4 New Technologies

This chapter considers the IPR-related aspects of two technological fields of considerable strategic and economic importance in today's global economy that have experienced tremendous advances in recent years: biotechnology and information and communication technology (ICT).

Biotechnology

Biotechnology, the genomics revolution and developing countries

According to a report by the United States Office of Technology Assessment (1989): "biotechnology, broadly defined, includes any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses."

This definition is rather broad and would embrace what some experts refer to as the first-, second- and third-generation biotechnologies. The first generation includes traditional technologies like beer brewing and bread making, and the second begins with microbiological applications such as those developed by Louis Pasteur, which culminated in mass production by fermentation of the antibiotics. Tissue culture and modern plant and animal breeding also fall within this "generation". The third generation biotechnologies or the "new biotechnologies" include recombinant DNA ("gene splicing"), hybridoma technology,[1] and genomics.[2]

The rate of advancement of biotechnology varies considerably in developing countries, depending on the capacity of their research institutions and businesses to generate biotechnological inventions. For example, Brazil, China, Cuba and India have adopted third- generation biotechnologies. However, the overwhelming bulk of biotechnology applications, even in these countries, are of the earlier generations, such as fermentation and tissue culture. While health biotechnology is more important than agro-biotechnology in the United States and Europe, in developing countries, such as India and Kenya, agro-biotechnology has been made a priority. This is largely due to their dependence on the viability of their agricultural sector for food security and employment, and in many cases, for foreign exchange and political stability.

The rate of advancement of biotechnology varies considerably in developing countries

Given the likelihood that sequencing and analysing human, animal, plant and microbial genomes will take less and less time and money, one can anticipate a lowering of barriers to entry. This increases the likelihood of a few developing countries, such as Brazil, China and India, becoming sources of innovations in this field in the coming years. It is perfectly feasible, then, to envisage a time in the near future when a developing country like India will not just be a recipient of gene technologies and products but will be a provider to global markets as well.

Correa (2002) is of the view that while biotechnology may be applied in a wide range of activities in developing countries, and generate new industrial and trade opportunities, the most visible and profitable industrial applications, such as in pharmaceuticals, have largely been beyond the reach of most developing countries.[3] A few cases show that with the appropriate infrastructure and policies, some developing countries have been able to modestly participate in the emerging market of bio-pharmaceuticals. Significant efforts from the private and public sector would be required, however, to exploit such opportunities, especially in order to catch up with new developments in genomics and other technologies. Correa adds that developing countries face

serious challenges in the field of agricultural biotechnology, including the risks posed to health and the environment by the release of genetically modified organisms (GMOs), the potential negative impact of GMOs for export to GMO-averse markets, as well as the risk of substitution of local produce by GM crops grown in developed countries. The use of biotechnology in agriculture thus raises some fundamental dilemmas for developing countries, in view of their need to balance these risks with the potential it offers for increased production and poverty alleviation.

Intellectual property rights

As has been pointed out in this report, the IPRs regime cannot be separated from other policies and institutions that are concerned with the growth and development of a country. A solid national system of innovation is needed, including a basic R&D base, skilled personnel and a strong educational system, for a country to develop a particular industry and thus benefit from an IP regime (see discussions in chapter 3). While a few developing countries may be reaching this critical mass, their domestic research institutions and businesses are unlikely to be heavy users of patent systems, at least in the short term.

Article 27.3(b) of the Agreement deals with IPR protection of life-forms

But the truth of this proposition provides no definitive answer to the question of whether these countries should offer broad and strong patent protection in the field of biotechnology or take a TRIPS de minimis approach that excludes plants and animals, defines "micro-organism" narrowly, and opts for a sui generis alternative to patents for plant varieties. While many developing countries will prefer to opt for the latter approach, at least for the time being, it is worth pointing out that if biotechnological inventions were well protected, developing countries could conceivably benefit, even if there were few, if any, domestic patents applicants. This would depend on whether foreign firms are encouraged to transfer technologies to those countries or to establish R&D facilities there because of the existence of IPRs. But at this stage it is unclear whether strong IPR protection would make this happen. One complicating factor is that such business decisions depend on a range of factors, of which intellectual property may be just one of many. Professor John Barton from Stanford University is of the view that "based on factors such as market size and research capability, a developing nation should decide whether to adopt a UPOV style system in minimal compliance with TRIPS or instead to adopt a stronger biotechnology-oriented patent system".[4]

Developing countries need first to determine to what extent and how they wish to harness biotechnology for their economic development before designing an IPR regime that supports the objectives they decide to pursue. The TRIPS Agreement gives them some choice in terms of how they prefer to define a patentable invention in the context of biotechnology. Since discussing this first task is beyond the scope of this paper, the remainder of this section discusses how TRIPS deals with IPR protection of biotechnological inventions and how the relevant provisions may be interpreted.

TRIPS makes no reference at all to biotechnology, but Article 27.3(b) of the Agreement deals with IPR protection of life-forms. It allows Members to exclude from patentability "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof."

With respect to products, plants and animals, it would mean that they may be excluded from patentability. As regards processes, essentially biological processes for the production of plants or animals may also be excluded. However, patents must be available for micro-organisms as products, and for non-biological and microbiological processes for producing plants or animals. Patent protection need not be available for plant varieties, but an effective IPR system is still obligatory. This may be a UPOV-type plant variety IPR system (see box 2.4), an alternative system yet to be devised, or some combination of systems (see also the discussion on the challenges posed by plant breeders rights to food security, under chapter 8, below.). Drawing distinctions between micro- and macro-biological

processes is by no means easy, especially in the biotechnology age. Therefore, different jurisdictions are likely to draw the line in different places according to how these terms are understood in specific cases.[5] Box 4.1 summarizes the relevant provisions of TRIPS.

Box 4.1: Article 27.3(b), TRIPS: a summary of its relevant provisions

WTO Members may exclude from patent protection:

- Plants
- Animals
- Essentially biological processes for the production of plants or animals
- Plant varieties

WTO members must provide protection for:

- Micro-organisms (by patents)
- Non-biological processes (by patents)
- Microbiological processes (by patents)
- Plant varieties (by an IP system which may be patents, a sui generis alternative, or a combination)

Much of the language in Article 27.3(b) is open to conflicting interpretations. For example, it is unclear whether an application relating to a genetically engineered plant would necessarily include plant varieties within its scope or not. This is important, because in some jurisdictions plants can be patented but plant varieties cannot; in others, neither can, but there may be a separate IPR system exclusively for plant varieties.

Since the language follows quite closely that of the European Patent Convention,[6] it may be useful to examine how the European Patent Office (EPO), which allows plants to be patented but not plant varieties, has addressed this complex issue. In 1995, the Technical Board of Appeal of the EPO[7] determined that a claim for plant cells contained in a plant is unpatentable since it does not exclude plant varieties from its scope. This implied that transgenic plants per se were unpatentable because of the plant variety exclusion. But in December 1999, the Enlarged Board of Appeal of the EPO declared that "a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b), even though it may embrace plant varieties", but that "plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability".[8] It goes without saying that WTO Members do not have to follow this interpretation.

The language in Article 27.3(b) is open to conflicting interpretations

Even words like "micro-organisms" can be interpreted differently from one legal jurisdiction to another. According to the EPO, for example, "micro-organism" "includes not only bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plant cells, i.e. all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory. Plasmids and viruses are also considered to fall under this definition." This seems rather over-expansive since it is not at all obvious that a single cell from a multi-cellular organism is itself an organism, even if it has been cultured in a laboratory. There is no reason why developing countries should not define the term in a narrower sense if they consider it advantageous to do so.

TRIPS makes no reference to genes or DNA sequences. On the one hand, one could argue that DNA is merely a chemical. Consequently, complementary DNA (cDNA) sequences, which are produced in the laboratory and differ from their naturally occurring counterparts – in that certain sections of the molecule are "edited out" – should be patentable subject to fulfilment of the novelty, inventive step and industrial applicability requirements.

The alternative view is that the deletion of non-protein coding DNA is not inventive enough to deserve the reward of a patent. Why? Because a claimed cDNA molecule is likely to be obvious to somebody "skilled in the art" who might know the sequence of its naturally occurring equivalent. Furthermore, techniques for isolating and purifying DNA sequences are well known and no longer require a great deal of skill to use. But what if nobody knew about the naturally occurring equivalent? Such a claim should still arguably fail for the lack of an inventive step since the techniques employed have become routine (see box 4.2 on patenting natural substances).

Box 4.2: Patenting natural substances

TRIPS requires micro-organisms to be patentable, while plant variety rights must come under some kind of IPR system, but not necessarily patents. But what about genetic and biochemical resources? Must these also be patentable? Since they are not expressly excluded, patents must be made available for these, subject to the conditions that they be new, involve an inventive step and be capable of industrial application. Presumably these requirements mean that resources existing in nature cannot be patented. But is this correct?

In Europe and North America, which have the most experience in the patenting of apparently natural substances, there has never been any kind of blanket exclusion of certain types of invention on the basis that because they were not 100-per-cent human-made they could not be patented. For example, adrenaline was first patented in 1903, and insulin in 1923. Shortly after the Second World War, Merck was granted patents on two products extracted from a micro-organism called Streptomyces griseus: the antibiotic streptomycin and vitamin B12. While there was a general assumption that living things could not be invented, patents were occasionally granted in some countries on plants and micro-organisms. The United States even had a plant patent system from as early as 1930 for certain kinds of plants. But for most of the twentieth century the legal situation in Europe and North America was uncertain. From the 1970s, though, things became clearer as the scope of patent protection was extended not just to micro-organism products, but also to micro-organisms themselves, followed by plants and animals; and DNA sequences started appearing in patent applications in about 1980.

How can such products, some of which are obviously discoveries, be protected by patents as if they are inventions? The technical explanation is that patent law treats them as if they are chemical substances, and these have been patentable for at least 150 years. It is well established in the patent laws of Europe and North America that while you cannot claim as an invention something as it occurs in nature, it is possible to do so if you extract it from nature and thereby make it available for industrial utilization for the first time. This argument may not always convince a patent examiner or a court, but almost certainly will if a change is made to the substance or life-form in some way such as by adding something to it (e.g. a gene), subtracting something from it (i.e. purifying it), mixing it with something else to create a new or synergistic effect, or structurally modifying it so that it differs in an identifiable manner from what it was before. It also appears to be possible in some jurisdictions to get a patent on a natural substance by simply being the first to describe it in the language of biochemistry. Thus the South African Council for Scientific Research has a patent on certain compounds found in a plant called the hoodia which is used by the Bushmen as an appetite suppressant, and which the Council hopes will form the basis of a successful anti-obesity treatment. The patent may well provide the first biochemical description of how the plant produces its commercially promising effect, but the intended use of the plant would hardly be considered as novel by the Bushmen. According to the European Patent Convention's standards, though, the Council has a legitimate claim. The European Patent Office Guidelines for Examination state that: "if a substance found in nature has first to be isolated from its surrounding and a process for obtaining it is developed, that process is patentable. Moreover, if the substance can be properly characterised either by its structure, by the process by which is it obtained or by other parameters … and it is 'new' in the absolute sense of having no previously recognised existence, then the substance per se may be patentable".

To a large extent, the patenting of DNA sequences and genes depends on how policy makers and the courts decide how the law should define novelty, or how they interpret the term if it is not explicitly defined. For example, most developed countries' patent laws and their courts allow "purified" or "isolated"' DNA sequences to be patented as long as a credible use is disclosed. Other jurisdictions may prefer to raise the novelty standards so that purification or isolation of a naturally occurring substance is insufficient to demonstrate novelty.

It has also been argued that allowing patents on genes and gene fragments is inadvisable because, for the reasons given earlier, such as increased transaction costs, it is likely to increase the cost of doing

research. Objections to such patents have also been raised on moral or religious grounds, as have patents on plants, animals and other life-forms.[9]

Such objections notwithstanding, the extent of patenting relating to DNA has increased tremendously in those jurisdictions that do allow it. According to Derwent Information, "DNA sequences first began appearing in patents in 1980, just 16 sequences all year. By 1990 that figure had risen to over 6,000 sequences. Throughout the 1990s the growth in the patenting of sequences expanded exponentially, and this looks set to continue. In 2000 over 355,000 sequences were published in patents, a 5000 percent increase over 1990."[10]

TRIPS Article 27.3(b) was to be reviewed by the Council for TRIPS in 1999. In fact, at the time of writing this report, the review was still going on. Many countries had submitted proposals concerning how the review should be conducted and suggesting changes to the language of the sub-paragraph.[11] However, it does not seem as if the review will result in any changes to the present text.

Information and communication technologies (ICT)

Information technology has multiple industrial applications

Electronic information-processing and communication is another key technological field in which tremendous advances have been achieved in a very short time. Like biotechnology, information technology has multiple industrial applications. The main sources of innovation in ICT are the software (see chapter 3 above), hardware, semiconductor and telecommunications industries. But there are also other types of business involved in the ICT sector that have an interest in intellectual property regulation including those that do not themselves innovate in this particular field, such as those which use ICT to provide services or "content" to consumers.

On the Internet such businesses can be divided into:

- World Wide Web browsers. This sector is essentially a duopoly, since virtually all computers use either Microsoft's Internet Explorer or Netscape's Navigator or Communicator.
- Internet service providers (ISPs), which enable users to access the Internet. These include companies like America On Line (AOL), Compuserve, and telecommunications companies.
- "Content" providers, which make information and creative works available on the Internet. These include publishing and media companies, non-profit organizations, universities and individuals.
- The content creators. These include authors and entertainment companies, who sometimes are also providers.
- E-commerce businesses. These include dedicated e-commerce firms (e.g. Amazon) and those using e-commerce in addition to more conventional means of selling goods and services to the public. These businesses have increased their presence in recent years.

Content providers tend to take a hard line on intellectual property rights, favouring protection as strong as, if not stronger than, the levels of copyright protection available to businesses operating in the more conventional environments such as print.

On the other hand, ISPs generally have little reason to favour strong copyright protection of Internet content, especially given the possibility of finding themselves held liable for the copyright infringements of their users. But this situation may change if other ISPs follow the example of one of the biggest, America On Line, which owns Netscape; it has merged with Time Warner to form AOL Time Warner, a new corporation which is not just an ISP but also a large-scale provider and creator of content.

ICT and developing countries

Access is likely to be a greater priority than the promotion of innovation

Although innovation in the field of ICT takes place in a number of developing countries, access is likely to be a greater priority than the promotion of innovation. In several ICT-related businesses such as software, hardware, semiconductors, telecommunications, and Internet service providers, the markets tend to be highly concentrated. This has not been the case so far with Internet content, but this situation may change. Therefore innovative start-up firms based in developing countries may find it difficult to grow. And while software and hardware products are often manufactured in developing as well as developed countries, the companies that design and sell the products capture most of the value by far (see chapter 3).

Intellectual property rights

The ICT revolution has pushed the boundaries of the IPR system

While there is nothing new in patenting telecommunications technologies or copyrighting books and motion pictures, the ICT revolution has pushed the boundaries of the IPR system in a number of different ways, and it has the potential to push them still further. For example, though software programs are, arguably, no more than a long sequence of binary-coded instructions to a computer, copyright law nowadays treats them as if they are literary works. In the United States, programs are now patentable as well. There are two types of software-related intellectual product that may be regarded as an invention in some jurisdictions: "a) computer programs that produce a technical effect within the computer or on other hardware components; and b) computer programs that produce technical effects different from those described in (a), entailing changes in the state of physical matter such as effects on equipment applied to a specific industrial task."[12] In the United States it is possible to obtain patents for both types. In Europe, programs are not patentable officially, although patents on type (b) inventions have been granted.

The semiconductor manufacturers came up with a different approach to the software industry. They deemed existing IPRs to be unsuitable for the protection of their chip designs and successfully lobbied for a sui generis system, first in the United States and now globally through the TRIPS Agreement. The United States legislation, passed in 1984, is known as the Semiconductor Chip Protection Act (SCPA). To a large extent, the SCPA provided the model for the 1989 WIPO Treaty on Intellectual Property in Respect of Integrated Circuits (Washington Treaty). Despite this, the agreed text of the Treaty was not fully to the satisfaction of the main semiconductor-producing countries. Thus, while it was incorporated by reference into TRIPS, modifications were made that strengthened the rights provided.

As for digital information, views on the applicability of IPRs vary, from some who believe that IPRs are completely inappropriate, to others who contend that IPRs have evolved over time and that there is nothing new for them to accommodate into new technologies even while there may be problems at first. Among the former are those who believe that "information wants to be free",[13] and that attempting to use IPRs only holds up technological development while intruding on freedom of expression. Many, if not most, others hold to a view somewhere in between.[14]

Software and database producers use copyright law not only to protect expressions but also to limit access to information. For example, software developers in the United States can copyright the code of their programs without having to fully disclose it. Additional protection can be secured by keeping the source code secret (and thereby protecting it under trade secrecy law), and through restrictive licences.

Developing countries are required, under TRIPS, to protect software by means of copyright law and semiconductor designs through the sui generis system. However, TRIPS does not explicitly state that they have to allow the patenting of programs, although they may be required to do so under the terms of bilateral free trade agreements (see the discussion in chapter 2, above). It is possible to argue that since patents must be available for all fields of technology, protection must be extended to computer programs. But this may not necessarily be

the case. The European Patent Convention expressly disallows the patenting of computer programs. The reason is that legal protection of inventions requires evidence of a technical contribution to the state of the art. Computer programs as such are not considered to meet this requirement. But in spite of this, the European Patent Office and national patent offices in Europe have so far granted thousands of patents for computer-implemented inventions, including over 20,000 by the EPO alone.[15]

The two 1996 "Internet treaties" – the WIPO Copyright Treaty (WCT) and the WIPO Performers and Phonograms Treaty (WPPT) (see chapter 2) – are particularly important since they attempt to meet the challenge of a new and rapidly expanding field of mass communications: the Internet. While the Internet was clearly becoming a promising new medium for making intellectual works available to the public, concerns were raised that in the digital environment, opportunities for large-scale counterfeiting were massively increased. Moreover, copyright enforcement was also highly problematic because members of the public and competitors could access Internet content from virtually anywhere in the world. There were also concerns that technological barriers to copying could never be totally secure. That is why content providers are not only developing ever more sophisticated technological barriers to copying, but are also keen to prevent the production, use and dissemination of technologies which aim at, or are merely capable of, circumventing those barriers. The new anti-circumvention measures seek to restrict access to works as well as allowing owners of IPRs to deny users their lawful rights of usage under any of the fair use/fair dealing or educational exceptions.

While these concerns motivated certain WIPO member States to lobby for new norms to address these problems, a quite different concern was also raised at the 1996 conference at which the above treaties were negotiated and adopted. This other concern was that the creation of new norms, if driven purely by the interests of content producers, could lead to overprotection, thereby upsetting the mutually beneficial balance between the interests of (a) the public, (b) the content producers, who are likely to be copyright owners of such content, and (c) the content access providers, such as Internet service providers and libraries. Because many of the delegates accepted the need to address this matter, the agreed texts of the two treaties are generally considered to reflect a much more reasonable balance between the different interests involved than there might have been. Thus the basic premise of the WIPO treaties acknowledges that there is a need to maintain a balance between rights of authors and the wider public interest, particularly with respect to education, research and access to information. In this regard, one important feature of the WCT and the WPPT is the possibility of establishing limitations and exceptions in national legislation in special cases, that do not conflict with the normal exploitation of the work and do not unreasonably prejudice the legitimate interest of the authors. These types of exceptions are optional and have to be implemented through national law.

Nonetheless, subsequent copyright reforms in a few countries have gone so far as to outlaw the circumvention of technological barriers, not only to illicit copying but also to uses that may be perfectly legal because, for example, they constitute fair dealing or the copyright has expired anyway. Moreover, most users are not technologically capable of circumventing digital lock-up systems by themselves; they require devices or software created by other users. In many regions, such as the United States and the EU, both the manufacture and the distribution of such devices is outlawed (for further discussion of the challenges posed by these developments, see chapter 9, below).

The premise of the WIPO treaties acknowledges a need to maintain a balance between rights of authors and the wider public interest

The Report of the Commission on Intellectual Property Rights (see box 1.2) cautions developing countries on these new developments. It concludes that:

"Users of information available on the Internet in the developing nations should be entitled to 'fair use' rights such as making and distributing printed copies from electronic sources in reasonable numbers for educational and research purposes, and using reasonable excerpts in commentary and criticism. Where suppliers of digital information or software attempt to restrict "fair use" rights by contract provisions associated with the distribution of digital material, the relevant contract provision may be treated as void. Where the same restriction is attempted through technological means, measures to defeat the technological means of protection in such circumstances should not be regarded as

illegal. Developing countries should think very carefully before joining the WIPO Copyright Treaty and other countries should not follow the lead of the US and the EU by implementing legislation on the lines of the DMCA or the Database Directive."

(Report of the Commission: 109)

CHAPTER 4: END NOTES

[1] Hybridoma cells result from the fusion of a type of cancer cell known as a myeloma with another antibody-producing cell. Hybridomas produce multiple antibodies of a highly specific type, which are called monoclonal antibodies. The technology has considerable potential in both diagnostics and therapeutics.

[2] Genomics refers to the mapping, sequencing and analysis of the full set of genes (i.e. the genome) of different organisms or species. The human genome has always been the most interesting for governments and foundations, as well as for companies seeking to identify commercial applications from genomics.

[3] Correa, C, "From biotech innovation to the market - Economic factors driving developing economies' competitiveness in biotech production", in Meléndez Ortiz, R and Sánchez , V, *Trading in Genes: Development Perspectives on Biotechnology, Trade and Sustainable Development*. London: Earthscan, 2003 (forthcoming).

[4] Barton, J, "Nutrition and Technology Transfer Policies", UNCTAD-ICTSD, 2003 (forthcoming).

[5] See Cornish op cit: 226-227.

[6] See the *Resource Book,* Part 2.5.5, on Article 27.3(b) of TRIPS.

[7] In *Greenpeace v. Plant Genetic Systems*, 1995.

[8] EPO Decision G 01/98 - http://www.european-patent-office.org/dg3/biblio/g980001ex1.htm.

[9] See Bruce, D and Bruce A, "Engineering Genesis - The Ethics of Genetic Engineering in Non-human Species", London: Earthscan, 1998: 223-244. See also Joint Communication from the African Group to the Council for TRIPS of 26 June 2003 (IP/C/W/404), which states: "Patents on life forms are unethical and the TRIPS Agreement should prohibit through modifying the requirements to provide for patents on micro-organisms and on non-biological and microbiological processes for the production of plants or animals. Such patents are contrary to the moral and cultural norms of many societies in Members of WTO."

[10] http://www.derwent.com/ipmatters/2001_01/genetics.html.

[11] See in particular the proposals made by the African Group (WTO document WT/GC/W/202 and IP/C/W/404) and by India (WTO document WT/GC/W/147) with respect to the relationship between the TRIPS Agreement and the CBD. These proposals are presented in the *Resource Book*, Part 2.5.5 (on Article 27.3(b) of TRIPS).

[12] Correa, 2000, op cit: 134.

[13] For example, Barlow, JP, "The economy of ideas: everything you know about intellectual property is wrong", *Wired*, March, 1994.

[14] For example, McManis, CR, "Taking TRIPS on the information superhighway: international intellectual property protection and emerging computer technology", *Villanova Law Review* 41(1), 1996: 207-288; Samuelson, P, "A case study on computer programs", in Wallerstein, MB, Schoen RA and Mogee ME (eds), *Global Dimensions of Intellectual Property Rights in Science and Technology*, Washington, DC: National Academy Press, 1993.

[15] European Commission (2002), "Proposal for a directive of the European Parliament and of the Council on the patentability of computer-implemented inventions" [COM (2002) 92 final].