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THE UNEXAMINED ASSUMPTIONS OF INTELLECTUAL PROPERTY

Adopting an Evaluative Approach to Patenting Biotechnological Innovation

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I. INTRODUCTION

As intellectual property rights are increasingly the subject of national and international study, any deficiencies in our understanding of these rights and their place in society may have serious negative repercussions on policy formation. For example, in previous work, the authors of the present article noted the lack of an integrated understanding of intellectual property systems revolving around biotechnology.[1] Different disciplines possess deep-rooted assumptions about the working of patents that have little grounding in either fact (a lack of empirical support) or theory (a failure to understand the nature of patent rights or the behavior of market players). In addition, the prevailing fragmented approach to the analysis of intellectual property rights, whereby the various relevant disciplines work in isolation, leads to research results which can be incomplete or misleading. Unfortunately, the products of these research results often form the basis of both national and international intellectual property policy.

In an effort to address this deficiency in the development and implementation of intellectually property policy at both the national and international level, particularly in the field of biotechnology, the authors are in the process of developing a transdisciplinary approach to the study of intellectual property rights. The goal of the authors' work is to establish an effective and integrated conceptual framework, and the present article outlines a preliminary approach based on the results of the research conducted to date. While the primary unit of analysis is the design, use,

and implications of patent rights, this selection being based on the significance of patent rights in the field of biotechnology, the importance of other rights such as trade secrets and ordinary property rights in this area is acknowledged.

The first step in suggesting a new approach is to describe the manner in which intellectual property issues are currently analyzed and identify inherent deficiencies. Specifically, this article addresses the prevailing assumptions associated with biotechnology patents within key disciplines for the purposes of illustrating that these assumptions lack both conceptual clarity and empirical foundation. At the very least, given the legal and technological complexity of biotechnology patents and the numerous constituencies involved, assumptions specific to a particular discipline are unlikely to lead to modes of analysis sufficiently comprehensive to provide the basis of policy decisions. This article proposes moving beyond discipline-specific, assumption-based reasoning in developing intellectual property policy and suggests instead the use of transdisciplinary, evaluative analysis.

The methodology designed specifically to implement this approach involves replacing discipline-specific, overarching and ostensibly predictive assumptions with a preliminary set of seven transdisciplinary and evaluative probes. Each of these probes provides the basis for formulating more targeted research and policy questions that better account for both the different disciplinary approaches that exist and the ways that patent rights are awarded and used. The proposed framework of seven probes provides a mechanism through which academics and policy-makers can evaluate patent law's real time performance in relation to its central goal of social benefit. Academics and policy-makers can use the framework to analyze how the patent system actually operates in its social context, rather than basing their research on discipline-specific preconceptions.

In this article, the following four assumptions are investigated for the purposes of illustrating the manner in which intellectual property issues are currently framed:

1. That patents improve economic efficiency by encouraging invention and disclosure of new inventions;

2. That patents represent the optimal public policy tool to stimulate research and development;

3. That patents create "equity gradients" between those with and those without patent rights, and;

4. That patents are ethically neutral in the sense that they do not significantly create, magnify or diminish ethical concerns that already exist.

Part II of this paper explains why the validity of these largely unexamined assumptions is open to question. The analysis in Part III demonstrates that the authors' proposed conceptual framework of seven transdisciplinary, evaluative probes provides a more effective and comprehensive analysis of patent systems and their social effects at both the domestic and international level.

II. The Unexamined Assumptions of Intellectual Law and Policy

The four assumptions discussed here do not constitute an exhaustive list, but have been identified by the authors' working group, the Intellectual Property Modelling Group (IPMG),[2] as the key assumptions upon which decision-makers tend to rely in developing intellectual property law and policy. During the course of several IPMG workshops, the authors used a nominal group technique discussed below to compare and contrast the assumptions made within their respective disciplines. In most cases the four assumptions were operative in least two disciplines, and had immediate and significant impact on at least one other disciplinary domain. In effect, the identified assumptions form a web of relations between economics, law, management and ethics. Although discipline-based analyses of the assumptions can be an informative process on its own terms, it is only when the four assumptions are aggregated into a focused unit of analysis that they reveal the constraints on the traditional analysis of patent law and policy.

A. Assumption: Patent Rights Provide a Necessary Incentive to Innovate

The literature in law, economics and ethics raises two concerns regarding the nature of the incentives required to encourage investment in research and development costs for the purposes of producing socially beneficial innovations. The first is that the scholarship reveals an unquestioning and therefore unjustified acceptance of the assumption that patents are needed to ensure: 1) that innovation is disclosed;[3] and 2) that would-be inventors and their sponsors will invest in the risk of innovating given the economic returns derived from patents.[4] The extent to which the economic case for patent rights has been adopted within legal literature and leading jurisprudence (particularly in the United States) is surprising, given that very few scholars present compelling economic rationales in support of intellectual property rights in general, and even fewer for patent rights in particular. Nevertheless, economic efficiency remains the dominant justification within legal literature for the grant of exclusive patent rights. The second concern is that despite the fact that intellectual property regimes have a significant effect on social arrangements, i.e., the distribution of the benefits and burdens of innovation, these issues have largely been ignored by professional ethicists. Instead, the literature reveals that ethicists working in this area tend to focus on discrete issues such as the patentability of genes rather than a systematic treatment of a position like the economic efficiency justification for patents.

1. The Economic Case for Patent Rights as Incentives for Innovation

The starting point for the economic analysis of patent systems is the assumption that innovators expect profits to compensate for the cost of innovation. The patent system compensates innovators through the grant of rights to exclude all others from the economic value of the innovation. Patent systems augment the size and/or duration of profits accruing to the innovator and can thus increase the

incentive to innovate. The bulk of economic analyses holds that without these rights to exclude, the market for innovations would operate inefficiently, resulting in a socially detrimental rate of innovation. To understand this, one must step back and examine the benefits of innovation.

Innovation often creates knowledge spillovers, i.e., knowledge that can be used by others at no or low cost, which lowers the costs of follow-on research and development ("R&D") for other firms. This reduction in follow-on costs of R&D is a social benefit accruing to not only other firms but to consumers who will be able to purchase improvements at a lower cost. Because the innovating firm receives none of these benefits it does not take them into consideration when deciding whether to invest in innovation. Even where social benefits of innovation may be high, the actual financial returns to the innovating firm may not cover its R&D costs. Thus, despite the high social benefit, the firm may decide not to innovate. By capturing some of the social benefit in the form of higher prices, the patent system is able to increase the innovating firm's financial returns, thus encouraging it to invest in R&D.

This traditional view does not exclude the possibility of situations where innovation is detrimental, that is, where innovation occurs despite the fact that the resulting social benefit is lower than the cost of the innovation. Such a situation may arise, for example, due to "profit destruction." Part of the benefit to an innovator may come from taking profits from existing firms, such as if a firm improves upon the quality of an existing product. The innovator will then see a benefit that could be larger than the overall benefit of his or her contribution to society. In this case, patents could be detrimental to society's welfare in industries where most R&D involves new entrants improving upon existing products.

Even absent profit destruction concerns, there is a risk of having too much patent protection. Patents create monopolies, or at least temporary increases in monopoly power for innovators. The increase in innovation generally comes at the expense of higher prices and reduced quantities sold. Patents that are too long may provide more benefit to innovators than is actually required to induce innovation, leading to monopoly distortions that persist longer than necessary. Similarly, patents that are too broad may needlessly block related innovations. The most significant challenge for designing socially optimal patent law may be that one size does not fit all. The patent length that maximizes economic efficiency in one industry may not be the same for other industries. Similarly, the depth and breadth of patents will have different effects for start-up firms searching financing than for large and mature firms seeking to replenish their pipeline of products.

Traditional accounts of patents also hold that the patent system increases the dissemination of innovation because patent law requires public disclosure of the innovation through the patent application. Reality can, however, be quite different. The role of patents in knowledge dissemination varies across industries. For some products, the nature of an innovation may be fully revealed by inspection

of a sample or by simple reverse engineering. For these products, the information contained in patents has little effect in encouraging others to conduct further R&D. For other products, inspection and reverse engineering may reveal little if anything, especially if the innovation is an improvement in process technology. In this case, the role for knowledge dissemination through patents can be substantial. But even here, firms may strategically disaggregate an innovation into component parts for the purposes of patent protection. That is, firms will patent portions of the innovation but leave vital elements not patented, preferring to protect these portions as trade secrets. This strategy entails a certain amount of risk in that someone else may patent what the firm has been treating as a trade secret. When this risk is thought to be small, however, it is quite possible that patents do not play a substantial role in the diffusion of knowledge.

Patents may, on the other hand, reduce the difficulties inherent in licensing technologies. In the course of negotiating a licensing agreement, the firm wishing to sell or license its invention to an outside firm will need to reveal the invention to that outside firm. Without patent protection the innovating firm is left unprotected if the purchasing firm takes and uses the idea without compensation to the innovating firm. Patents protect the innovating firm against uncompensated use by the purchasing firm.

Beginning with Schumpeter, the early theoretical literature in economics provides a justificatory explanation for the potential benefits of patents as outlined above, yet empirical studies have been less supportive of according exclusive rights in the products of innovation. Empirical work conducted in the 1960s and onward seems to support the positive effect of patents on innovation, crediting patents with up to 15–25 percent (depending on industry and the study) of innovation.[5] Most of this research is found in the industrial organization literature and focuses on the role of patents within a single country (or closed economic) setting. More recent work has, however, cast doubt on this conclusion. The international economics literature considers cross-country differences in patent systems and the implications of these differences for economic behavior.[6] The link between patents and innovation in the multi-country (open economy) setting is less clear.

Even within a closed economy, patents on initial innovations may deter later discoveries that build on patented innovations.[7] There are also structural reasons to believe that one can never know, in fact, whether patents actually encourage or discourage innovation. First, as pointed out earlier, while patent law takes a "one-size-fits-all" approach to innovation, the markets for different products and knowledge assets differ significantly from one another.[8] Second, the empirical study of the effects of patents on innovation suffers from the lack of control. Given that innovation is driven by many factors (including access to capital, access to skilled managers, first mover advantage, curiosity, etc.), cross-jurisdictional comparisons are difficult. Since countries rarely radically change their patent systems without changing fundamental aspects of their economies, single jurisdiction

controls are usually lacking. Several studies that examine changes within a single jurisdiction—the semi-conductor industry in the US between the 1970s and 1980s[9] and the strengthening of the Japanese patent system in the 1980s[10]—indicate that patents either reduced innovation or had no effect. Third, also discussed above, industry rarely relies solely on a single patent to secure its inventions. Normally, firms use a combination of patents or of patents, trade secrets, and even trademarks to protect their innovations.[11] In addition, firms also use other mechanisms such as complementary asset management (by forming alliances) and innovation lead-time to gain advantage over competitors.

All of these intellectual property management mechanisms make it difficult, if not impossible, to isolate the effect of patents on innovation. And as with the effects of any policy, there is the issue of potential reverse causality—patent rights might encourage innovation but ability to innovate may also create demand for adopting stronger patent rights. Further research is therefore needed to: (i) distinguish the line between patents and innovation in idiosyncratic sectors such as biotechnology; (ii) disentangle the effects of patents on innovation from the effects of other economic factors; (iii) examine the effects of alternative forms of intellectual property rights (and their simultaneous use) on innovation; and (iv) analyze the direction of causality between the development of national patent systems and national capacity to innovate.

2. Patent Law and the Rhetoric of Economic Efficiency

Despite unresolved ambiguities concerning the relationship between innovation and patent protection, leading jurisprudence demonstrates that the utilitarian justification of economic efficiency is embedded within legal reasoning, at least in Western legal systems. In *Graham v. John Deere Company*,[12] the United States Supreme Court was called upon to articulate the appropriate test for "non-obviousness," a requirement for patentability that had recently been added to the existing requirements of "novelty" and "utility" in U.S. patent legislation. As part of the process of statutory interpretation, the Court engaged in a relatively lengthy discussion of the nature and extent of Congress's power to enact patent legislation, including by necessity the rationale for protection. Art. I, §8, cl. 8 of the United States Constitution authorizes Congress "To promote the Progress of Useful Arts, by securing for limited Times to Inventors the exclusive Right to their Discoveries."

The Court interpreted this constitutional grant of legislative authority as providing "both a grant of power and a limitation." The limitation is derived from the normative justification for granting such exclusive rights, i.e., as a necessary economic incentive to encourage innovation and disclosure in the subject matters to which patent law extends. The Court covered the historical development of patent law in the United States at some length, including reference to the well-known writings of Thomas Jefferson who, as Secretary of State, was administrator of the 1790 Act, the first patent legislation enacted in the United States, and author

of the 1793 Act. As the Court noted, Jefferson's philosophy of patent protection was based on the notion of economic incentive, and not on any natural property right in relation to intellectual creations:

> [Jefferson] rejected a natural rights theory in intellectual property rights and clearly recognized the social and economic rationale of the patent system. The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge.[13]

The Supreme Court of Canada has similarly institutionalized economic efficiency as the normative rationale for granting patent rights, again with reference to the necessity of according exclusivity in exchange for disclosure. Binnie J. in *Cadbury Schweppes Inc. v. FBI Foods Ltd.* noted this point:[14]

> [A bargain] . . . lies at the heart of patent protection. A patent is a statutory monopoly that is given in exchange for a full and complete disclosure by the patentee of his or her invention. The disclosure is the essence of the bargain between the patentee, who obtained at the time a 17-year monopoly on exploiting the invention, and the public, which obtains open access to all of the information necessary to practise the invention. Accordingly, at least one of the policy objectives underlying the statutory remedies available to a patent owner is to make disclosure more attractive, and thus hasten the availability of useful knowledge in the public sphere in the public interest.[15]

These representative passages demonstrate that the assumption that patent protection can be justified as a necessary and sufficient condition for economic efficiency is firmly entrenched in both legal literature and jurisprudence. Given that this assumption is currently subject to challenge in economics literature, particularly at the international level, the wholesale adoption of economic rationales as a decision rule for resolving intellectual property disputes is problematic, both in terms of providing optimal but not excessive incentives to innovate and in structuring the distributional consequences of granting these exclusive rights.

3. Ethical Analysis and the Economic Case for Patent Rights

Patent regimes are designed to alter people's behavior through the allocation of rights and burdens in respect to inventions. By doing so, patent regimes enable and sustain a particular set of social arrangements. These arrangements, in turn, reflect various normative commitments. As current patent regimes are premised on the granting of individual reward to induce innovation, the underlying normative commitments are controversial. Reasonable people can and do disagree about them at a theoretical level, particularly when they are opposed to the idea that individual reward is more important than social benefit. Reasonable people also disagree with the practical impact of patent regimes if they believe that these regimes inexorably lead to social inequities.

That people can and do disagree about these fundamentally normative issues suggest there would be a substantial literature on the ethics of patents. As it turns

out, much of the literature on the subject arises in contexts other than academic ethics of the kind written by philosophers, a point to which this article returns below. With respect to the literature produced by professional ethicists writing for academic audiences, it can be noted that first, the contributions are surprisingly few in number, and second, the literature that does exist often fails to grapple with the full complexity of ethical issues arising with patents.

The key piece of evidence for the first claim is the paucity of literature on the subject. A search of the Philosopher's Index from 1940–2002 for items containing the search terms "patent" or "patents" produced sixty-one results. A search for "intellectual property" produced twenty-seven results, overlapping with the first set, and the majority of which (85 percent) are academic journal articles. One third of the articles examined intellectual property from a well-established theoretical stance that was then extended to the consideration of intellectual property.[16] The remainder of the articles had methodological orientations that were neither traditional ethics nor bioethics. Instead, they examined intellectual property from the vantage point of innovation studies, religious analyses or studies of intellectual property as market forces.[17] Perhaps most striking, a search for "patent," "patents," "intellectual property," and "IPR" generated no citations for the flagship journal *Bioethics*.

Turning to the second claim regarding the shortcomings of the extant literature on the ethics of patents, it is useful to begin with a fact: two thirds of the citations found in the above-described literature search were published within the last ten years. This indicates that the ethical consideration of biotechnology patents lags behind the initial explosion in the number of patents during the 1980s. The literature in this field generally relies on traditional philosophical conceptual frameworks as platforms for analysis of patents. This approach lacks the conceptual and methodological robustness of the approach proposed in this paper. The ethical analyses focus instead on worthwhile but narrow issues such as the special status of DNA and its role in patents, the effects of patents on the distortion of science toward profit and subordinate issues such as whether natural entities like genes ought to be the objects of patent rights. While these are important issues that are also addressed in this paper, the most significant deficiency of the existing ethics literature (as in other literature) is the lack of a systematic, overarching conceptual analysis of intellectual property.

Two conclusions can therefore be offered. The first is that literature reviews do not disclose a rich literature on the ethics of patents, particularly with respect to the claim that patents are justified because they are the most economically efficient means of achieving some social goals. The second conclusion is that until the field matures, ethicists may not be able to provide systematic treatment of a position such as the economic efficiency justification for patents.

B. Assumption: Patents are an Optimal Policy Tool for Stimulating Research and Development

Turning to the policy literature, one often finds intellectual property lauded as one of the chief means by which scientific research and development (R&D) is enabled. Patents are treated as inter-sectoral currency, facilitating the movement of capital from the site of primary production (often universities) to the site of application (primarily the private sector) under a centralized coordinating and approving body (government). Good examples of this role accorded to patents exist in many jurisdictions,[18] but one of the clearest is Canada as it well shows not the breadth, but the depth of the use of patents in shaping optimal public policy to stimulate R&D.

Arguably the best example of this phenomenon lies in granting agencies' increasing reliance on patents obtained by researchers in the evaluation of research productivity. The Canadian Government's Innovation Strategy, for example, places more emphasis on training and on the tripling of commercialisation efforts than it does on increasing the amount of basic research conducted in the country.[19] One of Canada's principal funding agencies, the National Research Council (NRC), targets research funding to specific sectors identified by the federal government of Canada. The NRC promotes intellectual property management as a core part of its granting strategy and stipulates that large funding opportunities that generate commercially valuable research will require an intellectual property management plan that may be integrated into a business development strategy.[20] This policy follows the sentiment expressed by former Canadian Industry Minister Alan Rock when he stated at a National Summit on Innovation and Learning that the Proposed Framework Agreement on Federally Funded Research "marks the first time that academia has formally acknowledged its responsibility to generate economic wealth."[21] There are other, corollary institutions supporting this federal policy that will provide the requisite management expertise, coordination and training.[22] The effect of adopting this policy is that Canada now relies more heavily on its universities and colleges to be sources of intellectual property for business development than any other country in the OECD, a fact documented by the Canadian government and the OECD itself.[23]

This assumption that patents provide the optimal strategy to encourage the right kind of innovation is deeply embedded in many systems, of which Canada's Innovation Strategy is just one example. This assumption necessarily proceeds from the assumption that the patent system is economically efficient, but differs in important aspects. While the assumption of economic efficiency merely puts patents forward as a necessary way to encourage innovation and dissemination, the assumption that patents are the optimal policy tool goes further in suggesting that governments ought to increasingly rely on patents, and intellectual property in general, rather than on other measures to encourage innovation. That is, governments should not only accept unconditionally the assumption that the patent

system is economically efficient, but also institutionalize this assumption by relying to an ever-greater degree on patent protection as a policy tool.

That governments should be so willing to adopt patent rights as an optimal tool for stimulating scientific research and development is inconsistent with the history of the role of the public sector in contributing to the advancement of knowledge in this area. According to lore,[24] biotechnology's expansion in the 1980s can be explained by the occurrence of two events. First, the United States Supreme Court allowed the first patent of a genetically modified organism in 1980, giving industry an incentive to engage in biotechnological research.[25] Second, the US Congress passed the Bayh-Dole Act[26] in 1980, providing universities with the right to obtain patents in the results of federally funded research. This opened the door to universities transferring their technology to industry. Observers credit these two developments for ushering in the biotech boom.

The reality is that industry only became interested in genetics once governments, universities and not-for-profit research centres (largely subsidized by funding from the National Institutes of Health) had spent decades developing the technology to the point where it could be turned into products that could be commercialized.[27] The *Chakrabarty* decision and the Bayh-Dole Act were not sole causes of the biotech revolution of the 1980s and 1990s;[28] rather, all three phenomena likely arose out of the fact that biotechnological science had matured by 1980. Researchers could begin to contemplate commercial applications of the science and thus push for patent monopolies. Accordingly, comparing levels of innovation before and after 1980 implies little about the link between patents and levels of biotech innovation.

Large scale, basic biology research projects have all been accomplished by the public sector. Consider, for example, the most recent of these efforts, the Human Genome Project. This project is a multi-national, public-sector effort to sequence the entire human genome—the entire set of codes contained in a typical human being.[29] The original date for completing the project was 2005 but the project was ahead of schedule and is now largely complete.[30] In fact, the project has done so well that in June 2000, Francis Collins, Director of the National Human Genome Research Institute, released a preliminary draft of the human genome.[31]

The public effort to map the human genome was matched privately by Craig Venter of Celera Genomics who joined the mapping effort in order to create proprietary databases from which it could obtain revenue. Industry's involvement resulted in a gene-mapping frenzy.[32] By June 2000, both the public and private efforts were at the same place; both announced the draft genome at the same time.[33] While private industry may have added some competition to the mapping effort, therefore speeding it up,[34] it only succeeded because it relied on the public effort's work in two ways. First, Celera entered the mapping effort after the public international project had already developed the basic science to complete the project.[35] Second, because of the way the Celera mapped the human genome, it had to rely on the public sector's map to verify the accuracy of its own.[36]

These two examples—the development of fundamental biotechnological knowledge and the mapping of the human genome—reveal important facets of industry-university collaboration. Industry, by and large, has not advanced the search for basic scientific knowledge. The public sector has supported the labor-intensive and time-consuming effort to create new knowledge.[37] Thus, without public research there would be no biotechnology industry. Once the public sector has advanced knowledge sufficiently to lead—and lead directly—to commercial products, the private sector will develop and market those products. While the latter is important, the engine of knowledge production has mainly been the public, not the private, sector. Should levels of public funding change, the effects on industry are difficult to predict. To the extent that industry relies on out-sourced research from universities, they are left vulnerable to changes in the university research agenda (which could shift to a greater emphasis on discovery research, for example). In addition, an inevitable lag exists between university research and industry uptake that controls the speed of the conversion of research into commercial technologies.

Industry copes by sponsoring university research that will more directly and immediately meet its needs. While industry-university partnerships are not new and are in no way unique to the field of biotechnology patents, the conjunction of intellectual property with flourishing biological sciences and the rise of the biotechnology industry is responsible for a rapid change in university research agendas. These factors have raised concerns that university research is turning from discovery research to applied research. Some have connected this criticism to changes in the university's role in society, arguing that universities have vested financial interests in their joint initiatives with industry. These interests may lead universities into an advocacy position rather than one as disseminators of disinterested knowledge. At issue is whether universities will be able to remain accountable to the public, and hold the public's trust.[38]

Others have objected that the splintering of intellectual property between numerous university-industry collaborations makes it difficult for mature technologies to be developed, particularly when the freedom to operate sought by industrial partners cannot be granted by a single institution.[39] A new public sector initiative—Public-Sector Intellectual Property Resource for Agriculture (PIPRA)—will investigate this problem with a view to changing public sector patenting and licensing, the creation of a public database of intellectual property and the development of "shared technology packages."

Finally, it is noteworthy that these issues are debated within the academy itself. A polarization between two cultures of science is thus emerging. One of these cultures ascribes to a doctrine of discovery science that seeks the public dissemination of enlightenment as its principle objective, whereas the other culture seeks to develop rewarding practices that bring about shorter-term advancements in knowledge, some of which may have industrial applications.[40] This tension between traditional scholarship and applied research in the sciences is exacerbated

by the incursion of patents into universities. The fundamental objectives of university science research are consequently being called into question.

These observations suggest two further considerations. First, when one discusses the policy of relying on patents to stimulate the "right" kind of research, one must be careful in defining what one means by the "rightness" of that research. A second and related consideration is whether patent systems ought to be evaluated according to their ability to achieve a balanced (as between basic and applied research) approach to research.

C. Assumption: Patents Create Undesirable Distributional Gradients

As noted above, a comprehensive literature search reveals that philosophers have written very little on the ethics of patents for academic audiences. This does not suggest, however, that no literature exists in any discipline on the ethics of patents. Many of the most forceful arguments on the ethical implications of patents arise in other disciplines and spheres of activity. Within this body of literature the common thread is that patents have negative distributional effects. That is, patents set up negative "equity gradients" in which some individuals profit at the expense of others. One of the principal arguments put forward in this regard is that patents have inherently distorting influences on social life—they cannot help but advantage some to the detriment of others.

The competing interpretation is that patents do not have direct negative effects on distributional equity. These negative effects arise, rather, from the fact that market economies are predisposed toward substantive distributional inequalities. Through market action patents, being property rights, result in unequal (although not necessarily inequitable) alterations in the distribution of income and the accumulation of wealth. Some libertarians object to some of the redistributive effects of patents on the basis that the state has intervened where the market could do better.[41] Liberals support further redistributive interventions, however, on the basis that the initial distributions resulting from granting patent rights are both unequal and inequitable. In other cases, the observation has been made that patents are a means by which private interests can lure public institutions into doing commercial work that more directly benefits private than public interests.[42]

There are limitations to the usefulness of pointing out that patent rights establish equity gradients. While any property regime, by its very nature, alters the distribution of goods within a society, this does not mean that the equity gradient thus created is unjust. A gradient could be justified, for example, if one person is made better off while nobody else suffers (Pareto optimal). The mere existence of the gradient thus tells us little and criticisms of patents that simply argue against the resulting equity gradients are accordingly are not persuasive. Thus, while this assumption is descriptively accurate, it is not normative. In particular, it does not provide criteria to evaluate whether a particular distribution is or is not just.

Despite the significant limitations of the observation that patents lead to equity gradients, the literature endorsing this view has had a significant impact on policy formation, particularly at the international level. Of primary concern in this context are issues of distributional equity between developed and developing countries, although distributive justice concerns also arise in domestic contexts. In terms of international issues of distributive justice, two distinct but inter-related claims are that of bio-piracy and benefit sharing. The claim that biotechnology patenting is a harm perpetuated against developing countries in the form of bio-piracy is predicated in part on the related claim that exclusive patent rights violate a positive obligation to share the benefits of biotechnological innovations.

1. Bio-Piracy

Ever since Calestous Juma published *The Gene Hunters*[43] in 1989, the literature has investigated the connection between biological diversity, "bioprospecting," and intellectual property regimes. One prominent issue is whether patents aid and abet the so-called "biopiracy" of commodifiable biodiversity in the equatorial zone—a zone that consists primarily of developing countries—for the economic benefit of developed countries. Celebrated cases such as the patent issued (and later invalidated) over the neem tree have propelled writers such as Dr. Vandana Shiva to characterize the biodiversity of developing countries, domesticated and not, as fodder for the controlling interests of patent-wielding prospectors.[44]

Shiva lays blame on the developed world, particularly the U.S., for having direct influence in development of the World Trade Organization's TRIPs agreement.[45] The result, she argues, is that TRIPs universalizes the U.S. patent system.[46] Shiva claims that TRIPs "calls for a system of uniform patent laws . . . , discounting the differences in ethics and value systems of Third World nations, where life is sacred and exempt from patenting."[47] This quotation combines two distinct arguments opposing biotechnology patents.

On the one hand is Shiva's contention that living things ought not to be patented, particularly in the developing world where life is sacred. The underlying assumption that life is more sacred in the developing world is dubious at best, and in any event patenting life forms is also contentious in the developed world. The recent Supreme Court of Canada decision regarding the Harvard Mouse—in which the Court held that Canadian patent law provides no patents over animals and plants—contrasts markedly with decisions in other countries by explicitly taking into account the natural origins of mice. It is further unclear what Shiva means by the phrase "exempt from patenting" since Indian law, for example, has since been amended to explicitly permit the granting of patents over biotechnological inventions.[48]

Shiva's second contention is that TRIPs is an agreement that subsumes sovereign national patent systems to a global system predicated on values not shared by the developing world. Signatories to the WTO and its agreements must stay

in compliance with those agreements to avoid complaints and possible sanctions, but this is very different from the claim that patents under TRIPs turn developing countries into "police states" run by the hegemonic West.[49] By portraying agreements under WTO as if they are crafted to subjugate the East to the West and the South to the North, Shiva fails to understand both the linkage-bargain diplomacy through which the TRIPS Agreement was negotiated, and more importantly, the flexibility built into the TRIPs Agreement itself. TRIPs merely establishes minimum standards, leaving considerable room to Member States to formulate their own patent policies.[50] The subjects of much of her vehemence—patents over plants, seeds and animals—are specifically not required by TRIPs.[51] Thus India could have excluded patents on living things in its most recent amendments to its patent law; its decision to allow such patents is a domestic policy choice, not a response to international mandates or constraints. In addition, countries hold significant power to withhold patents on particular inventions for reasons of morality.[52]

Part of the problem with Shiva's critique of the patent system as a global law indifferent to the diverse needs of states is that she often fails to distinguish between patent *law* and the *administration* of the patent system. Her concern regarding the patent granted over the neem tree exemplifies this. According to patent law, the neem tree was never eligible for a patent because it was previously known. The problem was that the patent office—the administrative unit responsible for enforcing patent legislation—did not know this. While this was regrettable and certainly a cause of concern, no amendment to patent law will avoid the problem of a patent examiner mistakenly granting a patent where one ought not to have been granted. Patent law anticipates and addresses this eventuality by creating opposition and re-examination processes as well as by giving the courts, and not patent offices, the final say on whether a patent was properly granted. Even should Shiva succeed in convincing governments to exclude plants and animals from patentability, the patent office can always make a mistake, especially in borderline cases. Confusing patent law with patent administration thus does little to engage, let alone solve, ethical concerns.

The fundamental problem, however, with Shiva's approach is not simply its mistakes but the fact that it draws attention away from the more significant distributional effects of patents in general. Other, more nuanced work addressing these issues by Calestous Juma and Karen Fang argues that a biotechnology divide may open up between developed and developing countries if some, but not all, nations have access to the means of building scientific and industrial capacity in this field.[53] Contrary to Shiva's assertions, a robust intellectual property system may be a critical component of a nation's capacity to manage its resources and innovation. Intellectual property in and of itself cannot be held to account for the existence of global inequities. Instead, used correctly, intellectual property may be one of the building blocks that will lead to greater equity between nations.

2. Benefit Sharing

The distributional effects of patents are also evident in debates concerning the extent to which the benefits of intellectual property rights should be shared. It is widely alleged that a positive obligation exists to share the financial and other benefits arising from the exploitation of biotechnology with those groups from which the knowledge originates.[54] One can see this position at work in certain international agreements, national laws and regulations, and in guidelines that seek to promote "benefit sharing" between those who exploit "traditional knowledge"[55] and those from whom the knowledge or resources derive.[56]

This assumption is problematic primarily because it is based on the implicit assumption that traditional knowledge is the property of the groups from which it derives. The normative starting point for any discussion of property, however, is that goods generally ought to be free for anyone to use. States create property rights only in circumstances were the granting of such rights can be justified on some normative basis.[57] For intangible goods, such as knowledge, this is particularly true. Patent systems, for example, are justified on the basis that they lead to the creation and dissemination of more knowledge.[58] As discussed earlier, patents provide a financial lure to would-be inventors to invent new things. Without this lure, the inventor may not have undertaken the risk and expense involved in developing this knowledge. As Gold and Caulfield have pointed out, no such arguments exist with respect to traditional knowledge.[59] By its very nature, traditional knowledge has been around for a long time, having being built up over many years. Granting a property right will provide no incentive to invent as the invention has already taken place. The significance of property rights as a necessary incentive for knowledge production is inherent in the patent system itself, which limits the award of property rights to "new" knowledge, thus excluding what was previously known.[60]

D. Assumption: Patents are Ethically Neutral

The ethical neutrality of patents is assumed by legal literature[61] and jurisprudence.[62] As bluntly stated by one commentator:

> Patenting, as such, is neither wrong nor right, but could be classed as "ethically neutral." To refuse a patent would be a futile gesture that would not by itself stop the invention being put to practical use. However, if society were to judge that the practice of a particular invention deserved to be banned by law then nobody would bother to patent it.[63]

From this perspective, whatever social concerns that may arise in the commercialisation of and access to biotechnological research—quite apart from more general concerns of distributional justice addressed above—are not related to the patent system per se. Were ethical review a necessary criterion for patentability (as opposed to an ancillary regulatory concern), so this argument goes, it would jeopardize the ostensible neutrality of the patent system which otherwise

coordinates the simultaneous and contradictory objectives of achieving maximum levels of innovation and access to the products of innovation.[64]

The ostensible ethical neutrality of the patent system is vulnerable to challenge. The prevailing view of patent rights as mere negative rights conceals the extent to which the grant of a patent right is in effect the grant of a fully constituted property right, and thus an exercise of private sovereignty. In other words, if property is power, and few property theorists would dispute this claim, control over significant biotechnological resources is being delegated to the private sector on an ad hoc basis, one patent at a time.

This mistaken assumption of ethical neutrality leads to inadequate formation of intellectual property law and policy, particularly in relation to issues of accountability and spillover effects. In terms of accountability, patent rights may grant the holder not only anticipated de jure control over the commercial exploitation of the invention but also unanticipated de facto decision-making control in relation to important public policy concerns unrelated to those issues that informed the grant of the patent itself: that is, providing sufficient economic incentives to produce the optimal level of innovation. As to the issue of spillover effects, given that a grant of a patent provides the holder with private property rights, these property rights must be taken into account and balanced with other, competing rights. The necessity of balancing competing interests is not limited to the confines of the incentives-access paradigm—i.e., the appropriate balance between exclusive rights and permitted exceptions. Legislatures and courts must also reconcile private property rights, including patent rights, with competing private and public interest concerns in relation to legal issues external to the patent regime. These issues involve more complex concerns, and thus require a more complex approach to intellectual law and policy, than is otherwise implicated in the more isolated and self-contained community of patent holders and putative infringers.

1. Patents as Mere Negative Rights

While the literature explored under Assumption C critiques the distorting effects of patents and, in particular, the distribution of goods in society that they entail, others deny that patent rights amount to a fully constituted proprietary relationship because they are mere negative rights.[65] At issue is whether a patentee has merely a negative right to prevent others from making, using or selling the patented invention, or may exercise as well the positive privileges (or liberties) traditionally associated with fully constituted property rights. The former, narrower (and arguably incorrect) characterization may be attributed to the manner in which patent legislation is typically drafted, the U.S. Patent Act being a representative example:

> Every patent shall contain a . . . grant to the patentee . . . of the right to exclude others from making, using, offering for sale, or selling the invention.[66]

Although patents are typically referred to as negative rights, this characterization is insufficiently inclusive to the extent that it obscures the true nature of

patent rights as fully constituted property rights.[67] If patentees possessed mere negative rights and no more, then some legal mechanism would be required before a patentee would be entitled to make, use or sell the invention. This is not the case. While a patented invention is subject to regulatory controls where appropriate, as for example in the case of health and safety regulation, the default position is that the grant of a patent includes an implied positive privilege or liberty to make use of one's intellectual property. Although this default position is merely implicit in the U.S. Patent Act, other states provide a more express recognition of affirmative privileges. For example, legislation in Canada grants patentees not only with the negative right to exclude, but also positive liberties and privileges in that a patentee has

> the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used.[68]

The combination of a negative right and a positive privilege is roughly functionally equivalent to a fully constituted common law property right in the tradition of Honore. That is, no affirmative permission is required for the holder of a property right to begin exercising the right.[69] The privilege of access, or the right to use, may be limited in the public interest, but such limitations as a matter of logic merely follow, and cannot precede, the granting of an affirmative right of use.

Fortunately, in some jurisdictions the legal status of patents as conferring property rights is expressly recognized in the relevant legislation, thereby saving us the necessity of the foregoing analytical exercise. Patent legislation in Australia, for example, defines patent rights as objects of personal property:

> Subject to this Act, a patent gives the patentee the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention. . . . The exclusive rights are personal property and are capable of assignment and of devolution by law.[70]

A similar definition exists in patent legislation in the United Kingdom: "Any patent or application for a patent is personal property (without being a thing in action). . . ."[71]

If, as argued above, a patent right is indeed a fully constituted property right, then the ethical implications of granting a patent in any field of endeavor revolve around concerns of resource allocation and conflict resolution. These may be far more complex than simply setting the appropriate balance between incentives and access in relation to maximizing innovation. Narrowing the focus of the scope of a patent to a negative right to exclude focuses social, legal and political attention on a limited range of public policy objectives. As noted by Adams:

> Competing claims for control over new intangible resources . . . are typically framed as disputes between intellectual property holders seeking exclusive rights to a potential revenue stream and others seeking unrestricted access to information

> in the public domain. The terms of the debate are thus limited by the incentives-access paradigm, an all-or-nothing process of commodification that presumes that the only relevant public policy objective is balancing private rights to gain with pubic rights to unrestricted access.[72]

The grant of a patent inevitably alters equity gradients not only between the patentee and undifferentiated users of the public domain in relation to rights of access, but in all other areas in which the grant of a property right affects the allocation of resources and thus balance of power between all members of a given community. The relationship between property rights and positions of power and dependency has been identified and examined by both legal realists[73] and advocates of a social relations theory of property law.[74] A decision to protect some interests as proprietary in nature, but not others, can lead to an institutionalized bias in reconciling competing interests given the power of property rhetoric and mistaken notions of absolutism[75] in common law property regimes. As noted by Gold:

> The difficulty with property discourse is that it pre-empts other discourses. The conception of property as having absolute dominion, although supplanted, continues to inform our understanding of how property rights interact with other rights. A person holding a proprietary interest in a good is entitled to do anything with respect to that interest unless doing so is specifically prohibited. On the other hand, a person with a non-proprietary interest in the good is not entitled to do anything with that good unless specifically entitled.[76]

To the extent that patent rights are proprietary in nature, equity gradients will tend to favor holders of patent rights to the exclusion of other members of a given community because of a systemic bias in which property rights tend to trump all but the most compelling competing rights, including human rights. Thus, while the mere existence of patent rights is not necessarily unfair, to the extent that property discourse pushes aside competing interests, patents engender, at a minimum, the possibility of unfairness.

2. Accountability

Granting patents over genetic sequences could threaten the decision-making autonomy of physicians and other health care providers in meeting legal and ethical obligations to provide an acceptable standard of care for patients. The exclusive rights granted to patent holders are intended to correct market deficiencies in relation to commercial exploitation of the patented invention and to advance dissemination of knowledge by providing inventors with an incentive to disclose the workings of their new, useful and non-obvious product or process. Inventors are granted autonomy to exercise the appropriate decisions relating to the commercial exploitation of their patented invention subject to regulatory controls to protect the public from harm. The exercise of decision-making authority in the commercial sector of the biotechnology industry, however, can have unintended consequences for health care. Most significantly, control over a patented gene

sequence can result in de facto control over a potentially broader range of genetic test options available to a patient. Holders of patent rights are neither competent nor sufficiently accountable to exercise such de facto authority over the standard of care in the health care system.

The recent controversy in Canada over genetic tests for breast cancer illustrates the problem of possible compromises in physicians' decision-making autonomy where gene patents are concerned.[77] Myriad Genetics is the patent holder of the BRCA1 and BRCA2 genes and the associated procedures for diagnostic genetic testing. If a woman possesses mutations in these genes, she faces a higher risk of developing breast and ovarian cancer. In cases of high family incidence of such cancers, a physician has a prima facie duty to advise his or her patient of the availability of the test. Anyone ordering the genetic screening test must have the test conducted using Myriad's process and then send their sample to Myriad's laboratory facilities in Salt Lake City for processing.

The level of control over the access and quality of the test by Myriad is significant. Myriad Genetics charges US$2,500 for the service. A comparable test is available in Canada from Genetic Diagnostic Laboratories for Cdn$1,150. Despite the lower cost alternative, the risk of patent infringement and the contractual requirements imposed by Myriad Genetics in licensing its diagnostic genetic test means that laboratories are reluctant to develop, clinically validate and implement generic versions of these diagnostic tests.[78] Second, concerns have arisen regarding Myriad's authority over the method used to analyze submitted samples. The method mandated by Myriad for conducting the test may not be the most appropriate for the patient. Thus through the exercise of its patent rights, Myriad Genetics, a corporation presumably concerned with its legal obligation to maximize shareholder value, affects the decision-making autonomy of patients, physicians and other health care providers and may interfere with their legal and ethical obligations to provide an adequate standard of care.

3. Spillover Effects

A particularly illustrative and timely example of unanticipated spillover effects involves the controversial practice of granting patents in higher life forms. It is worth noting from the outset that having scope for ethical review in a patent system does not constitute an automatic prohibition against the grant of patents on higher life forms. The European Patent Office's decision to grant a patent for the Harvard Oncomouse—albeit in a restricted form—is a case in point.[79] Since different outcomes are possible, consideration of selected judicial decisions alone does not provide compelling support for the assumption of patent neutrality.

A recent example can be found in the reasoning of both the majority and dissenting judgments in *Commissioner of Patents v. President and Fellows of Harvard College*,[80] in which the Supreme Court of Canada held in a 5-4 decision that higher life forms such as an "oncomouse" (a mouse genetically engineered to be susceptible to cancer) are not patentable in Canada. While disagreeing on

the interpretation of the *Patent Act*, both the majority and dissenting judgments agreed that, for the most part, ethical concerns are more appropriately addressed though targeted legislation external to the patent regime. They agreed that objections to biotechnology patents on higher life forms are misplaced if they focus on the granting of the patent. The focal point ought to be the regulation of the underlying activity in terms of upstream development and downstream commercial exploitation of genetically engineered animals.[81] According to this view, withholding patent rights from genetically engineered higher life forms will have no effect on either of these activities.

This does not lead to the conclusion, however, that the patent system is ethically neutral. That a patentee is not exempt from regulation in the exercise of a patented invention is irrelevant to the question of ethical neutrality. What is of significance is the fact that the patentee's default position is entitlement, not constraint. As a patentee has both a negative right of exclusion as well as a positive privilege to use the invention, the onus is not on the patentee to justify why certain uses should be unlimited but on those seeking to impose limitations to make their case. In other words, this notion of entitlement places the onus to justify limitations on other parties involved in a social conflict. Joseph William Singer describes the nature of this property relationship between owners and non-owners as involving presumptive control and burdens of persuasion:

> Property law creates presumptions about who gets to control valued resources. The ownership model suggests that ordinarily one person (or entity) controls all rights in a particular piece of property. Once we identify the owner, we can ask whether her rights should be limited because of overriding public interests or values. The burden falls on nonowners to demonstrate that these public policies are sufficiently strong to justify restricting the owner's rights.[82]

A patent granted introduces a strong competing interest in the form of a property right that must now be reconciled with existing ethical concerns. Independent of considerations of patent rights, a utilitarian analysis of the genetic engineering and animal welfare may not justify animal suffering in terms of human interests in the advancement of science and medicine. Accordingly, advocates must persuade legislators not only that animal welfare legislation should privilege the interests of animals to a greater extent than is currently the case in relation to the public interest in scientific research,[83] but also that the property rights of patentees should be limited in the process. That is, instead of one hurdle, advocates face two. Unqualified acceptance of the economic justification for patent rights, and the presumed importance of these rights in maintaining a country's competitive position in the biotechnology industry, will mean that the burden of persuasion placed upon those advocating for animal welfare concerns will be difficult to discharge.

To conclude, because of the nature of patent rights as property rights, as well as concerns with accountability and spillover effects, the patent system is far from

ethically neutral. Patent rights fundamentally change the landscape concerning who is entitled to make decisions about what.

E. Critiquing the Prevailing Assumptions

The four assumptions identified and discussed above underlie much of current scholarly research and policy making. While using these assumptions may have the advantage of simplifying debates among academics, policy-makers and the public over biotechnology patents, they lead to limited and distorted understandings of the patent system and its role in society. In particular, they conceal emergent ethical, social and economic consequences of the patent system in various spheres of life.

When examining each assumption in turn, their distorting influence on different discourses becomes apparent. Taken together, the assumptions' distortions are amplified. Consider, for example, the combination of the assumption that the current patent system is economically efficient and the assumption that patents present the optimal policy tool to encourage R&D. Together, they lead to a policy of relying on the patent system to encourage most research. But as the patent system provides a reward for commercial products and processes and not for the acquisition of basic knowledge, the combination of these assumptions leads to an over-emphasis on applied, as opposed to basic, research.[84] Although such an approach may be economically favorable in the short term, it threatens longer-term sustainability and economic competitiveness.

The assumptions also raise problems of institutional competence. In addition to the accountability and spillover effects discussed above, the assumption of ethical neutrality also raises the difficult question of which institutions ought to deal with ethical concerns. If, as the assumption would have one accept, patent systems are ethically neutral, then regulation of the ethical implications of biotechnological research will either have to occur during upstream development or downstream diffusion of the technology. What this assumption ignores, however, is that both upstream and downstream actors often tend to consider themselves less well equipped to deal with ethics for lack of appropriate tools. This leads to a responsibility void not dissimilar to that which arises in biotechnology research. It is not uncommon, for example, for scientists to refuse to take responsibility for the consequences of their research, either claiming that science is value free or that they lack "expertise" in the evaluation of ethical and social consequences. The public usually refrains, on the other hand, from critically examining this research because they fear they are not qualified to do so.

Despite their deficiencies both in isolation and in the aggregate, the basic assumptions critiqued in this analysis are not without value. Rather than dismissing the assumptions as simply unhelpful or problematic, they can be regarded as precursors in the development of a contextual analytical framework for understanding patents in biotechnology innovation. Consideration of the assumptions with

respect to the discourses in which they arise, their relationship to each other and their conceptual deficiencies is a necessary first step, following which researchers and policy-makers can develop tools to examine how the patent system actually works with respect to biotechnological innovation. To accomplish this second task, the authors propose the adoption of seven evaluative and transdisciplinary probes, each of which focuses on different aspects of biotechnological innovation, development and commercialisation in a contextual manner. By replacing mistaken, discipline-specific assumptions (and the resulting faulty predictions) with evaluative, transdisciplinary probes, researchers and policy makers will be in a better position to generate and answer contextual inquiries concerning the implications of the patent system in several spheres of operation.

A note of caution is in order before proceeding. In the following presentation of the evaluative probes, it will be readily apparent that while the probes are well thought-out and carefully developed, it can neither be assumed that they are applicable in all cases nor that the list of problems is exhaustive.

III. A Compelling Alternative: Evaluating Intellectual Property Through the Use of Transdisciplinary Probes

A. Methodology

If the prevailing assumptions that shape the investigation of biotechnology patents are faulty, the need for an improved framework within which to advance scholarly and policy work in this field becomes more apparent. Through a nominal group technique, the authors' IPMG research group described above identified seven probes that enable a more subtle, contextual and structured analysis of the social, economic, and policy implications of patents in the field of biotechnology. The technique used is described first, and then a few programmatic remarks are made in advance of the discussion of the probes themselves. The nominal group technique adopted by the IPMG belongs to the family of consensus methods. These methods provide a means of harnessing the insights of experts in order to make decisions in a field in which there is either an insufficient amount of published information or in respect of which there is an overabundance of conflicting scientific evidence.[85] Two consensus methods are commonly used in health research: the Delphi process and the nominal group technique (also known as the expert panel).

Although both the Delphi and expert panel methods seek to overcome the disadvantages associated with collective decision-making, particularly domination by individuals or professional interests, they differ substantially in process. Whereas the Delphi process enables a large group of experts to be contacted inexpensively, usually by mail with a self-administered questionnaire, the nominal group technique uses a structured meeting to gather information from relevant experts (usually 9-12 in number) on a given topic. The Delphi process usually involves three rounds in which participants are invited to re-rank anonymously

their agreement concerning a specific matter. The expert panel, on the other hand, consists of two rounds in which panelists rate, discuss, and then re-rate a series of items or questions with the help of a facilitator. The role of the facilitator in a nominal group approach is to insure that all participants are able to express their views freely.

In order to develop novel probes with which to analyze the impact of patent systems, the authors followed a nominal group approach, holding a structured meeting, distributed in time and location (one meeting to provide a factual background on the major assumptions in each field and a second at which considerations were ranked). The nominal group meeting was structured according to the following format:

a. Participants spent several minutes writing down their views concerning the topic in question;

b. Each participant, in turn, contributed one idea to the facilitator, who recorded it on a flip chart;

c. Similar suggestions were grouped together, where appropriate. There was a group discussion to clarify and evaluate each idea;

d. Each participant privately ranked each idea (round 1);

e. The ranking was tabulated and presented;

f. The overall ranking was discussed and re-ranked (round 2); and

g. The final rankings were tabulated and the results returned to participants.[86]

The premise in developing the seven probes is that patent systems ought to be evaluated within a broad transdisciplinary context consisting of economic, ethical, philosophical and management concerns. Each probe generates a series of particular questions spanning the various disciplines, thus providing the basis of subsequent aggregate analysis. The probes can be used to tease out elements of patent systems as they occur generally or in particular jurisdictions. Appropriately, the probes and the questions they engender are intended to be approximately comprehensive to map out a "state-space" of possible positions any actual or potential patent system could realistically occupy. As with any modelling process, it may be the case that certain combinations of variables will be in conflict with one another. For example, issuing patents with narrow scope reduces successful infringement cases, but ties the hands of innovators. When tensions occur between the probes it is because the probes map empirical realities, rather than ideal states.

This last point illuminates a general programmatic thrust of this endeavor, which is to map out models of alternate intellectual property regimes that have different social effects. There is *no* intention to produce an idealized one-size-fits-all legal system that will magically overcome troubled assumptions noted

earlier. Instead, only the multi-factorial and trans-disciplinary approach offered here will provide a range of adaptable alternatives for positive law, legislative reform and institutional change. The probes provide insight into the constitution and conduct of patent systems from a generalized theoretical standpoint but are nonetheless analytically robust and can therefore form the basis of concrete policy alternatives. Accordingly, more than one model can—and will—arise out of the analytical framework generated by the probes. Which model to choose is a fundamental question for good governance of biotechnology innovation that can be based on the transparent and robust framework offered here.

B. The Evaluative Framework: Transdisciplinary Probes

1. Distributive Justice

This probe seeks to rectify the gap between the equity gradients caused by patents and the claim that they are an optimal policy tool. Unfortunately, there is no single theory or universal definition of distributive justice. The principles of distributive justice are varied, taking into account factors such as the particular goods subject to distribution, the subjects of the distribution, and most significantly, the basis on which the goods should be distributed. Strict egalitarianism, for example, is a rather blunt measure of distributive justice in that this principle requires that every person should have the same allocation. More sophisticated principles would include the widely discussed difference principle articulated by Rawls, wherein differences in allocation are justified provided that the allocation is of the greatest benefit to the least advantaged.[87] The one common denominator of the various principles is that the prevailing concern of distributive justice is the appropriate resolution of competing claims:

> Justice is the central ethical judgment regarding the effects of society on the situation of social entities, with respect to each entity's valuation of its own situation for its own purposes. . . . Natural individuals are most often the entities in view. But questions of justice also arise as regards looser groupings. . . . Included here are nations, families, firms, cities, classes, regions and perhaps even cultures. When the purposes of such entities oppose each other, and the issue is how to arbitrate among their competing claims, the question is one of "distributive justice" . . . the allocation of the goods, resources, services or commodities that are scarce and raise rival desires, directly or indirectly.[88]

This probe takes into account the distributional consequences of a property system, such as patent regimes, and openly addresses the nature of the distribution achievable through that regime. More specifically, distributional equity establishes a normative framework within which to evaluate the patent system. It comprises concern over justice at both the national and international levels, the sharing of benefits arising from biotechnology as a universal norm, access to technology and to information, and affordability (which may also affect access).

This probe differs from the assumption that equity gradients are inherently unfair since it provides a normative basis to assess rather than assume the fairness (or lack thereof) of any particular distribution of the financial, health or agricultural rewards of biotechnology. This article previously discussed and critiqued claims to share benefits derived from the use of traditional knowledge in biotechnological research based on an implicit assumption that this knowledge constitutes the "property" of the groups from which it derives. Rather than relying on implicit claims to be compensated for the use of property, distributive justice focuses on the question of what constitutes a just distribution of the financial, health and agricultural goods deriving from biotechnology. Such an analysis avoids the need to establish prior claims by resting claims to share benefits on distributional fairness. Following a Rawlsian approach, for example, one could claim that the least well off on a global scale ought to receive some share of biotechnological goods.[89] This would mean that one would need to investigate both the nature and extent of this claim and the mechanisms to achieve it.

In contrast to the assumption that patents adversely affect social welfare by creating equity gradients, the distributive justice probe provides a more subtle and useful way to investigate the manner in which patent systems affect the distribution of the benefits and burdens of biotechnological innovation within nations and between nations. When taken together, the questions raised cross the boundaries between academic disciplines, providing for a transdisciplinary analysis of the patent system relating to biotechnological innovation. A sample of such questions includes the following:

a. What does "just" mean in the context of a distribution of the benefits and burdens of biotechnological innovation?

b. Is there a claim that the benefits of biotechnology are *global public goods*?[90] This would mean establishing a distribution whereby one achieves the greatest good for the greatest number of people globally.

c. Alternatively, is it better to conceive as just the condition under which individuals and other agents have the full opportunity to exploit their potential subject to constraints only as needed to prevent damage to others?

d. Should patent systems determine what is considered to be a fair distribution or should patent systems respond to an external norm?

e. Is it possible to assess the justness of a particular intellectual property transaction or practice or is assessment possible only by aggregating transactions and practices?

f. If a distribution at either the national or international level cannot be described as just, what change(s) to the relevant intellectual property rule are necessary to achieve a just distribution?

g. Which institution(s) has (have) the competence to assess the adequacy of the distribution at the national and/or international level?

2. Innovation Management

This probe focuses on the nexus between the patent system and the management or governance of innovation systems. It has three aspects. The first is the management of research and development from the discovery phase, through to innovation and finally to development and its ties to the patent system. This involves the determination of which organizations—public, private or mixed—conduct biotechnological research, how research results are communicated, how research material is shared and whether and how innovation is bundled prior to commercialisation. The second aspect is more clearly focussed on the effects of the patent system on research and development. This itself has several aspects including how patents affect the choice of scientific approach (fundamental vs. applied), research targets (enlightenment vs. use), bias (overt and inherent) and delay in the diffusion of research results.[91] The third is how patents contribute to attracting financing to carry on R&D and the development of entire supply chains that make possible the manufacturing and distribution of these innovations. In addition, patents have an impact on the heterogeneity of core and applied biotechnology firms in the many sectors in which they carry out their activities.

This probe provides a better understanding for the context in which biotechnological innovation takes place and is used. It thus leads to a better understanding of the ethical and legal issues at play, revealing some that would otherwise go unnoticed—such as the effect of patents on the selection of research targets—and diminishing others—such as a fear that patents will lessen disclosure. The probe also focuses attention on the interaction between financing and the patent system. Unlike the assumption which presumes that patents are necessary to increase innovation, this probe provides the opportunity to frame questions about the degree that industry actually investigates the breadth and validity of patent claims as opposed to their very existence. Given the existence of substantial levels of uncertainty in the biotechnology field over questions of validity and patent breadth, it is unclear at present whether introducing other forms of uncertainty—for example, with respect to ethical validity—will affect a company's ability to attract financing. This probe thus provides a more subtle way of assessing the needs of industry with respect to patent rights.

Through this probe, one can put forward a number of questions that could steer future research. These include the following:

a. Ought firms to be left free to determine the use of biotechnological innovation?

b. How important are patents to attracting financing (venture capital) in different countries?

c. Is the distribution of what is being researched affected by the existence of the patent system? If so, how? If so, is it ethically problematic to skew this distribution of research targets?

d. How clear and certain must a patent claim be in order to attract financing? That is, to what degree do uncertainty in the validity and breadth of patent claims affect a company's ability to attract investment?

3. Knowledge Management

Rather than focusing on innovation systems, this probe centres on the diffusion of information. It thus captures an important element inherent in the assumption that intellectual property protection is an optimal policy tool, but in a more precise manner. Among its several components is an analysis of the relationship between knowledge transfer and competence building. At the national level, these strategies may be combined but their relative importance has yet to be determined. At the international level, these strategies tend to be seen in opposition to one another. Second, this probe involves analyzing alternative (or perhaps complementary) diffusion strategies, e.g., licensing, sale, foreign direct investment or nothing at all. Third, this probe provides for an analysis of knowledge accumulation, whether through patent pools, consortia or other means of complementary asset management. Fourth, it calls for an analysis of various strategic management capabilities, from human resource management, skill development, to business organization options to security options.

Using this probe, one focuses attention on how firms transfer knowledge between universities, between university and industry, among industry players and also between firms internationally. The probe draws attention to the need to develop a skilled set of managers and the investigation of licensing options and practices.

Following this probe, one is led to formulate questions such as the following:

a. To what extent ought the holders of intellectual property rights to be able to enter into private contractual arrangements that negate statutory limitations (presumably enacted for a valid public purpose) placed upon the exercise of those rights? For example, to what extent ought a patent holder to be able to impose contractual provisions that take away a licensee's ability to conduct research under a research exemption?

b. To what extent ought one to use technology transfer to assist developing countries as opposed to more traditional systems such as the direct provision of goods and services?

c. How ought the tension between intellectual property law—which creates property rights limiting control over innovation—and competition law—which seeks to limit the potential for market power that comes from control over goods—to be resolved? Which institutional actor(s) ought to determine the boundary between intellectual property law and competition law?

d. To what degree ought knowledge management questions be delegated to the private sector? In other words, should they be regulated by the public or by the private sector?

4. Integrity of Living Things

This probe aims at providing a more subtle contextual analysis of patent rights that takes into consideration not just the consequentialist arguments normally used to justify or critique patent systems or changes to those systems, but also those involving duty-based analyses and evaluations. It examines the way that the patent system influences perceptions of life and of living organisms. In doing so, it follows up on the criticism provided earlier under the assumption that patents are ethically neutral. By focussing attention on flourishing (of both human beings and other organisms) in the context of ecosystem health, biodiversity, human health, and the issues associated with dignity, freedom and integrity of life,[92] this probe provides a way to examine the spillover effects of patents on ethical norms.

This article proposes the use of this probe as a way to open discussion rather than presuming that there is something necessarily special about the integrity of non-human life forms. The purpose here is to investigate claims that too often fall outside of the patent debate, not to resolve them in favor of one position or another. The status of animals is contentious within society and thus it is appropriate that one not ignore the impact that the patent system has on this status in one's consideration of the patent system. As the following quotation from the majority decision in *Commissioner of Patents v. President and Fellows of Harvard College* in Canada case illustrates, the way that one views animals has a clear impact on one's analysis of patent questions:

> Although some in society may hold the view that higher life forms are mere "composition[s] of matter," the phrase does not fit well with common understandings of human and animal life. Higher life forms are generally regarded as possessing qualities and characteristics that transcend the particular genetic material of which they are composed. A person whose genetic make-up is modified by radiation does not cease to be him or herself. Likewise, the same mouse would exist absent the injection of the oncogene into the fertilized egg cell; it simply would not be predisposed to cancer. The fact that it has this predisposition to cancer that makes it valuable to humans does not mean that the mouse, along with other animal life forms, can be defined solely with reference to the genetic matter of which it is composed. The fact that animal life forms have numerous unique qualities that transcend the particular matter of which they are composed makes it difficult to conceptualise higher life forms as mere "composition[s] of matter." It is a phrase that seems inadequate as a description of a higher life form.[93]

Patent law does include one tool linked to the type of non-consequentialist concern raised by this probe: the *ordre public* or morality clause. This provision exists in the patent laws of most jurisdictions (e.g., within the European Patent Convention) and permits patent offices to withhold patents over inventions the

commercialisation of which is likely to cause public disorder or to undermine shared fundamental norms.[94] This tool is not without criticism. In fact, the clause is seldom used and, when it is, it seems to be invoked in an ad hoc manner.[95]

Through the use of this probe, one can focus attention on the use of the *ordre public* clause and its alternatives, e.g., blanket exclusions from patentability and regulations external to patent systems for dealing with ethical concerns, if these are necessary to protect the integrity of living things.

Specific questions relating to this probe include the following:

a. How does one determine the normative framework in which to evaluate claims of the integrity of living organisms?

b. Does an organism's integrity entail duties for others?

c. Is the intrinsic value of biodiversity, as highlighted in the Convention on Biological Diversity, a coherent basis on which to formulate soft or hard law?

d. Is it coherent to consider non-consequentialist ways of thinking about patents?

e. If so, to what extent ought the patent system to take into account shared fundamental norms within society?

f. Does a given decision to grant a patent over a life form work in opposition to principles relating to the protection of living things?

g. Does innovation fail to take into account the natural way of things including the tendency for the evolution of plants and animals to achieve the survival of the fittest?

h. Do domestic patent systems and/or international patent rules provide adequate mechanisms to protect the integrity of living things?

i. Which actor(s) is (are) institutionally competent to make the above determinations: legislatures, courts, patent tribunals, patent holders, regulatory bodies or others?

j. Is it permissible for decision-making to not take into account the complicated nature of the interaction between living things?

k. If norms are to be taken into account within the patent system, which structures are required to accomplish this?

5. Sovereignty

This probe analyses the implications of patent regimes within the international legal and political context. Starting with an understanding of nation states and their legal capacities (and incapacities), it provides an avenue to explore the ability

(and desirability) of states to exercise unconstrained domestic decision-making authority as a matter of both de jure regulation and de facto economic and political reality. Through the use of this probe, one can also explore questions of optimal institutional design in terms of national or international regulatory regimes.

In order to apply this probe effectively, one must first distinguish between sovereignty as a function of the political reality of international relations and sovereignty as a matter of international law. The sovereignty of states, a foundational principle of international law,[96] provides that all states are juridical equals, notwithstanding significant differences in political and economic power. Accordingly, states are at liberty to establish their own domestic norms without interference from other states. States may cede sovereignty by agreeing to comply with international norms, but such consent, except in certain limited circumstances,[97] cannot be compelled. Thus states are free to decide on the basis of enlightened self-interest or other normative rationales whether to act in concert with others in establishing and maintaining international norms to address particular concerns transcending the territorial boundaries of any one state's sovereign jurisdiction.

One of the most compelling imperatives for ceding sovereignty is the increasing pace of economic liberalization and integration. States appear willing to forego a certain amount of autonomy over domestic legal affairs in order to participate in an increasingly liberalized international trade regime. Of particular relevance for this analysis is that an overwhelming majority of states have ceded sovereignty in matters of domestic intellectual property law and policy to the World Trade Organization.[98] Pursuant to the TRIPs Agreement, while intellectual property rights remain bounded by territorial jurisdiction—that is, no truly international intellectual property rights exist—the degree of regulatory harmonization imposed by minimum substantive levels of intellectual property protection pursuant to the TRIPs Agreement are in many cases functionally equivalent to a supranational intellectual property regime.[99]

No clear consensus yet exists as to whether universal standards of protection benefit developing states,[100] thus making it difficult to assess the implications of harmonized standards in relation to concerns of state sovereignty. For example, as to the inherent tension in the international legal order between universality and particularity, one could argue that the TRIPs regime provides sufficient transitional periods and "wiggle room" for developing states to tailor universal standards in a manner that does not compromise domestic objectives.[101] On the other hand, several issues of particular importance to developing states remain unaddressed. For example, the TRIPs regime is not capable as yet of accommodating or fairly allocating gains from trade involving traditional knowledge, i.e., the various methods by which communities collectively gather, process and transfer information that is of potential use to the biotechnology industry. Fitting traditional knowledge into a standard Western intellectual property regime predicated for

the most part on the notion of possessive individualism is not only undesirable in normative terms, but for practical reasons may not even be possible.

Another difficult area of focus involves the potential for regulatory arbitrage and the effect this has on domestic intellectual policy even in the absence of legal constraints. Again, the recent Supreme Court of Canada decision in *Harvard College*[102] provides an illustrative example. The universal minimum standards of patent protection mandated by the TRIPs Agreement provide sufficient scope for regulatory diversity in relation to the patenting of higher life forms. Art. 27(1) obliges Member States to make patents available "for any inventions, whether products or processes, in all fields of technology" and requires that patent rights must not discriminate on the basis of "the place of invention, the field of technology and whether products are imported or locally produced." Certain express exceptions to these requirements, however, are provided in Art. 27(3)(b) for "animals other than micro-organisms," and most importantly, in Art. 27(2) which permits Member States to "exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect . . . animal . . . health."

As a matter of positive law, Member States are free to withhold patents for higher life forms. This scope for regulatory diversity acknowledges that states may have various rationales, whether economic or ethical, for limiting the scope of patent protection in living beings to micro-organisms. As a matter of political reality, however, given increasing global economic integration and the mobility of capital and research and development facilities, states may decide (often mistakenly) that the availability of regulatory arbitrage in the biotechnology industry acts as a de facto constraint on regulatory diversity. Justice Binnie articulated this concern in dissent in the *Harvard College* decision, where he stated that "[t]he mobility of capital and technology makes it desirable that comparable jurisdictions with comparable intellectual property legislation arrive (to the extent permitted by the specifics of their own laws) at similar legal results."[103]

While the imperative of increasing economic liberalization may lead states to cede sovereignty in matters of domestic patent protection to international regimes such as the WTO, states may also decide to cooperate at the international level in circumstances where the transboundary nature of a particular problem renders domestic autonomy irrelevant. In other words, while internal decision-making may be directed towards achieving a particular result, the desired domestic objective will be frustrated unless the domestic decision is consistent with a critical mass of international consensus.

Once again, the issue of patenting higher life forms provides a particularly apt example of the type of ethical considerations that tend to overwhelm domestic decision-making capacity. As stated above, the WTO does not impose legal constraints upon Member States seeking to implement a particular (as opposed to universal) ethical conclusion regarding the legitimacy of patenting higher life

forms. States are also permitted in more expansive and direct terms to restrict the scope of patentability on the basis of considerations of public order and morality. Accordingly, states such as Canada, following on the Supreme Court of Canada's decision in *Harvard College*, could reform patent legislation by incorporating ethical considerations directly into the patenting process. The end result may be to grant patent protection over higher life forms, but the normative rationale would include both the standard utilitarian justification for patent protection as well as an ethical analysis of the legitimacy of property rights in higher life forms.

Lacking an international consensus, however, as to the efficacy and ethical legitimacy of granting patents in higher life forms, a unilateral decision to withhold patent protection is unlikely to promote a state's ethical and social values. Sovereignty in this regard both enables and constrains; states may regulate to achieve internal policy objectives in relation to the patenting of higher life forms but are unable to exert extraterritorial effect upon the ethical decision-making (or lack thereof) taking place in other states. As stated by Gold, "[i]n the absence of an international consensus to the contrary, research undertaken in the rest of the world may well be conducted without regard to ethical and social concerns."[104]

Given the extent to which intellectual property has been linked with the normative justifications and positive international trade rules implemented by the WTO, a significant if unexamined deficiency of the institutional design of the TRIPs Agreement is the lack of any formalized process for working toward international consensus on the ethical legitimacy of controversial applications in the field of biotechnology. Allowing scope for moral particularity as an exception to otherwise universal minimum standards of protection may appear to be an exercise in cultural sensitivity. As a practical matter, however, localizing ethical concerns at the national level amounts to nothing more than moral procrastination. Moral particularity has a certain prima facie appeal, given the difficulty of rehabilitating universality such that the term no longer echoes an oppressive and colonizing history. Humanity's common genetic heritage, however, transcends geopolitical boundaries, as does the nature of humans' shared existence on this planet with other species. Presumably, collective decision-making is required prior to adopting controversial genetic engineering technology capable of altering this shared destiny. Moral particularity in these circumstances offers sovereign states nothing more than the promise of conscientious but ineffective objection.

This probe leads to the formation of specific questions relating to the interaction of intellectual property and international law, such as the following:

a. Might the international intellectual property rules that apply to a particular transaction or practice provide scope for ethical considerations to be taken into account?

b. Might the international intellectual property rules applying to a particular transaction or practice provide for regulatory diversity in the event that an ethical consensus cannot be reached?

c. Do international trade conventions provide an appropriate institutional structure through which to consider ethical diversity and consensus?

d. Can legitimate ethical concerns be distinguished from attempts to impose non-tariff barriers to trade?

e. Notwithstanding that international trade rules mandate only minimum standards of protection, does protection ahead of the curve—that is, beyond what is required by international convention—in any one state require other states to "ratchet up" domestic levels of protection in order to maintain the expected allocations of benefits and burdens under the WTO regime?

6. Economic Efficiency

The optimal patent policy is apt to differ across countries, especially across countries at different levels of development. One reason for this is that most innovation occurs in the developed world. Consequently, developed countries such as the United States, Europe (in particular Germany), and Japan are the major sources of knowledge-based goods.[105] Developed countries favor stronger patent protection because this protection enhances their international comparative advantage in those goods that embody intellectual property.

In contrast, developing countries are mainly imitators (and some countries lack even the ability to imitate). Developing countries typically favor weak patent protection so that they can take the fullest advantage of knowledge in-flows. The developing world lags behind the technology frontier and views weak patent protection as vital to its efforts to close the technology gap. The bulk of sales revenues for high-tech goods come from developed countries. Developing countries argue that stronger patent protection in their small markets would make little difference for encouraging R&D, but would come at a large sacrifice. Jobs (wage income), profits and consumer surplus would be lost due to local firms no longer being allowed to sell imitations in the local market. Also, few consumers have the income to buy original products from abroad, so sales of imitations do not truly deprive innovators of revenues.

Despite the above differences in incentives between developed and developing countries, the TRIPs Agreement seeks to standardize patent protection globally. The goal of knowledge dissemination also casts doubt on the need for global patent harmonization. Knowledge is disclosed upon the first patent for an invention. If an inventor patents a product in the United States, the knowledge dissemination goal has been achieved for that invention. There is then essentially no additional knowledge revealed through filing patents in other countries. From the view of sharing knowledge, a system of strong protection in the United States could be sufficient. The maximum protection among the major markets could be more important than the minimum protection among the minor markets.

Grossman and Lai argue that harmonizing patent protection is not necessary for global economic efficiency.[106] Any degree of incentive to innovate can be achieved

by a mixture of patent policies, from harmonization to strong protection in developed countries and weak protection in developing countries. Harmonization is the extreme that is worst for developing countries. McCalman has also argued that the United States and other developed countries (with the notable exception of Canada) are the primary gainers from the TRIPs Agreement.[107]

Many developing countries are urging that the TRIPs Agreement be re-examined in the next round of trade negotiations. As part of the process of linkage-bargain diplomacy through which the WTO was negotiated, they agreed to TRIPs in exchange for trade concessions from the developed world in such areas as agriculture. Many developing countries argue that the developed countries are not holding up their end of the deal and that the TRIPs Agreement is turning out to be harder on their economies than anticipated. To the extent that the developing countries regret agreeing to TRIPs, the agreement may be difficult to enforce.

The economic efficiency probe seeks to place the traditional concept of economic efficiency of patents in a broader context. This context includes considerations of: (i) industry differences in the effects of patents, (ii) country differences in patent systems, (iii) differences in forms of intellectual property (e.g., patents vs. trade secrets), (iv) differences in economics conditions (such as level of development) that influence the effects of patents, (v) differences in the means of exchanging intellectual property (e.g., via trade, foreign direct investment, and licensing), and (vi) the direction of causality between the national development of patent systems and national capacity to innovate.

Application of this probe involves a series of questions to help assess the design of patent policy for improving economic efficiency:

<u>Industry differences in the effects of patents:</u>

a. How does the knowledge disclosed by patents differ across industries?

b. How does the optimal strength of patent protection depend on the ease of imitation relative to innovation in an industry?

c. Does the current patent system skew R&D in an industry: a) by type, such as too many quality improvements and too few new varieties of goods or too few improvements in process technologies, b) by innovation versus imitation, or c) by basic versus applied?

d. Is the overall level of R&D too low in some industries?

<u>Country differences in patent systems:</u>

e. Do global minimum standards for patents increase economic efficiency? Or should patent policy differ across countries at different levels of development?

f. What re-distribution mechanisms could be developed to ensure benefit sharing from patents?

Differences in forms of intellectual property:

g. How are different forms of intellectual property rights (e.g., patents and trade secrets) used simultaneously by strategic firms?

h. What re-distribution mechanisms could be developed to ensure benefit sharing from patents?

Differences in economics conditions:

i. How does the size of domestic market, number of firms, R&D capability, and other factors influence a country's optimal patent system?

j. What are the distributional implications of patents *within and across* countries at different levels of development?

Differences in the means of exchanging intellectual property:

k. What are the effects of patents on various means of international exchange (e.g., trade, foreign direct investment, licensing, etc.)?

Direction of causality:

l. Does national capacity of innovation necessarily create incentives for the development of national patent protection or visa versa?

m. What is the optimal timing for the strengthening of patents in developing countries?

7. Risk Management

This probe examines the link between the patent system and the triad of scientific risk assessment, risk analysis and the management of various forms of environmental risk and potential harms to biodiversity. Among the tools relevant to the science-policy interface used to handle such risks have been the precautionary principle and the principle of future generations (that costs and risk ought not to be imposed on future generations).

As one of the mechanisms intended to encourage innovation, the patent system can be used as a tool to direct where inventive effort is put. This probe thus offers the opportunity to concentrate on mechanisms available to adjust incentive effects within the patent system—for example, through determinations of patent scope and exemptions—to better concentrate inventive activity.

This probe leads to the formulation of questions relating specifically to the link between innovation and safety, such as the following:

a. When new forms of harms are introduced (e.g., GMOs), what is the effect, if any, of the patents in increasing/decreasing/managing these harms?

b. Which institution(s) is (are) responsible for managing risk?

IV. Conclusion

The limitations placed on current thinking about the role of patents in law, ethics, economics, management and philosophy hinder academic analysis and policy development in developed and developing nations alike, at both the domestic and international level. Illustrating the limitations of four of the most significant assumptions in the literature ought to encourage academics and policy makers to take a more holistic and contextual approach to intellectual property regimes in the biotechnology sector.

In this article, the authors have designed a conceptual framework that focuses more on transdisciplinary evaluation than discipline-specific predictions based on questionable assumptions. The seven probes adopted to implement this conceptual framework provide the comprehensive analysis necessary before societies around the world can develop intellectual property law and policy designed to capture the benefits from advances in biotechnological development. These probes provide researchers and policy-makers with a flexible analytic framework within which to investigate how patent systems related to biotechnology actually work. These probes do not impose the narrow perspective of the assumption-based approach that they replace. Rather, they lead researchers and policy-makers to ask better, more contextual questions about the patent system that can be answered within a transdisciplinary framework capable of providing comprehensive solutions.

The questions set out in the above discussion of the probes are general in nature. While these questions are interesting in themselves, they can be further refined and contextualized within a more directed analysis of particular aspects of biotechnology intellectual property. In particular, they can be used to help understand and eventually resolve particular problems that may arise with respect to, for example, the patenting of genetically modified plants or of human genes used in determination of disease risk. More work is therefore needed to transform these general questions into more particular and concrete research and policy questions.

Finally, the probes articulated here are the raw materials for manufacturing alternate models of intellectual property regimes that will illustrate how changes to patent systems could bring about desirable changes in the social effects of patentable innovation. Is this social engineering? Yes, but what is the alternative? Patent systems are widely criticized for a number of reasons, many of which were captured in the analysis of the assumptions. Adopting the transdisciplinary methodology of the seven identified probes can lead to conceptions of intellectual property regimes lying outside the norm, a response to the reality that the even the most ideal legal system will always inevitably make concessions to other social considerations.

Purists about matters legal will no doubt object that intellectual property law is not the domain of social engineers and should therefore not be co-opted as a multi-purpose policy tool. If the foregoing can reach any general conclusion, it is

that intellectual property is already a multi-policy purpose policy tool. As disclosed above, intellectual property, particularly patents, not only structures innovation but also allocates the resulting benefits and costs of innovation. Indeed in fields such as biotechnology innovation patents are as much an input norm of innovation and the resulting distributional consequences as they are a market-based output product of innovation. Ultimately, then, the development of the analytical probes suggested here is as much a reflection on how intellectual property structures biotechnology innovation and governance as it is a door to visioning exercises and model building about alternative intellectual property regimes.

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NOTES

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12. *Graham v. John Deere Company*, 383 U.S. 1 (1966).

13. *John Deere* (1966, p. 13).

14. *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, 1 S.C.R. 142 (1999).

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16. See, for example, M. Dale, "A Lockean Argument Against Gene Patenting," *Business and Professional Ethics Journal*, vol. 20 (2001), pp. 129–143.

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18. Testimony of R. Scott, President and Chief Scientific Officer of Incyte Genomics Inc., before the U.S. House Judiciary Subcommittee on Courts and Intellectual Property, July 13, 2000, available at http://www.bio.org/laws/comments071300.html (last accessed June 24, 2003) ("in the absence of patents, it will become much more difficult for companies like Incyte to obtain access to capital. This in turn will inevitably slow the development of genomic information and technologies, which will have a seriously negative impact on the promised acceleration in health care research. . . . The patent system is playing a key role in the genomics revolution").

19. Government of Canada, *Achieving Excellence: Investing in People, Knowledge and Opportunity* (Government of Canada: Ottawa, 2001), p. 80 available at: <http://www.innovationstrategy.gc.ca/cmb/innovation.nsf/vRTF/PDF/$file/achieving.pdf> (accessed March 11, 2003).

20. According to the NRC: "If knowledge and innovation are the currencies of the new economy, then NRC is Canada's Mint. The importance of new knowledge, managed effectively by organizations as intellectual property (IP), has grown dramatically in the past decade. Original discoveries, know-how, software and new technologies—protected by patent or copyright—are the foundations for new products, process innovations and commercialisation in the world's marketplaces" available at: http://www.nrc-cnrc.gc.ca/doingbusiness/transfer_1property_e.html.

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26. P.L. 96-517 (1980), now 35 U.S.C.A. §§200–212 (1984).

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Traditional Knowledge Holders," 1999 WIPO Report on Fact-Finding Missions 1998–1999, WIPO, Geneva (Publication Number 768E).

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59. E. R. Gold and T. A. Caulfield, "Human Genetic Inventions, Patenting and Human Rights," report commissioned by the Department of Justice, Government of Canada (2003), at p. 46.

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"To Patent or Not to Patent: The European Union's New Biotech Directive," *Houston Journal of International Law*, vol. 23 (2001), pp. 569–607; Daniel J. Kevles, "Of Mice and Money: The Story of the World's First Animal Patent," *Daedalus*, vol. 131 (2002), pp. 78–88. For one of the few commentators taking the opposing viewpoint, see Peter Drahos, "Biotechnology Patents, Markets and Morality," *European Intellectual Property Review*, vol. 21 (1999), pp. 441–449. For similar expressions of patent neutrality from public policy organizations, see Canadian Biotechnology Advisory Committee, "Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada, Biotechnology Ministerial Coordinating Committee" (June, 2002), available at http://www.cbac-cccb.ca/documents/en/E980_IC_IntelProp.pdf (accessed March 27, 2003);Nuffield Council on Genetics, The Ethics of Patenting DNA: A Discussion Paper (accessed 27 March 2003); Nuffield Council on Genetics, "The Ethics of Patenting DNA: A Discussion Paper" (2002), available at www.nuffieldbioethics.org (accessed 26 March 2003).

62. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *Commissioner of Patents v. President and Fellows of Harvard College*, SCC 76 (2002).

63. R. Stephen Crespi, "Biotechnology, Morality and Patents," *Trends in Biotechnology*, vol. 15 (1997), p. 123–133, at p. 124.

64. Notwithstanding the prevailing assumption of ethical neutrality, provisions for ethical review exist in the intellectual property regimes of most developed states (with Canada, Australia, and the United States being notable exceptions). The most common method of conducting this review is to include a provision within patent legislation whereby inventions the commercial exploitation of which would violate notions of "ordre public" or morality may be excluded from patentability. See, among others, Gold and Caulfield, "Human Genetic Inventions"; E. Richard Gold, "Patenting Life Forms: An International Comparison" (February 2001), prepared for the Canadian Biotechnology Advisory Committee, Project Steering Committee on Intellectual Property and the Patenting of Higher Life Forms, available at www.cbac-cccb.ca (accessed March 26, 2003).

Similar clauses exist in international and regional agreements directed towards harmonizing patent law, including the European Patent Convention, the European Union Directive on the legal protection of biotechnological inventions, NAFTA and the TRIPs Agreement. Note, however, that the inclusion of a process for ethical review in the European Union Biotech Directive may have more to do with jurisdictional issues than with an assessment of the efficacy of integrating ethics within the patent regime rather than addressing the relevant issues through complementary regulatory regimes. E. Richard Gold and Alain Gallochat, "The European Biotech Directive: Past As Prologue," *European Law Journal*, vol. 7 (2001), pp. 331–366.

65. Gitter, "International Conflicts."

66. 35 USC §154—Similar terms are to be found in the TRIPs Agreement, which also sets out the rights of patentees in negative terms, and does not refer to privileges or liberties: "A patent shall confer on its owner the following exclusive rights: . . . to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product" (TRIPs Agreement, Article 28).

67. Drahos, "Biotechnology Patents," p. 443.

68. Patent Act (Canada), s. 42.

69. Drahos, "Biotechnology Patents."

70. Patents Act 1990 (Australia), s. 13 (1), (2).

71. Patents Act 1977 (U.K.), s. 30.

72. W. A. Adams, "Beyond Trademark and the Public Domain: Allocating Property Rights in Domain Names," *I. P. Forum*, vol. 52 (2003), pp. 10–19, at p. 17.

73. See, for example: Morris Cohen, "Property and Sovereignty," in *Property: Mainstream and Critical Positions*, ed. C. B. Macpherson (Toronto: University of Toronto Press, 1978), at p. 159; Felix S. Cohen, "Dialogue on Private Property" *Rutgers Law Review*, vol. 9 (1954), p. 357.

74. See, for example, Joseph William Singer, "Sovereignty and Property," *Northwestern University Law Review*, vol. 86 (1991), pp. 1–56; David Lametti, "The (Virtue) Ethics of Private Property: A Framework & Implications" (manuscript on file with the authors).

75. See, for example, Joseph William Singer, *Entitlement: The Paradoxes of Property* (New Haven, Conn.: Yale University Press, 2000).

76. E. Richard Gold, "Owing Our Bodies: An Examination of Property Law and Biotechnology," *San Diego Law Review*, vol. 32 (1995), pp. 1167–1247, at p. 1230.

77. E. Richard Gold, Timothy Caulfield, and Peter Ray, "Gene Patents and the Standard of Care," *Canadian Medical Association Journal*, vol. 167 (2002), pp. 256–257; *Genetics, Testing and Gene Patenting: Charting New Territory in Health Care* (Toronto: Ontario Ministry of Health and Long-Term Care, 2002), available at http://www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/report_e.pdf (accessed March 29, 2003).

78. See, for example, M. K. Cho, S. Illangaskekare, M. A. Weaver, D. G. B. Leonard, and J. F. Merz, "Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services," *Journal of Molecular Diagnostics*, vol. 5 (2003), p. 3; J. F. Merz, A. G. Kriss, D. G. B. Leonard, and M. K. Cho, "Diagnostic Testing Fails the Test: The Pitfalls of Patents are Illustrated by the Case of Haemochromatosis," *Nature*, vol. 41, no. 5 (2002), p. 577.

79. EPO Board of Appeal Decision, October 3, 1990, T 0019/90-3.3.2.

80. *Commissioner of Patents v. President and Fellows of Harvard College*, SCC 76 (2002).

81. See: Dresser, "Ethical and Legal Issues in Patenting New Life"; Merges, "Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies."

82. Singer, *Entitlement: The Paradoxes of Property*, p. 68.

83. Elaine L. Hughes and Christiane Meyer, "Animal Welfare Law in Canada and Europe," *Animal Law*, vol. 6 (2000), p. 32 (citing Peter Singer's view that analysis carried out by humans is biased in favor of humans).

84. E. R. Gold, *Body Parts: Property Rights and the Ownership of Human Biological Materials* (Washington, D.C.: Georgetown University Press, 1996).

85. A. Fink, J. Kosecoff, M. Chassin, and R. H. Brook, "Consensus Methods: Characteristics and Guidelines for Use," *American Journal of Public Health*, vol. 94 (1984), p. 979; J. Jones and D. Hunter, "Qualitative Research: Consensus Methods for Medical and Health Services Research," *British Medical Journal*, vol. 311 (1995), p. 376.

86. Jones and Hunter, "Qualitative Research."

87. J. Rawls, *A Theory of Justice* (Cambridge, Mass.: Harvard University Press, 1971).

88. Serge-Christophe Kolm, "Distributive Justice," in *A Companion to Contemporary Political Philosophy*, ed. Robert E. Goodin and Philip Petit (Cambridge: Blackwell Publishers, Ltd., 1993), at p. 438.

89. Rawls, *A Theory of Justice* (1971), pp. 7–8 (difference principle); J. Rawls, *A Theory of Justice*, 2nd ed. (Oxford: Oxford University Press, 1999), at pp. 63, 72–73; C. Beitz, "Rawls's Law of Peoples," *Ethics* (July 2000), p. 7; A. Buchanan, "Rawls's Law of Peoples: Rules for a Vanished Westphalian World" *Ethics* (July 2000), p. 697; C. Beitz, "Social and Cosmopolitanism Liberalism," *International Affairs* 75/3 (1999), pp. 515 at 518. This is particularly important in the area of health biotechnology, where health status has a strong influence on other spheres of life. See N. Daniels, *Just Health Care* (Cambridge: Cambridge University Press, 1985).

90. I. Kaul and M. Faust, "Global Public Goods and Health: Taking the Agenda Forward," *Bulletin of the World Health Organization*, vol. 79 (2001); L. C. Chen, T. G. Evans, and R. A. Cash, "Health as a Global Public Good," in *Global Public Goods: International Cooperation in the 21st Century*, ed. I. Kaul, I. Grunberg, and M. A. Stern (New York: Oxford University Press, 1999), at pp. 284–304; D. Woodward, N. Drager, R. Beaglehole, and D. Lipson, "Globalisation, Global Public Goods, and Health," *Trade in Health Services*, vol. 3 (2001).

91. See Gold and Caulfield, "Human Genetic Inventions."

92. International Forum for Genetic Engineering (*If*Gene), *Genetic Engineering and the Intrinsic Value and Integrity of Animals and Plants* (Edinburgh: *If*Gene, 2003).

93. *Commissioner of Patents v. President and Fellows of Harvard College*, SCC 76 (2002), para. 163.

94. Gold and Gallochat, "The European Biotech Directive," pp. 358–359.

95. Ibid., p. 360.

96. The principle of sovereignty, also understood in legal terms as the juridical equality of states, has been codified in the Charter of the United Nations, 892 *U.N.T.S.* 119, Art. 2(1): "The Organization is based on the principle of the sovereign equality of all its Members."

97. One such exception would be the requirement that all states comply with those international norms which have achieved the status of *jus cogens*, i.e., a norm "accepted and recognized by the international community of states as a whole" and "from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character." See Vienna Convention on the Law of Treaties, 1155 *U.N.T.S.* 331.

98. The nature of the TRIPS Agreement, however, being only one component within an extensive framework of trade liberalization within the WTO regime, makes it difficult to identify the rationale pursuant to which any particular state might decide to cede sovereignty over domestic intellectual property policy. WTO negotiations are a package deal whereby states with disparate economic interests seek to achieve reciprocal concessions. Many commentators have indicated that the TRIPS Agreement does not represent unqualified acceptance by developing states of arguments in favor of increased intellectual property protection, but is instead a quid pro quo for benefits such as increased access to

agricultural and textile markets in developed states. Any decrease in domestic welfare arising from the implementation of strengthened intellectual property rights was presumably offset by increasing gains from trade in these areas. See, for example: Jackson, "GATT and the Future of International Trade Institutions," *Brook Journal of International Law*, vol. 18 (1992), p. 13 (characterizing concessions in agriculture and textiles as trade-offs for concessions relating to services and intellectual property rights); Reichman, "The TRIPS Agreement Comes of Age: Cooperation of Conflict with the Developing Countries?" *Case Western Reserve Journal of International La*w, vol. 32 (2000), pp. 455–456.

99. That so many states functioning at such disparate levels of economic and technological capacity would form a consensus in relation to universal minimum standards for intellectual property rights was not a foregone conclusion. In the negotiating rounds leading up to the creation of the WTO and the promulgation of the TRIPS Agreements, support for universal minimum standards of protection did split along lines roughly parallel to the technological divide between developed and developing states. Many developing states argued that the imposition of heightened standards of protection would have an adverse impact on domestic welfare. Heightened levels of protection would simply transform a nation of imitators into a nation of infringers, leading to a wave of technological neocolonialism. See, for example: Keith Aoki, "Neocolonialism, Anticommons Property and Biopiracy in the (Not-So-Brave) New World Order of International Intellectual Property Protection," *Indiana Journal of Global Legal Studi*es, vol. 6 (1998), p. 11. Developed states, on the other hand, argued that strengthening intellectual property protection in developing states would result in a net positive welfare benefit. Rather than relying on imitation to establish and increase technological capacity, these states would be able to advance by means of a combination of increased technology transfer and foreign direct investment. For a concise summary of the arguments presented by both developing and developed/least developed states in relation to the economic justification of heightened levels of intellectual property protection, see, for example, Su, "The Winners and the Losers: The Agreement on Trade-Related Aspects of Intellectual Property Rights and Its Effects on Developing Countries," *Houston Journal of International Law*, vol. 23 (2000), p. 169; Okediji, "Copyright and Public Welfare in Global Perspective," *Ind. J. Global Legal Stud.*, vol. 7 (1999), p. 117; Braga, "Trade-Related Intellectual Property Issues: The Uruguay Round Agreement and its Economic Implications," in *The Uruguay Round and Developing Economies*, ed. Will Martin and L. A. Winters (World Bank Discussion Papers, No. 307, 1996).

100. Su, "The Winners and the Losers."

101. See, for example, Reichman, "The TRIPS Agreement Comes of Age."

102. *Harvard College* (2002).

103. *Harvard College* (2002), para. 13), citing with approval *Théberge v. Galerie d'Art du Petit Champlain inc.*, 2002 SCC 34, at para. 6.

104. E. Richard Gold, "Biomedical Patents and Ethics: A Canadian Solution," *McGill Law Journal*, vol. 45 (2000), p. 413. See also Drahos, "Biotechnology Patents."

105. J. Eaton and S. Kortum, "Trade in Ideas: Patenting and Productivity in the OECD," *Journal of International Economics*, vol. 40 (1996), pp. 251–278.

106. Grossman and Lai, "International Protection of Intellectual Property."

107. McCalman, "Reaping What You Sow."