, the possibility of more effective therapy (if they can afford it), as will indigenous (and other) peoples elsewhere who never before had even the original treatment.[17] The wider availability of both the original treatment and the newly developed drug after biopiracy perhaps deserves more emphasis. In her article referenced above, Professor Whitt states:

> *Across the planet, at an accelerating pace, collectively owned traditional medicines and seeds are being privatized and commodified. Altered sufficiently to render them patentable, they are transformed into the 'inventions' of individual scientists and corporations and placed on sale in the genetic marketplace.*

But it is difficult to see just how the people who *collectively owned* the forerunners of the now improved medicines and seeds have been harmed. Moreover, the improved products are now available to a much wider range of users, including indigenous peoples from other parts of the globe. The patent may, indeed, mean that the price everywhere is higher than it would be were the product available without patent protection. It remains a fair question, however, whether the improved product would exist at all but for the patent incentive. We must bear in mind that no one is forced to buy the new product. Everyone is free to continue using whatever he or she has used in the past. Those who do choose to buy patented seed, for example, presumably believe that the higher seed cost is more than compensated by the beneficial improvements brought about by the newer product. It is true that patent law does not do much to alleviate the most important problems facing the people of developing countries, such as poverty, contaminated water, and lack of education. In developing countries, 840 million people currently suffer from malnutrition and 1.3 billion are afflicted with poverty.[18] But, to the extent that patent law serves as an incentive to the development of new products, especially medicines and improved agricultural varieties, it increases the options of everyone,

including indigenous peoples, marginally to improve their lives. If the goal is to alleviate the wretched conditions under which many people in developing countries live, it cannot be right to say that information held by some of them that could be useful in addressing parts of the problem should remain confined to the small group discovering it, provided at least that the information is acquired in ways that are both legal and moral. It is also important to note that most indigenous groups will have no resources at all, genetic or otherwise, on which profitable products can be built. All such people potentially benefit if patent law serves as an incentive to create products that meet important human needs.

Third, denying patents in these cases will not necessarily stop the supposed *misuse* of the original information. It may well be *commodified* by an outsider anyway, in the hope of sufficient return from first mover or secrecy advantages. If, therefore, we are to accept the economic inefficiency of recognizing exclusive rights in information held by indigenous societies, some justification that outweighs the inefficiency should be offered. As mentioned above,[19] creation incentives are not involved, which distinguishes information collected from indigenous peoples from information that can be protected by patents and copyright. Claims of unfairness in these scenarios should articulate precisely what is unfair about developing, perhaps at great expense, something new and useful out of existing knowledge (which is what the patent incentive is all about). If the unfairness in a particular case is acquisition of information by fraud or other surreptitious or dishonest means, existing legal principles may supply a remedy, or at least an approach for statutory regulation. If the unfairness is lack of equal bargaining power because of ignorance of western legal customs, again a limited statutory approach setting default assumptions on agreement to pay a royalty or some other compensation may be in order. Cases in the United States show that using information to create a patented product without adequate disclosure to the source of the information is not limited to developing countries or indigenous populations.[20] Breach of a confidential relationship, fraud, invasion of privacy, and even more general notions of unfair competition may, in a given case, justify accepting the economic inefficiency of protecting traditional information.

It is possible that the availability of patents based on information derived from indigenous peoples creates a perverse incentive for western scientists and their employers to attempt to gain information through nefarious means, such as fraud or breach of confidence. One could surely find examples of creative inventors who have been cheated out of the financial return that would have been theirs under patent law by the illegal or unsavory actions of others. By providing exclusive rights, patent law does produce the occasional bonanza for the patentee, and logically the hope of such a bonanza would lead to at least some activity aimed at getting an unfair share of the prize. But this is again simply a general feature of patent law and property rights in general. The existence of property rights is indeed a prerequisite to theft. Biotech patents would seem an unlikely candidate for supplying a *special* incentive in this regard, given that most inventions require a huge investment to convert the initial information into a commercial product and test it for health and safety. Indeed, the numerous *enclosure* laws that a number of developing countries have adopted to maintain control over their genetic heritages may be driving researchers away from bioprospecting, due to the difficulty of identifying source material that will lead to a valuable product and to the complexity of achieving the necessary consents.[21] In other words, the causal link between a biotech patent and any assumed fraud in obtaining the information on which it is based from indigenous sources is weaker than for many other products. Moreover, the vast majority of patents, biotech and otherwise, are the result of unobjectionable behavior (that is, for example, there exists no fraud or breach of confidence). We therefore return to the need to identify the behavior that is wrongful when information derived from indigenous sources is turned into a patented product and to look for an appropriate sanction for that behavior.

Some commentators assert more generally that indigenous peoples often object to the

use of their traditional knowledge on ethical grounds, arguing that IP should be treated as a pure public good.[22] Indeed, as Sabrina Safrin has argued, the numerous *enclosure* laws that a number of developing countries have adopted in an effort to maintain control over their genetic heritages may be driving researchers *away* from bioprospecting, due to the difficulty of identifying source material that could lead to a valuable product and to the complexity of achieving the necessary consents. No one can say that this view is *wrong*, as it comes down in the end to a question of fundamental values. Still, the question remains whether the members of any group following this belief should retain exclusive rights, with respect to people outside the group, to use information they have discovered. If the information is freely available simply by visiting the group and observing their lifestyle, and if a visitor does this without fraud or duplicity, saying that the visitor cannot use the information as the basis for creating a new, and perhaps patentable, product is equivalent to recognizing exclusive, perhaps group, rights in the information. Maybe such recognition can be justified on the ground that the group's culture should be respected by outsiders. But if this is the claim, we should be able to articulate it in terms of western notions like breach of confidence or privacy rights. Something besides "*We discovered it so it's ours*" is necessary unless one takes the extreme step of embracing a full-fledged natural rights basis for IP or one simply has a preference for economic inefficiency over economic efficiency.

A related view is that patents impoverish indigenous cultures by ultimately providing products that displace traditional sources and methods, leading to a loss of biodiversity and, eventually, an irretrievable loss of crucial elements of traditional knowledge and culture. Few would deny that such losses occur and that these losses represent ones suffered not only by the indigenous group but by all who, but for the displacement, might later have learned from such knowledge how to improve the physical or spiritual quality of their lives. If preventing the loss of indigenous culture is the goal, however, it is quite myopic to focus attention on patents derived from traditional information. Most indigenous groups do not end up being the source of information that leads to profitable patents. Moreover, even for those groups that do supply information leading to a patent, that specific information is only a small part of their entire cultural heritage, much of which is under threat from other sources, like music, films, and clothing. Indeed, to the extent that patents inhibit technology transfer to indigenous cultures (due to higher prices or lack of local implementation know-how), those patents should actually impede slightly the deleterious effects of the onslaught of western culture. Eliminating patents for advances in biotechnology will not eliminate biotech innovation or the adverse effects of patented and unpatented advances in other fields of technology. Needless to say, eliminating biotech patents will have no effect on cultural losses resulting from the adoption of western style music, cinema, clothing, and fast food. In short, the harmful influences of western life style for indigenous cultures are serious and real. Unfortunately, they will not be ameliorated by what would inevitably be minor adjustments to patent law in western countries or in locales of traditional cultures.

The core of the biopiracy claim thus appears to be not the availability of patents based on traditional indigenous information but rather the unfair acquisition of the knowledge and the absence of fair sharing of the profits that ultimately derive from developing it into a valuable product. The problem to be addressed becomes one of ensuring that traditional information is acquired in a fair and equitable way and that fair compensation is paid to the group from which the information derives. Some developing countries have proposed amending TRIPS to mandate disclosure of the source of genetic resources used in an invention, of evidence that the country of origin had consented, and of evidence of fair sharing of the benefits as conditions to the issuance of a patent. My colleagues George Schatzki and Ralph Spritzer have suggested to me the possibility of refusing to enforce any patent based on information that has been unfairly acquired, or of placing on enforcement the condition that a fair sharing exists (as determined by court ruling)

between the patent holder and the people who served as the information source. This would not be a major extension of the doctrines of patent and copyright misuse, under which the intellectual property rights owner is denied enforcement until the abuse is cured.[23] It is important to keep in mind that without the patent there would be no profit for *any* compensation to be paid. [24]

One policy implication of this analysis for developing countries is straightforward: to the extent one is concerned about biopiracy, it is a mistake to focus on patent law as a crucial, or even an important, part of the problem. Addressing the real problems associated with biopiracy is much more difficult. To the extent a given country or group considers its traditional knowledge sacred and not available for economic exploitation, rules and statutes can always be created that make illegal any attempt to learn or exploit such information. That will surely discourage what would otherwise be legal activities leading, perhaps, to products that could improve the lives of many, both within the source country and without. But that is the expected cost of attempting to respect the local view concerning traditional knowledge. The problem is that, in the long run, such an approach is unlikely to work. It takes just one person who has knowledge of information to transmit it outside the group, and once the information is out it is impossible to make secret again.

To the extent that a given group's biological knowledge or makeup is considered an economic resource, it is important to encourage exploitation of that resource by those who are willing to pay for it. Policy-makers must define, or find ways of allowing markets to define, what is fair and equitable compensation for indigenous peoples' contribution of information to what ultimately becomes a profitable product and who is entitled to such compensation. Then policy-makers must seek ways of rendering potentially valuable information inaccessible without prior agreement concerning compensation. And they must do this in ways that do not raise the costs of bioprospecting so much that they discourage people and companies that *could* potentially make valuable use of the information from seeking it. None of this is easy. The proper direction in which to look for legal approaches, however, is in areas like contract and unfair competition law.

3. TECHNICAL ISSUES INVOLVED IN GENE-RELATED PATENTS

Patents on genes, especially human genes, and gene products (such as proteins and enzymes) raise some important technical issues in the interpretation of current patent law.[25] In addition, there is always the basic policy question for patents of whether the gain from affording patent protection (new products and processes that, but for the patent incentive, would not have been invented or disclosed) justifies the harm that flows from a government-enforced monopoly for the patent period (such as higher prices for products that would have been invented anyway and inhibitions on further research). Finally, some biotechnology patents raise ethical issues of a very different type than patent law has faced in earlier periods.

3.1 *Naturally occurring substances*

Analysis of biotech patent issues under U.S. law always begins with *Diamond v. Chakrabarty*, in which the Supreme Court held that the law did not preclude patents on living organisms (447 U.S. 303 (1980)). The court stated that the patentability line was "*not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions*." The case is justifiably controversial for such a broad interpretation of section 101 of the Patent Act, which allows a patent for one who *"invents or discovers any new and useful process, machine, manufacture, or composition of matter*." Living organisms do not fit easily into any of these categories.[26] For present purposes, however, the most important aspect of *Chakrabarty* was its express retention of the long-standing prohibition on the patenting of naturally occurring substances. Upholding and distinguishing an earlier case[27] that the *Chakrabarty* court characterized as denying a patent for merely discovering *"some of the handiwork of nature*,"[28] *Chakrabarty* emphasized that the bioengineered microorganism at issue was not *"a hitherto unknown natural phenomenon"* but

rather a *"product of human ingenuity"* that differed markedly from anything found in nature.[29]

Genes and gene products, as they exist or are created in the cells of living organisms, are naturally occurring substances. They may be difficult to find, but we know they are there and that they can be found if enough effort is put into the project. One would have thought that the prohibition on patenting naturally occurring substances would have ruled out at an early stage patents for genes and gene products.[30] Yet, notwithstanding the highest court's reaffirmation of the prohibition on patenting naturally occurring substances, lower U.S. courts and the Patent and Trademark Office (PTO) have deviated substantially, further expanding patent coverage in the process. In the case of genes, the discussion got sidetracked at an early stage into the issue of whether a raw gene sequence, without disclosure of the gene's function or utility, could satisfy the *utility* requirement of the Patent Act.[31] In response to arguments that inventions are patentable, but mere discoveries (such as a particular gene) are not, the PTO held that:

[W]hen the inventor ... discloses how to use the purified gene isolated from its natural state, the application satisfies the "utility" requirement. That is, where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.[32]

Thus, while a gene in its natural state inside the cells of a living organism is not patentable, anyone who succeeds in isolating and purifying a gene (even by a perfectly routine methodology) and discloses an appropriate utility for it can obtain a patent on the gene.

Many commentators have decried treating an isolated and purified form of a naturally occurring substance as patent subject matter just because the purified form does not exist in nature.[33] Professors Linda Demaine and Aaron Fellmeth have recently supplied a thorough and convincing analysis criticizing this contention and demonstrating that it deviates substantially from precedent.[34] They argue that section 101 of the Patent Act mandates *invention* rather than mere *discovery*,[35] based on the express statutory requirement that the object of the patent be *new and* something that arises from application of human intellectual thought. They point out that the *isolated and purified* interpretation abrogates the requirement for *invention* and allows patents for essentially any alteration of a naturally occurring substance if increased commercial or therapeutic value results. As they point out, under this rationale to patentability, the first person to purify water or blood cells could have patented them.

Demaine and Fellmeth recommend a test of whether the naturally occurring substance has been transformed in such a way as to create a new product that is substantially different in biological function from the naturally occurring phenomenon. For biological substances, passing such a test would require in practice a change in molecular structure, because biological function is largely, if not wholly, determined by molecular structure. By requiring a substantial change in function, this test obviates the otherwise thorny problem of deciding whether a slight structural change (for example, adding or removing an extraneous atom or two) is sufficiently creative to deserve a patent. If the gene or its product still function as they do in nature, the new version will simply not be sufficiently creative under their test to be patentable. For naturally occurring substances unmodified by human-initiated structural change, another possibility would simply be to state expressly that only process patents, covering new and nonobvious *uses* of the now isolated and purified substance that occurs in nature, will be available.[36] Either approach would leave the substance itself, purified or not, free for research and for yet additional uses not envisioned by the owner of the use patent. (According to the PTO, a product patent covers *all* uses of the product, whether or not they are disclosed in the patent.) Finding a new use for such substances may well involve substantial investment and require the incentive of patent protection. While process patents are generally considered weaker than product patents, if a purified gene or gene product is used in a specific therapeutic method, there may be no readily available substitute, so the method-patent owner would maintain exclusive rights to that use.

A more substantial objection to method patents for new and nonobvious uses of genes and gene products derives from the TRIPS rule that permits excluding from patentability "*diagnostic, therapeutic, and surgical methods for the treatment of humans or animals"* (TRIPS Article 27(3)(a)). Much of Europe and many other countries have availed themselves of this exclusionary possibility. While the U.S. does not preclude patents on therapeutic processes, it does exempt medical practitioners from liability for infringement arising in the course of performing a medical activity (35 U.S.C. § 287(c)(1)). Among other exclusions, however, the immunity does not apply to infringements arising from practicing a process *"in violation of a biotechnology patent*" (35 U.S.C. § 287(a)(2)(A)). This would seem to leave unimpaired, in the U.S. at any rate, a patented method for using a naturally occurring substance derived through biotechnology. In any event, whether and to what extent therapeutic methods should be protected under patent law involves fundamental policy issues. If patent law today, under the TRIPS permissive exclusion, supplies insufficient protection to therapeutic methods, that aspect of it should be amended. It is not a satisfactory solution to make an end-run around the current spate of exclusions for therapeutic methods by protecting naturally occurring substances as products.[37]

In any event, while U.S. law has deviated from its long-standing prior position that naturally occurring substances are unpatentable and that merely extracting them in purified form does not make them patentable, arguments are available everywhere else in the world that such substances are not patentable because they are not new. TRIPS requires patents only for inventions that are new, and member states are free to decide whether or not a naturally occurring substance, like a gene or gene product, is new in the sense required by their patent statutes. Moreover, merely finding raw genes is not particularly difficult or inventive. Consequently, denial of patents on raw genes could also be predicated on absence of an inventive step.[38]

3.2 *Patent conditions for biotech inventions*

Many biotech inventions, as in *Chakrabarty*, will creatively alter a naturally occurring substance. In such cases, an objection to patenting based on the absence of something new, in the sense of *not previously existing*, is unavailable. Neither, at least in many cases, is an objection based on the absence of sufficient human creativity in the final product. Consequently, if a product, like the microorganism in *Chakrabarty*, otherwise meets the requirements for a patent, such as the technical standards for novelty and the substantive standards for nonobviousness, there are no grounds in the Patent Act itself for denying a patent.[39] TRIPS, of course, allows for the exclusion of plants and animals (other than microorganisms) from patentability,[40] and many countries may choose to do likewise on ethical grounds. But the absence of patent protection for genomic innovations does not ensure that no products based on modified genes or gene products will appear. Moreover, recognition of patents in this area does not mean that there can be no regulation or even outright prohibition by specific legislation. We should bear in mind that a huge potential exists for genetically modified organisms to contribute to the elimination of hunger and disease in developing countries, particularly if access to the technology is available. If patents on such products, at least in developed countries, serve as an incentive for their creation—meaning that without patents we would all have the benefit of less innovation—outright denial of patent rights would appear to effect a net social loss.

4. BALANCING THE COSTS AND BENEFITS OF GENE-RELATED PATENTS THROUGH POLICY

4.1 *Naturally occurring substances*

Whether or not patents on gene sequences or naturally occurring gene products conflict with the earlier prohibition on the patenting of naturally occurring substances, until the Supreme Court addresses the matter we must accept that the courts and the PTO have expanded the notion of patent subject matter to include them, provided that they have been isolated and purified. Still, does this expansion of traditional patent law make sense as a matter of policy?

Professor Epstein has articulated the basic policy issue that must be examined in deciding whether to recognize gene-related patents: Do the incentives for the creation of these inventions justify the restrictions on output that follow from exclusive rights?[41] Few, if any, have argued on economic grounds that gene-related patents should be wholly proscribed. But many able commentators have argued cogently that patents on raw gene sequences could inhibit, rather than promote, the progress of science and the development of products that are actually useful. Gene sequences alone, even in their isolated and purified forms, rarely have any direct use.[42] Useful products are normally the result of implanting the gene into the genome of an organism, such as a bacterium, that will then manufacture the protein or enzyme encoded by the gene. Then that protein or enzyme must be extracted from the cellular environment in which it was produced by the *vector* organism (in this case, the bacterium) and ultimately tested for safety and efficacy in its hypothesized use. These latter *downstream* activities that go from the gene itself to a useful product usually require a huge effort, quite often more than the *upstream* effort required to determine the gene in the first place. Thus, patents on basic upstream tools can inhibit, rather than promote, valuable downstream research.[43] Indeed, Professors Demaine and Fellmeth point out that when an upstream patent lacks ingenuity (which is the case for naturally occurring gene sequences), the patent incentive may not even be necessary to induce innovation but may still strongly preclude downstream research.[44]

It has also been argued that patents on raw genes may result in too much investment in the search for genes and insufficient investment in developing new products and carrying them to market.[45] Such patents can also inhibit information flow, which in turn duplicates research.[46] Finally, Professors Heller and Eisenberg have argued that gene-sequence patents can lead to a *tragedy of the anticommons*, in which many overlapping claims to gene fragments or *stacked* rights established by reach-through license agreements[47] between upstream patentees and downstream researchers must be coordinated to develop a useful product. Too many such claims may make negotiations among all affected parties difficult or impossible.[48] Moreover, a biotech anticommons is more likely to endure than in other areas of IP because of higher transaction costs, heterogeneous interests among owners, and cognitive biases of researchers.[49]

These policy arguments, therefore, suggest that it was a mistake for U.S. law to deviate from its traditional refusal to protect naturally occurring substances, even though purified, in the case of gene sequences. Like the argument against such patenting based on the absence of *invention* or *newness*, however, nothing in it suggests differential treatment of indigenous peoples from anyone else. If patenting genes or gene products is wrong on either statutory or policy grounds, we should correct the law, not because it imposes a particular burden on indigenous peoples, but because it imposes an unreasonable burden on everyone.[50]

4.2 *Modified genes and their products*

In the cases of human-created DNA sequences that do not occur naturally, and products derived from such sequences, we can no longer say, in general, that there is no invention or that the invention is not new. Such inventions, like the oil-spill-eating bacterium at issue in *Chakrabarty*, have much potential for ameliorating some of humankind's worst afflictions. Whether and to what extent patents supply the necessary incentive to undertake the research leading to such inventions is, as with all inventions, a difficult and unresolved question. However, I see no reason to distinguish these genomic inventions from any other on this score.

5. ETHICAL ISSUES ARISING FROM GENE-RELATED PATENTS

Patents confer upon their owners the right to exclude all others from making, selling, or using the patented invention. Thus, patents covering genes of living organisms, particularly patents covering pieces of the human genome, raise ethical questions concerning:

- whether such private control over genes or their products involves monopolization of the *common heritage of mankind*
- whether they denigrate human life by reducing life to a commodity
- whether they interfere with individual or collective privacy
- whether they promote distributive justice when they are concentrated in a few economically developed countries

Patents on crop varieties have also been said to threaten biodiversity.[51] These are serious issues that will continue to be examined for some time. I only touch upon them here, because it seems to me that indigenous and nonindigenous populations are equally affected or, at least, where there are differences in how costs or benefits deriving from gene-related patents are distributed, analysis shows that it is not the patent that is responsible for the problem.

5.1 *Monopolizing the common heritage of mankind*

We should first note that any objection to gene-related patents as monopolizing the common heritage of mankind must in fact refer only to patents on human genes, as it is those genes that have been passed down to us over the generations. If all living things were deemed part of the common heritage of mankind, there could be no property rights at all, let alone patent rights, in domestic animals, or indeed even plants. This objection to human-gene-related patents would seem to be subsumed in the *naturally occurring substance* controversy. If we upheld the traditional ban on patents covering naturally occurring substances, whether or not isolated and purified, human genes and their protein products would not be patentable.[52]

On the other hand, it is at least possible that a full-fledged cost/benefit analysis might show gains, from recognizing patents in genes and their products, that outweigh the losses. Patents may actually serve as an incentive to discover these products and their desirable uses to such an extent that the disadvantages of temporarily higher pricing and reduced information-flow should be accepted. If we assume for the moment that this is in fact the case, we must deal with the claim that human-gene-related patents should be denied, notwithstanding their economic advantages, because they would amount to undesirable monopolies on the common heritage of mankind.

This claim is most potent if a patent on a human gene or its protein product were construed to cover the naturally occurring processes that take place within human cells, where the gene itself resides and causes the manufacture of its protein product. Literally, the cell, and thus the human being to whom the cell belongs, is *making* the gene every time the cell divides, and the cell *uses* the gene in the process of *making* the gene product. Thus, it would appear that a patent covering the gene or its product would be infringed by these natural activities.[53] Although the patent only issues upon the applicant's claim that the product has been isolated and purified from its natural form, once issued the product (or composition-of-matter) patent covers any use of the chemical composition. A patent on a new drug, for example, will cover any form of chemical packaging into which the drug is incorporated or mixed. If it did not, the patent would be worthless. Thus, the logic of composition-of-matter patents on naturally occurring genes and their products leads to an absurd result when applied to living organisms and represents a basic flaw in the theory.[54]

The problem arises, however, not because genes are part of the common heritage of mankind but because gene and gene-product patents, by their nature, cover things that are not inventions. One can imagine, for example, someone or some group whose cells contain a unique mutation in a particular gene that gives the gene some special value. It is not part of the common heritage of mankind because, by hypothesis, at most a limited group carries the gene.[55] Moreover, by limiting focus on human genes, the common heritage approach would leave naturally occurring genes in other plants and animals free for the patentable taking. It would therefore seem that opposing gene patents on the ground that genes comprise the common heritage of mankind is less fruitful analytically than simply staying within

the bounds of traditional patent law and seeking denial of patents on the ground that patents on naturally occurring genes and gene products give a theoretical monopoly over the life processes of the organisms from which they derive. Such a monopoly, even though apparently more theoretical than practical at the moment, is simply unacceptable, regardless of the economic cost/benefit analysis.

In any event, and of most relevance for the present topic, nothing in the common heritage argument distinguishes indigenous from nonindigenous peoples. If it is bad for indigenous peoples that anyone should get a patent in a piece of the common heritage of mankind, it is equally bad for everyone else.[56]

5.2 *Reduction of life to a commodity*

Many maintain that patents on pieces of the human genome are morally wrong because they reduce life to a commodity.[57] While this argument has a certain rhetorical ring, its high level of generality renders analytical application difficult. A patent on a gene that is useful for diagnosing potential disease, for example, may mean that anyone who wishes to undergo the genetic test will have to pay more than if the gene were in the public domain. It is not clear to me, however, how this commodifies human life any more than a patent on any other medical diagnosis device or procedure. Slavery commodifies human life. Patents on the whole genome might well be said to commodify human life. While at bottom it may come down to questions of fundamental ethical or religious values,[58] to me no single gene or gene product can be meaningfully deemed *human life*. While the entire human genome may validly be thought of in many contexts as a *blueprint for human life*, no patents are going to issue anywhere on the entire human genome. A product is *commodified* when it becomes the subject of market transactions—it is widely available, like aspirin, against payment of the purchase price. It is easy to imagine markets in unpatented products based on human genes, and such products, like aspirin, will be commodities. They are no less commodities if they were never subject to a patent, or if the patent has expired, than they are while they are under patent. Moreover, the unavailability of patents will not stop scientific activity on human genes or all market activity in gene products.[59] Conversely, the availability of patents is not synonymous with commodification.[60]

Finally, this again raises the question of how making and selling a product based on a human gene differentially affects indigenous and nonindigenous peoples. It may be more likely that an indigenous group that has managed to remain relatively isolated from the onslaught of modern society will have in its collective genome a genetic characteristic of particular interest to those who would seek to develop genes into patentable products.[61] But it is difficult to see how studying the genetic characteristic of interest reduces to a commodity the lives of the people from whom the information is derived. More often, the complaint is that these people should be able to benefit from any profits that are eventually derived from the results of such studies, which is simply the human genome variant of the more general biopiracy problem discussed above with respect to nonhuman resources. Indeed, if it is true that the benefits of developments in modern medicine are slow to reach many indigenous societies, it is difficult to see how commodification in developed countries affects them at all.

5.3 *Privacy and human dignity*

Many have decried the recognition of gene-related patents as being fundamentally in conflict with norms of privacy and human dignity.[62] The underlying notion seems to stem from the intimate relation between an individual's genes and his or her phenotype, as expressed in physical, intellectual, and emotional characteristics.[63] Because genes are also part of our collective make up, it has been suggested that gene patenting may violate some sort of collective privacy right as well.[64]

At the individual level, there is no doubt that knowledge of someone's genome, in particular the presence of specific genes known to have a causal relationship to a particular disease, can be put to unfair discriminatory use in areas like employment or insurance.[65] To the extent that such a gene is known to be differentially preponderant

in a specific group, the danger of group stigmatism is also very real. Without downplaying the importance of either of these problems, it is difficult to see how gene-related patents exacerbate the problems. Genomic research has been going on for some time and is not likely to stop, regardless of the availability of patents. Indeed, it is the identification of the gene and its function that sets the stage for any subsequent discrimination that may occur, individual or collective. One of the major policy arguments against patenting such naturally occurring substances is that patents are *not* necessary as an incentive for this kind of research.[66] There is good reason to hope that much of this research, even when it identifies a particular set of genes with a given generally undesirable phenotypical response, such as a disease, will ultimately lead to valuable therapeutic interventions, or at least methods of prevention. Withdrawing the patent incentive will almost surely be detrimental for these developments.

Interference with privacy norms and affronts to human dignity through the misuse of the results of genomic research would also seem to be at least as problematic for people in developed countries as it is for indigenous peoples. The most likely worst case scenario for indigenous peoples might be the finding of a gene specific to a particular group that plays a causal role in some undesirable phenotypical attribute (as viewed from outside the group). Such a discovery could unfairly stigmatize the group in the eyes of outsiders. Patents, however, would seem unrelated to such a discovery. When outsiders have sought patents based on the genetic make up of an indigenous group, it is usually because the group is perceived as having a genetic *advantage* over the rest of humankind.[67] By the nature of the patent incentive, it is unlikely that the possibility of a patent would encourage anyone to look for a gene causing what is perceived in developed countries as a disadvantage that is unknown in those countries.

5.4 *Crop monocultures and monopolization of crop genomes*

Even outside the human genome some commentators have raised ethical questions concerning the appropriateness of gene patents. Patents on crop varieties, for example, may result in monocultures and the use of expensive inputs, such as fertilizers, that cause environmental harm.[68] It has been claimed that broad plant variety patents have conferred on a few corporations virtual monopolies on the genomes of important crops.[69]

Here again we find some potentially serious problems. If all the world's wheat is a single variety, for example, and if that variety turns out to be susceptible to a rapidly spreading blight of some sort, a significant portion of the world's food supply could be wiped out, with catastrophic consequences. Still, we must consider the role patents might play in creating or exacerbating these problems. If the use of expensive inputs is the problem, it would seem that not everyone would use the variety (in particular, those who cannot afford to pay). It should be borne in mind that a patent on a crop variety obligates no one to buy the seed. All farmers are free to continue using their traditional varieties in their traditional ways. Patents can serve as an incentive for finding or commercializing environmentally friendly crops and other inventions, and the existence of a patent can reduce resort by the distributor to economically inefficient and perhaps environmentally dangerous self-help approaches.[70] Moreover, if environmental harm is the problem (and a susceptible monoculture is one such example), environmental regulation is most likely necessary to remedy it.[71] Because of the human tendency toward free riding, no one can be expected to adopt an environmentally friendly approach to food production without the assurance that his competitors are operating at the same (economic) disadvantage. Moreover, if a given but advantageous variety is unpatented, it is likely to be adopted even more widely than if it is patented, increasing the danger of dependence on a monoculture.

6. POLICY IMPLICATIONS

This section demonstrates that the major policy problem for patent law in biologic materials is not peculiar to indigenous peoples or developing countries. Rather, it is the treatment under current U.S. and European law of naturally occurring chemicals (DNA sequences and genes, and their

natural products) as patent subject matter when extracted in isolated and purified form. Nothing in the language of the extant patent statutes or in the international IP or trade agreements compels this treatment. Allowing patents for naturally occurring substances goes against a long patent tradition even within the United States, and so far no one has made a convincing policy case that such a radical change from traditional patent principles should be made. Policy-makers in developing and developed countries should therefore resist pressure to adopt such a change, not because such patents have an untoward effect on privacy and human dignity but because denying patents on naturally occurring substances is simply good patent policy.

6.1 *Patents and developing countries*

Any country that wishes to have the free-trade advantages supposedly supplied by the World Trade Organization (WTO) must comply with the IP requirements of TRIPS. Among other things, TRIPS mandates that its member states adopt patent laws in keeping with those of the developed nations of the United States and the European Union. Many commentators have argued that developing countries have little to gain from recognizing foreign patents, as required by TRIPS, except to avoid trade retaliation.[72] A lively debate continues over whether patent laws promote or inhibit technology transfer to developing countries. That, in turn, raises the question of whether the costs of establishing a patent system, largely for the benefit of developed countries, are outweighed by the benefits. In addition, some commentators have raised ethical and human rights issues outside the specific realm of biotechnology. These include issues of distributive justice[73] and access to pharmaceuticals.[74] Other commentators have asserted that developing countries may view IP as a community (public domain) asset that no individual should own.[75] Patenting, in particular, has been said to clash with indigenous knowledge and value systems.[76]

6.1.1 *Technology transfer*

There is little doubt that TRIPS impedes the ability of developing countries to determine their own IP standards and policies in the hope of achieving a better fit to their own economic and social conditions.[77] In particular, TRIPS does not allow the choice of simply not recognizing patents for inventions by nationals of other member states.[78]

The advantages to developing countries of having a patent law have also been seriously questioned. It has been claimed, for example, that recognizing patents stimulates technology transfer, allowing the patenting country to gain not only the knowledge supplied in patent applications themselves but also the necessary know-how to start going into many of these fields of technology themselves. Others have disputed these claims, however, arguing that foreign patents deter developing countries from appropriating new technologies and products.[79] The needs of developing countries are often quite basic, for example, and some lack the ability to assimilate the latest technologies. A foreign patent owner may have little incentive to transfer technological know-how related to a patented invention if profits are available from imports. Most obviously, the information contained in a patent application is always available in the developed countries in which the invention is patented. Therefore, if a developing country is indeed capable of making use of such information in local industry, it would have access to the information without having its own patent law, and its citizens could make use of the information sooner, or at least without having to license it.[80]

6.1.2 *Access to inventions*

It is routine to observe that patented goods that reach the market will have a higher price than if they were not patented.[81] To the extent that this is true, it reduces access to the patented goods if there is any elasticity in demand, because people at the margin, by definition, could afford a lower price but not the higher one. It has been argued, moreover, that a patent owner might choose neither to enter a market nor to authorize local production, thereby reducing access in that country.[82] Probably the most convincing argument against patent laws in developing countries is Professor Oddi's observation that few inventions are *patent-induced* with respect to a given developing

country.[83] That is, most inventions likely would have been invented, anyway, regardless of whether any given developing country has a patent law that might protect it. To the extent that an invention is not patent-induced in this sense, patent protection in a developing country necessarily adds to that country's costs, because institutions in that country have access to the information in the patent in the countries where the invention is patented, so recognizing such a patent brings nothing more to the table.[84]

6.1.3 *Balancing the costs and benefits of patent law*

The above analysis implies that patents in developing countries can add significantly to those countries' costs with respect to new inventions,[85] and this cost is likely not offset by an increase in local technological development or in access to inventions that are, indeed, patent-induced. Still, consideration of the most dramatic case, which is access to vital pharmaceuticals, shows that the problem is more complex than this basic theoretical analysis would suggest.

In an effort to investigate the effect of patent laws on access to effective treatment in developing countries, Attaran and Gillespie-White looked at the availability of antiretroviral drugs for AIDS treatment in Africa.[86] Somewhat surprisingly, and contrary to conventional wisdom, they found no correlation between access to antiretroviral treatment and patent status across Africa.[87] Access to these drugs was found to be uniformly poor across Africa, independent of whether and where the drugs were patented.[88] Thus, at least in the poorest countries, access to potentially life-saving drugs seems not to be inhibited by patents but by the lack of funding to obtain access to these drugs at any price reflecting the cost of their production and administration.[89]

This suggests that the problem of access to inventions, and technology generally, in developing countries will not be solved by the denial of patents in those countries. It certainly will not be solved by denying patents in the developed world, if such denial eliminates the incentive for their discovery—the innovations would then be available to no one. The issue brings us back to the fundamental nature of IP and, in particular, its infinite multipliability without reduction of supply.[90] We can ask, for example, why the owner of IP should care whether the product embodying such IP is copied and distributed in that market if a given market offers no expected return from the exploitation of IP, such as a patent.

Consider an extreme case for the sake of illustration. Suppose country X has zero dollars to pay for a patented, potentially life-saving drug. The patentee could not have been thinking of X as part of his expected return while developing the drug, and indeed the patentee gets no return from X after the drug is on the market, *whether or not the drug is copied and distributed in X*. The copying and distributing of the drug in X does nothing to the patentee's exclusive right to market the drug in other countries where it is patented and where people can afford to pay something for it. This activity thus has utterly no effect on the patentee, provided that all of the drug that is copied and distributed in X actually stays in X and is used solely for the benefit of X's citizens. The problem for the patentee, then, is not the copying and distribution in X but rather the potential for grey-market leakage into markets where the drug is profitable for the patentee, because such leakage could potentially bring down the price of the drug in those markets.[91] There is no economic reason, therefore, why the patentee (on these extreme facts) would not be willing to sell the drug in X at cost, provided the patentee could ensure that none of it would leak back into his or her more lucrative markets.[92] In other words, the presence or absence of a patent law in X is essentially irrelevant to the patentee, whose only concern is with competition in his or her other markets from drugs originally distributed in X.

In any realistic situation, of course, there will always be at least a few people who can afford to pay the patentee's price, so selling the drug at cost would actually reduce the patentee's return.

For the poorest countries of the world, however, the number of such people will be very small. For other countries, where more resources are available for health care, discriminatory pricing (charging more where the demand is inelastic and less where it is elastic) will likely result in

wider access to drugs in developing countries and a profit to the patentee.[93] But even these schemes will be avoided by patentee drug manufacturers if products sold at a low price in one country find their way back to their more lucrative markets elsewhere.[94] Moreover, under any price discrimination scheme aimed at maximizing the patentee's profits, the price will likely be higher than it would be in the absence of the patent's exclusive rights, which to that extent continues to reduce access below that of a completely free market.

Another variation of the problem of balancing public access with the need for incentives occurs in university research, because research universities both actively seek the financial returns that are available from patented research and engage in public service. It was recently reported that a number of research universities had formed the Public-Sector Intellectual Property Resource for Agriculture in an effort to standardize their licensing practices to allow them to engage in humanitarian endeavors. Some of these universities are owners of valuable biotech patents that they have licensed away and now find themselves needing to use in efforts to create new crops that could feed impoverished people. The patent rights thereby stand in the way of their humanitarian mission. One idea is to include a *humanitarian use* clause in future licenses to make sure that universities retain the right to engage in such activities.[95]

TRIPS does allow for some amelioration of the exclusive rights of a patent through compulsory licensing.[96] The Doha Declaration on the TRIPS Agreement and Public Health expressly gives member states the freedom to determine the grounds on which compulsory licenses can be granted.[97] For countries that lack the facilities and technological expertise to manufacture complex pharmaceuticals locally, the TRIPS Council adopted a decision, which was implemented by the WTO in 2004,[98] waiving the obligations of an exporting member under Article 31(f) with respect to a compulsory license to produce and export pharmaceuticals to *eligible importing members*, subject to conditions like producing no more than necessary to meet the needs of the eligible importing country.

We may conclude that access to patented inventions, especially pharmaceuticals, is not as readily available as it might be were these inventions unpatented everywhere in the world. TRIPS is part of the problem, and the perceived danger of parallel importing is another.[99] It is important for these problems to be resolved in a way that maximizes worldwide access to all types of innovation, but especially to life-saving pharmaceuticals. Solutions should avoid undercutting incentives for more innovation in developed countries. To many it seems just plain wrong not to provide universal access to life-saving innovations in pharmaceuticals.[100] We are forced, however, to make a tradeoff between universal access to existing technology and future access to new technology. If the attempt to supply universal access to a given innovation reduces or eliminates future innovation, the ultimate result is no, or at least reduced, access to innovation for anybody.

7. CONCLUSIONS

Understanding the effect of patent rights in biotechnological inventions on the interests of indigenous peoples requires a more nuanced analysis than has generally appeared in the literature. The problem of so-called biopiracy, for example, is not one of the availability of patents based on traditional indigenous information but rather the failure to share fairly the profits that ultimately derive from developing the information into a valuable product. Patents on naturally occurring genes and gene products raise serious problems under traditional patent law on both technical and policy grounds, and they raise important ethical questions as well. These problems and questions, however, are not unique to indigenous peoples. Rather, they should, and must, be addressed by all peoples in the world, developing and developed. The basic problem with respect to indigenous peoples is patent law generally, beyond mere biotech patents, and whether its forced adoption by TRIPS will result in a net benefit to developing countries. Serious questions have been raised concerning whether local adoption of a patent law will improve technology transfer or increase access to desirable inventions in those

countries. The issue boils down to the extent that the absence of patent protection in developing countries erodes the incentive for innovation in developed countries, either through the absence of a profitable market in countries lacking a patent law or through grey-market arbitrage that allows patented products to flow back into the markets that do serve as incentives to innovate. ■

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1 See for example, Paterson RK and DS Karjala. 2003. Looking Beyond Intellectual Property in Resolving Protection of the Intangible Cultural Heritage of Indigenous Peoples. *Cardozo J. Internat'l & Comp. L.* 11:633.

2 See Karjala DS. 2003. Distinguishing Patent and Copyright Subject Matter. *Conn. L. Rev.* 35:439 (arguing that functional subject matter belongs under the patent, and not the copyright, regime).

3 A modification of trade secret law aimed at protecting group privacy interests in sacred symbols and rituals might be effective. See Paterson and Karjala, *supra* note 1, at 665–66. Fellmeth has suggested that some might argue for a collective trade secret in the indigenous use of herbs or other natural materials, including biological materials. Such knowledge might qualify for protection under ordinary modern trade secret law because it may have independent economic value resulting from its not being generally known and the group may take reasonable measures to maintain secrecy. See Uniform Trade Secrets Act § 1(4), 14 U.L.A. 537–51 (1980 & Supp. 1986), defining *trade secret*. Article 39(2) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires such protection for "natural and legal persons." Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS]. It is not much of a step further to recognize protection for cultural or ethnic groups collectively if the other conditions of trade secret protection are satisfied. To the extent that such knowledge is ineligible for trade secret protection, the problem is essentially that of biopiracy discussed in Part 2 of the chapter.

4 Lemley MA. 2000. Reconceiving Patents in the Age of Venture Capital. *J. Small & Emerging Bus. L.* 137, 139.

5 For a recent critique of this assumption, see Moore AD. 2003. Intellectual Property, Innovation, and Social Progress: The Case Against Incentive Based Arguments, *Hamline L. Rev.* 601.

6 See *supra* note 1, at 662–67.

7 See also Chen, J. 2006. There's No Such Thing as Biopiracy … And It's a Good Thing Too. *McGeorge L. Rev.* 37, at p.1 (2006)(arguing that the biopiracy narrative is largely a myth and that the term should be stricken from the ethnobiological discussion).

8 As Mark Lemley has stated: "*The economic rationale underlying much privatization of land, the tragedy of the commons, simply does not apply to information goods. It is possible to imagine physical bandwidth or server capacity being overconsumed, although the danger of that currently seems remote. But it is not possible to imagine overconsumption of a nonrivalrous thing like data. …From an economic perspective, the more people who can use information, the better.* Lemley MA. 2003. Place and Cyberspace. *Cal. L. Rev.* 91:521, 536 (citations omitted).

9 Whitt LA. 1998. Indigenous Peoples, Intellectual Property & the New Imperial Science. *Okla. City U. L. Rev.* 23:211, 220.

10 Seeratan NN. 2001. *Comment,* The Negative Impact of Intellectual Property Patent Rights on Developing Countries: An Examination of the Indian Pharmaceutical Industry. Scholar: *St. Mary's Law Review on Minority Issues* 3:339, 353–54.

11 See *supra* note 8. On the Economic Inefficiency of Protecting Works That Have Already Been Created; see also Karjala DS. 1997. The Term of Copyright, in *Growing Pains: Adapting Copyright for Libraries, Education, and Society* 33, 42–44 (ed., LN Gasaway). For a basic analysis of the underlying theories of property as they relate to traditional property (rivalrous in consumption) and intellectual property (nonrivalrous in consumption), see Epstein RA. 2005. Liberty Versus Property? Cracks in the Foundations of Copyright Law. *San Diego L. Rev.* 42:1 (arguing that for both types of property utilitarian tradeoffs are necessary).

12 Professor Whitt describes how the Brazilian Guajajara treated glaucoma with a local plant now depleted by exports to the tune of US$25 million per year, with corporations holding patents earning even more. See *supra* note 9, at 213–14. To the extent depletion of the plant is the problem, this dispute would seem to be between the Guajajara and the Brazilian government, not between the Guajajara and the foreign patentees. Brazil has the legal right and power to regulate or even prohibit the exporting

of the plant in question, especially if it is in danger of depletion.

13 As is discussed in detail below, the whole notion of composition-of-matter patents on naturally occurring substances is shaky under U.S. patent law itself, resting on a rationale that it is the isolated and purified form of the substance that is patented, not the substance as it exists in nature. In any event, the source country's long use of the plant for particular medicinal or other purposes would not be novel. Any claim that covered such a use (in the original source country) should be invalid for want of novelty.

14 For an argument that naturally occurring substances were long deemed by courts to be unpatentable and that Congress showed no intent in the 1952 Patent Act revisions to change that, see Demaine LJ and Fellmeth AX. 2002. Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent. *Stan. L. Rev.* 55:303, 366–84.

15 Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods (TRIPS) Article 27(1).

16 This is likely to be the case, at least in the United States, for any biotech patent based on indigenous information. Simply claiming a procedure observed in use by an indigenous non-U.S. group is likely to result in an invalid patent, because U.S. patent law requires that the patent applicant be the inventor. 35 U.S.C. § 102(f) (listing as an exception to patent entitlement that the applicant "*did not himself invent the subject matter sought to be patented*").

17 See also Heald PJ. 2003. The Rhetoric of Biopiracy, *Cardozo J. Int'l & Comp. L.* 519, 527: "*[N]o international patent can diminish [the indigenous group's] ability to cultivate, maintain, and use their existing resources.*"

18 Kowalski T. 2002. International Patent Rights and Biotechnology: Should the United States Promote Technology Transfer to Developing Countries? *Loy. L.A. Int'l & Comp. L. Rev.* 25:41, 42. (citing Clive J. 2000. Global Status of Commercialized Transgenic Crops, Section 1. www.isaaa.org/kc/Publications/pdfs/isaaabriefsBriefs%2021.pdf)

19 See *supra* text accompanying note 11.

20 The *Moore* case, in which spleen cells extracted during therapy were used without the patient's knowledge to develop a new line of cells that became the object of a valuable patent, is surely the most notorious. *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990). However, there are reports of other cases in which people discovered that cell or tissue donations were used in ways beyond their expectations and the original purpose of their donations. See Kolata G. Sharing of Profits Is Debated As the Value of Tissue Rises, *New York Times,* May 15, 2000, at A1.

21 Safrin S. 2004. Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life. *Am. J. Internat'l L.* 98:641, 657.

22 See, for example, Gutterman AS. 1993. The North-South Debate Regarding the Protection of Intellectual Property Rights. *Wake Forest L. Rev.* 28:89, 122; Sturges ML. 1997. Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind. *Am. U. Int'l L. Rev.* 13:219, 244. (asserting that developing countries view intellectual property as a publicly owned community asset that no single person should own); Whitt, *supra* note 9, at 252–53 (discussing a type of knowledge that the Maori call "tapu" and regard as sacred, believing that its misuse would cause the knowledge to lose its power).

23 See *Morton Salt Co. v. G.S. Suppiger,* 314 U.S. 488, 490–92 (1942); *Lasercomb America, Inc. v. Reynolds,* 911 F.2d 970, 977 (4th Cir. 1990). Another approach to limiting biopiracy directly under the patent law would be to eliminate the geographical limitations on disqualifying prior art; Bagley MA. 2003. Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World. *Minn. L. Rev.* 87:679, 724–27.

24 Kieff notes the need to find ways, possibly through contract, to solve the problem of allocating the wealth generated by a patent based on access to biodiversity, but he points out that without a patent system the wealth itself would be sacrificed. Kieff FS. 2002. Patents for Environmentalists. *Wash. U. J. L. & Policy* 9:307, 318.

25 I address technical questions of patent law primarily by reference to U.S. patent law, which is the only patent law with which I am even modestly familiar. I assume, but am willing to stand corrected, that my comments will apply in at least some general way to the patent laws of most countries.

26 This broad interpretation of section 101 also conflicts with the special statutes aimed specifically at protecting plants. These included the Plant Patent Act of 1930, 35 U.S.C. §§161–64 (protecting a new and distinct variety of plant that is asexually reproduced) and the Plant Variety Protection Act of 1970, 7 U.S.C.A. 57 (giving patent-like protection to sexually reproduced plants constituting a "new variety"). As a result of the *Chakrabarty* decision, plants are also patentable under the general Patent Act, a conclusion that the Court recently confirmed in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.,* 534 U.S. 124 (2001). These interpretations of section 101 render both specific plant protection statutes largely extraneous. Had Congress thought that the Patent Act covered all living organisms invented by man, it is unlikely it would have seen any need for special plant protection statutes.

27 *Funk Brothers Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127 (1948).

28 447 U.S. at 309–10.

29 See Demaine and Fellmeth, *supra* note 14, at 316–17.

30 While the proteins or enzymes that constitute gene products do occur naturally in living organisms in the form for which patents may be sought, genes themselves rarely do. A typical gene as found in the DNA of a living organism contains both exons and introns, which are regions that, respectively,

are and are not "expressed" in protein production through the process of RNA transcription. See Karjala DS. 1992. A Legal Research Agenda for the Human Genome Initiative. *Jurimetrics J.* 32:121, 129-33. If a gene researcher seeks to patent a DNA sequence composed only of the natural gene's exons, he would be technically correct in saying that such a sequence of DNA does not occur naturally and he has therefore created something "new." Excluding such DNA sequences from patentability, therefore, requires more than appeal to the traditional exception for "naturally occurring substances." The basis for exclusion must lie in the fact that this DNA sequence stands in a complementary one-to-one correspondence with the messenger RNA that serves as the template for protein production. Karjala DS at 130–32. The issue is whether exon-only DNA is sufficiently different from natural substances—the messenger RNA—to justify a patent. The substantial transformation test offered by Demaine and Fellmeth addresses this question and would deny a patent unless the new sequence shows a substantially different biological function from its natural forebear in the organism. See Demaine and Fellmeth, *supra* note 14, at 444–45.

31 Section 101 of the Patent Act requires that the invention be "useful."

32 PTO Final Examiner Guidelines on Utility Requirement, 66 Fed. Reg. 1092, Dec. 29, 2000, at 1093 (Response to Comment 1).

33 For example, see Drahos P. 1999. Biotechnology Patents, Markets and Morality. *E.I.P.R.* 441, 443, which argues that treating an isolated and purified form as an invention exalts form over substance. Epstein contends that granting patents to the discovery of cDNA tags would be like giving Madame Curie a patent for radium because she first isolated it from pitchblende, in Epstein RA. 1996. Property Rights in cDNA Sequences: A New Resident for the Public Domain. *Roundtable* 575, 579. Meyers argues for distinguishing between a discovery and an invention, in Meyers, AS. 1996. Intellectual Property at the Public-Private Divide: A Response. *Roundtable* 581; and Looney makes the case that a gene unaltered by human intervention does not necessarily lose its status as an object of nature simply by taking it outside the body identifying its function, in Looney B. 1994. Should Genes Be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement. *Law & Pol'y Int'l Bus.* 26:231, 264.

34 See *supra* note 14, at 366–84.

35 Section 101 provides for a patent to whoever "invents or discovers" patentable subject matter. In addition, the Constitution actually uses the word "discoveries" for the object of the exclusive rights Congress may afford to inventors: Congress shall have the power *"to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."* U.S. Constitution, Article I, § 8, cl. 8. The PTO has latched onto the "discover" aspect of section 101 as a basis for gene-sequence patenting. With painstaking care, Demaine and Fellmeth argue that the word "discovery" was more narrowly understood at the time the Constitution and the first Patent Act were adopted and in those contexts required some creative act by the inventor ("invention") and not merely that he had "found" something. See *supra* note 15, at 366–84. Demaine and Fellmeth argue further that the word "discovery" in the current Patent Act still requires "invention" and that Congress could not have intended to abrogate the requirement for human intellectual creativity if a patent is to be obtained. See also King J and D Stabinsky. 1999. Patents on Cells, Genes, and Organisms Undermine the Exchange of Scientific Ideas. *Chronicle of Higher Ed.,* at B6, B7; (*"'Products of nature' such as animals, plants, elements, and minerals could not be patented [before Chakrabarty], because they are found or discovered, not invented"*); compare to Sturges, *supra* note 22, at 242 (asserting not entirely correctly, see *supra* note 30, that gene researchers do not create anything new but only indicate where a gene might lie along a naturally occurring sequence).

36 This suggestion was made to the PTO but they rejected it. Their response was simply that *"Patent law provides no basis for treating DNA differently from other chemical compounds that are compositions of matter."* PTO Utility Guidelines, *supra* note 32, at 1095 (Response to Comment 10). This, of course, is completely erroneous, insofar as naturally occurring sequences of DNA are concerned. Technically, a naturally occurring DNA sequence is usually not patented in the form it is found in nature.

37 I am indebted to my former student Fariba Sirjani for making me aware of section 287(c) and the alternative approaches to limiting therapeutic-method patents elsewhere.

38 Erramouspe M. 1996. Comment on Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races. *UCLA L. Rev.* 43:961, 997.

39 Rai AK. Patenting Human Organisms: An Ethical and Legal Analysis, Draft paper prepared for President's Council on Bioethics, June 21, 2002. www.law.upenn.edu/fac/akrai/rai.patents.cob.doc.

40 TRIPS Article 27(3)(b). Fellmeth has pointed out to me in a private communication that Article 27(3)(b) of TRIPS may soon be ineffective as a result of bilateral free trade agreements between the United States and many other countries, especially in the western hemisphere. These agreements require protection generally equivalent to that available in the United States after *Chakrabarty*.

41 Epstein RA. 2003. Steady the Course: Property Rights in cDNA Sequences. *U Chicago Law & Economics,* Olin Working Paper No. 152, p. 577. Here Professor Epstein argues against patentability for the discovery of cDNA sequences, equating it to giving the first person to capture a fox an exclusive right to all foxes (an analogy that admittedly conflates physical and informational resources).

42 Obviously, gene sequences inside the organisms from which they derive often have very important uses. The issue here is whether there is another use, therapeutic or otherwise, to which the purified form of the gene can be put.

43 Barton J. 1995. Patent Scope in Biotechnology. *International Review of Industrial Property* 26:605, 614. Barton argues that *"highly basic patents that preempt a large area of research are unlikely to be beneficial."* Dickson describes Human Genome Organization (HUGO) officials' opposition to patents on cDNA sequences as "routine discoveries" that could inhibit incentives to establish gene function or develop applications, in Dickson D. 1995. HUGO and HGS clash over "utility" of gene sequences in US patent law, *Nature* 374:751. Epstein decries cDNA patents as opposed to patents for the fashioning of some new bacterium or virus with commercial applications. See *supra* note 41, at 578. See also Horn ME. 2003. *Note to* DNA Patenting and Access to Healthcare: Achieving the Balance among Competing Interests. *Clev. St. L. Rev.* 50:253, 263–64, 274–76.

44 See *supra* note 14, at 417–18.

45 Carroll AE. 1995. Comment on Not Always the Best Medicine: Biotechnology and the Global Impact Of U.S. Patent Law. *Am. U. L. Rev.* 44:2433, 2482; See Drahos, *supra* note 33, at 443.

46 See Carroll, *supra* note 45, at 2483–84; Chapman AR. 2000. Approaching Intellectual Property as a Human Right: Obligations Related to Article 15(1)(c), U.N. ESCOR, *Comm. on Econ., Soc. & Cultural Rts.*. U.N. Doc. E/C.12/2000/12, at ¶¶ 6, 57; but see Looney, *supra* note 33, at 244–45 (concluding that the impact of gene patenting on the dissemination of information is unclear).

47 See Marshall E. 1997. Need a Reagent? Just Sign Here.... *Science* 278:212 (describing the complex bureaucratic web resulting from general implementation of *materials transfer agreements* requiring the surrender of property rights in subsequent discoveries in exchange for materials intended for research use).

48 Heller MA and RS Eisenberg. 1998. Can Patents Deter Innovation? The Anticommons in Biomedical Research. *Science* 280:698, 699-700; see also *supra* note 14, at 419–21 (noting that *"multiple patentable sequences [ESTs, codons, SNPs, etc.] can originate in the same gene, resulting in upstream patentees owning rights to different parts of the same gene"*); See Horn, *supra* note 43, at 265–67.

49 See Heller and Eisenberg, *supra* note 48, at 700–701; see also Burk DL and MA Lemley. 2002. Is Patent Law Technology-Specific? *Berk. Tech. L.J.* 17:1155, 1195–96 (arguing that the Federal Circuit's application of a stringent disclosure requirement and a lax nonobviousness requirement to biotech inventions exacerbates the anticommons problem by resulting in a multitude of narrow upstream patents that can strangle downstream product development).

50 But compare *to* Kieff FS. 2001. Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science: A Response to Rai and Eisenberg. *Nw. U. L. Rev.* 95:691, 704. (concluding, contrary to the premise in the text, that patent availability for basic biotechnological inventions increases the funds available for research and commercialization and will more likely promote traditional scientific norms, such as independence and objectivity, than would be observed in a world without such patents); Adelman DE. 2005. A Fallacy of the Commons in Biotech Policy. *Berkeley Tech. L.J.* 20:985, 988 (states *"there are few signs that biotech patenting has impeded biomedical innovation"*). One commentator has argued that biomedical patents, by raising the cost of research tools, actually promotes fundamental scientific advances by giving scientists additional incentive to innovate at the level of basic scientific theory. Lee P. 2004. *Note to* Patents, Paradigm Shift, and Progress in Biomedical Science. *Yale L.J.* 659, 694–95.

51 Center for International Environmental Law. *The 1999 WTO Review of Life Patenting Under TRIPS*. ciel.org/Publications/WTOReviewofLPunderTRIPS.pdf (hereinafter cited as 1999 CIEL Report).

52 Demaine and Fellmeth's substantial transformation test would allow a product patent on genes, including human genes, biochemicals, and tissues, that are so substantially transformed from their natural state that they perform a different biological function than they do naturally. Thus, anything taken out of the "common heritage" would have to be so changed from its natural state that a patent could not be used to control its natural use. See *supra* note 14, at 444–45. Effectively, the substantial transformation test they recommend for patentability should mean that no composition-of-matter patents would issue on naturally occurring genes or their products, because in order to perform a different biological function the substances almost certainly would have to have a different structure. Their test is thus one of the degree of *inventiveness* an applicant must show in order to get a patent on a composition of matter that he has modified from its natural form. This test does seem to leave the theoretical issue of whether a composition-of-matter patent could issue on a naturally occurring substance that has been isolated and purified and found to perform not only its natural function but also a completely different biological function. In this purely theoretical case, there remains a danger of control over its natural use. Product patents give rights to make, use, or sell the product, covering even uses not disclosed in the patent application. Limiting protection to a method patent covering only the use of the isolated and purified substance in a specific therapy would avoid even this theoretical objection. Expressly restricting naturally occurring substances to method patents would not in any way preclude application of the substantial transformation test to substances that *are* structurally transformed. Indeed, that test is then vital in determining whether the applicant has truly "invented" something new or has simply made minor modifications of nature's handiwork.

53 For example, Demaine and Fellmeth (see *supra* note 14, at 434: *"From a purely positivistic perspective, a patent on a DNA molecule or protein entitles the patentee to forbid cell building, transcripting, and reproducing by any individual whose genome contains that DNA molecule or uses that protein, as such activities constitute using and making unauthorized copies of the DNA molecule or protein."*

54 See *supra* note 14, at 435. While no court will be led to find infringement based on the natural operations of living organisms that have been taking place for eons, Demaine and Fellmeth point to other examples that may be closer to reality: A patient whose cells have been patented, for example, would be prohibited from donating or selling blood or sperm without a license from the patentee.

55 In a private communication, Aaron Fellmeth has offered some variations on the "universal heritage" argument. Some might argue, for example, that a gene is still part of the common heritage of mankind even though only a limited group carries it. The underlying principle would be that a gene is nature's, or God's, handiwork and cannot therefore be legally owned or monopolized by anyone other than the whole of humankind. One can get to this same result much more mundanely, but analytically more cleanly, by reactivating the traditional rule against the patenting of naturally occurring substances. And insofar as the argument is based on not monopolizing something created by God or nature, it still leaves open the question of whether and when patents should be available for structurally modified products of nature. For *that* determination we need something like the substantial transformation test of Demaine and Fellmeth. Another argument might be that genes are not just physical products but constitute information about nature and that such information should not be monopolized. This, however, is at bottom an attack on all of intellectual property law, because monopolization of information is precisely what patent and copyright laws do. Every invention carries with it information about the operation of nature, because technology works by natural laws. Consequently, the "information about nature" argument is not easily limited to genes and gene products.

56 It might be noted that the Biodiversity Convention requires that members facilitate access to genetic resources, subject to fair sharing of the benefits after genetic resources have been obtained by prior informed consent. Convention on Biological Diversity Arts. 15(2), 15(4), 15(5), & 15(7). The convention thus rejects any form of the "common heritage" doctrine that would prohibit all forms of commercialization. Downes DR. 1993. New Diplomacy for the Biodiversity Trade: Biodiversity, Biotechnology, and Intellectual Property in the Convention on Biological Diversity, *Touro J. Transnat'l L.* 4:1, 9. Similarly, Article 4 of the *Universal Declaration on the Human Genome and Human Rights,* adopted by the United Nations General Assembly, G.A. Res. 152, U.N. GAOR, 53d Sess. U.N. Doc. A/53/625/Add.2 (1998)[hereinafter referred to as *Universal Declaration*], declares that the human genome in its natural state shall not give rise to financial gains. This too seems to allow commercialization of the human genome outside its "natural state," which would presumably include its "isolated and purified" form. This goes well beyond what would be permitted by traditional patent law under the exception for naturally occurring substances.

57 See Chapman, *supra* note 46, at 3; see Downes, *supra* note 56, at 4; see Sturges, *supra* note 22, at 242, 244–45; see 1999 CIEL Report, *supra* note 51, at 4.

58 The argument might be that every part of the human body is sacred and therefore may not be commodified. If this is the argument, however, it rejects even commodification of an unpatented human-gene-related product. It is markets, not patents, that make something a commodity. This approach risks losing many products that have a potential for reducing human suffering and disease, which is a heavy price to pay in support of what is essentially a metaphysical principle.

59 Poste G. 1995. The Case for Genomic Patenting. *Nature* 378:534, 536; see Rai, *supra* note 39, 55.

60 Rai, *supra* note 39, at 55.

61 Compare Gross N and J Carey. Who Owns the Tree of Life? *Business Week,* Nov. 4, 1996, p. 194 (describing the Papua New Guinea Hagahai's apparent immunity to a virus that usually causes leukemia); See King and Stabinsky, *supra* note 35, at B6 (describing patent applications for cells and genes of New Guinea tribes because of an apparent immunity against certain viruses); see Frow J. 1995. Elvis' Fame: The Commodity Form and the Form of the Person. *Cardozo Stud. L. & Lit.* 7:131, 150 (describing applications for patents on the cells of individuals from Papua New Guinea and the Solomon Islands, each of them carriers without apparent harm of the HTLV-I virus). In addition, remote, isolated populations often make it is easier to trace disease heredity, which means that studying the genes from these groups can speed up gene discovery and drug development. See Gross and Carey, *supra* note at 61; See Safrin, *supra* note 21, at 660–61 (DNA from homogeneous and isolated populations can facilitate discovery of disease-causing genes).

62 See *supra* note 14, at 437–38 (discussing the worldwide concern about these issues).

63 See Looney, *supra* note 33, at 238.

64 *Id.* at 238–39.

65 See Karjala, *supra* note 30.

66 See *supra* text accompanying note 44.

67 See *supra* note 61 (describing attempts to patent cells and genes of indigenous groups based on an apparent immunity to diseases that afflict developed countries).

68 See CIEL Report, *supra* note 51, at 4.

69 See Chapman, *supra* note 46, at ¶ 64.

70 See Kieff, *supra* note 24, at 318–19 (arguing that a patent can obviate the perceived need of the innovator of a new and valuable seed to use potentially dangerous technologies to protect against competitive sale of seed by initial purchasers).

71 *Id*. at 318 (arguing that where new technologies are harmful to environmental goals, the existence of a patent at least does not exacerbate the harm, because a patent's right to exclude does not provide an affirmative right to *use* the technology by the patentee, so such use can be regulated or prohibited).

72 See Carroll, *supra* note 45, at 2471 (citing ET Penrose, *The Economics of the International Patent System* 116–17 (1951)).

73 See Looney, *supra* note 33, at 240.

74 Lazzarini Z. 2003. Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil. *Yale Hum. Rts. & Dev. L.J.* 6:103, 115–119 (arguing that access to pharmaceuticals should be thought of as a human right).

75 See Sturges, *supra* note 22, at 244.

76 See Whitt, *supra* note 9, at 240.

77 See Chapman, *supra* note 46, at ¶ 16. One commentator has said that forcing countries to adopt patent laws and accept conditions of technology transfer laid down by the holder of the patent is "technological colonialism." See Carroll, *supra* note 45, at 2466-67.

78 Anawalt HC. 2003. International Intellectual Property, Progress, and the Rule of Law. *Santa Clara Computer & High Tech. L.J.* 19:383, 404 (*"The linkage of WTO membership to mandatory intellectual property rights and procedure should be ended"*).

79 See Gutterman, *supra* note 22, at 122, 137; *compare* Downes, *supra* note 56, at 22–23 and Lazarini, *supra* note 74, at 111 (both concluding that the empirical evidence on the inhibiting or beneficial effects of intellectual property rights on technology transfer is scanty); see Seeratan, *supra* note 10, at 383 (noting that industrialized countries did not adopt strong intellectual property laws until they themselves had reaped the benefits of nonprotectionist policies). Even within the United States there is much anecdotal information that recent advances in medicine do not reach many of those who need it or their physicians, often even years after the information is publicly available. For example, Begley S. Too Many Patients Never Reap Benefits Of Great Research. *Wall Street Journal,* Sept. 26, 2003, at B1.

80 On these issues see Oddi AS. 1987. The International Patent System and Third World Development: Reality or Myth? *Duke L.J.* 831–52.

81 See Carroll, *supra* note 45, at 2468; see Chapman, *supra* note 46, at ¶61; see Seeratan, *supra* note 10, at 375 (asserting that the TRIPS requirement for both product and process patents will substantially increase the cost of pharmaceuticals).

82 See Gutterman, *supra* note 22, at 122-23. One might question why a patent owner would adopt this strategy, however. It would seem that if he or she is unwilling to import into a given country, one would be better off economically by licensing local production. One possible explanation is fear of grey market "leakage" that is difficult to control by contract. But even this explanation is unsatisfying, because under TRIPS, if the country has the local ability to manufacture the invention, it may grant a compulsory license. TRIPS Article 31. Of course, any such compulsory license is supposed to be primarily for local consumption. *Id*. Article 31(f). However, if grey market leakage is a problem under a negotiated license, where the patentee has direct contact with the licensee, it would seem to be an even bigger problem under a compulsory license.

83 See Oddi, *supra* note 80, at 844; see also Seeratan, *supra* note 10, at 386 (*"None of the pharmaceutical companies really depend on achieving profits in developing countries, which generally only account for a minimal percentage of drug sales worldwide"*); *compare to* Anawalt, *supra* note 78, at 397 (*"Adequate incentives for innovation do not depend on mandatory international intellectual property rules"*).

84 See Oddi, *supra* note 80, at 846.

85 Additional costs of a patent system come in the form of training patent officials, lawyers, and judges. See Carroll, *supra* note 45, at 2468.

86 Attaran A and L Gillespie-White. 2001. Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa? *J. Am. Med. Ass'n* 286:1886.

87 *Id.,* at 1890. They also discovered that the option to patent antiretroviral drugs often went unexercised, surely the result of the meager expected financial return from very poor countries. This supports the conclusion of Professor Oddi that increased incentive for innovation from the possibility of obtaining patents in poor countries is negligible, that is, none of these drugs is "patent-induced" with respect to the patent law of any given African country. See Oddi, *supra* note 83 and accompanying text.

88 See *supra* note 86, at 1891. Attaran and Gillespie-White blame lack of international funding, even to purchase drugs at cost, rather than patents, for the low level of antiretroviral treatment in Africa.

89 See *supra* note 86; see Lazzarini, *supra* note 74, at 135. Aaron Fellmeth has reminded me in a private communication that an effective monopoly might result not only from a patent but also from trade secret law or pursuant to exclusive pharmaceutical marketing approvals.

90 See Lemley, *supra* note 8 and (text at) note 11.

91 See Scherer FM and J Watal. 2002. Post-TRIPS Options for Access to Patented Medicines in Developing Nations, *J. Internat'l Econ. L.* 913, 928 (*"When prices are higher in one nation than in others, there is a tendency for arbitrage to occur through what is known as 'parallel trade'."*); see also *supra* note 82.

92 More generally, enforceable and accurate price

discrimination should push output to the full competitive output level, but for this to occur arbitrage between high- and low-value users must be prevented. See Kieff, *supra* note 24, at 311 and note 23.

93 See Scherer and Watal, *supra* note 91, at 9:25–28; see Lazzarini, *supra* note 74, at 125.

94 They will also be avoided to the extent the developed countries adopt notions of "reference pricing," requiring, for example, that their own domestic prices to be no higher than those charged elsewhere. See Scherer and Watal, *supra* note 91, at 929.

95 Blumenstyk G. 2003. Coalition Seeks to Make Agricultural-Biotechnology Tools More Widely Available. *Chr. Higher Ed.,* July 11. chronicle.com/daily/2003/07/2003071105n.htm.

96 TRIPS Article 31; See Lazzarini, *supra* note 74, at 125.

97 World Trade Organization, Ministerial Conference, Doha Declaration on the TRIPS Agreement and Public Health, No. 01-5770, Nov. 14, 2001, ¶ 5(b). In most cases compulsory licenses can be granted only after good faith negotiations with the patentee have failed to result in a voluntary license "on reasonable commercial terms and conditions." TRIPS Article 31(b). However, nothing in TRIPS supplies any standard of reasonableness, so the failure of the patentee to agree to a member state's good faith offer to pay what it believes it can afford, given its other obligations and the country's needs, should suffice to permit going ahead with the compulsory license. Moreover, even the obligation to negotiate is waived in cases deemed to be a "national emergency."

98 World Trade Organization General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of 30 August 2003, WT/L/540, 43 I.L.M. 509 (2004).

99 Some drug manufacturers have begun experimenting with "out-licensing," under which the patentee licenses generic manufacturers who agree to supply medicines to poorer countries. Friedman MA, H den Besten and A Attaran. 2003. Out-licensing: a practical approach for improvement of access to medicines in poor countries. *The Lancet* 361:341. Requiring pills to have different colors and shapes could be helpful in inhibiting parallel importing back into the more lucrative markets. *Id.* at 343; see also Hensley S. Pharmacia Nears Generics Deal On AIDS Drug for Poor Nations, *Wall Street J.,* Jan. 24, 2003.

100 See Seeratan, *supra* note 10, at 403–4 (*"Many human rights activists assert that the TRIPs provisions on the patenting of pharmaceuticals violates basic human rights by compromising the ability of poor countries to access essential medicines"*). The *Universal Declaration on the Human Genome and Human Rights demands* that *"Benefits from advances in biology, genetics, and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual."* See *Universal Declaration*, *supra* note 56, Article 12(a). Another commentator argues that distributive justice requires providing all countries with access to the benefits of gene research. See Looney, *supra* note 33, at 240 (*"Gene patenting is ethically suspect if it concentrates genome benefits in those few countries fortunate enough to have the resources to obtain gene patents, when all humans should enjoy such benefits"*). In these situations, however, it is not clear why gene patents or even medicine generally are singled out. Starvation is a huge problem in the world, which has a production capability more than sufficient to supply everyone alive with at least a minimal food supply. Unequal distribution of resources, both natural and human-made, almost inevitably raises questions of distributive justice. To the extent that patent law serves as an incentive for innovation, a patent does not create the injustice. It only brings more clearly into focus that there is widely different access to valuable resources between rich and poor countries. Without the patent, by assumption, *nobody* would have access to the innovation. With the patent, some relatively wealthy people do. But the poor are no worse off than they were before the innovation became available.