Biotechnology and Patents: What Can Developing Countries Do About Article 27.3(b)?

By Graham Dutfield

Article 27.3(b) is an enduring subject for trade negotiations and NGO activism on TRIPs. Undoubtedly, this part of TRIPs is extremely important for developing countries. What is less clear is how they can take advantage of its provisions to further their sustainable development objectives. The situation is not helped by disagreement on what the paragraph actually means. In addition, many developing countries find themselves in circumstances that make it difficult to plan for the future and therefore to tailor their regulatory policies to attain specific development goals. So it is hardly surprising that they are still unsure about where their national interests lie with respect to the paragraph's provisions, and have barely implemented any part of it, except by default in the sense of continuing not to allow patents on plants and animals.

In this article I would like to reflect on what Article 27.3(b) means for developing countries and suggest ways to advance the debate over what to do about it.

First, it should be clarified that while TRIPs does not allow WTO members to exclude biotechnological inventions from their patent systems in any explicit sense, Article 27.3(b) allows them to use their discretion in determining the extent to which inventions in this technological field can be protected.

Developing countries need to define their biotechnology policies before a rational IPR system can be developed.

The problem facing developing countries is that if they lack a clear idea of how – and even whether – biotechnology can benefit their economies and improve the lives of their citizens, they are in no position to design an IPR system to promote welfare-enhancing biotechnological innovation. Moreover, many of these countries have no biotechnology industries to speak of, and there is every reason to be highly sceptical that such businesses will spring up just because life-forms and micro- and non-biological processes can be patented.

Biotechnology: good for developing countries?

It is frequently argued – or at least strongly implied – that biotechnology has nothing to offer developing countries. This view tends to be founded upon two convictions: first, that transnationals are aggressively promoting inappropriate and potentially dangerous genetic modification technologies in countries where biosafety regulations are either non-existent or cannot easily be enforced; and second that because GM crops are bad for developing countries, then so is biotechnology. Yet, it is not always clear that actors in international debates on biotechnology interpret the word in the same way. This is important, because it is difficult to see what is wrong with longer-established biotechnologies like beer brewing and bread making, or even tissue culture and plant breeding. Presumably, the critics are referring only to what I would prefer to call 'the new biotechnologies', such as recombinant DNA, monoclonal antibodies, and genomics. But the distinction is not always made clear, and it sometimes seems as if anti- and pro-biotechnology activists are talking past each other because they are applying the word 'biotechnology' differently.

It is not the purpose of this article to recommend that developing countries should learn to love the new biotechnologies or alternatively that they should reject them outright. The appropriate policy response should probably be based on a view somewhere between these two extremes. But until they have come up with an informed decision, a rational and effective IPR system cannot possibly be developed.

Varied capacities

Another reason why it is difficult for developing countries to come up with a common position on the review of Article 27.3(b) is that they vary so much in their national capacities to generate biotechnological inventions.

Policy makers in the more technologically-advanced developing countries who believe that the new biotechnologies can be beneficial should design their IPR system with the goal of encouraging domestic innovation and technology transfer, and attracting funds for start-up firms. Developed country experience suggests that a carefully-designed IPR system could indeed stimulate innovation, although there is a real danger of a carelessly-designed one turning out to be worse than having none at all, for example, by over-protecting upstream research and thereby inhibiting more applied downstream research, or by allowing large companies to control markets, raise prices and distort research priorities. But for many, if not most, other developing countries, it is difficult to see how strong IPR protection will encourage innovation if the capacity to do the necessary research is barely existent anyway.

To define or not to define?

Logically, developing countries should take a TRIPs *de minimis* approach for now, excluding plants and animals, construing 'micro-organism' narrowly, and opting for a *sui generis* alternative to patents for plant varieties. This is not as straightforward as it may seem. These terms are open to different interpretations. The European Patent Office (EPO) considers 'micro-organisms' to include '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.' 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 more restrictive sense if they should consider it advantageous to do so.

To make matters even more complicated, the unclear meaning of 'micro-organism' means that drawing a distinction between micro- and macro-biological processes is hardly straightforward either.

Josef Straus of the influential Max-Planck Institute for Foreign and International Patent, Copyright and Competition Law shows us how much is at stake when he argues that 'if micro-organisms are mandatorily declared subject matter eligible for patent protection, naturally occurring biochemical substances, such as sequences of nucleotides (DNA), *per argumentum a maiore ad minus* are also to be regarded as subject matter, for which WTO Members have to offer product patent protection.'[1] He therefore links the stated obligation to protect micro-organisms to an unstated requirement to extend protection to DNA sequences, as if the latter falls within the scope of the former.

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This link does not seem very logical or for that matter scientific. Nonetheless, *if* we accept that DNA is not 'life' but merely a chemical, then one could make the following interpretation in favour of complementary DNA (cDNA) patenting: cDNA sequences are produced in the laboratory and differ from their naturally-occurring counterparts in that certain sections of the molecule are 'edited out'; therefore, as with any other synthetic chemical, they should be patentable provided they fulfil the criteria of novelty, inventive step and industrial applicability.

Alternatively, one can reasonably be sceptical that the deletion of 'junk DNA' is inventive enough to deserve the reward of a patent, in that a claimed cDNA molecule is likely to be obvious to somebody 'skilled in the art' who knew the sequence of its naturally-occurring equivalent. This is because techniques for isolating and purifying DNA sequences are well-known and no longer require much skill to use. But what if nobody knew about the naturally-occurring equivalent? Such a claim should still arguably fail on the basis of the techniques employed being routine. Nonetheless, several countries do allow 'purified' and 'isolated' DNA sequences to be patented as long as a credible use is disclosed.

Developed countries should refrain from imposing their interpretation of Art. 27.3(b) based on their own jurisprudence or economic interests.

It has also been argued that allowing patents on genes and gene fragments is inadvisable because, for the reasons given earlier, it is likely to raise the cost of doing research. Objections to such patents have also been raised on moral or religious grounds, as have patents on living organisms.

Such objections notwithstanding, the extent of patenting relating to DNA has increased tremendously in the last two decades. According to Giles Stokes of 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'.[2] It is far from easy to know how best to respond to such a phenomenon.

What about plants and plant varieties? It remains an open question 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, it may be useful to see how the 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[3] 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'.[4] Of course, other WTO Members do not have to follow this interpretation.

Another big problem that is often overlooked is the huge task developing country patent offices face in processing large numbers of lengthy and highly technical patent applications. To give some idea of the potential difficulties here, in 2000, the U.S. Patent and Trademark Office received a biotech patent application that was the equivalent of 400,000 pages long! And courts having the knowledge and experience to adjudicate disputes between different patent holders and to determine the appropriate scope of a biotech patent may simply not exist.

What to do?

Developing countries are justifiably concerned that TRIPs furthers the interests of the advanced industrialised countries much more than their own. A good example of the built-in biases of the TRIPs Agreement is that while protection must be extended to high-technology fields such as semiconductors, biotechnology, pharmaceuticals and software, traditional knowledge and folklore are entirely excluded. Developing countries also find themselves pressured to raise their national standards even beyond those of TRIPs through bilateral agreements with the US and the EU, and through threats of trade sanctions. Consequently, they lack confidence in the Agreement to the extent that one can realistically envisage the possibility of a campaign among those countries and NGOs to have TRIPs taken out of the WTO. Therefore, it is in the interests of the developed countries that benefit from TRIPs (or at any rate believe that they do) to heed the concerns of developing countries and respond sympathetically.

Developed countries must give developing countries time to determine how to respond to the challenges and opportunities of the new biotechnologies, even if this means that they delay full implementation of Article 27.3(b) until several years beyond the offical deadlines. It is unreasonable to pressure them to speed up implementation before they feel they are ready to introduce legislation that furthers their long-term interests.

Developed countries should also refrain from imposing their own interpretations of Article 27.3(b) based on their own legislation and jurisprudence, and their own economic interests. As long as developing countries see TRIPs as a legal straightjacket rather than a looser-fitting garment, they are bound to feel not only uncomfortable, but resentful. In the longer term this suits nobody.

As for developing countries, both biotechnology and IPRs are highly controversial subjects that have provoked a heated debate and propaganda, and been the focus of highly-committed advocacy campaigns both in favour and against. This is all the more reason for these countries to be sceptical about much of the advice they get from the developed world on both topics, even when its providers claim to be objective and non-partisan.

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[1] Straus, J. (1998) Biodiversity and intellectual property. *AIPPI Yearbook 1998. XXXVIIth Congress – Rio de Janeiro (May 24-29, 1998) – Workshops I-VII.* International Association for the Protection of Industrial Property, Zurich.
[2] http://www.derwent.com/ipmatters/2001_01/genetics.html.
[3] In Greenpeace v Plant Genetic Systems NV.
[4] EPO Decision G 01/98 – http://www.european-patent-office.org/dg3/biblio/g980001ex1.htm.