BIOTECHNOLOGICAL INNOVATION AND PARTNERSHIPS

E. Richard Gold*

Cite as 10 J. HIGH TECH. L. 1 (2009)

I. Introduction

The biopharmaceutical industries are undergoing a significant, perhaps radical, restructuring. Due to a variety of factors ranging from the current economic slowdown, to the increasing recognition that the biotech business model has failed, to pressures on the pharmaceutical industry to find new ways of identifying promising medicines, companies, universities and policy-makers are seeking new ways to carry out research and bring products to market. Pharmaceutical companies are dramatically cutting back staff, engaging in more collaborative efforts, and becoming more flexible in the way they sell their products on the market.[1] For its part, the biotechnology industry

* Associate Professor, McGill University's Faculty of Law. This article was originally submitted as part of the Advanced Legal Studies symposium, "The Impact of Patent Law on the Economy – Stimulus or Impediment?" held at Suffolk University Law School on March 27, 2009. The symposium was sponsored with the Journal of High Technology Law and Suffolk University Law School's IP Law Concentration.

[1] *See, e.g., Billion Dollar Pills*, THE ECONOMIST, Jan. 27, 2007, at 69-71 (discussing major changes among the largest pharmaceutical companies); *Triple Therapy*, THE ECONOMIST, Aug. 16, 2008, at 66 (describing the changing business model of pharmaceutical giant GSK); *Buying Opportunity*, THE ECONOMIST, Oct. 11, 2008, at 84-85 (describing the buying trend among pharmaceutical firms even amid the 2008 economic downtown); *Winds of Change*, THE ECONOMIST, Dec. 13, 2008, at 75-76 (discussing growing acceptance among pharmaceutical firms of price reductions and of health care reform).

 ISSN 1536-7983.

has, thirty years into its existence, failed to make a profit.[2] As Harvard Business School Professor Gary Pisano states, "[w]hile there have been a few very successful biotechnology firms (e.g., Amgen, Genentech, Genzyme), the economic performance of the sector overall has been disappointing by any objective standard."[3]

Beyond these economic considerations, pressure from government to provide greater access to their products, particularly, but not exclusively, in low and middle-income countries, has increased the need to restructure.[4] Efforts to increase patent protection through traditional fora-such as the World Intellectual Property Organization and the World Trade Organization-have met steep resistance.[5] The industries have had to reformulate their arguments away from the incentive-access paradigm to one based on health protection in eliminating counterfeit medications.[6]

In this essay, I describe the biopharmaceutical industries' restructuring in terms of intellectual property ("IP"): why and when patents are acquired, how they are licensed and shared, and how they are enforced. The essay draws on the work of the International Expert Group on Biotechnology, Innovation and Intellectual Property (the "IEG"), which released a report and case studies that examine the changing ways in which private and public sector actors create, use, and share knowledge within

[2] *See Billion Dollar Pills*, *supra* note1, at 69-71.

[3] GARY P. PISANO, SCIENCE BUSINESS: THE PROMISE, THE REALITY, AND THE FUTURE OF BIOTECH 5 (Harvard Business School Press 2006).

[4] *See generally Billion Dollar Pills*, *supra* note 1, at 69-71 (describing governmental pressures reducing pharmaceutical costs).

[5] *See generally* WORLD INTELLECTUAL PROPERTY ORGANIZATION, REPORT OF THE PROVISIONAL COMMITTEE ON PROPOSALS RELATED TO A WIPO DEVELOPMENT AGENDA (2007), *archived at* http://www.webcitation.org/5jdqDM3lR; *See generally,* Arvind Panagariya, TRIPS and the WTO: An Uneasy Marriage (July 20, 1999) (unpublished policy paper, on file with Columbia University), *archived at* http://www.webcitation.org/5jf73Ij66.

[6] *See, The Anti-Counterfeiting Trade Agreement (ACTA) Fact Sheet* (European Comm'n, Directorate General for Trade, Brussels, Belg.) Nov. 2008, *archived at* http://www.webcitation.org/5fgpDnvft. (describing possible approach to health protection based IP protection).

innovation systems.[7] The essential argument of the IEG is that the biotechnology and pharmaceutical industries are undergoing a change: from the old era of IP ("Old IP"), in which innovation was heavily patented and shared only on a limited basis, to "New IP," in which patents are obtained in order to build relationships and increase sharing of innovation.[8]

I will begin then, by describing the IEG's conclusions and illustrate them through a discussion of two of the case studies conducted by the IEG. The first describes the failure of the classic biotechnology business strategy in high-income countries, while the second illustrates pressures on the model from low and middle-income countries in relation to traditional knowledge.

II. A Change of Intellectual Property Era

After a seven-year study involving seven academic disciplines and engagement with industry, government and civil society representatives, the IEG released its report on the role that IP actually plays in biotechnology innovation in the health, agricultural and industrial fields, in September 2008.[9] The IEG was funded by the Canadian government through a rigorous peer-review process.[10] While the primary researchers in the IEG were located in Canada and the United States, an international expert advisory group and researchers from literally around the world supported their work. The IEG further relied on the knowledge and expertise of its private and public sector partners from high, middle and low-income countries.[11]

The IEG consciously established itself to overcome disciplinary-based barriers to analyzing how the IP system

[7] *See* International Expert Group on Biotechnology, Innovation and Intellectual Property (IEG), *archived at* http://www.webcitation.org/5k83vnhAv

[8] *See id.* (discussing changes in IP protection).

[9] *Toward a New Era of Intellectual Property: From Confrontation to Negotiation*, IEG, Sept. 2008, *archived at* http://www.webcitation.org/5fgslW92P [hereinafter *IEG Report*].

[10] *See* IEG History, *archived at* http://www.webcitation.org/5fgu6Idox.

[11] *See id.*

practically functioned to facilitate or hamper innovation in the biotechnology sector.[12] As the IEG found, legal scholarship tends to place priority on legal rules rather than other factors that modulate the effect of those rules in practice:

> An analysis of IP laws alone gives a distorted understanding of how IP facilitates innovation and dissemination. Such an analysis must be complemented by an understanding of business and governmental practice as well as the public and private institutions and entities that create, grant and govern IP.[13]

According to the IEG, "Old IP understood patents, copyrights and trademarks to be simply mechanisms that permitted a company, having invested in research and development, to recoup its costs and make a profit before others are allowed to copy its idea."[14] Old IP resulted from the recognition that intellectual assets had become more valuable than tangible assets.[15] Unlike tangible assets that could effectively be controlled through physical barriers, those wanting to similarly control intangibles needed to construct legal barriers.[16] That is, in order to deploy intangible assets as a substitute for tangible assets, actors sought control through the construction of higher and more expansive intellectual property laws.[17]

The problems with this approach became increasingly obvious toward the end of the 1990s and beginning of the 2000s, as new product development was decreasing and companies faced pressure to make their products accessible to middle and

[12] *See id.*
[13] IEG Report, *supra* note 9, at 23.
[14] IEG Report, *supra* note 9, at 17 (describing property value basis emphasized by Old IP).
[15] IEG Report, *supra* note 9, at 18.
[16] IEG Report, *supra* note 9, at 18.
[17] *See* IEG Report, *supra* note 9, at 17.

low-income countries.[18] The essential difficulty is that intellectual assets are not substitutes for tangible assets and business models based on tangible assets did not transfer well to the world of intangibles.[19] Intellectual assets do not combine in the same way as physical assets and acquire value through use rather than hoarding.[20] Beyond this, intellectual assets involve global, rather than local, deployment and thus the effects of intellectual property are felt around the world rather than in the immediate environment.[21] Because of these characteristics, Old IP encountered severe and increasing resistance not only by civil society, but by government and industry in the early 2000s.[22] The abandonment of a lawsuit launched by thirty-nine pharmaceutical companies against the government of South Africa over the importation of medicines to combat the HIV/AIDS epidemic began the descent of Old IP.[23] As the IEG pointed out:

> The logic of expansion inherent in Old IP became its downfall. The beginning of the end of Old IP was the lawsuit over South African laws brought in to respond to the HIV/AIDS crisis. The assumption that IP increases biomedical innovation came face to face with the reality that the expansion of IP rights could prevent countries from meeting their critical health needs.[24]

Other examples of the decline in Old IP include a series of decisions from the Supreme Court of the United States that curtailed patent rights and decisions by the World Trade

[18] *See* IEG Report, *supra* note 9, at 18-20 (discussing difficulty of old IP business to adapt to gain access to lower income markets).

[19] *See* IEG Report, *supra* note 9, at 29-30 (discussing reports conclusion that industry focus on sharing information more financially sound than information hoarding).

[20] *See* IEG Report, *supra* note 9, at 29.

[21] *See* IEG Report *supra* note 10, at 29 (discussing recommendations in report based on international approaches to IP business models).

IEG Report, *supra* note 9, at 31.

[22] *See* IEG Report, *supra* note 9, at 19.

[23] IEG Report, *supra* note 9, at 17.

[24] IEG Report, *supra* note 9, at 19.

Organization, World Intellectual Property Organization and World Health Organization to prioritize health and development over intellectual property rights.[25] By 2007, the logic had permeated the head offices of the major pharmaceutical companies, with senior officers from companies such as GlaxoSmithKline, Sanofi-Aventis, and Pfizer admitting that their business model, which was built around the exclusive protection of blockbuster intellectual assets, was no longer functioning.[26]

The failure of Old IP is not a failure of intellectual property laws themselves, but the interaction of those laws with practices (e.g., business and university practices with respect to the protection, licensing and enforcement of patents) and institutions (e.g., the inability of patent offices to vigorously apply legal standards in an efficient and timely manner). In fact, a change of patent or other intellectual property right alone would likely be ineffective in addressing the problems with Old IP.[27] Rather, industry, government, universities and non-governmental organizations need to pay equal or greater attention to the ways they use, share and institutionalize patent and other intellectual property rights.[28] That is, any call to reform that focuses solely on patent statutes will necessarily miss the mark unless they are accompanied by a modification in the way universities think about and manage technology transfer and the way that industry licenses its ideas.[29]

As Old IP falls into decline, new visions of IP are taking root.[30] The IEG found that these visions have a common form and, according to the IEG, constituted 'New IP': "[i]n the era of

[25] *See generally.*, eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006); KSR v. Teleflex, 550 U.S. 398 (2007); Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005); Quanta Computer, Inc. v. LG Electronics, Inc. 128 S. Ct. 2109 (2008).

[26] *See* IEG Report, *supra* note 9, at 9 (describing statements by industry leaders relative to failure of Old IP).

[27] *See* IEG Report, *supra* note 9, at 14 (describing rationale IEG report to formulating New IP).

[28] *See* IEG Report, *supra* note 9, at 14.

[29] *See* IEG Report, *supra* note 9, at 14-16.

[30] IEG Report, *supra* note 9, at 14.

New IP, the focus turns away from amassing IP and toward managing it in such a way as to enhance the functioning of innovation systems."[31]

For example, there is already significant questioning among governments, industry, and leading universities over the purposes and most effective mechanisms through which university research should be transferred to external actors.[32] For years, universities measured the success of technology transfer in terms of the number of patents filed and granted, the number of licenses issued, the number of start-ups created and the royalties obtained.[33] On these measures, almost every university fails.[34] As the IEG pointed out:

> Universities find that the riches they were promised from protecting IP have not materialized. Instead, universities have, overall, lost money after over 20 years of commercialisation activities. Governments hoping to spur economic growth and productivity increases, by relying significantly on increasing IP, wonder why they are not yet seeing the benefits.[35]

We are only now discovering that much of the problem with university technology transfer has been the mistaken understanding of how IP contributes to innovation. As Gary Pisano writes:

> Any strategies or policies at the university level (such as exclusive licensing) that discourage or inhibit the broad flow of basic scientific information are clearly problematic. . . . Even worse, in contexts like biotechnology, where basic scientific knowledge evolves with application of that

[31] IEG Report, *supra* note 9, at 16.
[32] *See* IEG Report, *supra* note 9, at 16.
[33] IEG Report, *supra* note 9, at 31.
[34] IEG Report, *supra* note 9, at 31.
[35] IEG Report, *supra*, note 9, at 28 (citations omitted).

> knowledge to specific therapeutic problems, putting the science into the hands of more explorers is likely to accelerate the pace of scientific advance.[36]

Since it is not possible to forecast the exact evolution of New IP, the IEG identified six characteristics that define it.[37] I will illustrate several of these in the examination of the two case studies that follow, but these themes are as follows:

- **Trust:** In order to build the partnerships and collaborations between researchers, universities, NGOs and industry that are necessary to facilitate research and development, actors will need to trust one another.[38] Under Old IP, trust of the motivations and strategies of one's partners was not essential since each actor was able to protect itself through high IP walls.[39] In the New IP era, trust and not IP becomes the glue that facilitates innovation.[40] IP rights play a secondary role in reducing partnerships to legal agreements but cannot substitute for trust in ensuring sharing and building.[41]
- **Communications:** Actors must engage in better communications if they are to build trust.[42] Many of the debates over the last few decades over IP, innovation, and access reflect more a state of talking past one another than talking with one another.[43] If actors are to overcome previous biases and fears, they need to be more open about what they are doing and why.[44]
- **New Models of Collaboration and Dissemination:**

[36] PISANO, *supra* note 3, at 188.
[37] *See* IEG Report, *supra* note 9, at 26-37.
[38] *See* IEG Report, *supra* note 9, at 26-27 (describing elements of trust permaeating IP business model structure).
[39] *See* IEG Report, *supra* note 9, at 26.
[40] *See* IEG Report, *supra* note 9, at 26.
[41] *See* IEG Report, *supra* note 9, at 26-27.
[42] IEG Report, *supra* note 9, at 27 (discussing importance of communication between industry NGOS researchers and indigenous peoples).
[43] *See* IEG Report, *supra* note 9, at 27-28.
[44] IEG Report, *supra* note 9, at 28.

Industry, universities, and governments are recognizing the failure of Old IP but do not yet have the business and institutional models necessary to replace Old IP.[45] While there has been much talk about particular models—patent pools, patent clearinghouses, open source and open science, for example—all have yet to be proven effective.[46] Experimentation with new forms of collaboration in pre-competitive research, new partnerships to design and test products and new dissemination channels need to be investigated, examined and communicated to others.[47]

- **Scientific Infrastructure:** High-income countries and actors have done a poor job of addressing the health, social and economic needs of low and middle-income countries.[48] If the world is to take seriously the needs of these countries, it must ensure that they have the capacity to carry out their own research and development.[49] Many of these countries suffer, however, from an insufficient scientific infrastructure—in terms of equipment, access to high-speed Internet connections, access to research funds, qualified personnel, and management experience in bringing products from the laboratory to the clinic—to permit them to do so.[50] Investments in infrastructure, reversing the brain drain toward high-income countries and access to research funds are all required.[51]
- **Cross-Cutting Thinking:** One of the reasons for the problems posed by Old IP is that its strategies made sense on paper and in isolation but did not work in practice.[52] This is because innovation systems involve a complex mix of actors, motivations and scientific problems that are not

[45] *See* IEG Report, *supra* note 9, at 28-29.
[46] *See* IEG Report, *supra* note 9, at 29.
[47] *See* IEG Report, *supra* note 9, at 31-32.
[48] IEG Report, *supra* note 9, at 41.
[49] *See* IEG Report, *supra* note 9, at 33.
[50] IEG Report, *supra* note 9, at 33.
[51] *See* IEG Report, *supra* note 9, at 33 (recommending establishing infrastructure in poorer nations to aid IP research).
[52] *See* IEG Report, *supra* note 9, at 34.

amenable to evaluation in isolation from one another.[53] In order to better manage the New IP era, academics and policy-makers need to find methods of analyses that cross traditional disciplinary boundaries.[54]

- **Data and Metrics:** Part of the reason that Old IP is so entrenched and that developing new business and institutional models is so challenging is that our empirical data on the role of IP in innovation is incomplete and is based significantly on opinion rather than on objective measures.[55] In addition, the measures we do use, such as number of patents and revenues, not only measure the wrong thing, but can easily be manipulated.[56] If we are to manage the transition from Old IP to New IP in the least disruptive way, then we need to have better data on which to base our decisions.[57] We also need measures of success that reflect what institutions actually want to achieve rather than the arbitrary measures we use today.[58]

To the question of whether industry, universities and governments are destined to remain stuck in Old IP, "the answer, quite simply, is that things are only inevitable as long as we are unwilling to change them," at least according to Ernst & Young in their 2008 review of the global biotechnology industry.[59] At bottom, there is no choice about whether to make the transition.[60] Either we collectively resist it, and suffer from declining levels of innovation, financing and revenues, or we embrace it and proactively make the changes needed for a

[53] *See* IEG Report, *supra* note 9, at 41.

[54] *See* IEG Report, *supra* note 9, at 44.

[55] *See* IEG Report, *supra* note 9, at 35 (Discussing IEG research revealing strong assumptions in Old IP data collection)

[56] *See* IEG Report, *supra* note 9, at 36 (stating current ad hoc data collection lacks common standards limiting value of comparisons).

[57] *See* IEG Report, *supra* note 9, at 36.

[58] *See* IEG Report, *supra* note 9, at 36.

[59] Ernst & Young, *Global Introduction: Reinnovation and Reinvention* in, BEYOND BORDERS: GLOBAL BIOTECHNOLOGY REPORT 2008 3, *archived at* http://www.webcitation.org/5fhLBR23r [hereinafter *Reinnovation Report*].

[60] *See id.* (discussing inevitability of need to change IP business model).

smooth and relatively painless transition.[61] For its part, drawing on the above themes, the IEG set out a series of short to medium term steps that governments, patent offices, industry, universities and even the media could undertake to help in this process.[62]

III. Case Studies

In order to illustrate both the findings and some of the themes that the IEG discusses, I draw on two of the case studies that informed the IEG report. The first case study examined the controversy that ensued following on the patenting and subsequent attempt to enforce several gene patents held by a US company, Myriad Genetics.[63] The case study was prepared by bringing together, for the first time, the major players in the dispute to discuss the case study.[64] The second case study examines indigenous peoples' claims over traditional knowledge regarding medicinal use of plants, land use and the environment.[65] It provides a comparative examination of traditional knowledge across three countries and continents, with each national study prepared by local experts.[66]

A. Myriad Genetics

In the late 1990s and early 2000s, controversy poured over a small, Utah-based biotechnology company active in the

[61] *See id.*

[62] *See* IEG Report, *supra* note 9, at 43-44.

[63] *See generally* E. RICHARD GOLD & JULIA CARBONE, MYRIAD GENETICS: IN THE EYE OF THE POLICY STORM (Int'l Expert Group on Biotechnology, Innovation, and Intellectual Prop. 2008), *archived at* http://www.webcitation.org/5lHstM6Sx.

[64] *See id.,* at 6 (discussing objectives of case study).

[65] *See generally* Tania Bubela, Edson Beas Rodrigues Jr., Cherie Metcalf, Kent Nnadozie, Eliana Rodrigues & Julia Carbone, Respecting, Promoting, and Protecting Traditional Knowledge: A Comparative Case Study of Brazil, Kenya, and Northern Canada (2008) (unpublished Working Document, on file with the Int'l Expert Group On Biotechnology, Innovation, and Intell. Prop.) *archived at* http://www.webcitation.org/5jdt33lzw [hereinafter *Comparative Case Study*].

[66] *See id.,* at 1 (describing theory of analysis).

human diagnostics and, to a lesser extent, therapeutic fields.[67] Myriad Genetics, Inc. and its affiliates ("Myriad") filed and obtained patents covering two genes, BRCA1 and BRCA2, mutations of the genes that are linked with increased risks of breast and ovarian cancer and an associated diagnostic test.[68] While only a small minority of breast and ovarian cancers have a known genetic link, those families suffering from mutations in these genes have from forty to eighty-five percent chance over their lifetimes of suffering from these cancers without preventative action.[69]

The controversy arose within several communities. First, there was an intense and divisive competition among researchers to be the first to sequence the two genes and to patent them.[70] Myriad won the publication race over one gene but lost the other, having nevertheless filed a patent application the day before its competitors published the second gene sequence.[71] The hostile nature of the race and accusations that Myriad deposited its patent application just before the other team published led to years of distrust and accusations.[72] Once Myriad had secured patents, researchers feared that Myriad would enforce its patents and impede research.[73] Second, Myriad's strategy of controlling the diagnostic market, which it based on industry practice, caused concern in the majority of countries with public health care systems.[74] Myriad had built, in the 1990s, a laboratory costing thirty-million dollars that it wanted to pay off by being the sole provider of the principal test for breast and ovarian cancer and used its patent rights to attempt to achieve this end (it would allow local laboratories the right to carry out the less

[67] Gold & Carbone, *supra* note 63, at 5.

[68] Gold & Carbone, *supra* note 63, at 7-12.

[69] *See* Gold & Carbone, *supra* note 63, at 5 (discussing breast cancer incidence in relation to mutation in BRCA1 and BRCA2 discovered).

[70] Gold & Carbone, *supra* note 63, at 7.

[71] Gold & Carbone, *supra* note 63, at 8.

[72] Gold & Carbone, *supra* note 63, at 39-40.

[73] Gold & Carbone, *supra* note 63, at 12.

[74] *See* Gold & Carbone, *supra* note 63, at 12 (describing negative public health care system reaction to industry controlling access to diagnostic test through patent).

expensive and demanding testing of family members to see if they possessed the same mutation).[75] When Myriad exported this business model outside the United States, public health administrators cried foul, saying that they, and not Myriad, should decide how the test was to be introduced into the health system.[76] They preferred to administer another, less expensive test first that, together with a woman's medical history, would help identify those women who should take the more expensive test that Myriad proposed.[77] In contrast, Myriad wanted all women to immediately use its test.[78] Third, Myriad eventually decided to experiment with direct-to-consumer advertising of its genetic tests in the United States, leading to criticism from clinical geneticists and patient constituencies that Myriad was trying to scare women who did not need the test to take it and that women would not seek proper genetic counseling prior to taking the test.[79]

Because of these controversies, Myriad became the lightning rod for concern over gene patenting.[80] Critics called for a ban over gene patenting, institutions lined up to challenge Myriad's patents, and Myriad was effectively locked out of any significant activity outside the United States.[81] As a result, Myriad has lost sources of revenue, researchers have lost

[75] Gold & Carbone, *supra* note 63, at 9 (describing Myriad business plan).

[76] *See* Gold & Carbone, *supra* note 63, at 22 (discussing international reaction to Myriad's control of test).

[77] *See* Gold & Carbone, *supra* note 63, at 22. For example, Ontario, Canada provides a protein truncation test (PTT) to those patients who are at risk for hereditary ovarian or breast cancer. A positive PTT does not pinpoint a patient's particular mutation, but identifies those patients who produce the full-length proteins, which might be harboring a genetic mutation. Those positive patients would then be used in conjunction with the patient's history in determining whether the DNA-based test is appropriate. Gold & Carbone, *supra* note 63, at 22.

[78] *See* Gold & Carbone, *supra* note 63, at 15.

[79] *See* Gold & Carbone, *supra* note 63, at 18 (discussing reaction to Myriad's direct advertising).

[80] Gold & Carbone, *supra* note 63, at 35 (describing overall negative reaction to Myriad's business plan in seeking monopoly over cancer test using blocking patent).

[81] *See* Gold & Carbone, *supra* note 63, at 33-34.

opportunities to collaborate with Myriad, and patients may be losing access to the best diagnostic testing available.[82] The purpose of the case study was to understand why this occurred and how it could be avoided in the future.[83]

The case study revealed several mistakes made by Myriad and those dealing with the company.[84] In order to relate these to the findings of the IEG, I will discuss them in terms of the three of the six themes that the IEG identified: trust, communications, and new models of collaboration and dissemination.[85]

Probably the most significant problem was a lack of trust. There was clear evidence that the research community did not trust Myriad.[86] They assumed that Myriad would pursue them if the research community conducted research on the patented genes.[87] For example, some researchers reported being told not to contribute their findings to public databases out of fear that Myriad would use this as evidence in a patent infringement case.[88] Public health administrators did not trust Myriad to bargain in good faith about the licensing of the tests and so did not even bother to try to negotiate a solution.[89] Clinical geneticists did not trust Myriad and leveled considerable criticism at its tests.[90] Myriad distrusted all of the actors, describing itself as under attack from all sides.[91] Rather than attempt to negotiate with public health administrators in Canada, for example, Myriad decided to preemptively send cease-and-desist letters.[92] Within Canada, there was significant distrust between provincial authorities with jurisdiction over health care

[82] *See* Gold & Carbone, *supra* note 63, at 35-37.
[83] *See* Gold & Carbone, *supra* note 63, at 5-6.
[84] *See* Gold & Carbone, *supra* note 63, at 5-6 (describing mistakes made by the Myriad controlling patent conflict in relation to case study's focus).
[85] IEG Report, *supra* note 9, at 26.
[86] *See* Gold & Carbone, *supra* note 63, at 40.
[87] Gold & Carbone, *supra* note 63, at 40.
[88] Gold & Carbone, *supra* note 63, at 13.
[89] *See,* Gold & Carbone, *supra* note 63, at 26, 34.
[90] *See* Gold & Carbone, *supra* note 63, at 15.
[91] *See* Gold & Carbone, *supra* note 63, at 40.
[92] Gold & Carbone, *supra* note 63, at 40.

and federal officials responsible for patent law.[93] Neither level of government trusted the other to resolve the dispute.[94] With so much distrust and no actor in a position to overcome it, no attempt was ever made to find a solution satisfactory to all.[95]

The trust problem was exacerbated by the failure to communicate positions.[96] The research community presumed that Myriad would sue anyone conducting research on the genes.[97] Myriad had, in fact, a very open and progressive policy on research, not requiring those using the test directly as part of a research protocol to even ask for a license.[98] Myriad knew, however, that many in the research community did not know this, yet it never took the step of publicly announcing its research policy.[99] Similarly, communication broke down in Canada between Myriad and the provincial government authorities in charge of the question.[100] Instead of communicating, each side kept its own counsel, leading each side to assume the worst of the other.[101]

At bottom, however, the problem was with Myriad's business model.[102] While, as a recent set of studies from Duke University demonstrates, Myriad business model does not differ from that of the rest of the biotechnology industry, the model was inappropriate to meet the needs of either Myriad or its potential partners and clients.[103] The model followed the Old IP dogma of

[93] *See* Gold & Carbone, *supra* note 63, at 27.
[94] *See* Gold & Carbone, *supra* note 63, at 29.
[95] Gold & Carbone, *supra* note 63, at 29.
[96] *See* Gold & Carbone, *supra* note 63, at 35-37.
[97] *See* Gold & Carbone, *supra* note 63, at 40.
[98] *See* Gold & Carbone, *supra* note 63, at 13,40 (discussing contrast of perception of Myriad and Myriad's policies and relationship with National Cancer Institute, based on promoting progressive research).
[99] *See* Gold & Carbone, *supra* note 63, at 40.
[100] *See* Gold & Carbone, *supra* note 63, at 40.
[101] *See* Gold & Carbone, *supra* note 63, at 40.
[102] *See* Gold & Carbone, *supra* note 63, at 40
[103] *See Generally* DUKE UNIVERSITY CENTER FOR GENOME ETHICS, LAW & POLICY, COMPENDIUM OF CASE STUDIES ON THE IMPACT OF GENE PATENTS AND LICENSING PRACTICES ON ACCESS TO GENETIC TESTING (2009) *archived at*

obtaining many patents and using them to hoard control the use of innovation.[104] It also assumed that patents actually are effective at maintaining control.[105] Both the dogma and the assumption turned out to be wrong.[106] The business model led not to profit but to being locked out of the world market.[107] If Myriad had entertained a business model in which it licensed the diagnostic tests broadly to local providers rather than attempting to control the use of the test, Myriad would undoubtedly have been more profitable and would have had more partners for the roll out of its subsequent tests.[108] As far as its patents were concerned, they were either ignored or challenged around the world, completely undermining Myriad's real ability to control the market.[109]

While Myriad has learned the lesson that the existing business model in the biotechnology industry, at least as it concerns diagnostics, is mistaken, the Duke University studies show that others are unwittingly following in Myriad's footsteps.[110] The industry and its university partners – virtually all the diagnostic tests studied by the Duke team, including that of

http://www.webcitation.org/5jdsbwFhW [hereinafter *Compendium of Case Studies*]

[104] *See* IEG Report, *supra* note 9, at 13.

[105] *See* Gold & Carbone, *supra* note 63, at 9-10.

[106] *See* Gold & Carbone, *supra* note 63, at 10.

[107] *See* Gold & Carbone, *supra* note 63, at 29, 32 (describing loss of markets by Myriad due to inability to adapt).

[108] *See* Gold & Carbone, *supra* note 63, at 10. Myriad's business model did not allow it to penetrate the cancer testing market. Instead of achieving a monopoly over the testing procedures through its patent, Myriad was left in a position where the ten centers it had licensed its test to, were unable to compete with the several other centers that had developed to compete with Myriad and in reaction to the exclusivity of the Myriad test and licensing procedures, by using alternate tests. In the end, Myriad was unable to compete in a market it created because it did not license its test widely enough and therefore did not have the capacity to compete with other testing centers who used their own tests and never had to rely on Myriad. *See* Gold & Carbone, *supra* note 63, at 10.

[109] *See* Gold & Carbone, *supra* note 63, at 14-15.

[110] Robert Cook-Deegan, Subhashini Chandrasekharan & Misha Angrist, *The Dangers of Diagnostic Monopolies*, 458 NATURE 405, 406 (2009) [hereinafter *Diagnostic Monopolies*].

Myriad, originated in a university – need to explore other ways in which to patent and license their technology if the industry is to actually one day make a profit.[111]

B. Traditional Knowledge

At least since the coming into force of the Convention on Biological Diversity (CBD),[112] the issue of the protection of traditional knowledge (TK) has entered into national and international debates about intellectual property and indigenous rights.[113] TK is knowledge that indigenous communities hold around the world and takes various forms.[114] The World Intellectual Property Organization defines TK as "tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields."[115] Despite its traditional nature, TK is anything but static: "[i]n practice, TK is continuously evolving, encompasses every aspect of the existence of the holders, their relationship and interaction amongst themselves and with others and their environment."[116]

Traditional knowledge is under threat from a variety of sources, most notably through the displacement of indigenous peoples and environmental destruction, whether intentional, such as in the cutting of forests, or unintentional, such as through climate change.[117] TK is also subject to (mis)appropriation[118] as,

[111] *See id.*, at 406.

[112] *See generally* Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 79, *archived at* http://www.webcitation.org/5frt8PyV9.

[113] *See* Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Traditional Knowledge – Operational Terms and Definitions,* WIPO/GRTKF/IC/3/9 (May 20, 2002), at 9-10, *archived at* http://www.webcitation.org/5fru08YlK.

[114] *See id.*, at 9-10

[115] *See id.*, at 11.

[116] Comparative Case Study, *supra* note 64, at 3.

[117] *See* WIPO: Traditional Knowledge, *supra* note 113, at 10-11, n.40.

for example, when indigenous music is incorporated into western music or when a researcher draws on TK to identify a plant with pharmacological effect.[119] This is because "most useful drugs derived from plants have been discovered by follow-up of ethnomedical uses."[120] Indigenous communities feel real attachment to their TK as being a fundamental aspect of their culture, spirituality and world view.[121] They and the governments of the countries in which they live—although not always for the same reasons—have argued for greater protection of TK against destruction and appropriation.[122]

Since the CBD, the dominant discourse surrounding the protection of TK has been rooted in property rights, either as a sui generis right, or as a separate intellectual property right embedded within international treaties dealing with intellectual property or trade.[123] While there have always been indigenous communities opposed to treating TK as property, only recently has the thrust of international discussions recognized the problems with such an approach.[124] From the perspective of an indigenous community, the limited term of protection over and the alienability of intellectual property both present difficulty given that TK is part of a culture that has spanned centuries.[125] At the same time, an inalienable and potentially infinite property right over knowledge not only runs counter to intellectual property theory; it presents serious barriers to scientific investigation.[126]

More to the point of this essay, protecting TK as a property right would subject it to the same kind of failed models

[118] Daniel S. Fabricant & Norman R. Farnsworth, *The Value of Plants Used in Traditional Medicine for Drug Discovery*, 106 ENVIRONMENTAL HEALTH PERSPECTIVES 69, 74 (2001).
[119] *See id.*, at 70-71.
[120] *See id.,* at 74.
[121] *See id.,* at 71.
[122] *See id.,* at 74.
[123] *Comparative Case Study*, *supra* note 65, at 5.
[124] *See Comparative Case Study*, *supra* note 65, at 5.
[125] *See Comparative Case Study*, *supra* note 65, at 5-6.
[126] *See Comparative Case Study*, *supra* note 65, at 6.

of interaction that caused Myriad to lose its markets.[127] Thinking about TK as property to be hoarded and controlled is no more viable for an indigenous community than it is for a biotechnology company.[128] As the IEG concludes: "contrary to widely held beliefs, property rights will likely not enhance the interests and rights of indigenous and local communities in their traditional knowledge (TK). Promoting autonomy rather than property is the key."[129] That is, if we are to protect TK in such a way as to promote both research and the interests of indigenous peoples, we will need to develop new models of collaboration and dissemination and build trust by treating indigenous peoples as equals.[130]

The three examples surveyed in the case study illustrate this well. In Brazil, which put into place a property-based regime of TK, research has come to a halt and indigenous peoples have failed to benefit from their TK.[131] At the same time, their environments are threatened and their TK, which is tied to their land and the plants that grow on it, is likely to disappear.[132] Kenya chose to protect TK belonging to groups such as the semi-nomadic Maasai and Turkana peoples, through constitutional protection based on state protection of indigenous people.[133] The government has not, until recently, however, followed through on the constitutional principles, displacing indigenous peoples from their land, thus threatening the TK that they hold.[134] While Canada has no official policy on TK, through a combination of constitutional provisions and processes laid down by its Supreme Court, TK is effectively protected through the obligation on the government to consult with its indigenous

[127] *See* Gold and Carbone, *supra* note63 at 40 (discussing traditional business structure contributing to Myriad's failure).

[128] *See Comparative Case Study*, *supra* note 65, at 6.

[129] *Comparative Case Study*, *supra* note 65, at 1.

[130] *See Comparative Case Study*, *supra* note 65, at 5-7.

[131] *See Comparative Case Study*, *supra* note 65, at 17 (discussing stagnation of IP development in Brazil).

[132] *See Comparative Case Study*, *supra* note 65, at 80-81.

[133] *See Comparative Case Study*, *supra* note 65, at 78, 122.

[134] *See Comparative Case Study*, *supra* note 65, at 75.

peoples on matters that affect their land or culture.[135] The unintended effect of these rules is to provide *de facto* protection over TK, since it becomes a relevant consideration in decision-making.[136]

The Brazilian example illustrates particularly well the failure of a regime based on control through property rights. In 2000, the Brazilian government promulgated a Provisional Measure (which effectively has the status of a law) to protect against the misappropriation of TK and to ensure the sharing of benefits arising from the use of TK.[137] The Provisional Measure vested the Council for the Management of the Genetic Heritage (CGEN) with the power to issue certificates that would permit research on Brazil's plants and animals and to use TK.[138] CGEN in turn established rules for the granting of these certificates based on the notion that indigenous communities have a property right in any TK with which they may be affiliated.[139] CGEN has interpreted TK to include not only knowledge held within communities, but published reports of TK available through scholarly journals.[140]

The effect of these measures is that before CGEN will issue a certificate, a researcher wanting to use TK (even if previously published) within Brazil will need to negotiate with every traditional community that may have an interest in the TK.[141] Since CGEN's notions of who has an interest in TK is broad, this effectively means that a researcher wishing to access TK will need to spend years negotiating agreements with the various communities.[142] The case study reveals an example of

[135] *See Comparative Case Study*, *supra* note 65, at 123.

[136] *See Comparative Case Study*, *supra* note 65, at 123 (concluding Canadian constitutional provisions and focus on consulting with indigenous peoples protects *TK*).

[137] *Comparative Case Study, supra* note 65, at 27 (citing MP No. 2.052, June 29, 2000 (Brazil), *archived at* http://www.webcitation.org/5jdvXm7ID).

[138] *See Comparative Case Study*, *supra* note 65, at 30.

[139] *See Comparative Case Study*, *supra* note 65, at 31-32.

[140] *See Comparative Case Study*, *supra* note 65, at 36.

[141] *See Comparative Case Study*, *supra* note 65, at 41-42.

[142] *See Comparative Case Study*, *supra* note 65, at 41-42.

researchers who, working with an indigenous community willing to participate in the research, had to give up their research after five years of fruitless negotiations.[143] The researchers had to throw out their research which had identified fifty-four unknown plants that seemed to have pharmacological effect.[144] These plants will now be lost to science unless the regime is replaced.

IV. Conclusions

What the above case studies illustrate is the failure of Old IP to result in any economic, health or social gain. The focus on the ability to say "no" though property rights has, in both the case of Myriad and of CGEN in Brazil, resulted in less innovation and less benefit. If intellectual property is to fulfill its role of facilitating not only research, but the economic and social benefits arising from that result, industry, governments and research institutions must change their behaviors in terms of when to seek IP protection and how to deal with the IP they have.

There is no quick fix to the problems of Old IP and the transition to New IP will be difficult for some. As the IEG points out, however, it is not a question of whether we should adopt New IP but a question of when we will acknowledge that it has come. There are signs that industry, universities and governments are accepting the changes. But there remain many who believe that it should be resisted. We listen to them at our peril.

[143] *See Comparative Case Study*, *supra* note 65, at 60-61 (describing example of professor refusing to continue research without industrial backing).
[144] *See Comparative Case Study, supra* note 65, at 60-61.