

January 2006

Biotechnology, Innovation and Health

Arnold Naimark

Follow this and additional works at: <https://scholarlycommons.law.case.edu/cuslj>

 Part of the [Transnational Law Commons](#)

Recommended Citation

Arnold Naimark, *Biotechnology, Innovation and Health*, 32 Can.-U.S. L.J. 220 (2006)

Available at: <https://scholarlycommons.law.case.edu/cuslj/vol32/iss1/38>

This Speech is brought to you for free and open access by the Student Journals at Case Western Reserve University School of Law Scholarly Commons. It has been accepted for inclusion in Canada-United States Law Journal by an authorized administrator of Case Western Reserve University School of Law Scholarly Commons.

It is my pleasure to welcome you, Dr. Naimark.

SPEAKER

(Dr. Naimark has submitted a paper which is published below in its entirety.)

BIOTECHNOLOGY, INNOVATION AND HEALTH

*Dr. Arnold Naimark**

INTRODUCTION

Innovation has been a hot topic in Canada in recent years. Pundits, policy wonks, captains of industry, politicians and academics have come to espouse a strong culture of innovation as Canada's best hope for long-term economic growth. Although Canada's economy is doing relatively well just now, we recognize that much of our current prosperity relies on export of commodities and that we still have a significant distance to go to reach the productivity levels of the United States.

Beginning in the 1990's the federal government and the wealthier provinces introduced targeted and well-funded initiatives to support the academic, research and infrastructure requirements of an "innovation agenda" with a strong emphasis on collaborative efforts through the development of innovation clusters and networks. A significant portion of this investment has been directed to the life sciences generally and in particular to the applications of biotechnology in health, agriculture, aquaculture, forestry, health and the environment – with the lion's share going to human and animal health.

The area of biotechnology attracting most of the attention are the result of revolutionary discoveries in molecular biology and genetics – discoveries that have produced powerful new tools to promote health and to aid in the prevention, diagnosis and treatment of disease and disability. Knowing the

* Dr. Arnold Naimark is currently Professor of Medicine and Physiology at the University of Manitoba and Director of its Centre for the Advancement of Medicine. He is the Founding Chairman of the Canadian Health Services Research Foundation and of the Canadian Biotechnology Advisory Committee, Chairman of the Science Advisory Board of Health Canada and Chairman of Genome Prairie. Dr. Naimark serves on the Council of the Canadian Institute for Advanced Research, on the National Statistics Council of Canada, and as a Director of the Robarts Research Institute. He also serves as director of or consultant to several voluntary, public and private sector organizations.

genetic make-up of plants, animals and microbes helps us to create new vaccines, to identify disease susceptibility of individuals and populations, to tailor the development and use of therapeutic drugs to the specific characteristics of individuals; and to use advanced methods of gene transfer and stem cell transplantation to restore normal structure and function to diseased or malfunctioning organs and tissues. When one adds to these developments, the integration of biotechnology and nanotechnology to produce microscopic diagnostic probes or precisely targeted molecular delivery systems for drugs, it is easy to understand why many believe that biotechnology-based health innovations will have profound effects on the practice of medicine and on health care systems generally.

The promise of health-related biotechnology comes with significant challenges for policy makers and legislators as they seek to promote innovation on the one hand and to address the social, ethical and legal issues associated with life-altering technologies on the other. The tension between these two social objectives was put into bold relief in a study we have recently completed that examines the nexus between biotechnology, innovation, the intellectual property (IP) protection regime and the health sector.

The study focused on innovations based on human genetic materials (DNA, RNA and the proteins they code for) and on patenting (the most common form IP protection in this field). Before describing the results of our exploration let me begin with a few comments about the current status of patenting and licensing of human genetic materials.

PATENTING OF HUMAN GENETIC MATERIALS

Canada's patent act of 1869 was modeled on the US act of 1790. Changes to the Canadian patent act since its inception have been influenced by the evolution of the acts in the UK and US and more recently by the European Patent Convention and by the need to align the act with Canada's international treaty obligations including treaties dealing with trade related aspects of intellectual property (TRIPs), classification of patents, recognition of micro-organism deposits, norms for protection of new plant varieties, and the Patent Cooperation Treaty.

Although human genetic materials, as they exist in nature, cannot be patented in either country, legal precedent has established that chemicals isolated from nature through human intervention are patentable. This precedent has been applied to the specific polynucleotide sequences in human genetic materials. Patents have been granted for years on the isolated polynucleotide sequences *per se*, as well as on processes for identifying and isolating (purifying) the sequences and on methods of using them.²

² The Center for Intellectual Property Policy, *Genetic Patents and Health Care in Canada*

Not everyone is happy about this state of affairs. Some oppose the patenting of HGM on religious or moral grounds. Other opponents base their arguments on what they regard as the unique characteristics of nucleotide sequences; namely, that they are of a “hybrid nature ... (in that) they are both a chemical product and pure information”. They see the granting of patents on DNA as “crossing an important barrier: (namely), the (traditional) exclusion of information as such from patent coverage.”³ However all “chemical products” contain information, to the extent that their physical structure is known. The unique feature of nucleotide sequences therefore is not that they contain information, but rather that they contain specific information about the genetic predisposition not only of the individual from whom the sequence has been derived, but also of their predecessors and their progeny – matters that, in our society, are deemed to be private and are protected as such under law.

As with other kinds of invention, to obtain a patent involving human genetic materials the inventor must show that the invention falls in the class of patentable subject-matter and is new, useful, and not obvious to someone skilled in the particular field. In particular the inventor must be able to identify the novel genetic sequence, specify the product of the sequence and how it functions in nature, and show that it has utility. The utilities of the nucleotide sequences patented to date include their role in gene regulation, in encoding for therapeutic proteins, as diagnostic probes, as receptors used for identifying molecular targets for therapeutic drug development, as immunogens, and gene replacement therapies.

The non-obviousness (inventiveness) criterion of patentability is intended to enable distinguishing between innovations that justify the potential economic rewards of patenting and those that do not. Many scientists question whether, in an era of high throughput automated DNA sequencing, some patents provide undue potential reward for minor advances that would in any case have been made by others working in the public domain and impose cost burdens on researchers working on fundamental problems in molecular genetics. The U.S. Report, *A Patent System for the 21st Century*⁴ points out that, as a result of judicial decisions, a new genetic sequence claimed in the U.S. is automatically considered non-obvious, whereas the European Patent Office requires the applicants to “demonstrate either that obtaining the sequence was in fact a technical achievement or that they have discovered a new or unexpected property associated with the gene.”⁵

(2005), available at <http://www.cipp.mcgill.ca/data/publications/00000015.pdf>. (comparing Canada’s patent system with those of other key jurisdictions).

³ E. Richard Gold, *Gene Patents and Medical Access*, 49 INTELL. PROP. F. 20 (2002).

⁴ A PATENT SYSTEM FOR THE 21ST CENTURY (S.A. Merrill, R.C. Levin & M. B. Myers eds., The National Academies Press 2004).

⁵ *Id.* at 93.

The extent to which the claims allowed are viewed as meeting the three criteria of novelty, non-obviousness, and utility is often referred to as “patent quality.”⁶ As we shall see later, one facet of patent quality that has proven to be particularly contentious in the health sector is the scope or breadth of protection identified in the description of the IP and the allowed claims.

The diffusion of patented IP in society is influenced by the ways in which patent holders seek to exploit their patent rights, including the approach they take to licensing; namely, whether they license at all, and if so whether they license exclusively or freely. Diffusion of patented IP can also be affected by the transaction costs associated with negotiating licenses and/or the level of fees and royalties involved. Both of these elements can be particularly problematic in attempting to negotiate licensing of gene patents. Among the over 3 million gene patents that have been issued worldwide, there are many areas in which there are thickets of overlapping patents involving many patent holders.

THE PROBLEM

We were asked to undertake our study by Canada’s federal departments of health and industry. The terms of reference included the statement: “The objective of an effective and balanced intellectual property regime is to act as an important stimulus for innovation, by protecting and nourishing creativity and investment, to the mutual advantage of producers and users of such innovation, and in a manner conducive to economic and social benefits.”

For the purposes of our study we took the term innovation as applied to health to mean the introduction (implementation, application) of new ideas, goods, services, processes and practices into the organization, management and delivery of health services. (In other words to innovate means doing something new – not just thinking of something new.) From a health policy perspective, the goal is to foster innovation that improves health or that prevents or mitigates its deterioration. In practical terms this means fostering the capacity to:

- generate knowledge that may lead to novel goods, services, processes and practices

⁶ See *id.* at 46-63 (A detailed discussion of patent quality in general); See *id.* at 991-95 (non-obviousness in particular); See also J. Paradise, L. Andrews & T. Holbrook, *Patents on human genes: an analysis of scope and claims*, 307 *Sci.* 1566, 1566-7 (2005) (While the methodology used in this study has been disputed, *e.g.* K. Murashige and J.J. Rolla, Response, *Problems in Patenting Human Genes* 308 *Sci.*, 1868, 1868-9 (2005), this peer-reviewed article is one of the few available studies to date on patent quality).

- develop, produce and market new goods, services, processes and practices
- regulate their introduction into the marketplace
- adopt their use in the promotion of health and in the prevention, diagnosis and treatment of disease and disability.

The recent surge in patenting of human genetic materials has fueled a growing debate and controversy about the effects of such patents and patent-related practices on each of these steps leading to health innovations.^{7,8} Some question the propriety of such patents on ethical grounds, while others are concerned about practices that act as barriers to industrial and economic development, to research, or to ready and affordable access to products and services.

In its 2002 policy on the patenting of the human genome, the Canadian College of Medical Geneticists⁹ put the concern this way:

We emphasize that the discoveries that result in patents on human genes are largely the product of massive public investment and decades of collaborative research involving innumerable participants around the world. We are concerned that human gene patents do not recognize the essential public investment in this process of collaboration and discovery. We are concerned that such patents can be used to unfairly restrict the potential benefits of discovery of the genome, and

⁷ ONTARIO MINISTRY OF HEALTH AND LONG-TERM CARE, GENETICS, TESTING AND GENE PATENTING: CHARTING NEW TERRITORY IN HEALTH CARE (MHLTC 2002), available at www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/report_e.pdf (endorsed by all provincial premiers of Canada); AUSTRALIAN LAW REFORM COMMISSION, GENES AND INGENUITY: GENE PATENTING AND HUMAN HEALTH (ALRC 2004), available at <http://www.austlii.edu.au/au/other/alrc/publications/reports/99/>; Nuffield Council on Bioethics, *The Ethics of Patenting DNA: a discussion paper* (2002) (unpublished manuscript available at <http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf>); Danish Council of Ethics, *Patenting Human Genes and Stem Cells: A Report* (2004) (unpublished manuscript available at http://www.etiskraad.dk/graphics/03_udgivelser/engelske_publicationer/patenting_human_genes/patents04/index.htm); NATIONAL ETHICS COUNCIL, *THE PATENTING OF BIOTECHNOLOGICAL INVENTIONS INVOLVING THE USE OF BIOLOGICAL MATERIAL OF HUMAN ORIGIN* (NEC 2005); NEW ZEALAND MINISTRY OF HEALTH AND MINISTRY OF ECONOMIC DEVELOPMENT, *MEMORANDUM TO CABINET POLICY COMMITTEE: REPORT BACK WITH RECOMMENDATIONS AND OPTIONS FOR ADDRESSING GENETIC MATERIAL PATENTS* (2004).

⁸ OECD, *Guidelines for the Licensing of Genetic Inventions*, http://www.oecd.org/document/26/0,2340,en_2649_37437_34317658_1_1_1_37437,00.html, (last visited May 2, 2005); *Best Practices for the Licensing of Genomic Inventions: Final Notice*, 70 Fed. Reg. 18413.

⁹ Canadian College of Medical Geneticists, *Patenting of the Human Genome* (2002) (unpublished manuscript available at http://ccmg.medical.org/pdf/ccmg_genome.pdf) (position statement approved by the CCMG Annual General Meeting, September 21, 2002).

that unreasonable exploitation of the entitlements of a patent holder will be detrimental to the health and well being of Canadians.

In short, we defined the *problematique* constituting the impetus for our study as follows. When the holder of a patent on an invention involving human genetic materials, sets prices that are excessive, fails to supply the market, or refuses to license the patent on reasonable terms, the ability to gain access to a beneficial health innovation either for research or clinical use may be significantly impaired and the achievement of the objective of mutual advantage of producers and users may be frustrated.

This is by no means a problem that is unique to Canada. Concerns about patenting of human genetic materials have been explored in other countries and we benefited considerably from work done by bodies in the US, Australia and Europe. In our analysis of the issues in gene patenting we kept in mind the fact that although current debates have been mainly prompted by disputes involving the patenting of diagnostic genetic tests, nearly all of the matters at issue and, as you will see later, nearly all of the remedies we propose, apply in some degree to other technological applications that involve patenting. Both the issues and remedies fall into two main categories – those having to do with the breadth of protection afforded by patents and the licensing behaviour of patent holders.

PATENT BREADTH

Although there is considerable disagreement in the literature about the extent to which patenting acts as a spur to follow-on inventions, there is no doubt that patenting is regarded as essential for attracting investment in the development and commercialization of health-related patented inventions involving lengthy and expensive processes required to meeting regulatory requirements. From a business perspective, the broader the patent protection the better, since it increases the likelihood that the patent holder will be able to bring the invention to market before competition emerges. Thus, on the one hand, if the patent protection available becomes too narrow, the business case for pursuing development and commercialization can be undermined and useful inventions may not become available to the public. On the other hand if the protection is too broad it can create the opportunity for patent holders to stifle follow-on inventions by others and limit access to beneficial innovations.

This begs the question of when a patent may be regarded as too broad. The emerging *de facto* consensus is that a patent may be too broad if the utility criterion of patentability is applied so liberally that it allows claims that are insufficiently specific, substantial and credible. This is illustrated, for example, in the case of some current patents on DNA sequences that cover all possible tests that might be devised for determining the presence or ab-

sence of particular gene mutations. In other words, such a patent confers the right to prevent all others from copying, using or selling the patented sequence and, since copying of the sequence may be an essential element in tests to identify mutations, the patent holder can effectively prevent anyone from giving or taking an alternative test even if it is superior in sensitivity and specificity to the particular test described in the patent application. With no competition from other tests, the patent holder can set whatever fees and conditions it likes, and can dictate by whom, how and where tests will be performed and how information gathered from performing tests will be handled and stored and by whom it may be accessed.

In molecular genetics research, unduly broad protection acts as an impediment in two ways. First, the specificity of nucleotide sequences may largely preclude the tactic of “inventing around” the patent. Second, as I mentioned a moment ago, broad patents on a multiplicity of closely related sequences can lead to a “thicket” of overlapping patent claims. The time and effort involved in identifying relevant patents and patent holders, the complexity of negotiating licenses with a plethora of patent holders, and the cost of royalty payments for those licenses may be impediments both for non-commercial research and for research performed in industry on the generation of follow-on inventions. One may speculate that some of the heightened concern among researchers about patent breadth may be due to recent court decisions in the US that appear to have narrowed the grounds upon which an exemption from claims of patent infringement is allowed for experimental use of patented inventions – a topic to which I shall return later.

EXERCISE OF PATENT RIGHTS

As I noted earlier, some patent holders abuse their monopoly rights by exacting rents that are excessive or insisting on unduly restrictive licensing terms. For example, in respect of genetic tests, the licensing terms may severely limit the choice of test methods or laboratories, require samples to be exported outside the jurisdiction of Canadian privacy legislation without substituting equivalent safeguards, fail to account for the public health research value of health information generated through genetic testing and prevent individuals from having access to their own genetic information.¹⁰

Some hard liners are unconcerned about such matters. They argue that the patent holder’s contribution to innovation would not have become available in the absence of a patent¹¹ and if patent holders exercise their monopoly

¹⁰ E. Richard Gold & Timothy A. Caulfield, *The moral tollbooth: a method that makes use of the patent system to address ethical concerns in biotechnology* 359 THE LANCET 2268, 2268-2270 (2002) (U.K.).

¹¹ Rebecca S. Eisenberg, *Why the gene patenting controversy persists*, 77 ACAD. MED.

rights in ways that potential customers don't like the customers can simply forego the use of the inventions in question, leaving them no worse off than they were without the invention. This view may be tolerable in the case of plasma television sets but is of little comfort when the invention may offer important health benefits to individuals in desperate need of them. This leads me to a brief digression on the question of medical necessity and its role in relation to health services in Canada.

Although the provinces in Canada have the constitutional responsibility for health services within their jurisdictions, the *Canada Health Act* establishes conditions that the provinces must meet in order to be eligible to receive federal fiscal transfers. The *Act* requires public insurance of "medically necessary" health care services and the courts have in effect interpreted medical necessity to be whatever physicians identify as a necessity.

The government sector is the largest buyer of many products and services and when dealing with a single seller is in a situation that some describe as a bilateral monopoly. However the balance of negotiating power this term implies is tilted heavily in favour of the seller because the government's negotiating power is impaired by the requirement to provide the product irrespective of cost. This perhaps explains why cost issues are a major albeit not the only concern of Canadian health care providers when anti-competitive practices by patent holders block the development of lower cost alternatives and impose excessively high prices.

The provinces and territories have made strong representations in favor of non-discretionary compulsory licensing as a means of preventing what they regard as detrimental effects of IP protection on costs and other aspects of health services. They noted that there was precedent for compulsory licensing in that prior to 1987 the Canadian *Patent Act* permitted any company to produce patented drugs under a compulsory license on payment of a royalty of 4 per cent of sales. Others argued strongly against actions that would remove or substantially weaken a crucial incentive to investment in an important sector of the Canadian economy. There were also calls for Canada to broaden its recognition of the moral and ethical dimensions of innovation and property rights in all areas of technology by including a public order and morality provision in the *Patent Act*, analogous to the "*ordre public*" provision in European law.

PROPOSALS FOR CHANGE

The federal government is generally wary of introducing changes to the IP regime unless the need to do so is compelling. We concluded that, despite a relative paucity of quantitative empirical data, there is sufficient qualitative

evidence to warrant changes in Canada's IP regime so that it is better able to achieve its objectives in fostering innovation while, in effect, making it more responsive to health concerns. Our recommendations fall into two main categories: the process of patenting and the uses of patents. Some of the changes we propose would align Canada's regime more closely with that in the US; others involve taking a different tack.

THE PROCESS OF PATENTING

As far as the patenting process is concerned, we recommended: addressing the issue of excessively broad patents through the enhancement clarification, and more rigorous application of patentability criteria. In particular, we recommended that, as is the case in the US, the utility criterion for patentability include the demonstration that any indicated use be specific, substantial and credible. We also called for significantly enhanced opportunities to challenge patents: before they are granted by a more open and responsive mechanism than exists now; and, after they are granted, by the introduction of a statutory opposition procedure.

We are opposed to including, as the Europeans have done, public order and morality considerations in the process of examining patent applications. In our view other methods of social control would be more effective in prohibiting the manufacture, sale or use of socially undesirable or illicit products and services. Moreover, imposing a responsibility to adjudicate moral and ethical issues on an IP regime that it is not equipped to discharge it would in our view be a mistake.

Uses of Patented Inventions

With respect to the uses of patents, we focused mainly on licensing and on provisions related to limitation of patent rights. We called for enhanced voluntary mechanisms to limit unduly restrictive licensing practices through development of Canadian licensing guidelines and encouragement of industry initiatives to create patent pools and other mechanisms to remove barriers to diffusion of HGM-based innovations. In the case of HGM-based inventions developed using public funds obtained through federal grants; we recommended that the federal granting bodies develop licensing guidelines adherence to which would be a condition of funding. We noted that Canada could benefit from the experience of the NIH and from work currently being undertaken by the OECD with respect to development of licensing guidelines.

We recommended amendment of the Patent Act to exempt research (experimental use) from claims of infringement where the research involves using a patented invention for non-commercial purposes. Currently, in both

Canada and the US, there is reliance mainly on case law to determine which experimental acts qualify for exemption.¹² Recent judgments in the US have been interpreted as establishing that experimental acts are only permitted if they are not in furtherance of the alleged infringer's legitimate business.¹³ In our view this is too restrictive and we have therefore proposed the introduction of a statutory exemption that draws on recommendations made recently in Australia and by a committee of the National Research Council of the National Academy of Sciences in the US.¹⁴ It is based on the view that the nature of the experimental acts themselves should determine their eligibility for exemption and the acts that qualify for exemption should be specified.

Limiting the Exercise of Patent Rights

To deal with concerns about exercise of patent rights, most IP regimes include mechanisms to limit patent rights under certain circumstances. The TRIPs agreement permits member countries to include a mechanism for issuing compulsory licenses under certain circumstances, providing that the mechanism does not discriminate among technologies.¹⁵ The Doha Declara-

¹² Exceptions include US Patent Act Section 271(e)(1) which exempts experiments done to develop and submit information required for FDA approval. Decision in *Integra vs Merck* means that drug discovery activities are not exempt if they do not directly generate data for submission to the FDA.

¹³ *Madey v Duke Univ.*, 413 F.Supp.2d 601 (M.D.N.C. 2006).

¹⁴ The proposed wording recommended is:

- (a) an exemption from claims of infringement be provided in the *Patent Act* for research related to the subject matter of an invention;
- (b) research be defined in the wording of the exemption as acts done for experimental purposes, including acts done to:
 - i. study the features, properties or inherent characteristics of the *invention* including how the invention works;
 - ii. determine the scope of the invention;
 - iii. determine the validity of the claims;
 - iv. seek an improvement to the invention or to discover novel methods of making or using the patented invention;
 - v. create non-infringing new products or processes, including alternatives and substitutes; and,
- (c) the exemption shall not apply where one seeks to realize economic gain by commercial exploitation of improvements or discoveries resulting from acts done under (b) iv.

¹⁵ TRIPs Art. 31:

Where the law of a member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: ...

- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms

tion on the TRIPs Agreement and Public Health “reaffirms the right of WTO members to use, to the full, the provisions in the TRIPs agreement, which provide flexibility ... to protect public health, and, in particular to promote access to medicines for all.”¹⁶

Government Use

Most IP regimes provide mechanisms for governments to issue or compel the issuance of a license of IP rights for government use. It is an option available to governments as they aim to maintain an appropriate balance between the rights of patent holders and the public interest.¹⁷ The Canadian *Patent Act* gives governments the right to request from the Commissioner of Patents a licence to use a patented invention. For a “public non-commercial use”, the application can be made without prior negotiation with the patent holder. Although It has been suggested that this section could be used in respect of any health care service provided (directly or indirectly) by government it has in fact not been used for this purpose - perhaps because of uncertainty about what would qualify as “government use”.¹⁸

In the United States, the Bayh-Dole Act of 1980¹⁹ includes a provision allowing a federal agency, in certain circumstances, to ensure that a federally funded invention is available for the public good. It allows the agency to license a funding recipient’s invention to a third party who has tried and failed to obtain a license from the patent holder on reasonable terms. The application of Canada’s government use provision is not restricted to federally funded inventions.

and conditions and that such efforts have not been successful within a reasonable period of time ...

¹⁶ Declaration on the TRIPs Agreement and Public Health, Ministerial Conference, Fourth Session, Doha [Qatar], 9-14 Nov. 2001, WT/MIN(01)/DEC/2, para. 4.

We agree that the TRIPs Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPs Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPs Agreement, which provide flexibility for this purpose.... Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPs Agreement, we recognize that these flexibilities include: Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

¹⁷ M. ADCOCK, ET AL., REPORT ON THE USE OF PATENTS BY GOVERNMENTS: A COMPARATIVE STUDY OF COMPULSORY LICENCES AND GOVERNMENT USE, FOR HEALTH CANADA (2005).

¹⁸ E. Richard Gold & Danial K. Lam, *Balancing Trade in Patents – Public Non-Commercial Use and Compulsory Licensing*, 6 THE J. OF WORLD INTELL. PROP. 5, 5-32 (2003).

¹⁹ 35 USC §202(c)(4) (2005).

Abuse of Rights Under Patent

In the US, cases of anti-competitive behavior are usually dealt with under federal trade legislation. In Canada, the Patent Act allows any interested person to apply to the Commissioner of Patents for a license to a patented invention if the patent holder refuses to negotiate a license on reasonable terms or where a patent is not being practiced. However, this provision has rarely been used, and never in respect of genetic inventions. There is very little guidance from the courts, legislature, or other sources of law on what factors are to be considered in assessing whether demand for a patented article is being met 'to an adequate extent and on reasonable terms'. Moreover, the language of the abuse of patent provision leaves considerable uncertainty as to whether it could be used by public health sector institutions.

Accordingly, we recommended strengthening current provisions of the Patent Act pertaining to both government use of patented inventions and to abuse of rights under patent so as to make the provisions more responsive to concerns related to health: by defining government use to include use in government-funded, not-for-profit, public enterprises in Canada that provide services pertaining to health and public safety; by developing criteria for testing whether the terms and conditions (both commercial and non-commercial) under which patent holders are willing to authorize use of a patented invention meet the reasonable requirements of the public²⁰; and, by developing criteria by which a use by a government would qualify as a public, non-commercial use that ought to be exempt from a requirement that the applicant attempt to negotiate reasonable terms with the patentee.

We called for the elaboration, under the abuse of patent provision, criteria for determining whether the demand for a patented article is being met to an adequate extent and on reasonable terms including "reasonable requirements of the public"; and, adding to the list of those who may be deemed to be prejudiced by a patent holder's refusal to grant a license on reasonable terms, government funded not-for-profit public enterprises providing services pertaining to health and safety.

We recommended that the criteria developed for adjudicating the reasonableness of terms and conditions of the licensing of rights under patent include reasonableness of prices of products and services.^{21,22,23} We also pro-

²⁰ Which in turn should include, for example, with respect to genetic testing, access for patients, allowing competitive perfection of the tests, facilitating research ethics board approved clinical research in academic medical centres, facilitating professional education and training, permitting independent validation of test results, protecting the privacy rights of individuals and ensuring regulatory compliance.

²¹ There have been calls from many quarters for the introduction of compulsory licensing of diagnostic genetic tests. (as used to be the case in Canada with respect to patented medicines). In order to clarify the debate, the term "compulsory licensing provision" needs some

posed the establishment of a Patented Inventions Licensing Review Board to advise and assist the Commissioner of Patents in the exercise of the Commissioners discretionary powers under the government use and abuse of patent provisions.

CONCLUDING OBSERVATIONS

Before concluding my remarks I should make three corollary observations. First, although patenting is the most common form of IP protection used for genetic inventions, copyright is also used - primarily to protect the IP inherent in genetic databases. Second, most of the debate about gene patents is focused on genetic testing - but patented HGM are increasingly important in therapeutics (drugs, gene therapy, cell/tissue/organ transplantation) and one should keep in mind that market dynamics, regulatory controls and impacts may vary according to the type of innovation involved. Third, the

elaboration. For present purposes, it is useful to distinguish between two types of compulsory licensing depending on who is compelled to do what. There can be statutory provisions **requiring a patent authority to issue licenses** on *a priori* grounds in respect of a certain class of invention (as used to be the case in Canada with respect to patented medicines). The second type of compulsory licence **provides the patent authority with discretionary power** to order a patentee to grant a licence to an applicant under certain conditions (e.g. those contained in Section 65 of the *Patent Act*).

²² Before it was removed from the *Patent Act*, Section 41.(4) stated: "*Where, in the case of any patent for an invention intended or capable of being used for medicine or for the preparation and production of medicine, an application is made by any person...the Commissioner shall grant to the applicant a licence to do the things specified in the application, except such, if any, of those things in respect of which he sees good reason not to grant such a licence...*"

²³ "Since 1923 Canada had a law providing for compulsory licensing of the right to manufacture within Canada drugs (and also food products) protected by patents (usually process patents, since product patents were not available at the time)... the Canadian Parliament amended the law in 1969 to permit compulsory licenses for importation. ... Despite opposition from consumer advocates and Canadian generic drug providers, the Canadian compulsory licensing law was weakened in 1987, with the imposition of a seven to ten year exclusivity period for drug patent holders, and eliminated altogether in 1992. The principal impetus was lobbying by U.S. and European pharmaceutical manufacturers anticipating the debate over the proposed free trade treaties between Canada, the United States, and (later) Mexico. As a quid pro quo, the multinational drug manufacturers agreed to locate in Canada drug research and development activities roughly proportional to Canada's share of their world sales and to accept a new regime of "reasonable price" controls by the Canadian Patented Medicines Prices Review Board." F. M. Scherer, *The Economics of Compulsory Drug Patent Licensing* (2003), [http://wbln0018.worldbank.org/HDNet/hddocs.nsf/9b2b70eeb6c333fb852568aa0073e2a1/2adc484a5d57888f85256d350054080f/\\$FILE/F.M.%20Scherer%20-%20paper.doc](http://wbln0018.worldbank.org/HDNet/hddocs.nsf/9b2b70eeb6c333fb852568aa0073e2a1/2adc484a5d57888f85256d350054080f/$FILE/F.M.%20Scherer%20-%20paper.doc) (extracted from F. M. Scherer and Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, 5 J. OF INT'L ECON. L. 913, 913-939 (2002), and written for Working Group 4 of the Commission for Macroeconomics and Health of the World Trade Organization, 2001).

introduction of hybrid products based on convergence of technologies (nanotechnology and biotechnology) may raise new issues.

Our study involving a major field of innovation (gene technology), an important sector of society (health) and a key modality of social control (IP regime) illustrates that the processes involved in innovation do not incur in a vacuum. They are imbedded in a constellation of social, ethical, economic and legal frameworks that vary from country to country and determine how the balance between the benefits of innovation and its social cost is struck.

Although discussions about innovation tend to focus heavily if not exclusively on technological innovation, it is important to keep in mind that social innovation is also critical in improving health status - not only in its own right but also in its interaction with technological innovations. The particular challenges associated with biotechnological health innovations are part of the much larger overarching challenge of how to create the capacity to adopt beneficial innovations in already heavily burdened health care systems. Meeting this challenge fully will require more than refinements of an IP regime. It is also likely to require new institutional mechanisms and perhaps new organizations – but that is a topic for another occasion.

Countries facing these challenges have much to learn from each other and much to gain through active bilateral and multilateral endeavours. I am grateful to the organizers of this conference for the opportunity to participate in the bilateral enterprise this conference represents.

DISCUSSION FOLLOWING THE REMARKS OF DR. ARNOLD NAIMARK

MR. NARD: Given that Dr. Naimark is a panel of one, maybe I could exercise the moderator's prerogative to say a few things before we open it up.

Someone like myself who focuses much of his professional time on patent law, there is a wonderful comparative advantage between us. You bring the medicine and the science and a healthy dose of the legal stuff, I must say, where my relative ignorance of molecular biology will probably manifest itself in the next 25 minutes.

But I can bring some of the patent law to it. Let me say this: I think it is important to distinguish between pharmaceuticals and biotechnology. And I think in the patent debate that when it comes to the end product in the pharmaceutical industry, most all policy makers would agree that patent law has a very strong role to play.

In biotechnology, where you are not dealing with small molecule chemistry, you have so many research tools and upstream research that we really don't know what's going to happen with them, but we know they have some use.