Patents in therapeutics

A divisive influence

Warren Bell, MD

During the last 150 years, monopoly rights over intellectual property have been more clearly defined. The process of securing and exploiting intellectual property rights (IPR), commonly known as copyright or patent, is so pervasive today that we rarely recognize its influential role.

Intellectual property rights are classically presumed to represent a necessary trade-off. On one hand, an individual is offered a time-limited monopoly over use or sale of an invention or innovation, which could result in large windfall profits. On the other hand, society as a whole gives this monopoly to stimulate the efforts of innovators and inventors, from whom it hopes to derive benefits.

In small, integrated communities in which patents were held by individuals, this once worked. In today's globalized economy, where patents are almost always held by huge transnational corporations, the trade-off between monopoly rewards and social benefit is often no longer favourable for society at large. This is particularly true in the realm of therapeutics.

Historical overview

The first global patent law was drawn up in 1883 by countries attending the "Convention for the Creation of an International Union for the Protection of Industrial Property." The first union consisted of only seven European nations and their principal colonies. Patent protection or "right of priority" applied for only 6 months. The original agreement, however, was repeatedly revised and broadened, and by the time of the last revision (1967 in Stockholm, Sweden), 90 countries were signatories. Many countries had extended the term of exclusive monopoly rights to a decade or two. Likewise successive revisions covered more and more items. By 1967 the Convention applied to "patents, utility models, industrial designs, trademarks, service marks, trade names, indication of source or appellations of origin [as well as] all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour." By 1967 also, the language of the original Convention, French, had been broadened, but only to include the languages of the major colonizing nations of Europe: English, German, Italian, Portuguese, Russian, and Spanish.

Drug patents in Canada

Patent law in general has specific relevance to health issues, because it has been the principal beacon guiding the search for therapeutic opportunities. The evolution of Canadian patent law has been a seesaw battle between patent holders and the rest of society.

The initial Patent Act in Canada established exclusive rights for 17 years to the *process* of creating a drug but not the drug itself. This meant that a drug was not likely to be reproduced by another company because of the large costs associated with developing a completely novel manufacturing process.

In 1923, a system of compulsory licensing was introduced, under which a Canadian company could make a foreign-developed drug after paying a licence fee. Before 1969, when the Patent Act was further amended, only 45 compulsory licences were granted because patent-holding companies used aggressive delaying tactics when asked to license their products, and because of the provision that the new version of the drug had to be manufactured in Canada, involving substantial start-up expenses.[1]

In 1967, the Harley Committee, established by the House of Commons, recommended a widely popular compulsory licensing system in which Canadian companies would finally be allowed to import drugs into the country, thus allowing real competition. Despite intense and well-financed lobbying from patent-holding drug companies (mostly American and European), and vocal opposition from most major medical bodies, the law

passed in 1969. By 1983, nearly 300 compulsory licences had been granted, a modest national generic drug industry had developed, and an estimated $85 million to $165 million in cost savings had accrued to the general public.[1]

In 1985 the Eastman Commission reviewed the Canadian system and confirmed its value, estimating savings to the public at $211 million.[2] A subsequent investigation by the Consumers' Association of Canada placed the figure at nearly $300 million.

As part of the recent negotiation of a "free trade" association (FTA) carried out by the government of Canada with first the US government and subsequently the US and Mexican governments (NAFTA), the federal government agreed to return the patent system to its pre-1969 state, with 17 years of monopoly protection and no importation of patent-holders' products permitted. This regressive decision has itself been recently challenged as overly restrictive, using World Trade Organization mechanisms.

Influence of patents on medicine

The influence of a global patent system on daily medical therapeutics cannot be overestimated. It has played a unique—but generally unrecognized—role in determining treatment choices.

The IPR system has inevitably focused on options that can be copyrighted or patented. These include some specific tools, technologies, or processes (surgical instruments, x-ray machines), but mostly centre on processes for synthesizing novel substances from various raw materials (eg, most drugs) or extracting chemically pure natural substances (eg, conjugated equine estrogens), as well as any novel synthetic substances themselves (eg, celecoxib). They also include branded or trademarked versions of otherwise unpatentable processes, procedures, or substances (eg, Johnson & Johnson's Baby Powder®, which is simply cornstarch).

Today's giant drug companies and medical equipment suppliers almost all started out as small, local concerns. Their phenomenal growth has, in general, been fueled by the earnings from one or more patented remedies or processes. It is precisely the global IPR system that has allowed them to become qualitatively different from community-based businesses. Almost all developed during or after the technological explosion that took place in the 19th century, the so-called "Industrial Revolution," a period when patent privileges on a global scale were enshrined in law. Many global drug companies have also produced other IPR-protected products, such as pesticides and plastics. They often earn billions of dollars annually—more, in fact, than the gross national product of many nations.

Corporations defend IPR

The multinational corporate pharmaceutical sector goes to great lengths to defend IPR, arguing that it inspires innovative research. A 1972 Canadian drug industry document asserted: "The respect of industrial property rights as represented by patents and trade marks is the essential foundation for progress in research and therapeutics in the pharmaceutical industry."[3]

But in fact most primary research has been carried out by academic scientists working in nonprofit institutions, not by employees of drug companies. Corporate funding for research has generally been restricted to only those substances or devices with direct sales potential.

In pure market terms, many economists today argue that "any form of protection for intellectual property limits the diffusion of the research results… it is more effective in generating the development of products than in generating scientific advances."[4] It is particularly interesting that economists most in favour of the unfettered play of market forces have been squarely opposed to patent privileges. The outspoken libertarian economist, Murray N. Rothbard, felt that "on the free market, there would… be no such thing as patents."[5] The noted free-market economist and Nobel Prize winner Milton Friedman also felt that, on balance, patents had a negative influence on society, "maintaining private collusive arrangements that would otherwise be more difficult or impossible to maintain."[6]

Distorting influence of IPRs

Because of the material attraction posed by IPR-protected products, a sort of schism has been created between patentable remedies and all others, resulting in "two solitudes." On one hand lie patentable remedies; on the other hand lie substances, procedures, or therapeutic systems that do not lend themselves to patenting (eg, biological remedies, such as vitamins and minerals; herbal remedies and extracts; homeopathic remedies; remedies from other cultures, such as Chinese or Native American; and physical therapies, such as massage). This schism is not necessarily related to therapeutic efficacy, availability, or social value; it stems primarily from economics. But the gulf

between the two sectors has widened because of the now startlingly large difference in terms of financial and material resources.

Patent law has not simply drawn economic lines in the therapeutic sector. It has also helped shape therapeutic values. These values, often embraced unconsciously by health care professionals,[7] have constrained therapeutic options; set aside whole systems of healing; and even engendered ethically questionable behaviour by researchers, regulatory officials, and corporations, all in the quest for the Holy Grail of therapeutic investigation: the patentable product.

A number of other factors have contributed to this hierarchy of therapeutic values. These include negative attitudes toward indigenous healing systems (eg, First Nations traditions), competition between orthodoxy and other systems (eg, chiropractic, homeopathy[8]), and a general fascination and somewhat magical belief in the powers of technology and progress.[9] But for now, I outline the particular part that patent law has played in shaping choice of therapeutic intervention.

Devaluation of naturally occurring remedies or processes. Patent law reinforces the 18th- and 19th-century idea that what is produced by the creative energies of a human mind is superior to what has been produced by the processes of the "primitive," "wild," or "untamed" natural world. In therapeutics, this has resulted in imbalances. For example, despite several decades of encouraging research, including a number of small, randomized controlled trials demonstrating substantial benefits in treatment of osteoarthritis, naturally occurring glucosamine sulfate has only recently become therapeutically acceptable. By contrast, despite their well-known adverse effects, including death from gastrointestinal hemorrhage, nonsteroidal anti-inflammatory drugs (NSAIDs) continue to be the mainstay of conventional osteoarthritis therapy.

This situation moved one observer to "conclude that unless big money can be made, the suffering of patients is minimally relevant to standard medical practice in the US. This results, not because American physicians are callous, but because they have been brainwashed to believe that the profit-driven pharmaceutical industry is the ultimate source of all genuine medical efficacy."[10]

A more disturbing example of this trend can be found in the relationship between breast milk and infant formula. Breast milk is a nutritionally irreplaceable substance produced naturally through a nuanced, dynamic interaction between mother and infant.[11] Breast milk therefore lies outside IPR rules. As a result, even though scientists, governments, professional bodies and non-profit organizations the world over advocate strenuously for breastfeeding, no corporate player promotes it.

Instead, for most of the last half century, breastfeeding has been progressively supplanted by branded, patented formula products. Coupled with the association of breastfeeding with so-called "primitive" cultures and behaviours, the promotion of infant formula products has undermined breastfeeding worldwide.

Promoting separative thinking. An essential principle of patents is that the benefits of holding them accrue to patent holders alone. No matter how much they are indebted to the antecedent insights or efforts of others, or how profoundly valuable the patented product might be to humankind, holders are under no clear obligation to acknowledge these facts. They (or it, in the case of a corporate patent holder) are in fact encouraged, by historical precedent, to sell use of the patented product for as high a price as the market will bear.

A dramatic example of this aspect of applied IPR law is the patenting frenzy surrounding deciphering the human genome. The Human Genome Project began in 1989. The project is publicly funded, and its findings are available to any researcher. But parallel patent applications by private companies have skyrocketed since even before 1989, from three gene-sequence applications in 1980 to 435 in 1995, more than 4000 in total worldwide, more than half in the United States.[12] The gene sequences covered by these patents are, with some exceptions, unavailable to researchers and to society at large. They are being withheld in the hopes of future profits from development of patented products.

A final example of this aspect of IPR might be called "biocolonialism." It is the patenting of an entire life form (eg, the Indian Neem tree, the patent on which was revoked 2 months ago. The decision was judged to be a stunning defeat for patent seekers). Even if the life form has had use for humans for thousands of years, the patent seeker generally claims that the use to which it will be put is novel. Two thirds of the world's plant species—at least 35 000 of which are estimated to have medicinal value—are in developing countries. Therefore this type of IPR application amounts to a new way for rich, technologically advanced countries to assert dominance over their former colonies.

The bottom line

The material imbalance created by the ownership of one or more patents often leads to serious inequity. Because of their purely economic basis, IPR downplay other values, such as kindness, generosity, and inclusiveness (including ecosystem awareness). It plays into the idea that "survival of the fittest" determines success, but fitness is determined solely by economic criteria. By such measures, Albert Schweitzer is a failure and Bill Gates is a success.

Intellectual property right laws were codified in an era of colonialism, environmental exploitation, and racism. They have limited the search for therapeutic options in this country and around the world for more than 100 years. Because of this, IPR must be radically restructured to address the compelling realities of the 21st century.

Dr Bell *practises family medicine in Salmon Arm, BC.*

Correspondence to: *Dr Warren Bell, Box 3458, Salmon Arm, BC V1E 4S2*

References

1. Lexchin J. *The real pushers: a critical analysis of the Canadian drug industry*. Vancouver, BC: New Star Books; 1984.
2. Eastman HC, Commissioner. *Report of the Commission of Inquiry on the Pharmaceutical Industry.* Ottawa, Ont: Ministry of Supply and Services, Canada; 1985.
3. Pharmaceutical Manufacturers Association of Canada. *Principles and code of marketing practice.* Ottawa, Ont: Pharmaceutical Manufacturers Association of Canada; 1972.
4. Cohen LR, Noll RG. Privatizing public research. *Sci Am* 1994;271:72-7.
5. Rothbard MN. *Man, economy and state.* Auburn, Ala: Ludwig von Mises Institute; 1993.
6. Kerton R. Canadian policy on pharmaceuticals is the best of all. *Toronto Star* 1986 Jun 16;Sect B:9-12.
7. Birchard K. Journals showing bias in reviews. *Med Post* 2000 Apr 18; News, Col 1.
8. Hamowy R. *Canadian medicine: a study in restricted entry.* Vancouver, BC: The Fraser Institute; 1984.
9. Sale K. 1625-1992: Columbus/Columbia. In: *The conquest of paradise.* New York, NY: Knopf; 1990. p. 350-3.
10. McCarty MF. The neglect of glucosamine as a treatment for osteoarthritis—a personal perspective. *Med Hypotheses* 1994;42:323-7.
11. Walker M. *Summary of the hazards of infant formula.* Raleigh, NC: International Lactation Consultant Association; 1992.
12. Caskey CT. Gene patents—a time to balance access and incentives. *Trends Biotechnol* 1996;14:298-302.