

INTELLECTUAL PROPERTY: AN OVERVIEW



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ABOUT THIS SERIES **2** // PART I: INTELLECTUAL PROPERTY RIGHTS: A WESTERN
PARADIGM **4** // PART II: INTELLECTUAL PROPERTY IN A FLATTENING WORLD **12** //
PART III: CASE STUDIES **20** // NOTES **29** // FURTHER READING & RESOURCES **33** //

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ABOUT THIS SERIES

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PART I: INTELLECTUAL PROPERTY RIGHTS: A WESTERN PARADIGM

Creations of the mind. There is perhaps no better description for the rights to claim ownership of an invention, be it a Eureka! moment while taking a shower or the collective efforts of hundreds of scientists in a university, government or company. Intellectual property rights protect the interests of creators by giving them property rights over their creations.¹



The Western concept of intellectual property rights (IPR) can be traced to fifteenth-century England. There, in 1449, King Henry VI awarded a patent to John of Utynam for his manufacture of stained glass, giving him a twenty-year monopoly on his methods.² Protections of printed works, called copyrights, came two centuries later on the heels of another invention, the printing press. The 1710 Statute of Anne revoked the royal charter of the Stationers Company, which had enforced a monopoly in favor of printers and booksellers. Until then, authors could not benefit from the sales of their own work.

Patents and copyrights are the biggest players in a broad classification of IPR, which includes trade secrets (what you know: information not available to the public); trademarks and brands (what you call it: unique identifiers of products and services); industrial design (what it looks like: visual designs of objects with aesthetic or commercial value); and geographical indication (where it's made: "Made in Germany").

For the sciences in general and life sciences especially, patents loom large. For the purposes of this overview, let's start with the patent—the lynchpin and driving force behind innovation and commercialization of biological inventions.

A Portrait of a Patent

Simply put, a patent is a right given to inventors of intellectual property, allowing them to exclude anyone from commercially exploiting (making, using or selling) their inventions for a set period of time, usually 20 years. The invention is protected within the country where the patent is granted. Inventions are, in essence, ideas. The protection of an invention under patent law does not require that it be a physical thing. But it is customary to distinguish between inventions that are products and those that are processes. The creation of a new cell line is an example of a product invention. The invention of a new method or process of making the cell line is a process invention.

Why patent? The reasons have to do with economic incentives, private and public. To discover and develop something new typically costs far more than to copy an existing idea. Without protection, imitators can quickly erode the profit available to the inventor, and investors will be discouraged from spending the money needed for more research and development. If inventors capture only a part of the benefit of their inventions, private returns won't reflect social returns and investment will go missing. In the U.S., the patent system is credited for fueling entire industries such as biotechnology, which boasts over 1,200 companies.³

Patents are based on a trade-off between the rights granted to inventors to exclude others from making, using or selling their invention and rules that require them to reveal the method behind the invention so others may understand and learn from it. They must also explain why this particular invention is different from others like it. (Not so for trade secrets. Coca-Cola jealously guards the recipes for its soft drinks.)

“Simply put, a patent is a right given to inventors of intellectual property, allowing them to exclude anyone from commercially exploiting their inventions...”

In order to receive a patent, an inventor must apply for it, and the protection doesn't start until the patent is actually issued. Patent applications are prepared by patent lawyers, but require input from the inventor. Jurisdictions vary in the rules for an application, but in general an application document, or *specification*, will include:

1. Title and abstract. For ease in cataloguing and searching in databases.
2. A brief description of the area to which the invention pertains, also called the *field of the invention*.
3. A thorough disclosure and description of past work done by others in the field, and what prompted the invention. This description is commonly called *prior art*. Sources of prior art can include publications, conference abstracts, issued patents, or other printed materials.
4. A progression of steps leading to the invention, along with the shortcomings of the prior art. The differences between prior art and the invention highlight its advantages. Required descriptions of the ways the invention is practiced or implemented, called *embodiments*, must be detailed enough to allow someone skilled in the art to reconstruct and use the invention.
5. Clearly labeled graphs, tables, figures, pictures, and drawings aid the descriptions.
6. The *claims* draw the boundaries of the invention using legal terms. The claims describe the essence of an invention, first as broadly as possible and later, more narrowly. Claims are essential for patent protection: making or using the invention or its equivalent under its claims and without the inventor's permission is considered *infringement*.

The Examination: A “civil” argument with your government

At its core, a patent application is an argument with your country’s patent examiners, subject matter experts who rule on how broad or narrow the claims will be. In order to be patentable, examiners put the application through a battery of tests.

- 1) *Novelty*. The invention must be the inventor’s own work. Novelty also has much to do with timing. If an invention was known before the date a patent application was filed or the priority date claimed on the patent application (see Box 1) then it can’t be claimed as new.
- 2) *Non-obviousness and Inventive Step*. These terms reflect the “Aha!” of an invention and the surprise of an unexpected result. A non-obvious invention will identify a problem and provide a solution. If others tried—and failed—to develop the invention or if it isn’t apparent to someone skilled in the art, then non-obviousness prevails.
- 3) *Utility and Industrial Application*. In the U.S., the patent application must express some credible usefulness or benefit. In contrast, European patent law asks if the invention shows an industrial application.

Timing is Everything

In the U.S., the inventor has a one-year grace period to file a patent application after the invention is made public; whether it is disclosed in print or by using or selling it. But other countries have a different system. If two applications compete for the same invention, the winner goes to the person who filed first with the authorities (the date in question is called “the priority date”). In essence, the U.S. is based on a “first-to-invent” system; virtually everyone else uses the “first-to-file” system. An international Patent Cooperation Treaty (see Part II starting on page 12) application gives the inventor up to 18 months to file in individual countries.


A U.S. inventor trying to patent in other jurisdictions is out of luck if the invention was known publicly or published in a journal even one day before the filing date.⁴ Each system has strengths and weaknesses. The first-to-file requirement is a simple, objective measure, but critics say it favors big corporations who can pay for each filing. On the other hand, a first-to-invent system favors the individual with little resources.

BOX 1

The process of examination, called *prosecution*, may take months or years to complete. Often some of the application’s claims will be rejected. The applicant may respond to the objections by arguing in support of or making amendments to the claims. If the examiner’s objections cannot be overcome, the application may be eventually abandoned.

A Marketplace for Intellectual Property

Intellectual property, including patents, trade secrets or other “intangible assets,” can be converted into monetary value—hence the term “intellectual capital.” Intellectual capital is quite worthless unless there is someone, somewhere, willing to buy it. Therefore, a patent is merely the starting point for a financial arrangement between different parties. The trick becomes how to efficiently transfer the technology from the inventor to the marketplace.

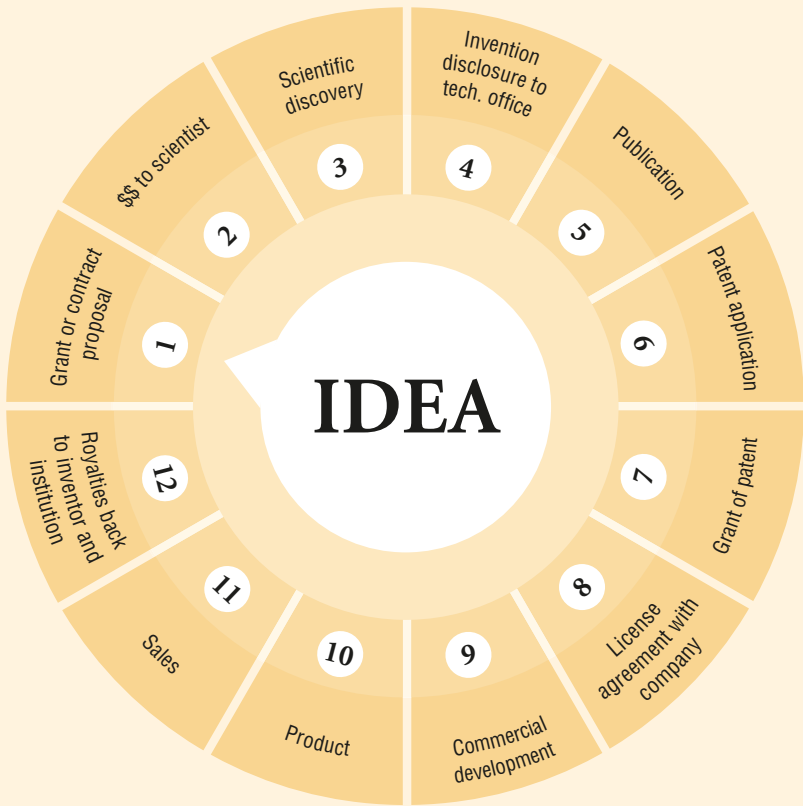


Who benefits from these arrangements? The answer depends in part on who owns the intellectual property. Patent owners can be governments, individuals or corporations. Under employment agreements, it is common for inventors to assign, or transfer, their ownership rights to the organization that employs them. In another example, in 1980 the U.S. Congress passed a law transferring ownership to institutions that receive government research funding. Assigning ownership increases the liquidity of a patent as property. Others then can own and sell the patents as if they had made the inventions themselves.

The license is the embodiment of the transaction between an owner and buyer of intellectual property. A legally binding contract, the license allows someone else to make, use and/or sell an invention, often in return for fees and a tax on future profits, called *royalties*, which can be shared between the inventor and his organization.

Licenses can be exclusive or nonexclusive. An exclusive license grants the right to use the invention to only one license holder, or *licensee*. Exclusive licenses usually allow the licensee to sublicense the invention to others for a fee. These sublicenses generate “pass-through royalties” as an additional source of income. A license also can be granted exclusively to one licensee for a specific application, or “field of use,” maintaining the owner’s option to issue licenses for other fields of use.⁵

From Idea to Royalty



BOX 2

PART II: INTELLECTUAL PROPERTY IN A FLATTENING WORLD

In his bestselling book *The World is Flat*, Thomas Friedman states that a significant barrier to a global economy is the nation-state, with its borders and laws:

*The biggest source of friction, of course, has always been the nation-state. Are national boundaries a source of friction we should want to preserve, or even can preserve, in a flat world? What about legal barriers to the free flow of information, intellectual property, and capital...?'*⁶



Nations protect intellectual property (IP) through their laws. IP law enables individuals and organizations to harvest the rewards of inventiveness. Yet these assets are products of the communities who make them. Herein lies a tension between the protection of individual interests and the need to provide broad access to the societies who need them. As scientists in developing countries generate more IP and become more collaborative, nations must sort out the best ways to diffuse these new technologies. Because different nations are in different stages of development, each has a unique approach to IP law. One thing is certain: in an increasingly flattening world, the IP landscape is decidedly bumpy.

The effort to speed the transfer of intellectual property across borders has led to profusion of organizations, treaties and laws through which to navigate. Described below are the important ones, how they came to be, and how they figure in the global scheme of things.

The World Intellectual Property Organization (WIPO)

Established in Stockholm and launched in 1970, WIPO is an agency of the United Nations. It's mission: "To promote through international cooperation the creation, dissemination, use and protection of works of the human mind for the economic, cultural and social progress of all mankind...to contribute to a balance between the stimulation of creativity worldwide, by sufficiently protecting the moral and material interests of creators on the one hand, and providing access to the socio-economic and cultural benefits of such creativity worldwide on the other."⁷

WIPO creates and manages multilateral treaties among nations, including these two:

- The Paris Convention. Signed in 1883, every member country must grant to nationals of other countries the same IP protection it grants to its own citizens. More practically, it allows inventors in one nation to use the patent filing date in that nation as the effective date in another nation, provided that they apply within 12 months of the first filing.
- Patent Cooperation Treaty (PCT). The PCT coordinates the filing of international patent applications among nearly 140 countries. A PCT filing contains the nuts and bolts for an examination, such as a search of prior art and a description of claims. A preliminary examination rules on its patentability. Finally, each contracting national or regional patent office (See the EPO, page 15) is free to carry out a formal examination and decide whether to issue a patent. Besides the unified procedure, the advantages to filing a PCT are streamlining and buying time before the national examinations commence. But local jurisdictions charge fees for filing, issuance and maintenance of the patent. One estimate places the cost of filing in all PCT countries at \$5 million over the patent's life.⁸

“China is fast becoming a world leader in intellectual property, and Western countries are scrambling to establish trade agreements to harmonize patent information.”

The Big Three

Among the world’s patent offices the three biggest are The European Patent Office (EPO), the United States Patent and Trademark Office (USPTO), and the Japan Patent Office (JPO). Together, the USPTO and the EPO review the lion’s share of the world’s patent applications, with Japan the fastest growing of the three.⁹

China is fast becoming a world leader in intellectual property, and Western countries are scrambling to establish trade agreements to harmonize patent information (Table 1). The differences among the big three are first-to-invent and first-to-file (Box 1, p. 9) and that the U.S. permits patents on software and business methods. While the EPO grants only one patent for any given inventive system, the same invention in Japan could constitute up to 10 different patents, with every aspect of the invention filed separately.

Like WIPO, the EPO does not issue patents, but carries out formal examinations on behalf of 37 European countries, along with examining oppositions against patents already granted.

Table 1: The World’s Most Active Patent Offices¹⁰

Country/Region	Number of examiners	Number of applications
United States (USPTO)	3,400	400,000
Europe (EPO)	3,500	208,000
Japan (JPO)	1,358	400,000
China (SIPO)	2,000	175,000
South Korea (KIPO)	728	160,000
India	135	14,500



Let's Harmonize

At the end of the General Agreement on Tariffs and Trade (GATT) treaty in 1994, the discussion turned to the wide variation of protection and enforcement of intellectual property rights. As IPR became more important in global trade, these differences became a source of tension in international relations. New trade rules were seen as a way to introduce more order and predictability, and for disputes to be settled more systematically. At the turn of the century, “harmonization” became the catchword. In mid-2000, the big three signed the Patent Law Treaty, which charts a path towards international normalization by 2010.

GATT eventually became the basis of the World Trade Organization (WTO), which oversees the Trade-Related Aspects of Intellectual Property Rights (TRIPs), a 1995 agreement that attempts to “narrow the gaps in the way that these [intellectual property] rights are treated around the world, and to bring them under common international rules.”¹¹ Expected benefits of TRIPs include decreased market uncertainties, increased foreign direct investment and increased royalty and license fees to developing nations.¹²

Its ratification became a mandatory requirement for membership into the WTO. The agreement attempts to gather and normalize all aspects of IPR and their enforcement, including protecting trade secrets, establishing transparency, and clarifying copyrights. The agreement attempts to crack down on reverse engineering of biotechnology products, and requires companies in developing countries to adhere to Good Manufacturing Practice (GMP) standards.

Most profound for developing countries were changes related to patents. They include:

1. Broad definition of what can be patentable.¹³ This requires many countries to extend protection to areas such as chemical and pharmaceutical products and processes, food products, microorganisms, microbiological processes and new varieties of plants.¹⁴
2. Harmonized patent length at 20 years from the date of filing.
3. Mandated that intellectual property laws not offer any benefits to local citizens that are not available to citizens of other TRIPs states while they are in that country (See India case study, p. 28).
4. Developing countries have the flexibility to allow someone else to produce a product without the consent of the patent owner. This “compulsory licensing” can be used in circumstances of extreme “national urgency” such as domestic health crises.

HIV/AIDS and the TRIPs Debate

The treaty had a rough start and is controversial still. The European Union, the United States and large pharmaceutical corporations played a major role in adopting TRIPs. The fact that corporations with a self-interest in favorable international IPR rules were themselves part of developing policy was a focus of intense debate. Developing countries such as Thailand, South America and Africa complained they were left out of critical negotiations.¹⁵ That poor countries are required to extend patent rights on pharmaceutical products made in the developing world also provoked criticism. New patents promise benefits and incur costs that differ by disease, and some diseases primarily affect poor countries. For these

disorders, patents are not attractive to private investment because purchasing power of developing countries is low. Widely available patent rights could increase the benefits derived from greater public financing of biomedical research for the developed world. For global diseases, the justification for extending patents in poorer countries is unclear.

The high profile of public health emergencies, such as the sub-Saharan African AIDS crisis, spotlighted the tension between public health and global IP protection. Whereas developed nations want their inventions protected, developing countries want wide distribution of the health benefits of drugs and agricultural advances, at low or no cost to their citizens. A sick or suffering working class does little to put the country on a road to economic prosperity.

Nongovernmental organizations (NGO) such as Oxfam and Médecins sans Frontières argued that the requirements led to increased drug prices used to combat HIV. Then, a consortium of 39 pharmaceutical companies attempted to sue to prevent the import of cheap generic antiretrovirals into South Africa. The move was a public relations fiasco for the industry, which settled in 2001. Just after, Brazil and a group of African countries, working with the NGOs, brought the problem of drug access to the global stage at a meeting of the world's trade ministers in Doha, Qatar.

The declarations of the Doha group affirmed members' right to protect public health and to promote access to medicines for all. Most importantly, it clarified the right to use compulsory licensing to meet public health concerns, stating, "public health crises, including those related to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency."

“Widely available patent rights could increase the benefits derived from greater public financing of biomedical research for the developed world.”

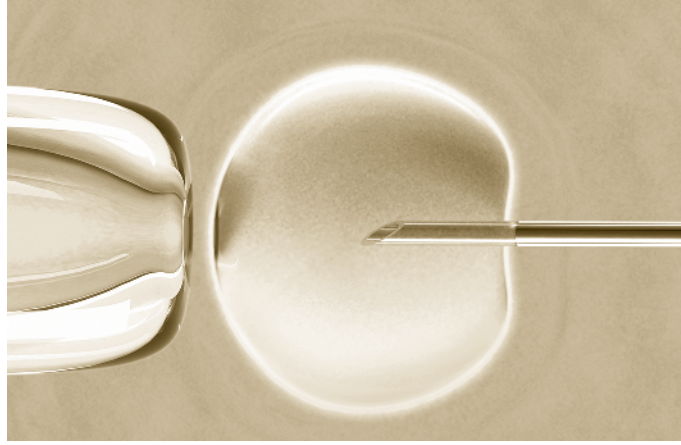
Though TRIPs is designed to level the IPR playing field and is necessary to spur development in developing countries, five major challenges remain.¹⁶

They include:

1. Despite deep reductions in drug prices, global funds cannot support purchase of therapy for the estimated 6 million people with HIV.
2. Most developing countries cannot afford to make generic versions of drugs, even with a compulsory licensing scheme.
3. TRIPs may require countries such as Brazil and India to stop making cheap, generic versions of drugs for import to Africa.
4. Drug companies must be persuaded to provide deep discounts on their products.
5. The possibility of compulsory licenses may weaken incentives to develop products for small markets.

In the end, a near-term solution for countries without the resources to develop intellectual property regimes while struggling with catastrophic health problems will be financial support provided by the developed world. Patent protections function better with “pull” rather than “push” economics, which require new regulatory frameworks and costly research and development.¹⁷ Allowing governments to subsidize the buying power of the poor may be the best means for propelling developing nations into a harmonized IPR future.


PART III: CASE STUDIES



The Patents that Shook the World. An American scientist, James Thomson, was awarded three patents by the USPTO for his path-breaking work with human embryonic stem cells. The patents, which cover cell cultures called lines, are unusual for two reasons. First, they were issued based on research using a morally controversial source of material: leftover two-day-old human embryos obtained through in vitro fertilization (IVF) clinics. Some believe that an embryo comprised of 100 cells is human, and destroying it is murder. The majority of Americans, however, approve of the use of embryos for research and medicine.

The second unusual feature is the patent claims themselves (Box 3, p. 23). Not only do they assert a right to charge anyone to use the lines Thomson created, they also prevent anyone from using any human embryonic stem cell lines, made by any method, in any laboratory, anywhere in the US. These patent claims are among the broadest ever granted in the life sciences.

Because embryonic stem cells may eventually lead to treatments or cures for maladies such as heart disease, diabetes, and cancer, the patents have produced a firestorm with ethical, social and legal implications. Due to the broad claims and the aggressive negotiating position taken by the patent-owning institute with interested line users, scholars fear that the monopolistic practices could squelch innovation and competition and distribute treatments to only those who can afford them. If the keys to practice the inventions are given to just a few, there will be little incentive to develop cheaper and better products.



The controversies have meant a rocky road for both the patent holder and its exclusive licensees. The European Patent Office (EPO) rejected the patents in 2008 on moral grounds. Because they involve the use of “human embryos for industrial or commercial purposes,” they consider them a violation of *ordre public* (immorality). Though the decision can be appealed, a confirmatory ruling would mean that no such patents would be issued by the EPO. Yet a grant of a patent does not automatically confer rights in EU member states. Each country is free to interpret the morality clause in its own fashion and decide whether to issue a patent. This means that the intellectual property cannot be protected in conservative states such as Germany, but can be protected in states with more permissive regulatory regimes, such as the UK.

Finally, the patents have been challenged on technical grounds. In 2007, the USPTO ruled the patents failed the nonobviousness requirement. The challenge referenced multiple cases of prior art (the teachings of two patents and four articles published prior to the filing of Thomson’s first patent in 1996), assuming that a “person having ordinary skill in the art” would be able to accomplish what Thomson and his laboratory did. Both the challengers and the research institute will battle back and forth for years before the issue is finally resolved. During that time, the patents remain fully in force.

Broad Claims: Embryonic Stem Cell Patients

“We claim: 1. a purified preparation of primate embryonic stem cells which (i) is capable of proliferation in an in vitro culture for over one year, (ii) maintains a karyotype in which all the chromosomes characteristic of the primate species are present and not noticeably altered through prolonged culture, (iii) maintains the potential to differentiate into derivatives of endoderm, mesoderm, and ectoderm tissues throughout culture, and (iv) will not differentiate when cultured on a fibroblast feeder layer.”¹⁸

BOX 3

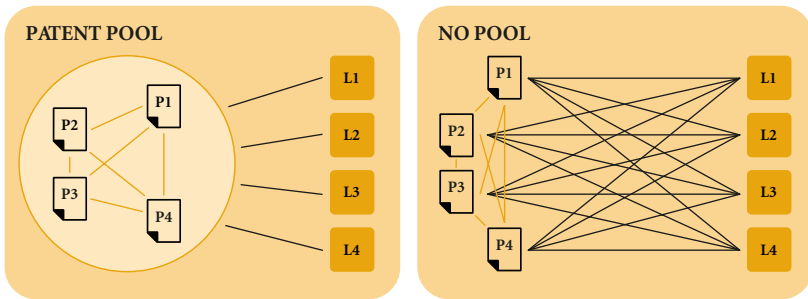
Everybody into the Pool

The development of new drugs, devices and tools comes at an astonishing price. The Tufts Center for the Study of Drug Development estimates the 2006 cost of bringing a drug to market at \$1.2 billion.¹⁹ The Tufts report—produced by data supplied by national and transnational pharmaceutical and biotechnology companies—estimates it takes eight years to get a complex biologic therapy through clinical trials and to the market. The costs are passed through to payers and providers—and the higher the development cost the more difficult it is to bring new biomedical products to underserved markets.

One of the problems associated with the increased time and cost are “patent thickets,” when companies need to license many bits and pieces of a complex chain of technology in order to successfully implement their own intellectual property. Nowhere is this more apparent than in vaccine development, where separate licenses may be required for specific genes, animal models, bioprocessing, and delivery systems. “Stacking” royalty payments in this fashion becomes very expensive. These barriers to entry become especially acute when trying to respond to global health crises such as malaria, Severe Acute Respiratory Syndrome (SARS) and tuberculosis.

One of the mechanisms put forward to deal with patent thickets are patent pools. A “patent pool” is an agreement between two or more patent owners to license patents to one another or to outsiders. Most are voluntary, devised when companies or organizations find their ability to innovate is stifled by key technical patents owned by others. Members of the pool share royalties paid by third parties. Proponents argue that such arrangements can help stimulate innovation (Figure 1, p. 24).²⁰

FIGURE 1



In response to the SARS outbreak, the World Health Organization (WHO) funded a network of laboratories to develop a vaccine. Several of the researchers filed patent applications on inventions related to the viral genomic sequence. Further research then by a large group of public and private sector entities led to additional patent applications. The agency proposed a patent pool strategy would avoid potential SARS-related intellectual property conflicts and speed the development of vaccines. If the negotiations among the parties succeed, then the first pool will be set up in the U.S., followed by other jurisdictions.²¹

Patent pools attempt to speed development by sharing risk and reward, but one intriguing model abandons intellectual property altogether. Consider this: in the past 20 years only four anti-malaria drugs entered the market—yet every 30 seconds a child dies from malaria.²² A non-governmental organization, Drugs for Neglected Diseases initiative (DNDi), and a French pharmaceutical company, Sanofi-Aventis, have developed a new anti-malarial drug, which will be available in Sub-Saharan Africa and elsewhere for less than \$1. Because there are no patents, other companies are free to make cheaper versions of the therapy, also called generics. The patent-free model could become one way to treat the world's neglected diseases.²³

“Iceland’s advantage was its isolated, small population and its fastidious practice of medical record keeping.”

The Commons and the Commoner

At the prompting of a U.S. corporation, deCode genetics, Iceland’s parliament passed the Health Sector Database Act in 1998. It authorized a 12-year, exclusive license to deCode to create a database of the medical records of all Icelandic citizens. Iceland’s advantage was its isolated, small population and its fastidious practice of medical record keeping. The country has kept medical and genealogical data on all of its citizens for a century or more. The act stated that while the government has access to the database, deCode could use it for commercial purposes, such as diagnostics or drug discovery.

The law provoked a firestorm of controversy. The Icelandic Government concluded that genetic information is a national resource, and citizens have no rights to it. Others worried whether the government and deCode could be relied upon to properly protect genetic information. Though confidentiality was promised, improper release of information could have devastating consequences, such as denial of health insurance or employment discrimination. Granting a proprietary right to one’s own genetic information, some said, would help individuals control its use. Others responded that the information belonged to all Icelanders, and as such, decisions about its use should have come from the community.²⁴

Another worry concerned the delay of publications. Kari Stephansson, deCode’s CEO, wrote in the *New England Journal of Medicine*, “The primary goal is to use medical discoveries to develop better methods to diagnose, prevent, and cure diseases. Today, this often

requires that an intellectual property be secured, which may delay publication of a discovery. The choice between early publication and the development of a product for the benefit of patients with a particular disease is, in our minds, an easy one.”²⁵ The biotech industry argued that without exclusive rights there would be no incentive to invest, and granting individual ownership might cause hundreds or thousands of people to demand royalties from companies using the data to develop products.

The textbook example of genetic property rights is found in the case of *Moore v. Regents of California*.²⁶ Moore’s claim was his property right had been violated when inventors did not share the commercial gains made from the commercial use of his cancerous spleen cells. The court concluded—as the Icelandic Government did with its citizens—that Moore did not have a valid ownership claim, and that giving him one would hinder biomedical research.

What lies ahead for Iceland? Some call for better balance between financial incentives and greater access to the information, such as a compulsory licensing to certified genetic researchers.²⁷ Private sector advocates say any future financial return negotiated on behalf of the country’s 280,000 denizens will be vanishingly small. As the debate continues, scientists at deCode have recently discovered genes associated with cancer, sleep disorders and heart disease.



What goes with the Shaman stays with the Shaman

A team of Western researchers learns of an herbal remedy practiced by a remote tribe of Amazon villagers. The group travels to Ecuador where they work with local shamans and elders to identify the right plant cultivars. The herbs are brought back to the laboratory, where the active ingredient is isolated and purified. The company receives a patent on the product and manufactures it to industrial scale, making a blockbuster drug with a billion dollar profit.

In examples like the above, critics say abuse of traditional systems of IPR devalue indigenous cultures, reduce biodiversity and steal the “pharmacy from the poor.”²⁸ Called biopiracy, the practice uses intellectual property to legitimize the ownership and control of biological resources used by developing countries. The 1992 Rio Convention on Biodiversity (CBD), ratified by 187 countries and the European Union (but not the United States) recognized that indigenous cultures have long contributed to global wealth generated by the commercialization of their native plants and animals.

Under the rules of the CBD and other international guidelines:

1. New intellectual policies and laws must involve community participation.
2. Access to traditional knowledge and resources (especially genetic resources) may only be obtained by informed consent.
3. Communities have the right to share the benefits of commercialization, and use by others can only proceed on the basis of mutually agreeable terms.

But it hasn't always worked that way. The textbook case is *neem*, a common Indian tree whose seeds have been long used for medicines, cosmetics and pesticides. Because agricultural products are not patentable in India, a foreign company patented a neem extract and began manufacturing a pesticide in India in the late 1980's. The company's demand for seeds drove the price beyond the reach of ordinary Indians, including farmers who enjoyed free access to stocks. Thus there were social, economic and ethical factors driving an EPO action in 2000, which revoked the patent based on lack of novelty, inventive step and theft of prior art.

The neem case has been characterized as plunder by many, but others say nothing prevented Indian companies from manufacturing the pesticide and exporting it, and there was little evidence that the transnational conglomerate had asserted its rights in India to prevent local companies from competing. And, India benefited as a supplier of seed and local technical talent.²⁹

How best to protect traditional knowledge? Preventing others from patenting is one strategy. Recording and storing knowledge establishes it as prior art and makes it more difficult to appropriate. The downside of this "defensive" approach is that it makes public community knowledge that may be held by custom to be private and sacrosanct. Positive measures could use laws to enact special *sui generis* rights to protect traditional knowledge. Under *sui generis*, indigenous peoples can argue that controlling use of their knowledge is a self-determining right, and modern laws can never overrule ancient systems of beliefs and traditions.

Notes

1. *Understanding Industrial Property*. World Intellectual Property Organization, 895 (E).
2. LexisNexis: <http://w3.nexis.com/sources/scripts/info.pl?278252>.
3. <http://bio.org/ip/>.
4. To complicate matters, patent law defines the word “publication” broadly. Either an abstract, oral presentation or poster session can qualify, and advertising brochures, grant applications, catalogues and magazine articles are fair game too. Each situation is different, and anyone planning to file a domestic or foreign patent must be aware of the kinds of information generated by their organization. Finally, be aware that publication of the application by the patent office for all to see will occur some months after the filing—irrespective of whether the patent ever issues. See Garabedian, Todd. *Nontraditional publications and their effect on patentable inventions*. *Nature Biotechnology*, (20) April 2002, 410-402.
5. *Making the Right Moves: A practical guide to scientific management for postdocs and new faculty*. HHMI-Burroughs Wellcome guide, second edition, 2006, p. 9.
6. Friedman, Thomas. *The World is Flat: a brief history of the Twenty-first Century*. New York, Farrar, Strauss and Giroux, expanded edition (2006) p. 237.

7. World Intellectual Property Organization *Intellectual Property Handbook*, (1.14), 2005.
8. Krattiger, Anita. *Financing the Bioindustry and Facilitating Biotechnology Transfer*. IP Strategy Today, August 2004, p. 16.
9. EPO website: <http://www.epo.org/focus/patent-system/patents-around-the-world.html>.
10. See note 3. Data assembled from national sources between 2004 and 2006.
11. World Trade Organization. *Intellectual property: protection and enforcement*. http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm.
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European Patent Office (EPO):
<http://www.epo.org>.

World Intellectual Property Organization

- WIPO Intellectual Property Handbook:
<http://www.wipo.int/about-ip/en/iprm/index.html>.
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