

7

Notes

- ¹ In 2004, the World Health Assembly officially adopted the following definition of “genomics”: the study of genes and their functions, and related techniques (WHA 2004, a57.16). See the Glossary for definitions of terms used in this report.
- ² This is not to say that it accepts all of the conclusions of these reports. Rather, in terms of its aims and the subject matter with which it is concerned, the present report can be said to find its place at the intersection of these three documents.
- ³ In this report, when we refer to *developing countries*, we refer broadly to countries, primarily in sub-Saharan Africa, Latin America and Asia, with a weak industrial base, and where a considerable proportion of the population lives near subsistence level. We acknowledge the shortcoming of this terminology, in light of the great diversity among countries in this category—diversity in health needs, economic development and scientific capacity. Where possible, we will try to point out where these factors make a difference in terms of the impact of DNA patents.
- ⁴ As Clegg and Weatherall’s review points out, there is a hypothesized relationship, with growing empirical support, between the haemoglobinopathies and protection against malaria, which provides clues about why these conditions are prevalent in malaria endemic areas.
- ⁵ See, for instance, the USA Department of Energy Office of Science’s human genome project information website, for a list of available genetic tests: http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetest.shtml#testsavailable (accessed 8 March 2004).
- ⁶ Civil law does not take prior cases to be precedent in the same way as the common law system. While judges do refer to previous cases, commentary plays a much more important role in the civil law. So, while precedent is important for common law system, doctrine is important for civilians.
- ⁷ This being said, neither the United States Constitution (Article I, Section 8) nor the United States Code (Title 35, Part II, Chapter 10, Section 101) distinguishes inventions from discoveries. The latter document states that: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.” Courts have consistently interpreted Article 101 as excluding natural phenomena, such as principles, powers and products of nature. *O’Reilly v. Morse* [56 U.S. (15 How.) 62 (1853)] rejected Samuel Morse’s claim seeking a patent on electromagnetism. Though he was the first to harness it in inventing the telegraph, the court argued that he had not invented electromagnetism, which is a force of nature and thus not patentable subject matter.
- ⁸ More specifically, they cover purified or isolated genes, the protein coded for by a gene, cells engineered to express the gene or protein to detect or treat disease (Andrews, Mehlman and Rothstein, 2002).

- ⁹ For example, the British Society of Human Genetics, the American College of Medical Geneticists, the Human Genetics Society of Australasia.
- ¹⁰ The patent holder may also opt not to use the patented invention in countries where local laws do not impose a working obligation. “Exclusive” licenses do not always confer rights for all uses. Sometimes an invention is exclusively licensed to multiple groups under different conditions.
- ¹¹ An agreement on a “common political approach” regarding the Community Patent, reached at the Competitiveness Council of Ministers in Brussels on 3 March 2003, brought this one step closer to realization. However, at their meeting in March 2004, the Ministers failed to reach agreement on the proposed Regulation, primarily due to a lack of consensus on how to treat infringements of patents that could arise due to mistranslations. See Results of the Competitiveness Council of Ministers (EC, 2004).
- ¹² See USPTO website on Trilateral Studies, <http://www.uspto.gov/web/tws/sr-3.htm> (accessed 29 September 2004).
- ¹³ All WTO Member States are eligible to import pharmaceuticals made under compulsory licences abroad, but 23 developed countries have already stated that they will not use this provision. All other members are eligible if they notify the Council for TRIPS of their intention to use the system as an importer.
- ¹⁴ TRIPS, as noted earlier, sets minimum standards for countries; it offers relatively little direction on how to implement these norms. Anything above these minimum standards falls within a zone of “flexibility” (see South Centre, <http://www.southcentre.org/info/southbulletin/bulletin63/bulletin63-09.htm>, accessed 14 May 2004). In bilateral negotiations, pressure has been brought to bear on developing countries to extend stronger IP protection than what is required in TRIPS, i.e. so-called TRIPS-plus provisions.
- ¹⁵ See, for example, <http://www.bio.org/ip/primer/patentsay.asp>, accessed 1 April 2004.
- ¹⁶ In 2000, Myriad Genetics claimed to have invested the equivalent of about 150 person-years of effort and tens of millions of dollars into the discoveries of these genes, and the development of a highly automated and accurate clinical test. The company has argued that this investment would not have been possible without the potential for patent protection on these discoveries. See Secretary’s Advisory Committee on Genetic Testing (Vol. III), 7 June 2000. It is not clear whether such figures would apply today, several years after the initial identification and sequencing of *BRCA1* and *BRCA2*.
- ¹⁷ See *Cutting-edge technology for low-cost diagnosis*. Sustainable Sciences Institute (www.ssilink.org/immunosensorhistory.html, accessed 14 May 2004).
- ¹⁸ Law No. 9.279 increases the patent term to 20 years for all products and processes, and removes prior prohibitions on the granting of patents for chemical products and processes for the production of pharmaceuticals and foods. Law No. 9.279 has an important affect on Brazil’s ability to manufacture generics. Brazil can no longer freely produce generic versions of pharmaceuticals that are patented overseas. The generics industry can, however, continue to produce generics based on products patented overseas before 1996. In addition Brazil has the option of issuing compulsory licences (see Glossary, Appendix 1) to produce generics under certain conditions.
- ¹⁹ Oxfam and the Consumer Project on Technology defended Brazil’s position and contended that the complaint threatened the most successful AIDS treatment programme in the developing world. In June 2001, a compromise was reached, where the United States agreed to drop the complaint and Brazil agreed to give United States officials advance notice before invoking the provision.

- ²⁰ Article 18, item III, states that living beings, in whole or in part, are not considered patentable. Article 10, item IX, states that natural living beings, in whole or in part, and biological material encountered in nature or isolated including the genome or germplasm of any natural living being, are not considered as inventions. The Brazilian Group states that if sequences of DNA are interpreted as chemical products they may be patentable.
- ²¹ *Ibid.*
- ²² For instance, New Zealand's Ministry of Health, in a report to the Cabinet Policy Committee, concluded that Brazilian patent law considers genetic material, even in a purified and isolated state, as a discovery and therefore not patentable; and in a paper presented for the *Frontiers of Innovation Research and Policy*, Maria da Graça Derengowski Fonseca and José Maria F.J. da Silveira state that Brazilian legislators have decided to allow patenting for genetically modified organisms *only* (Fonseca & Silveira, 2002). Ladas & Perry LLP also state that the patent law makes it clear that transgenic microorganisms are patentable. But they do not specify whether genes and DNA sequences are excluded from patenting.
- ²³ See the Beijing Genomics Institute website (<http://www.genomics.org.cn/bgi/english/1.htm>, accessed 5 March 2004).
- ²⁴ See *China Daily*, 2002.
- ²⁵ *Ibid.*
- ²⁶ See Chinese firms keen on patent application for WTO entry, *People's Daily* (2001).
- ²⁷ *Ibid.*
- ²⁸ Counting patent families can only provide a rough guide of a nation's technological activity relative to other countries, because differing national patent laws and customs can result in higher levels of patenting in some countries than in others. Because a patent generally offers protection only in the country in which it is issued, and because it can be very expensive to apply for patent protection in multiple countries, organizations are assumed to seek patent protection abroad only for those inventions they believe will have significant commercial value. Comparing *international patent families* (inventions for which patent protection has been sought in more than one country) makes international comparisons more accurate and provides a more precise measure of technological activity. A *priority application* refers to the first application filed anywhere in the world and it is generally assumed that the country in which the priority application was filed is the country in which the invention was developed.
- ²⁹ See *Science and engineering indicators*, 2002a.
- ³⁰ See Appendix table 6-15, Human DNA sequence patents: Number of international patent families, by priority country and priority year. *Science and Engineering Indicators*, 2002b.
- ³¹ See Achievements, Human Genetics and Genome Analysis (<http://dbtindia.nic.in/programmemes/progmain.html>, accessed 26 February 2004).
- ³² See Biotech Desk. *Biotechnology in India – Initiatives by the Government* (<http://www.biotechdesk.com/market4.php>, accessed 24 February 2004).
- ³³ *Ibid.*
- ³⁴ See Patents Office India. *Exclusive Market Rights* (<http://www.patentoffice.nic.in/ipr/patent/emr.htm>, accessed 26 February 2004).
- ³⁵ *Ibid.*
- ³⁶ See Gene Campaign. *International Trade Policy* (http://www.genecampaign.org/about_us/impact_efforts.html, accessed 24 February 2004).
- ³⁷ Although, as with Chinese and Indian programmes, there are aspects mainly aimed at export markets.

- ³⁸ The human genome, itself, is not currently patentable. Some have claimed that the human genome is therefore safeguarded from the charge of commodification, because it is only specific sequences that are subject to patents. But this protection is currently *de facto*, and is not the basis of any principled distinction; there is nothing within the current system that prohibits the eventual allowance of large-scale patenting of portions of the genome, or the genome in its entirety. Moreover, since the genome just simply is composed of DNA sequences, a principled objection to the patenting of the genome would seem to impose similar constraints on the patenting of its components.
- ³⁹ Groups such as the Action Group on Erosion, Technology and Concentration (ETC Group), however, have raised concerns that such guidelines establish national sovereignty over genetic resources, thus *reducing* the rights of indigenous peoples and rural communities and their decision-making capacity. According to the ETC Group, a national level approach to benefit sharing undermines customary systems of resource exchange (for example seed exchange between indigenous farmers). In response they call for the reformulation of the Bonn guidelines to encourage governments to establish non-proprietary systems of benefit sharing, and for the CBD to facilitate the establishment of a global biodiversity fund to support the conservation and development of biodiversity in a manner independent of IP rights (ETC, 2004).
- ⁴⁰ In 1984, John Moore filed a lawsuit against the University of California. While he was undergoing treatment for leukemia, his physician developed a medically useful cell-line against cancer, on the basis of which a patent was later obtained and commercial profits earned on the subsequently developed therapies. The California Supreme Court, in 1990, stated that donors do not have “property rights” in the tissue earned from their bodies, and that in fact such a position would hinder research and access to raw materials (*Moore v. Regents of the University of California*, 793 P.2d 479 [Cal. 1990])
- ⁴¹ In one respect, this represents a more technical basis for arguing for the special status of DNA. One version, as stated above, rests on DNA’s essential difference from other natural products, even those molecules that are similarly situated in the human body. What this argument seems to suppose, like the more technical argument, is that DNA is fundamentally valuable, in a “moral” sense, because it has a kind of “informational content” that separates it from other kinds of chemicals. It is a molecule that encodes instructions for every aspect of a cell’s function, and for yet-unknown aspects of a person’s behaviour and identity. It is therefore the so-called informational value of DNA that lends it its special-ness.
- ⁴² See USPTO’s announcement of its new guidelines for assessing utility of genetic inventions (<http://www.uspto.gov/web/offices/com/speeches/01-01.htm>, accessed 8 March 2004).
- ⁴³ See WTO (http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm, accessed May 12, 2004).
- ⁴⁴ Countries where there are significant differences in standards of invention between full patents and petty patents tend to grant more petty patents. According to WIPO statistics, in 1999, for example, China received 44 369 applications for utility model patents, Korea received 30 650, Germany received 23 584 and Taiwan received 17 954.