

## **Biotech Patents and Indigenous Peoples**

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## I. 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.<sup>1</sup> When the focus is on biotechnology, however, copyright does not play much of a role in protecting functional inventions,<sup>2</sup> and while trade secret is important, no biotechnology issues specific to the interests of indigenous peoples are apparent.<sup>3</sup> This paper

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\* Jack E. Brown Professor of Law, Arizona State University. The author gratefully acknowledges numerous helpful comments on an earlier draft from Aaron Fellmeth, Robert Clinton, and Douglas Sylvester. An earlier draft of this paper was presented at a conference entitled "Intellectual Property and Biotechnology in the Age of Globalization: Challenges, Opportunities and Risks," Sept. 19-20, 2003, at the University of British Columbia.

1. See Robert K. Paterson & Dennis S. Karjala, *Looking Beyond Intellectual Property in Resolving Protection of the Intangible Cultural Heritage of Indigenous Peoples*, 11 CARDOZO J. INT'L & COMP. L. 633, 669-70 (2003) (concluding that the justifiable claims of indigenous peoples with respect to their intangible cultural heritage can often be dealt with by applying concepts from the law of contract, privacy, trade secret, and trademark, but rejecting, as fundamentally antithetical to basic notions of free expression and the overall dissemination and development of culture, an expansion of the patent or copyright regimes by allowing group rights in otherwise publicly accessible works arising out of indigenous cultural tradition).

2. See Dennis S. Karjala, *Distinguishing Patent and Copyright Subject Matter*, 35 CONN. L. REV. 439 (2003) (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 & Karjala, *supra* note 1, at 665-66. Aaron 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

therefore concentrates on how patent rights in biotechnology affect the legitimate concerns of indigenous peoples.

Two issues in particular dominate the literature of 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 perhaps related (when, for example, the genetic information is taken from an indigenous group), it clarifies the analysis to attempt a conceptual separation between these two issues. The first raises questions of so-called "biopiracy" of indigenous information by developed countries. As such, it directly implicates the rights of indigenous peoples, even though most of these issues can be resolved when a few basic principles of patent law are brought to the fore. The second issue necessitates important ethical inquiries and also poses fundamental questions for patent law and patent policy, especially when information concerning the human genome is involved. Most of these problems, however, are not specific to the impact of biotechnology on indigenous peoples, and indeed many of them affect all people, whether living in a developing or a developed country. Parts II and III 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 problems specific to indigenous peoples, Part IV attempts to outline the real problems that the global patent system poses for developing countries. While it is difficult to make the case that adoption of a modern patent system supplies a direct benefit to developing countries, Part IV concludes that the worldwide patent system has little direct adverse effect either. The problem is not the existence of patents that prevents the diffusion of biotechnological advances in developing countries, so much as the danger of "leakage" through importing 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, which would not be good for anyone.

This last conclusion rests upon a basic assumption that

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that of "biopiracy" discussed in Part II below.

underlies the entire paper. Whether and to what degree patent law serves as an incentive to innovate or commercialize innovations remains a matter of serious debate. 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 intellectual property systems work in practice.<sup>4</sup> This paper does not aim at a fundamental analysis of the patent system generally. It therefore assumes that the patent system in developed countries generally achieves its basic goal of stimulating innovation by providing a period of exclusive rights to those whose intellectual creations qualify for patent protection.<sup>5</sup>

## II. "BIOPIRACY" AND PATENTS

### A. THE BASIC PROBLEM

The biopiracy problem is exemplified by the taking of indigenous peoples' information concerning the medicinal effects of a plant or other natural substance and developing it into a patented and popular drug by large pharmaceutical companies.<sup>6</sup> The fundamental question is whether or to what degree it is fair for outsiders to use, and especially to profit from, this knowledge. In earlier work, Robert Paterson and I

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4. Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137, 139 (2000).

5. For a recent critique of this assumption, arguing that incentive-based justifications for intellectual property fail, see Adam D. Moore, *Intellectual Property, Innovation, and Social Progress: The Case Against Incentive Based Arguments*, 26 HAMLINE L. REV. 601 (2003).

6. See, e.g., STEPHEN A. HANSEN & JUSTIN W. VANFLEET, AM. ASS'N FOR THE ADVANCEMENT OF SCI., TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY: A HANDBOOK ON ISSUES AND OPTIONS FOR TRADITIONAL KNOWLEDGE HOLDERS IN PROTECTING THEIR INTELLECTUAL PROPERTY AND MAINTAINING BIOLOGICAL DIVERSITY 3, 5, 11, 14 (2003) [hereinafter AAAS HANDBOOK] (discussing the use of *plao-noi* in Thailand to treat ulcers, of the *hoodia* cactus by African King Bushmen to stave off hunger, of turmeric for wound healing and neem as a pesticide in India, of *ayahuasca* in the Amazon basin for sacred religious and healing purposes, of maca (*Lepidium meyenii*) in the Andes for increased fertility, and of *j'oublie* in Camaroon and Gabon as a sweetener). The European Patent Office upheld the revocation of a patent on a neem-derived antifungal agent on the ground that prior existing knowledge, even though not written or published, could be used to challenge a patent. *India Hails EPO Ruling Against Patent Relating to Traditional Knowledge*, 19 WORLD INTELL. PROP. REP., Apr. 2005, available at <http://pubs.bna.com/ip/BNA/wipr.nsf/is/a0b0q7m3d0>.

considered this problem from the point of view of indigenous rights outside the traditional patent and copyright regimes. We concluded 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 intellectual property rights of patent or copyright law.<sup>7</sup> This article now addresses the problem from the other side: what, if anything, about patent law creates or exacerbates the problem of biopiracy?

#### B. PHYSICAL VERSUS INFORMATIONAL RESOURCES

In considering the problem of biopiracy, it is vital to distinguish between use of a physical resource and use of an informational resource. Physical resources are depletable; what one person uses is no longer available to another. Informational resources are nondepletable (infinitely multipliable) in that one person's use of information does not prevent another from making the same or different use of it.<sup>8</sup> This is why intellectual property is fundamentally different from tangible property, and why the legal rules relating to intellectual property must also be different. This point is obvious, indeed almost trite, to intellectual property scholars, but it often seems to be overlooked in the literature on biopiracy.<sup>9</sup>

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7. Paterson & Karjala, *supra* note 1, at 662-67.

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.

Mark A. Lemley, *Place and Cyberspace*, 91 CAL. L. REV. 521, 536 (2003) (citations omitted).

9. For example, see Audrey R. Chapman, *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* (2000) (treating as biopiracy the patenting of plants long cultivated in other cultures with no benefit going back to the group that developed them); AAAS HANDBOOK, *supra* note 6, at 5 (noting that "biopiracy" is used to describe the misappropriation of knowledge and/or biological materials from traditional communities); and Barbara Looney, *Should Genes Be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement*, 26 LAW & POLY INT'L BUS. 231, 240 n.40 (1994)

In one of the strongest condemnations of “biocolonialism” that I have read, Professor Laurie Anne Whitt states, “[b]y allowing access to and exportation of data, biocolonialism concentrates knowledge about a people and their environment in the hands of an imperial power.”<sup>10</sup> 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.

Professor Whitt also presents an extended theoretical analysis of “extractive biocolonialism,” defined as the coercive conversion into private property of indigenous genetic resources typically resulting in such things as environmental damage, physical and spiritual erosion of indigenous health or welfare, destabilization of social, economic, or legal structures, and similar problems.<sup>11</sup> Essentially all of the results she attributes to this coercive conversion are derived from physical extraction of resources or direct imposition of outside legal and moral values. As discussed below, coercion of any kind is to be deplored and sanctioned. When, however, the action does not go beyond noting and using information that is legally available under local rules, “coercion,” and its comparably negative relatives such as “misappropriation” or “exploitation,” are simply inapt labels, because the culture from which the information derives remains free to use the information as it had in the past.<sup>12</sup> Professor Paul Heald has cogently argued

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(worrying that gene patents might exploit mankind’s universal heritage to create products sold at prices prohibitive to developing countries). An early example of the erroneous conflation of physical and informational resources is Johan Galtung’s statement that “[a] major aspect of scientific colonialism is the idea of unlimited right of access to data of any kind, just as the colonial power felt it had the right to lay its hand on any product of commercial value in the territory.” Johan Galtung, *After Camelot*, in *THE RISE AND FALL OF PROJECT CAMELOT: STUDIES IN THE RELATIONSHIP BETWEEN SOCIAL SCIENCE AND PRACTICAL POLITICS* 281, 300 (Irving Louis Horowitz ed., 1967).

10. Laurie Anne Whitt, *Indigenous Peoples, Intellectual Property & the New Imperial Science*, 23 OKLA. CITY U. L. REV. 211, 220 (1998).

11. *See id.* at 214-15.

12. *Cf.* Chapman, *supra* note 9, at 17 (noting that traditional knowledge rarely qualifies for intellectual property protection, rendering it vulnerable to

that focusing the rhetoric of biopiracy on intellectual property rights is actually counterproductive to the goals of most advocates of indigenous peoples.<sup>13</sup>

On the other hand, it is incorrect to say that, in general, 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.<sup>14</sup> There is absence of harm only if a purchase of the pirated product does not substitute for purchase of the patented product. While this is often the case because some purchasers of a pirated product would wholly forgo its use rather than pay the higher price of 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 find their way back to developed countries, they may displace further sales and thereby reduce the patentee's profits.

Nondepletability of informational resources implies that once the information is publicly available, it is economically inefficient to afford exclusive rights in it.<sup>15</sup> 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 desirable works overall. Calls for exclusive rights in information outside

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"expropriation and inappropriate utilization" by outsiders); Zita Lazzarini, *Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil*, 6 YALE HUM. RTS. & DEV. L.J. 103, 113 (2003) (noting that the difficulty in patenting indigenous knowledge renders it vulnerable to "use or exploitation" by others).

13. Paul J. Heald, *The Rhetoric of Biopiracy*, 11 CARDOZO J. INT'L & COMP. L. 519 (2003).

14. Nadia Natasha Seeratan, Comment, *The Negative Impact of Intellectual Property Patent Rights on Developing Countries: An Examination of the Indian Pharmaceutical Industry*, 3 SCHOLAR 339, 353-54 (2001).

15. See *supra* note 8. On the economic inefficiency of protecting works that have already been created, see also Dennis S. Karjala, *The Term of Copyright*, in GROWING PAINS: ADAPTING COPYRIGHT FOR LIBRARIES, EDUCATION, AND SOCIETY 33, 42-44 (Laura N. Gasaway ed., 1997). 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 Richard A. Epstein, *Liberty Versus Property? Cracks in the Foundations of Copyright Law*, 42 SAN DIEGO L. REV. 1 (2005) (arguing that for both types of property utilitarian tradeoffs are necessary).

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 is mine”) carries no limitation on the duration of protection, nor can 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. This is difficult to explain if natural rights to one’s creative ideas and discoveries are the basis for exclusive rights. Moreover, if natural rights are the basis for protection, copyright could not distinguish, as it does universally, between protected “expression” and unprotected “idea.” Often the idea underlying a work is its most creative element.<sup>16</sup> Finally, in the case of indigenous populations who assert natural 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. Professor Heald also argues that natural rights theories of Locke and Hegel – “the rhetoric of philosophy and moral entitlement” – do not even in their own terms effectively supply a basis for intellectual property rights in information discovered by indigenous groups.<sup>17</sup>

### 1. Depletion of Physical Resources

To the extent the biopiracy complaint is that a physical resource is being depleted, it is something that may be controlled by the environmental regulations of the source country. In other words, this is not an intellectual property rights question but one of tangible property. There is no significant debate today that taking such resources without authority (theft) or by fraud is and should be unlawful. A

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16. See Karjala, *supra* note 15, at 42-43; Dennis S. Karjala, *Federal Preemption of Shrinkwrap and On-Line Licenses*, 22 U. DAYTON L. REV. 512, 517 (1997).

17. Heald, *supra* note 13, at 527-30.

patent elsewhere on the active ingredient of the plant simply has nothing to do with the problem of environmental depletion. 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 to manufacture the patented product. While the 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 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.

For example, Professor Whitt describes how the Brazilian Guajajara treated glaucoma with a local plant now depleted by exports valued at \$25 million per year, with corporations holding patents earning even more.<sup>18</sup> 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 exportation of the plant in question, especially if it is in danger of depletion. If the glaucoma treatment is now well-known throughout the world, denying a patent would likely exacerbate demand for the plant in question. If the complaint is that only the Guajajara should be able to use the treatment, the question is why a remedy for a worldwide ailment should be so confined. Would anyone deny the Guajajara the benefits of medical advances discovered elsewhere, whether or not patented? And if the complaint is that the Guajajara are entitled some recompense for their contribution to medical knowledge, we need only note here that there will be no profits to share unless the knowledge has led to a patent. Monopoly rents that would otherwise flow from the patent simply will not exist after the market competes

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18. Whitt, *supra* note 10, at 213-14.

the price down to marginal cost.

## 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 kept in mind. First, no patented invention based on the information can cover any prior use the source country's people made of the original resource. The source country's long use of the plant for particular medicinal or other purposes would render any claim that covered such a use (in the original source country) invalid for want of novelty. Indeed, that country may well be in a position to refuse a patent altogether if the end product is a naturally occurring substance. Even U.S. patent law, until relatively recently, denied patents on naturally occurring substances.<sup>19</sup> 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.<sup>20</sup> Moreover, the Agreement on

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19. Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 366-84 (2002) (arguing that naturally occurring substances were long deemed by courts to be unpatentable, and Congress showed no intent in the 1952 Patent Act to change that).

20. Another ground for denying such patents in the United States could be created by removing the geographical limitation on prior uses that disqualify an invention for a patent. A patent is denied when "the invention was known or used by others in this country" prior to the applicant's invention of it or where the invention was "in public use or on sale in this country" more than one year prior to the filing of the current patent application. 35 U.S.C. § 102(a), (b) (2000). If public use anywhere in the world were disqualifying, many patents based on naturally occurring substances would be blocked. See generally Jim Chen, *Webs of Life: Biodiversity Conservation as a Species of Information Policy*, 89 IOWA L. REV. 495 (2004). Professor Margo Bagley has argued recently that the geographical limitations on disqualifying prior art under § 102(a) and (b) are unconstitutional because they have come to be in conflict with the constraints on congressional power under the intellectual property clause of the Constitution. Margo A. Bagley, *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World*, 87 MINN. L. REV. 679, 690 (2003). Professor Bagley wrote, however, prior to the Supreme Court's decision upholding the Sonny Bono Copyright Term Extension Act of 1998, which appears to delegate all interpretations of the intellectual property clause, including the constraints on congressional power contained therein, to Congress itself. See *Eldred v. Ashcroft*, 537 U.S. 186 (2003).

Trade-Related Aspects of Intellectual Property (TRIPS) requires member states to have patent laws protecting inventions that are “new, involve an inventive step and are capable of industrial application,”<sup>21</sup> but TRIPS nowhere defines “new.” Any member state is therefore free to deny patents covering naturally occurring substances or traditionally used methods of treatment because they are not “new.” They can also deny method patents covering the use of naturally occurring substances, purified or not, for therapeutic or diagnostic purposes.<sup>22</sup> Moreover, following traditional U.S. law, they 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<sup>23</sup> and constitutes a true invention that has greater therapeutic value, a patent in the source country will indeed allow the patentee to charge, for the period of the patent, a monopoly price there 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 the possibility of more effective therapy (if they can afford it), as will indigenous (and other) peoples elsewhere who never had the original treatment.<sup>24</sup> It is important to note that most indigenous groups will have no resources at all, genetic or otherwise, on which profitmaking products can be built.<sup>25</sup> All

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21. TRIPS, *supra* note 3, at art. 27(1).

22. *Id.* at art. 27(3)(a).

23. 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 group outside the United States is likely to result in an invalid patent, because U.S. patent law requires that the patent applicant be the inventor. See 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”).

24. See also Heald, *supra* note 13, at 527 (“[N]o international patent can diminish [the indigenous group’s] ability to cultivate, maintain, and use their existing resources.”).

25. See Chen, *supra* note 20, at 569-72 (noting that while most drugs are derived from natural sources, the huge preponderance of species lacks commercial value).

such people potentially benefit if patent law serves as an incentive to the creation of products that meet important human needs.

The wider availability of both the original treatment and the newly developed drug after “biopiracy” perhaps deserves more emphasis. Professor Whitt states, “[a]cross 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.”<sup>26</sup> It is difficult to see just how the people who “collectively owned” the forerunners of the now improved medicines and seeds have been harmed. Furthermore, 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 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.<sup>27</sup> To the extent patent law serves as an incentive to the development of new products, especially medicines and improved agricultural varieties, it marginally increases the options of everyone, including indigenous peoples, to improve their lives. If the goal is to alleviate the wretched conditions under which many people in developing countries live, it cannot

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26. Whitt, *supra* note 10, at 250.

27. Tara Kowalski, *International Patent Rights and Biotechnology: Should the United States Promote Technology Transfer to Developing Countries?*, 25 LOY. L.A. INT’L & COMP. L. REV. 41, 42 (2002) (citing CLIVE JAMES, GLOBAL STATUS OF COMMERCIALIZED TRANSGENIC CROPS: 2000 § 1 (2000), available at <http://www.isaaa.org/kc/Publications/pdfs/isaaaabriefs/Briefs%2021.pdf>).

be right to say that information held by some of them that could be useful in addressing certain problems should remain confined to the small group that discovered it, provided at least that the information is acquired in ways that are both legally and morally proper.

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, creation incentives are not involved, which distinguishes this information from that protected by patent 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.<sup>28</sup> 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 an agreement to pay a royalty or some other compensation may be in order.<sup>29</sup> As *Moore v. Regents of the University of California*<sup>30</sup> shows, 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.<sup>31</sup> Breach of a

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28. See Paterson & Karjala, *supra* note 1, at 665-66 (arguing that a statute modeled on trade secret law and aimed at prohibiting the public display of sacred symbols and rituals could be effective in protecting group privacy interests in such symbols and rituals); see also Chen, *supra* note 20, at 579-81 (explaining how traditional trade secret law can be adapted to embrace ethnobiological knowledge but warning how “proptertizing” such knowledge lacks an economically justifiable basis and that maintaining secrecy would impede the progress of science).

29. See Paterson & Karjala, *supra* note 1, at 662-65.

30. 793 P.2d 479 (Cal. 1990) (involving spleen cells extracted during therapy used without patient’s knowledge to develop a new line of cells that became the object of a valuable patent).

31. See also Gina Kolata, *Sharing of Profits Is Debated as the Value of Tissue Rises*, N.Y. TIMES, May 15, 2000, at A1 (reporting cases in which people discovered that cell or tissue donations were used in ways beyond their

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, like 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 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. Again, this is simply a normal effect of patent law, and property rights in general. The existence of property rights is a prerequisite to theft. Biotech patents would seem an unlikely candidate for supplying a *special* incentive in this regard, however, given that most inventions require a huge investment to convert the initial information into a commercial product and test it for safety and effectiveness. 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 the complexity of achieving the necessary consents.<sup>32</sup> In other words, the causal link between a biotech patent and any assumed fraud in obtaining the underlying information from indigenous sources is weaker than for many other products. Moreover, the vast majority of patents, biotech or otherwise, are the result of unobjectionable behavior. 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

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expectations and the original purpose of their donations).

32. See Sabrina Safrin, *Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life*, 98 AM. J. INT'L L. 641, 657 (2004).

ethical grounds, arguing that intellectual property should be treated as a pure public good.<sup>33</sup> 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 any group following this belief should retain exclusive rights to use information they have discovered with respect to people outside the group. If the information is freely available simply by visiting the group and observing their lifestyle without fraud or duplicity, preventing the visitor from using 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, it should be articulable in terms of western notions, like breach of confidence or privacy rights. *Something* besides the rule of "we discovered it so it is ours" is necessary unless one takes the extreme step of embracing a full-fledged natural rights basis for intellectual property, or one simply has a preference for economic inefficiency over economic efficiency.<sup>34</sup>

A related view is that patents impoverish indigenous cultures by creating a supply of 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 represent a loss not only to the indigenous group but to 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 loss of indigenous culture is the goal, however, it is quite

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33. See, e.g., Alan S. Gutterman, *The North-South Debate Regarding the Protection of Intellectual Property Rights*, 28 WAKE FOREST L. REV. 89, 122 (1993); Melissa L. Sturges, *Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind*, 13 AM. U. INT'L L. REV. 219, 244 (1997) (asserting that developing countries view intellectual property as a publicly owned community asset that no single person should own); Whitt, *supra* note 10, 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).

34. Cf. Richard A. Shweder, *The Gatekeepers*, N.Y. TIMES BOOK REVIEW, Sept. 14, 2003, at 13 (reviewing MICHAEL F. BROWN, WHO OWNS NATIVE CULTURE? (2003)) ("[Brown] believes we can develop informal social norms of decency and respect that are responsive to the concerns of indigenous peoples without turning our society into a patchwork of legally empowered illiberal cultural enclaves.").

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 groups that supply information leading to a patent, that specific information is only a small part of its entire cultural heritage, much of which is under threat from other sources like music, films, and clothing. Indeed, to the extent patents inhibit technology transfer to indigenous cultures (due to higher prices or lack of local implementation know-how), they should actually impede the deleterious effects of the onslaught of western culture. Eliminating patents on 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 lifestyle for indigenous cultures are serious and real. Unfortunately, they will not be ameliorated by what would inevitably be minor adjustments to patent law, in either western countries or in locales of traditional cultures.

The core of the biopiracy claim thus appears to be the unfair acquisition of indigenous knowledge and the absence of fair sharing of the profits that ultimately derive from developing it into a valuable product, rather than the availability of patents based on such knowledge. The problem to be addressed then 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. Possible solutions include refusing to enforce any patent based on unfairly acquired information, or conditioning patent enforcement on a court-determined fair sharing with the people who served as the information source.<sup>35</sup> These measures would not be major extensions of the doctrines of patent and copyright misuse under which the intellectual property rights owner is denied enforcement until the abuse is cured.<sup>36</sup> Some developing countries have proposed amending TRIPS to mandate disclosure of the source of genetic resources

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35. I am indebted to my colleagues George Schatzki and Ralph Spritzer for this suggestion.

36. See *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 490-92 (1942); *Lasercomb Am., Inc. v. Reynolds*, 911 F.2d 970, 977 (4th Cir. 1990).

used in the invention, evidence that the country of origin had consented to the use of those genetic resources in the invention, and evidence of fair sharing of the benefits as conditions to the issuance of a patent.<sup>37</sup> Another approach to limiting biopiracy directly under the patent law would be to eliminate the geographical limitations on disqualifying prior art.<sup>38</sup> The important point for present purposes, however, is that without the patent there will be no profit out of which *any* compensation can be paid.<sup>39</sup> Therefore, 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.

### III. PATENTS ON GENES AND GENE PRODUCTS

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. In addition, there is always the basic policy question in recognizing patents in such compositions of matter: 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.

#### A. TECHNICAL ISSUES INVOLVED IN GENE-RELATED PATENTS<sup>40</sup>

##### 1. Naturally Occurring Substances

Analysis of biotech patent questions under U.S. law always

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37. See Safrin, *supra* note 32, at 666.

38. See *supra* note 20; Bagley, *supra* note 20, at 724-27.

39. See F. Scott Kieff, *Patents for Environmentalists*, 9 WASH. U. J.L. & POLY 307, 318 (2002) (noting the need to find ways, possibly through contract, to fairly allocate wealth generated by a patent based on access to biodiversity, but pointing out that without a patent system the wealth itself would be sacrificed).

40. I will address technical questions of patent law primarily by reference to that of the United States, 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 other countries.

begins with *Diamond v. Chakrabarty*,<sup>41</sup> in which the Supreme Court held that the law did not preclude patents on living organisms.<sup>42</sup> The case is justifiably controversial for such a broad interpretation of § 101 of the Patent Act.<sup>43</sup> 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.<sup>44</sup> Upholding and distinguishing an earlier case as denying a patent for merely discovering “some of the handiwork of nature,” *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.<sup>45</sup>

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. Therefore, one might have thought that the prohibition

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41. 447 U.S. 303 (1980).

42. *Id.* at 313 (stating that the patentability line is “not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions”).

43. See Demaine & Fellmeth, *supra* note 19, at 317. Section 101 of the Patent Act allows a patent for one who “invents or discovers any new and useful process, machine, manufacture, or composition of matter.” 35 U.S.C. § 101 (2000). Living organisms do not fit easily into any of these categories. See Demaine & Fellmeth, *supra* note 19, at 317. This broad interpretation of § 101 also conflicts with the special statutes aimed specifically at protecting plants. Plant Patent Act of 1930, 35 U.S.C. §§ 161-164 (2000) (protecting a new and distinct variety of plant that is asexually reproduced); Plant Variety Protection Act of 1970, 7 U.S.C. § 2402(a) (2000) (giving patent like protection to sexually reproduced plants constituting a “novel variety”). As a result of the *Chakrabarty* decision, plants are also patentable under the general Patent Act, a conclusion that the Court recently affirmed. See *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 129-30 (2001). These interpretations of § 101 render both specific plant protection statutes largely extraneous. Had Congress thought that the Patent Act covered all living organisms invented by man, there would have been no need for special plant protection statutes. See Demaine & Fellmeth, *supra* note 19, at 313-17. But see Jim Chen, *The Parable of the Seeds: Interpreting the Plant Variety Protection Act in Furtherance of Innovation Policy*, 81 NOTRE DAME L. REV. 105, 110-11 (2005) (arguing that the PVPA “remains a significant source of interest” notwithstanding *J.E.M. AG Supply*).

44. *Chakrabarty*, 447 U.S. at 313.

45. *Id.* at 309-310 (discussing *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)); see also Demaine & Fellmeth, *supra* note 19, at 316-17.

on patenting naturally occurring substances would have ruled out patents for genes and gene products.<sup>46</sup> Yet, despite the Supreme Court's reaffirmance of the prohibition on patenting naturally occurring substances, lower federal courts and the Patent and Trademark Office (PTO) have deviated substantially from this standard and further expanded 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.<sup>47</sup> In response to arguments claiming that while inventions are patentable, mere discoveries (such as a particular gene) are not, the PTO said:

[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.<sup>48</sup>

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

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46. 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 Dennis S. Karjala, *A Legal Research Agenda for the Human Genome Initiative*, 32 JURIMETRICS J. 121, 129-33 (1992). If a gene researcher seeks to patent a DNA sequence comprised 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. *Id.* 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 & Fellmeth, *supra* note 19, at 444-45.

47. Section 101 of the Patent Act requires that the invention be "useful." 35 U.S.C. § 101 (2000).

48. Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

gene.

Many commentators have decried treating the “isolated and purified” form of a naturally occurring substance as patent subject matter.<sup>49</sup> Professors Linda Demaine and Aaron Fellmeth have recently supplied a thorough and convincing analysis criticizing the notion of product patents for such substances and demonstrating that such patents represent a substantial deviation from precedent.<sup>50</sup> They argue that § 101 of the Patent Act mandates “invention” rather than mere “discovery”<sup>51</sup> based on the express statutory requirement that the object of the patent be “new” *and* something that arises

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49. See, e.g., Peter Drahos, *Biotechnology Patents, Markets and Morality*, 21 E.I.P.R. 441, 443 (1999) (asserting that treating an isolated and purified form as an invention exalts form over substance); Richard A. Epstein, *Property Rights in cDNA Sequences: A New Resident for the Public Domain*, 3 U. CHI. L. SCH. ROUNDTABLE 575, 579 (1996) (arguing 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 pitchblend); Abbey S. Meyers, *“Intellectual Property at the Public- Private Divide:” A Response*, 3 U. CHI. L. SCH. ROUNDTABLE 581, 581 (1996) (arguing for distinguishing between a discovery and an invention); Looney, *supra* note 9, at 264 (asserting 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 and identifying its function).

50. Demaine & Fellmeth, *supra* note 19.

51. Section 101 provides for a patent to whomever “invents or discovers” patentable subject matter. 35 U.S.C. § 101 (2000). 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 “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” U.S. CONST. art. I, § 8, cl. 8. The PTO has latched onto the “discover” aspect of § 101 as a basis for gene-sequence patenting. See Utility Examination Guidelines, 66 Fed. Reg. at 1093. With painstaking care, Professors 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. Demaine & Fellmeth, *supra* note 19, at 367-73. They 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. *Id.* at 373-76; see also Jonathan King & Doreen Stabinsky, *Patents on Cells, Genes, and Organisms Undermine the Exchange of Scientific Ideas*, CHRON. OF HIGHER EDUC., Feb. 5, 1999, 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”); cf. Sturges, *supra* note 33, at 242 (asserting, not entirely correctly, that gene researchers do not create anything new but only indicate where a gene might lie along a naturally occurring sequence).

from application of human intellectual thought.<sup>52</sup> 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 resulting in increased commercial or therapeutic value.<sup>53</sup>

Professors Demaine and Fellmeth recommend a test based on whether the naturally occurring substance has been transformed to the point that a new product is created that is substantially different in biological function from the naturally occurring phenomenon.<sup>54</sup> For biological substances this test requires 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 resolution of 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 functions as it does in nature, the new version will not be sufficiently creative under their test to be patentable. A supplemental possibility for naturally occurring substances unmodified by human-initiated structural change<sup>55</sup> would

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52. Section 101 requires that a patentable invention or discovery be “new” in addition to “useful” and to belong to a patentable class of “process, machine, manufacture, or composition of matter.” 35 U.S.C. § 101 (2000). Professors Demaine and Fellmeth offer two pithy summaries of their complex but convincing argument: “When the Patent Act speaks of discoveries in the sense of ‘discoveries and inventions,’ it follows the historical usage of the term ‘discoveries,’ meaning ‘inventions,’ because only inventions can be ‘new.’” Demaine & Fellmeth, *supra* note 19, at 370. “[I]t is a mistake to use the word ‘discovery’ to convey the sense of a ‘finding.’ Under traditional common law consistently reaffirmed by the Supreme Court, a ‘discovery’ is not patentable subject matter unless it is an ‘invention.’” *Id.* at 376. They go on to argue that § 103’s requirement of nonobviousness, measured against the prior *human-known* art, embodies only part of the traditional notion of “invention,” because otherwise an obvious but new variation on a naturally occurring object would be patentable. That the object of the patent arises from the application of human intellectual thought has always been inherent in the concept of “invention.” *Id.* at 377, 390. The long-standing, albeit unelaborated, requirement that a patent cover something “new” remains in § 101 and still demands that creative human “invention” be involved. *Id.* at 383-84.

53. *Id.* at 391. Under this rationale for patentability, the first person to purify water or blood cells could have patented them. *Id.*

54. *Id.* at 392.

55. Recall that genes themselves, in the precise form found in chromosomal DNA, are usually not the subject of patent claims. *See supra* note 46. However, the supplemental test that denies product patents to truly naturally occurring substances may simplify the patentability question for

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.<sup>56</sup>

Either approach would leave the substance itself, purified or not, free for research and uses not envisioned by the patent owner.<sup>57</sup> Finding a new use for such substances may well involve substantial investment and require the incentive of patent protection.<sup>58</sup> Process patents are generally considered weaker than product patents because it is often possible to invent around a process patent. Process patents may also be more difficult to enforce when the process is used in another country and the resulting product, which is not covered by the patent, is imported.<sup>59</sup> Still, at least some biotech method patents have a very high economic value.<sup>60</sup> Moreover, if a

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proteins and other gene products. For them, *only* process patents would be available, obviating any need to argue over whether the claimed new use in fact involved a substantially different function.

56. This suggestion was made to, but rejected by, the PTO. See Utility Examination Guidelines, 66 Fed. Reg. at 1095. The PTO's response was simply that "[p]atent law provides no basis for treating DNA differently from other chemical compounds that are compositions of matter." *Id.* 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. See *supra* note 46. However, the basis for distinguishing them from patentable compositions of matter is that they are not "inventions," because their composition is not the result of any creative human input. See *supra* notes 51-52 and accompanying text. The PTO expressly rejects the notion that naturally occurring compositions of matter, if they are isolated and purified, are ineligible for patents. See Utility Examination Guidelines, 66 Fed. Reg. at 1092-93.

57. A product patent covers *all* uses of the product, whether or not disclosed in the patent. See Utility Examination Guidelines, 66 Fed. Reg. at 1095; Demaine & Fellmeth, *supra* note 19, at 418. It also goes without saying that new and nonobvious processes for obtaining, isolating, or purifying genes and gene products should be patentable. See Matthew Erramouspe, Comment, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races*, 43 UCLA L. REV. 961, 997 (1996).

58. See Sturges, *supra* note 33, at 255 & n.203.

59. See, e.g., Demaine & Fellmeth, *supra* note 19, at 428-29 & n.550.

60. See, e.g., Goldie Blumenstyk, *Coalition Seeks to Make Agricultural-Biotechnology Tools More Widely Available*, CHRON. HIGHER EDUC., July 11, 2003, available at <http://chronicle.com/daily/2003/07/2003071105n.htm> (describing the difficulties of using, even for public or humanitarian purposes, fundamental genetic engineering techniques that were invented at universities but are now exclusively licensed to commercial operations); Eliot Marshall, *Depth Charges Aimed at Columbia's 'Submarine Patent,'* 301 SCIENCE 448 (2003) (describing Columbia University's patent on a technique for inserting genes into a cell as having netted "hundreds of millions of

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.<sup>61</sup>

In any event, while U.S. law has deviated from its long-standing position that naturally occurring substances are unpatentable and that merely extracting them in purified form does not make them patentable, other nations are free to argue that such substances are not patentable because they are not “new.” TRIPS requires patents only for inventions that are “new,” and member states may decide for themselves whether or not a naturally occurring substance, like a gene or gene product, is “new” in the sense required by their patent statutes.<sup>62</sup>

## 2. Modified Genes and Their Products

Many biotech inventions will involve creative alteration of a naturally occurring substance. In such cases, an objection to patenting based on the absence of something “new,” in the

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dollars”).

61. 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, *supra* note 3, at art. 27(3)(a). Much of Europe and many other countries have availed themselves of this exclusionary possibility. *E.g.*, Convention on the Grant of European Patents (European Patent Convention), Oct. 5 1973, art. 54(4), 1065 U.N.T.S. 255, available at <http://www.european-patent-office.org/legal/epc/>. The United States does not preclude patents on therapeutic processes, but it does immunize “medical practitioners” from liability for infringement arising in the course of performing a “medical activity.” 35 U.S.C. § 287(c)(1) (2000). 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(c)(2)(A)(iii). This would seem to leave unimpaired, in the United States 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. I am indebted to my former student Fariba Sirjani for making me aware of § 287(c) and the alternative approaches to limiting therapeutic-method patents elsewhere.

62. Moreover, merely finding raw genes is not particularly difficult or inventive. See Erramouspe, *supra* note 57, at 997. Consequently, denial of patents on raw genes could also be predicated on absence of an inventive step.

sense of “not previously existing,” is unavailable. Similarly, an objection based on the absence of sufficient human creativity in the final product is often unavailable. 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.<sup>63</sup> TRIPS, of course, allows excluding plants and animals, other than microorganisms, from patentability,<sup>64</sup> and many countries may choose to so act on ethical grounds. Nevertheless, 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.<sup>65</sup> Additionally, we should bear in mind the huge potential for genetically modified organisms to contribute to the elimination of hunger and disease in developing countries, particularly if access to the technology is available.<sup>66</sup> If patents on such products, at least in developed countries, serve as an incentive for their creation, then outright denial of patent rights would appear to affect a net social loss.

## B. POLICY BALANCING OF COSTS AND BENEFITS OF GENE-RELATED PATENTS

### 1. Naturally Occurring Substances

The courts and PTO have expanded the notion of patent subject matter to include patents on gene sequences or naturally occurring gene products, provided that they have been “isolated and purified.” Thus, until the Supreme Court

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63. See generally Arti K. Rai, Patenting Human Organisms: An Ethical and Legal Analysis (draft paper prepared for President's Council on Bioethics, June 21, 2002), available at <http://www.law.upenn.edu/fac/akrai/rai.patents.cob.doc>.

64. TRIPS, *supra* note 3, at art. 27(3)(b). Professor Fellmeth has pointed out to me 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*.

65. See generally Rai, *supra* note 63.

66. See Kowalski, *supra* note 27, at 42-45.

addresses the issue, we must accept the patentability of gene sequences and naturally occurring gene products, whether or not this conflicts with the earlier prohibition on patenting naturally occurring substances. It remains important to ask whether this expansion of traditional patent law makes sense as a matter of policy.

Professor Richard Epstein has articulated the basic policy issue that must be addressed in deciding whether to recognize gene-related patents: do the incentives for creation of these inventions justify the restrictions on output that follow from exclusive rights?<sup>67</sup> 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.<sup>68</sup> Gene sequences alone, even in their “isolated and purified” forms, rarely have any direct use outside the organisms from which they derive and are naturally used. 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 (such as the bacterium) and ultimately tested for safety and efficacy in its hypothesized use. These “downstream” activities that go from the gene itself to a useful product may require a greater investment of time and money than the “upstream” effort needed to determine the gene in the first place.<sup>69</sup> Thus, patents on basic upstream tools can inhibit rather than promote valuable downstream research.<sup>70</sup>

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67. Epstein, *supra* note 49, at 577-78 (arguing 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).

68. See *infra* notes 69-76 and accompanying text.

69. Opinion, *Genes and Patent Law*, 371 NATURE 270 (1994) (stating that the effort spent on gene identification is likely to be much smaller than that required to work out their normal function, which will be the basis for discovering means of treatment and prevention of disease).

70. See John H. Barton, *Patent Scope in Biotechnology*, 26 IIC 605, 614 (1995) (“[H]ighly basic patents that preempt a large area of research are unlikely to be beneficial.”); David Dickson, *HUGO and HGS Clash over “Utility” of Gene Sequences in US Patent Law*, 374 NATURE 751 (1995) (describing Human Genome Organization (HUGO) officials’ opposition to patents on cDNA sequences because they are “routine discoveries” that could

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 be necessary to induce innovation but may still be strongly preclusive of downstream research.<sup>71</sup>

It has also been argued that patents on raw genes may result both in too much investment in the search for genes and in insufficient investment in developing new products and carrying them to market.<sup>72</sup> In addition, such patents can inhibit information flow, which in turn results in duplicative research.<sup>73</sup> Finally, Professors Michael Heller and Rebecca 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<sup>74</sup> 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.<sup>75</sup> Moreover, a biotech anticommons is more likely to endure than in other areas of intellectual property because of higher transaction costs, heterogeneous interests among owners, and

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inhibit incentives to establish gene function or develop applications); Epstein, *supra* note 49, at 578 (decrying cDNA patents as opposed to patents for the fashioning of some new bacterium or virus with commercial applications); Melissa E. Horn, Note, *DNA Patenting and Access to Healthcare: Achieving the Balance Among Competing Interests*, 50 CLEV. ST. L. REV. 253, 263-64, 274-76 (2003).

71. Demaine & Fellmeth, *supra* note 19, at 417-18.

72. See, e.g., Drahos, *supra* note 49, at 443; Amy E. Carroll, Comment, *Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law*, 44 AM. U. L. REV. 2433, 2482 (1995).

73. See Carroll, *supra* note 72, at 2483-84; see also Chapman, *supra* note 9, at 7, 24-25. *But see* Looney, *supra* note 9, at 244-45 (concluding that the impact of gene patenting on the dissemination of information is unclear).

74. See Eliot Marshall, *Need a Reagent? Just Sign Here . . .*, 278 SCIENCE 212 (1997) (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).

75. See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 699-700 (1998); see also Demaine & Fellmeth, *supra* note 19, 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”); Horn, *supra* note 70, at 265-67.

cognitive biases of researchers.<sup>76</sup>

These policy arguments 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.<sup>77</sup> 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.<sup>78</sup>

## 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 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.

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76. See Heller & Eisenberg, *supra* note 75, at 700-01; see also Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERK. TECH. L.J. 1155, 1195-96 (2002) (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).

77. See Horn, *supra* note 70, at 281-82 (arguing for legislation providing compulsory licensing at reasonable cost for gene patents and suggesting an infringement exemption for those who use patented genes to develop products more medically useful). But see F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science - A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691 (2001) (criticizing generally the arguments of Professors Rai and Eisenberg against patents on basic biotechnological inventions, but not specifically attacking these arguments as applied to naturally occurring substances like genes or gene products).

78. Cf. Kieff, *supra* note 77, at 704 (concluding 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).

## C. 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 several ethical questions: First, whether such private control over genes or their products involves monopolization of the “common heritage of mankind.”<sup>79</sup> Second, whether they denigrate human life by reducing life to a commodity. Third, whether they interfere with individual or collective privacy. Fourth, whether they promote distributive justice when they are concentrated in a few economically developed countries.<sup>80</sup> And fifth, whether patents on crop varieties threaten biodiversity.<sup>81</sup> These are serious issues that will continue to be addressed for some time. I only touch upon them here because, as for the technical and policy bases for gene-related patents, indigenous and nonindigenous populations are equally affected or, 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 at the root of the problem.

## 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. This is inherent in the term “mankind.” 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 even plants. This objection to human gene-related patents would seem to be subsumed in the “naturally occurring substance” controversy.<sup>82</sup> If we upheld the traditional ban on patents covering naturally occurring substances, whether or

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79. See, e.g., Sturges, *supra* note 33.

80. See Looney, *supra* note 9, at 240.

81. CENTER FOR INT'L ENVTL. LAW, THE 1999 WTO REVIEW OF LIFE PATENTING UNDER TRIPS 4 [hereinafter CIEL REPORT], <http://www.ciel.org/Publications/WTOReviewofLPunderTRIPS.pdf>.

82. Cf. Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (noting objections to gene patents on the ground that the human genome is at the core of what it means to be human, which the PTO lumped with comments objecting to patents for discoveries in nature rather than inventions).

not isolated and purified, human genes and their protein products would not be patentable.

The substantial transformation test of Professors Demaine and Fellmeth should, as a practical matter, get to the same result. That test would allow a product patent on genes, including human genes, biochemicals, or 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.<sup>83</sup> 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 to perform a different biological function the substances almost certainly will have to have a different structure.<sup>84</sup> Their test is thus one of the degree of “inventiveness” an applicant must show to get a patent on a composition of matter that he has modified from its natural form, which takes the invention out of the “common heritage” and places it with all other patented inventions. 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.<sup>85</sup> 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.

Still, even though standard doctrine fairly applied can deal with the “common heritage” objection, as a policy matter it is at

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83. Demaine & Fellmeth, *supra* note 19, at 444-45.

84. *See supra* note 46.

85. *See supra* note 57.

least possible that a full-fledged cost-benefit analysis might show gains from recognizing patents in genes and their products outweighing losses therefrom. That is, 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.<sup>86</sup> 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. The logic of composition-of-matter patents on naturally occurring genes and their products thus leads to an absurd result when applied to living organisms and represents a basic flaw in the theory.<sup>87</sup>

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86. See, e.g., Demaine & Fellmeth, *supra* note 19, at 434 (“From a purely positivistic perspective, a patent on a DNA molecule or protein entitles the patentee to forbid cell building, transcribing, 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.”).

87. See *id.* 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, Professors 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 gametes without a license from the patentee. *Id.* at 436.

The problem arises, however, not because genes are part of the common heritage of mankind but rather because gene and gene-product patents, by their nature, cover things that are not “inventions.” One can imagine 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. Moreover, by limiting focus on human genes, the common heritage approach would leave naturally occurring genes in other plants and animals free to be taken and patented. Therefore, it would seem that opposing gene patents on the ground that genes comprise the common heritage of mankind is not fruitful analytically. Instead, we should stay within the bounds of traditional patent law and seek 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.

Some variations of the “universal heritage” argument are also possible.<sup>88</sup> 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. Moreover, 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 Professors Demaine and Fellmeth discussed above. 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

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88. I am indebted to Professor Aaron Fellmeth for the arguments discussed in this paragraph.

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.

It might be noted that the Biodiversity Convention requires that member states facilitate access to genetic resources, subject to fair sharing of the benefits after genetic resources have been obtained by prior informed consent.<sup>89</sup> It thus rejects any form of the “common heritage” doctrine that would prevent all forms of commercialization.<sup>90</sup> Similarly, Article 4 of the Universal Declaration on the Human Genome and Human Rights declares that the human genome in its natural state shall not give rise to financial gains.<sup>91</sup> 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.

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.

## 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.<sup>92</sup> 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

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89. United Nations Convention on Biological Diversity, June 5, 1992, arts. 15(2), 15(4), 15(5), 15(7), 31 I.L.M. 818, 828.

90. See David R. Downes, *New Diplomacy for the Biodiversity Trade: Biodiversity, Biotechnology, and Intellectual Property in the Convention on Biological Diversity*, 4 *TOURO J. TRANSNAT'L L.* 1, 9 (1993).

91. Universal Declaration on the Human Genome and Human Rights, art. 4 UNESCO Gen. Conference (Nov. 11, 1997), adopted by G.A. Res. 152, U.N. GAOR, 53d Sess., U.N. Doc. A/RES/53/152 (1999) [hereinafter Universal Declaration].

92. See, e.g., Chapman, *supra* note 9, at 3; Sturges, *supra* note 33, at 242, 244-45; CIEL REPORT, *supra* note 81, at 4.

potential disease 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. While at bottom it may come down to questions of fundamental ethical or religious values, to me no single gene or gene product can be meaningfully deemed "human life." 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 under patent. Moreover, the unavailability of patents will not stop scientific activity on human genes nor will it stop all market activity in gene products.<sup>93</sup> Conversely, the availability of patents is not synonymous with commodification.<sup>94</sup>

Finally, it is again unclear 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 relatively isolated from the onslaught of modern society will have in its collective genome a genetic characteristic of particular interest to those who seek to develop genes into patentable products.<sup>95</sup> In addition, remote, isolated populations often make it easier to trace disease heredity, which means that studying the genes from these groups can speed up gene discovery and drug development.<sup>96</sup> Yet, it is difficult to see how studying the genetic characteristic

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93. See George Poste, *The Case for Genomic Patenting*, 378 NATURE 534, 536 (1995); Rai, *supra* note 63.

94. See Rai, *supra* note 63.

95. Cf. Neil Gross & John Carey, *Who Owns the Tree of Life?*, BUS. WK., Nov. 4, 1996, at 194 (describing the Papua New Guinea Hagahai's apparent immunity to a virus that usually causes leukemia); King & Stabinsky, *supra* note 51 (describing patent applications for cells and genes of New Guinea tribes because of an apparent immunity against certain viruses); John Frow, *Elvis' Fame: The Commodity Form and the Form of the Person*, 7 CARDOZO STUD. L. & LIT. 131, 150 (1995) (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).

96. See Gross & Carey, *supra* note 95, at 197; Safrin, *supra* note 32, at 660-61 (stating that DNA from homogeneous and isolated populations can facilitate discovery of disease-causing genes).

of interest reduces the lives of the people from whom the information is derived to a commodity. 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.

### 3. Privacy and Human Dignity

Many have decried recognition of gene-related patents as being fundamentally in conflict with norms of privacy and human dignity.<sup>97</sup> 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.<sup>98</sup> Because genes are also part of our collective makeup, it has been suggested that gene patenting may violate some sort of collective privacy right as well.<sup>99</sup>

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.<sup>100</sup> To the extent that such a gene is known to be differentially preponderant in a specific group, the danger of group stigma is also very real. Without downplaying the importance of either of these problems, it is difficult to see how gene-related *patents* exacerbate them. 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. There is good reason to

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97. See Demaine & Fellmeth, *supra* note 19, at 437-38 (discussing the worldwide concern about these issues).

98. See Looney, *supra* note 9, at 238.

99. See *id.* at 238-39.

100. See generally Karjala, *supra* note 46.

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 methods of prevention. Withdrawal of the patent incentive will almost surely be detrimental for these developments.

Interference with privacy norms and affronts to human dignity through 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 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 particularly unrelated to such a discovery. When outsiders have sought patents based on the genetic makeup of an indigenous group, it is usually because the group is perceived as having a genetic *advantage* over the rest of humankind.<sup>101</sup> By the nature of the patent incentive, it is unlikely that 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.

#### 4. Crop Monocultures and Monopolization of Crop Genomes

Some have raised ethical questions concerning the appropriateness of gene patents, even outside the human genome. Patents on crop varieties, for example, may result in monocultures and the use of expensive inputs, such as fertilizers, that cause environmental harm.<sup>102</sup> It has been claimed that broad plant variety patents have conferred on a few corporations virtual monopolies on the genomes of important crops.<sup>103</sup>

Here we again find some potentially serious problems. If all the world's wheat is a single variety, 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

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101. See *supra* note 95 (describing attempts to patent cells and genes of indigenous groups based on an apparent immunity to diseases that afflict developed countries).

102. See CIEL REPORT, *supra* note 81, at 4.

103. See Chapman, *supra* note 9, at 22.

wiped out with catastrophic consequences.<sup>104</sup> Still, one can legitimately question the role patents might play in creating or exacerbating these problems. If the use of expensive inputs is the problem, it would seem that the patented variety would not be used by everyone (in particular, by 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. Patent 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.<sup>105</sup>

Moreover, if environmental harm is the problem (and a susceptible monoculture is one such example), environmental regulation is most likely necessary to remedy it.<sup>106</sup> 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 under the same (economic) disadvantage. 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.

#### IV. PATENTS GENERALLY AND DEVELOPING COUNTRIES

Any country that wishes to have the free trade advantages supposedly supplied by the World Trade Organization must comply with the intellectual property requirements of TRIPS. Among other things, TRIPS mandates that its member states

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104. The Irish potato blight is a classic example, as is the commercial banana today, which may be under serious threat. Jim Chen, *Webs of Life: Biodiversity Conservation as a Species of Information Policy*, 89 IOWA L. REV. 495, 506 (2004).

105. See Kieff, *supra* note 39, 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).

106. See *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 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).

adopt patent laws similar to the models 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.<sup>107</sup> A hefty 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<sup>108</sup> and access to pharmaceuticals.<sup>109</sup> Others have asserted that developing countries may view intellectual property as a community (public domain) asset that no individual should own.<sup>110</sup> Patenting, in particular, has been said to clash with indigenous knowledge and value systems.<sup>111</sup>

#### A. TECHNOLOGY TRANSFER

There is little doubt that TRIPS impedes the ability of developing countries to determine their intellectual property standards and policies in the hope of achieving a better fit to their own economic and social conditions.<sup>112</sup> In particular, it does not allow the choice of simply not recognizing patents for inventions by nationals of other member states.<sup>113</sup> At the same time, the advantages to developing countries of adopting and enforcing a patent law have been seriously questioned.

It has been claimed that recognizing patents induces technology transfer, allowing the patenting country to gain not

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107. See Carroll, *supra* note 72, at 2471 (citing EDITH T. PENROSE, *THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM* 116-17 (1951)).

108. See Looney, *supra* note 9, at 239-40.

109. See Lazzarini, *supra* note 12, at 115-19 (arguing that access to pharmaceuticals should be thought of as a human right).

110. See Sturges, *supra* note 33, at 244.

111. See Whitt, *supra* note 10, at 240.

112. See Chapman, *supra* note 9, at 6-7; cf. Carroll, *supra* note 72, at 2466-67 (stating that forcing countries to adopt patent laws and accept conditions of technology transfer laid down by the holder of the patent is "technological colonialism").

113. See Howard C. Anawalt, *International Intellectual Property, Progress, and the Rule of Law*, 19 SANTA CLARA COMPUTER & HIGH TECH. L.J. 383, 404 (2003) ("The linkage of WTO membership to mandatory intellectual property rights and procedure should be ended . . .").

only the knowledge supplied in patent applications themselves, but also the necessary know-how to start going into many of these fields of technology. Others have disputed these claims, arguing that foreign patents impede developing countries' ability to appropriate new technologies and products.<sup>114</sup> The needs of developing countries are often quite basic and some lack the ability to assimilate the latest technologies.<sup>115</sup> A foreign patent owner may have little incentive to transfer technological knowledge related to a patented invention if profits are available from imports.<sup>116</sup> 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.<sup>117</sup>

#### B. ACCESS TO INVENTIONS

It is routinely observed that patented goods reaching the market will have a higher price than if they were not patented.<sup>118</sup> To the extent this is true, it reduces access to the patented goods if there is any elasticity in demand because people at the margin, by definition, may afford a lower price but not a higher one. It has been argued, moreover, that a

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114. See Gutterman, *supra* note 33, at 122-23, 136-37 (1993); cf. Downes, *supra* note 90, at 22-23; Lazzarini, *supra* note 12, at 111 (both concluding that the empirical evidence on the inhibiting or beneficial effects of intellectual property rights on technology transfer is scanty); Seeratan, *supra* note 14, 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 evidence that recent advances in medicine do not reach many of those who need it or their physicians, often years after the information is publicly available. *E.g.*, Sharon Begley, *Too Many Patients Never Reap Benefits of Great Research*, WALL ST. J., Sept. 26, 2003, at B1.

115. See A. Samuel Oddi, *The International Patent System and Third World Development: Reality or Myth?*, 1987 DUKE L.J. 831, 843.

116. See *id.* at 852.

117. See *id.* at 850.

118. See Carroll, *supra* note 72, at 2468; Chapman, *supra* note 9, at 21; Seeratan, *supra* note 14, at 375 (asserting that the TRIPS requirement for both product and process patents will substantially increase the cost of pharmaceuticals).

patent owner might choose not to enter a market and not to authorize local production, thereby reducing access in that country.<sup>119</sup> One might question why a patent owner would adopt this strategy. It would seem that if he is unwilling to import into a given country, he would be better off economically by licensing local production. One possible explanation is fear of gray 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.<sup>120</sup> Of course, any such compulsory license is supposed to be primarily for local consumption.<sup>121</sup> However, if gray 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.

Probably the most convincing argument against patent laws in developing countries is Professor Samuel Oddi’s observation that few inventions are “patent-induced” with respect to a given developing country.<sup>122</sup> 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, a patent on it necessarily adds to that country’s costs because, even without recognizing the patent, the developing country has access to the information contained in the developed-country filings.<sup>123</sup>

### C. BALANCING 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.<sup>124</sup> This cost is likely not offset by an

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119. See Gutterman, *supra* note 33, at 122-23.

120. TRIPS, *supra* note 3, at art. 31.

121. *Id.* at art. 31(f).

122. Oddi, *supra* note 115, at 844; *see also* Seeratan, *supra* note 14, 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 world-wide”); *cf.* Anawalt, *supra* note 113, at 397 (“Adequate incentives for innovation do not depend on mandatory international intellectual property rules.”).

123. See Oddi, *supra* note 115, at 846.

124. *Cf.* Carroll, *supra* note 72, at 2468 (noting that additional costs of a patent system come in the form of creating legislation, establishing patent administrations, and training patent officials, lawyers, and judges to

increase in local technological development or in access to inventions that are 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, Amir Attaran and Lee Gillespie-White looked at the availability of antiretroviral drugs for AIDS treatment in Africa.<sup>125</sup> Somewhat surprisingly, and contrary to conventional wisdom, they found no correlation between access to antiretroviral treatment and patent status across Africa.<sup>126</sup> 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.<sup>127</sup> This supports Professor Oddi's conclusion 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 laws of any given African country. Access to these drugs was found to be uniformly poor across Africa, independent of whether and where they were patented.<sup>128</sup> Thus, at least in the poorest countries, access to potentially lifesaving drugs seems not to be inhibited by patents but rather by the lack of funding to obtain access to these drugs even at prices set only to reflect the cost of production and distribution.<sup>129</sup>

This suggests that the problem of access to inventions, and technology generally, in developing countries will not be solved by 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, because the innovations will then not be available to anybody. It also brings us back to the fundamental nature of intellectual property and, in particular, its infinite multiplicity without reduction of supply. We can ask, if a given market offers no

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administer and enforce patents).

125. Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 JAMA 1886 (2001).

126. *Id.* at 1890.

127. *Id.*

128. *See id.* at 1890 (noting the sole exception of South Africa).

129. *See id.* at 1891; Lazzarini, *supra* note 12, at 135.

expected return from the exploitation of intellectual property, why should the owner of the intellectual property care whether the product embodying such intellectual property is copied and distributed in that market?

Consider an extreme case for the sake of illustration. Suppose country X has zero dollars to pay for a patented and potentially lifesaving drug. The patentee could not have been thinking of country X as part of his expected return while developing the drug, and indeed the patentee gets no return from country X after the drug is on the market, *whether or not the drug is copied and distributed in country X*. The copying and distributing of the drug in country 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 for it. This activity thus has utterly no effect on the patentee, provided all of the drug copied and distributed in country X actually stays in and is used for the benefit solely of country X's citizens. The problem for the patentee then, is not the copying and distribution in country X, but rather the potential for copies made in X to be distributed outside X (gray-market leakage) in markets where the drug is profitable for the patentee, because such leakage has the potential to reduce the price and authorized sales volume in those markets.<sup>130</sup> There is no economic reason, therefore, why the patentee (on these extreme facts) would be unwilling to sell the drug in country X at cost, provided she could ensure that none of it would leak back into her more lucrative markets.<sup>131</sup> In other words, the presence or absence of a patent law in country X is essentially irrelevant to the patentee. Her only concern is with competition in her other markets from drugs originally distributed in country 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. However, for the poorest countries of the world, the

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130. See F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Nations*, 2002 J. INT'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.'").

131. See Kieff, *supra* note 39, at 311 & n.23 (showing more generally that enforceable and accurate price discrimination should push output to meet demand, but for this to occur arbitrage between high- and low-value users must be prevented).

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.<sup>132</sup> However, patentee drug manufacturers will avoid these schemes if products sold at a low price in one country find their way back to their more lucrative markets. Such schemes are also undermined if developed countries adopt notions of “reference pricing,” requiring, for example, their own domestic prices to be no higher than those charged elsewhere.<sup>133</sup> Moreover, under any price discrimination scheme aimed at maximizing the patentee’s profits, the price will likely be higher than it would in the absence of patent’s exclusive rights, so patent continues to reduce access below that of a completely free market.<sup>134</sup>

TRIPS does allow some amelioration of patent’s exclusive rights through compulsory licensing.<sup>135</sup> The Doha Declaration on the TRIPS Agreement and Public Health expressly gave member states the freedom to determine the grounds on which compulsory licenses can be granted.<sup>136</sup> The problem was that

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132. See Scherer & Watal, *supra* note 130, at 925-28; Lazzarini, *supra* note 12, at 125.

133. See Scherer & Watal, *supra* note 130, at 929.

134. Another variation of the problem of balancing public access with the need for incentives occurs in university research. Research universities actively seek both to garner the financial returns that are available from patented research and to engage in public service. A number of research universities have 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 need to use in efforts to create new crops that could feed impoverished people. The patent rights thereby stand in the way of the 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. See Blumenstyk, *supra* note 60.

135. TRIPS, *supra* note 3, at art. 31; see also Lazzarini, *supra* note 12, at 125.

136. World Trade Organization, Ministerial Declaration of 14 November 2001, ¶ 5(b), WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration]. In most cases compulsory licenses can only be granted after good faith negotiations with the patentee have failed to result in a voluntary license “on reasonable commercial terms and conditions.” TRIPS, *supra* note 3, at art. 31(b). However, nothing in TRIPS supplies any standard of reasonableness, so failure of the patentee to agree to a member state’s good

many countries lacked the facilities and technological expertise to manufacture complex pharmaceuticals locally. While the compulsory license could include imports, the only legally available suppliers were the patentee and the patentee's voluntary licensees. Any other country manufacturing the drug under a compulsory license could only do so, under TRIPS, "predominantly for the supply of the domestic market" of the manufacturing country.<sup>137</sup> Exporting to countries unable to produce for their own market would thereby have placed the manufacturing country in violation of TRIPS. The Doha Declaration recognized this problem and instructed the TRIPS Council to find a solution.<sup>138</sup> The TRIPS Council then adopted a decision waiving the obligations of an exporting member under TRIPS 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.<sup>139</sup>

We may conclude that access to patented inventions, especially pharmaceuticals, is not as great 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.<sup>140</sup> It is important that these problems be resolved in a way that maximizes worldwide access to innovation of all types, but especially to lifesaving pharmaceuticals, and avoids undercutting incentives for innovation in the developed countries. To many it seems just plain wrong not to provide universal access to lifesaving

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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." *Id.*

137. TRIPS, *supra* note 3, at art. 31(f).

138. Doha Declaration, *supra* note 136, ¶ 6.

139. 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).

140. Some drug manufacturers have begun experimenting with "out-licensing," under which the patentee licenses generic manufacturers who agree to supply medicines to poorer countries. See Michael A. Friedman, Henk den Besten & Amir Attaran, *Out-Licensing: A Practical Approach for Improvement of Access to Medicines in Poor Countries*, 361 LANCET 341 (2003). Requiring pills to have different colors and shapes could be helpful in inhibiting parallel importing back into the more lucrative markets. See *id.* at 343; see also Scott Hensley, *Pharmacia Nears Generics Deal on AIDS Drug for Poor Nations*, WALL ST. J., Jan. 24, 2003, at A1.

innovations in pharmaceuticals.<sup>141</sup> 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.

## V. CONCLUSION

Analysis of 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” is not one of the availability of patents based on traditional indigenous information but rather one of 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

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141. See Seeratan, *supra* note 14, at 403-04 (“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 “[b]enefits 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.” Universal Declaration, *supra* note 91, at art. 12(a). Another commentator argues that distributive justice requires providing all countries with access to the benefits of gene research. See Looney, *supra* note 9, 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 patent law serves as an incentive for innovation, patent law does not create the injustice. It only brings more clearly into focus the widely different access to valuable resources among rich and poor countries.

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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 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 gray-market arbitrage that allows patented products to flow back into the markets that do serve as an important part of the incentive to innovate.