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Trade-Related Aspects of Intellectual Property Rights and Biotechnology: European Aspects

John Linarelli
Touro Law Center, jlinarelli@tourolaw.edu

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Trade-Related Aspects of Intellectual Property Rights and Biotechnology: European Aspects

*John Linarelli**

There does not seem to be a widely held view among WTO members of the proper role and scope of TRIPS. One of the main reasons why TRIPS is controversial is because it allocates rights in innovation, some would say beyond the bounds of what a trade agreement should seek to do. The lines of the debate are often conceptualized in terms of 'developing' versus 'developed' country differences. One of the major areas of disagreement is how TRIPS deals with rights in biotechnology. Some developing countries are relatively rich in biodiversity and traditional knowledge but poor in capital and scientific expertise, while some developed countries are headquarters to firms developing this biodiversity and traditional knowledge into commercially exploitable forms of intellectual property. This paper examines how the European Community comes to this debate. It reviews the institutional history of the positions of the European Community and other WTO members during the ministerial conferences succeeding the Uruguay Round. It examines European law relating to biotechnological innovation, in search of European policy coherence on the subject. It also explains the European view of the Convention on Biological Diversity and the European Community's take on how the CBD relates to TRIPS. The European Community position on TRIPS coverage of biotechnological innovation does not depart significantly from the United States position or from the position of the Quad group of countries generally. Given the highly contentious nature of the subject and the sometimes-vociferous developing country opposition to strong intellectual property protection, it is likely that TRIPS and biotechnology will be one of the more hotly contested topics of the Doha Round.

I. INTRODUCTION

Biotechnology has proceeded at a remarkable pace in the latter twentieth century. Technological innovation, in the language of economics, pushes the production frontier outwards, allowing the production of more food, pharmaceuticals and other goods that benefit from biotechnological innovation with the expenditure of the same or fewer resources. But improvement in allocative efficiency is not the whole story. The institutions for allocating rights in technology have to be examined, which include domestic and international laws that set standards for intellectual property protection. Intellectual property rights matter because they affect both efficiency and distribution. From the standpoint of efficiency,

* Associate Professor of Law, University of La Verne College of Law, Ontario, California, USA.

they affect the ability of agricultural production to continue to outpace population growth, the ability of pharmaceutical innovation to deliver effective medicines and the ability of biotechnology generally to improve human well-being. Rights in intellectual property affect the choices that people make to invest or not to invest in biotechnology innovation. With the allocation of rights comes the allocation of rents. The issue of distribution has become contentious, as biological resources that for centuries had no commercial value, and were treated as common resources, now have significant commercial value. What has attracted international attention to distributional concerns is that key biotechnologies seem to concentrate in a few large multinational firms headquartered in North America and Western Europe.

One of the most important international agreements relevant to the allocation of rights in biotechnology is the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).[1] Although an international trade agreement and not a domestic intellectual property law, TRIPS is relevant to the question of ownership of rights in biotechnology. It specifies standards for the intellectual property laws of the WTO members. It is unlike any other trade agreement preceding it, unlike anything produced in the GATT/WTO framework since the GATT's humble beginnings as a provisional agreement to regulate tariffs.[2] TRIPS harmonises intellectual property protection at a high level of protection for rights holders, and this is one of its controversial characteristics. Another is that it shifts the *locus* of international regulation of intellectual property rights to the WTO from other international regulatory regimes, such as the World Intellectual Property Organisation (WIPO), a United Nations organisation, and the International Union for the Protection of New Varieties in Plants.[3]

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1 See WTO/intellectual property (TRIPS) – agreement text – contents, http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm for the TRIPS text.

2 Frederick Abbott, 'TRIPS in Seattle: The Not-So-Surprising Failure and the Future of the TRIPS Agenda', (2000) 18 *Berkeley Journal of International Law* 165; William A Dymond & Michael M Hart, 'Post Modern Trade Policy: Reflections on the Challenges to Multilateral Trade Negotiations After Seattle', (2000) 34 *Journal of World Trade* 21.

3 Carliene Brenner, 'Intellectual Property Rights and Technology Transfer in Developing Country Agriculture: Rhetoric and Reality,' (1998) OECD Technical Papers No 133; Phillip McMalman, 'Reaping What you Sow: An Empirical Analysis of International Patent Harmonization,' (December 1999), econ.ucsc.edu/faculty/mccalman/wkpaper.html; Keith Maskus, 'Lessons from Studying the International Economics of Intellectual Property Rights,' (2000) 53 *Vanderbilt Law Review* 2219.

This paper does not provide a detailed section-by section analysis of TRIPS. A significant literature already exists that does just this.[4] Rather, it examines the intellectual property rights of relevance to biotechnology: patents and *sui generis* rights typically in plant varieties, and how these rights are dealt with in TRIPS. *Sui generis* rights are intellectual property rights, designed for a particular technology, in the agricultural context rights in plant varieties. For plant varieties, the approach of the European Community (EC) member states has been to rely exclusively on a *sui generis* right, a Community plant variety right, to protect intellectual property in new plant varieties, under Council Regulation 2100/94 on Community Plant Variety Rights, which implements the International Convention for the Protection of New Varieties of Plants (UPOV Convention).[5] The EC member states appear to be moving towards a dual system of rights in plant varieties. In the European patent system, established under the European Patent Convention, which includes the fifteen EC member states and five other states and is separate from the EC, the scope of patent protection has broadened to include genetic transformations of plants that may include plant varieties in the scope of the patent. The US approach has been to permit multiple forms of protection of rights in plant varieties. In the US, three kinds of intellectual property rights are available for plant varieties: (i) patents under general patent law, available to all inventions meeting patentability criteria, also known as utility patents; (ii) plant patents under the Plant Protection Act 1930, available for asexually reproducing plants (hybrids); and (iii) plant breeders' rights (PBRs) under the Plant Variety Protection Act 1970, available for sexually reproducing plants, which implements the UPOV Convention in the US.[6] For inventions in biotechnology generally, other than plant varieties, the conventional patent system is available in both the EC member states and the US, provided the invention meets general patentability criteria and criteria particular to biotechnology. Criteria particular to biotechnology, regardless of whether the subject matter is plants, animals or humans, exists in the EC's Council Directive 98/44/EC on the Legal Protection of Biotechnological Inventions.[7]

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4 See *eg,* Michael Blakeney, *Trade Related Aspects of Intellectual Property Rights* (Sweet & Maxwell 1996); Carlos Correa & Abdulqawi Yusuf (eds), *Intellectual Property and International Trade* (Kluwer Law International 1998).

5 For the Regulation, see http://europa.eu.int/eur-lex/en/lif/dat/1994/en_394R2100.html. For the Convention, see http://www.upov.int/eng/convntns.

6 Neil D Hamilton, 'Who Owns Dinner: Evolving Legal Mechanisms for Ownership of Plant and Genetic Resources,' (1993) 28 *Tulsa Law Journal* 587.

7 The EC member states were required to implement the Directive by 30 July 2000.

While the focus on patents and *sui generis* protection is a reasonable limitation at present, it may not continue to be so in the future. Biotechnology innovation in bioinformatics databases will make copyright an important concern in the biotechnology sector. Trade secret laws are important to the extent that the biotechnology sector uses these laws to protect innovative ideas that they wish to keep confidential. Trademarks are important too, as companies begin to market products derived from biotechnological innovation. Examples are Monsanto's Roundup Ready®, Aventis's Liberty® and Libertylink technologies.®[8] Geographic indications are also of increasing relevance in identifying the source of genetic material in patents involving biotechnology, although it is unclear what sorts of positive rights, if any, result from such identification. Patents and *sui generis* protection remain the core methods of protecting technological innovation, however, and thus the focus of this chapter.[9]

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8 Eren Birenbaum, Carol Nottenburg, Philip G Pardey, Brian D Wright & Patricia Zambrano, *North South Trade, Intellectual Property Jurisdictions, and Freedom to Operate in Agricultural Research on Stable Crops, International Food Policy Research Institute: EPTD Discussion Paper No 70* 11 (2000).

9 This paper does not deal with TRIPS Articles that give concessions to developing countries in their provision of patent protection to agricultural and pharmaceutical chemicals. According to TRIPS Art 65.4, developing countries that do not provide patent protection for agricultural and pharmaceutical chemicals must do so as of 2005. TRIPS Art 70.8 makes special provision for WTO members who did not provide patent protection for agricultural and pharmaceutical chemicals as of 1 Jan 1995, the date of entry into force of TRIPS. Developing countries that take advantage of this provision are required to set up an interim system to permit applicants to file patent claims on agricultural and pharmaceutical chemical products, with novelty to be determined as of the date of filing. This is the so-called 'mailbox' rule. WTO members that use this interim system must give patent holders exclusive marketing rights for five years after the product obtains marketing approval, or until the patent is granted or rejected, which period is shorter. The TRIPS Art 70 provisions were the first TRIPS provisions to be the subject of a WTO dispute settlement proceeding. In 1997, the US won a WTO dispute settlement case against India involving the mailbox rule. The US successfully argued that India failed to maintain a mailbox mechanism in accordance with TRIPS Art 70.8. The panel rejected India's argument that an informal and unpublished administrative system of receiving applications complied with TRIPS Art 70: Report of the WTO Panel, India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/R; Report of the Appellate Body, India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, AB-1997-5, WT/DS50/AB/R. The Appellate Body upheld the ruling but reversed it to the extent that it applied the transparency requirements of TRIPS Art 63, reasoning that those provisions were not in the panel's terms of reference. The EC brought essentially the same dispute before the WTO. In the EC case, the panel ruled that India violated TRIPS Art 70.8 because it failed to publish the requirements of its mailbox system and violated TRIPS Art 70.9 because it failed

This paper is in two parts, excluding the introduction and the conclusion. Part II explains the provisions of TRIPS relevant to biotechnology. The important TRIPS provision for biotechnology is Article 27, dealing with patentability, and in particular, Article 27.3(b). Part II will analyse the obligations set forth in Article 27.3(b). It will also explore the controversy surrounding Article 27.3(b), as it surfaced in the aftermath of the Uruguay Round, in the WTO TRIPS Council, in the Seattle Ministerial Conference and thereafter. Throughout Part II, EC policy will be identified and discussed. Part III will furnish a European policy context for TRIPS, focusing on substantive obligations of the EC and its member states relevant to TRIPS. The EC and its member states are parties to the UN Convention on Biological Diversity. Further, a number of European laws exist that determine the content of intellectual property rights available in Europe. Several international agreements and undertakings, to which the EC and its member states are parties, and EC laws, are relevant to TRIPS. Part III will address the European Patent Convention, the UPOV Convention, the EC Biotechnology Directive and the EC Regulation on Plant Varieties.

II. TRIPS AND BIOTECHNOLOGY

A. *TRIPS Provisions Relevant to Biotechnology*

TRIPS was negotiated as part of the Uruguay Round and it was thus negotiated from 1986 to mid-1994. It is one of the most important developments in the GATT/WTO regime. TRIPS has been described as 'the most ambitious international intellectual property convention ever attempted' and as 'the most comprehensive multilateral agreement on intellectual property.'[10] It would not be an exaggeration to say that in the Uruguay Round, multilateral co-operation in the GATT/WTO regime on intellectual property matters transformed from a casual indifference to an intense preference for rigorous standards. TRIPS does much more than impose the traditional GATT/WTO obligations of most-favoured-nation and national treatment. It is the first international trade agreement to specify minimum standards of protection and

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to promulgate legislation granting exclusive marketing rights: Report of the WTO Panel, India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS79/R. India did not appeal the panel decision issued in the EC case.

10 JH Reichman, 'Compliance with the TRIPS Agreement: Introduction to a Scholarly Debate,' (1996) 29 *Vanderbilt Journal of Transnational Law* 29; Adrian Otten & Hannu Wager, 'Compliance with TRIPS: An Emerging World View', (1996) 29 *Vanderbilt Journal of Transnational Law* 391.

universal coverage of intellectual property rights. It imposes positive obligations on WTO members to protect seven categories of intellectual property.[11] The standards in TRIPS reflect the high standards of intellectual property protection typically found in the intellectual property laws of developed countries. Developing countries must meet the same standards as developed countries, although under the transition provisions of the Agreement, they have more time in which to achieve compliance with the Agreement.[12]

Rights in biotechnology were on the TRIPS negotiating agenda in the Uruguay Round. TRIPS includes provisions on the patentability of rights in biotechnology, and on establishing *sui generis* rights in biotechnology. The key TRIPS provision relevant to intellectual property rights in biotechnology is Article 27, entitled 'Patentable Subject Matter'. Article 27 provides that patents 'shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application.'[13] WTO members must make patents available in their territories 'without discrimination ... as to the field of technology.'[14] Three exceptions exist to this 'any technology' standard for patentability. Article 27.2 provides that WTO members may exclude from patentability inventions, 'the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.'[15] Article 27.3 provides that members may exclude from patentability (a) 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' and (b) '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.'[16] Further, under subparagraph (b), WTO members may provide for the protection of plant varieties either by patents, or by an 'effective *sui generis* system' or by a combination of the two methods.[17]

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11 Reichman, *supra* note 10.

12 Developed countries had until 1 Jan 1996 to achieve compliance, developing countries until 1 Jan 2000, and least developed countries have until 1 Jan 2006. TRIPS Art 65.

13 TRIPS Art 27.1.

14 TRIPS Art 27.1.

15 TRIPS Art 27.2.

16 TRIPS Art 27.3.

17 TRIPS Art 27.3(b).

To sum up what TRIPS Article 27.3 provides on patenting of rights in biotechnology, WTO members do not have to put in place a patent system that permits the patenting of plants and animals. WTO members must, however, provide patent protection to inventions relating to micro-organisms and non-biological and microbiological processes which could lead to the production of plants and animals. Finally, for plant varieties, WTO members may in their discretion grant *sui generis* protection, patent protection, or both.

One of the basic distinctions between *sui generis* protection and patents is that *sui generis* rights tend to be subject to a farmers' exemption and a research exemption. TRIPS does not explicitly permit either exemption. Such exemptions would arguably fall, at least implicitly, within the *sui generis* category of protection permitted under Article 27.3(b). In addition, TRIPS Article 30 provides that '[m]embers may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.'[18] Thus, Article 30 could be interpreted to permit such exemptions even for patented seeds and plants.[19]

Article 27 reflects a compromise between the approaches that Europe and America traditionally have taken on intellectual property rights in biotechnology. The original US text of TRIPS did not include the exceptions found in Articles 27.3 and 27.2, and opted only for patents for the protection of plant varieties.[20] Article 27 was negotiated in the Uruguay Round to substantially adopt the wording of Article 53(b) of the European Patent Convention, which provides:

> European patents shall not be granted in respect of:
>
> (a) inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
>
> (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.[21]

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18 TRIPS Art 30.

19 For discussion of these and other issues, see the Plant Intellectual Property web site at the University of Sheffield, http://www.shef.ac.uk/~pip/.

20 Hamilton, *supra* note 6.

21 European Patent Convention Art 53(b). The Convention, the official name of which is the Convention on the Grant of European Patents, can be found at http://www.european-patent-office.org/legal/epc.

Notably, Convention Article 53(b) uses the term 'shall' when referring to exclusions from patentability, but TRIPS Article 27 uses the term 'may.' The Convention excludes from eligibility for European patents rights in plant and animal varieties, and 'essentially biological processes' for plant and animal production, but leaves the door open for rights in microbiological processes. By contrast, Article 27 leaves the policy choice to WTO members to use patents, *sui generis* rights, or both, to protect rights in plants and animal varieties. WTO members, in addition, *may* exclude from patentability 'essentially biological processes' for plant and animal production, but not for the production of micro-organisms, or rights in non-biological and microbiological processes. TRIPS and the European Patent Convention are consistent with each other. The European Patent Convention will be discussed in more detail in Part II below.

Article 27.3(b) is controversial. The controversy is between the so-called 'Quad' group of WTO members – Canada, the EC, Japan and the US – and the developing countries. Article 27, and TRIPS generally, provides a strategic bargaining problem to WTO members as to which members, or the industries and communities they represent, capture the appropriable rents from intellectual property. The interests of the EC and the US, technology exporters, are in protecting the interests of powerful lobbying groups with influence in the political process, namely firms that produce biotechnological innovation, which have an interest in strong intellectual property laws. Representatives of these industries were involved in the preparation of the language currently found in Article 27. The clash with developing country interests is stark. Developing countries traditionally have been importers of innovation. With the growth of biotechnology, there is a growing perception that developing countries are exporters of biological resources and traditional knowledge, but without adequate recognition in the WTO agreements. Some TRIPS negotiators for developing countries, and advocates of developing country interests, contend that TRIPS fails to deal with these issues. They claim either that TRIPS should declare such resources as common heritage and incompatible with a private intellectual property rights regime, or that TRIPS should recognise or accommodate traditional knowledge as valuable by granting some sort of rights, as yet undefined, of excludability.

What makes biotechnological innovation all the more controversial is that it sometimes has origins in property held in common and found in developing countries. As a result of advances in science and technology, seeds and plants that were once of value only to isolated communities in the developing world now have significant commercial value in transnational markets. The result, predictably, are claims of

'bioprospecting' and worse, 'biopiracy', as interested parties seek to obtain private property rights in the biodiversity commons. For example, the US Patent and Trademark Office (PTO) granted and subsequently canceled a patent for an invention based on the pharmacological properties of the ayahuasca vine, a plant found in the Amazon rain forest. The PTO based its cancellation on the fact that publications describing the pharmacological aspects of the ayahuasca vine were known and available prior to the filing of the patent application. US patent law denies patentability to inventions described in printed publications more than one year prior to the date of the patent application. The pharmacological properties of the ayahuasca vine have been known for centuries and are part of the traditional knowledge of indigenous communities in Brazil. Patents have been claimed on inventions relating to turmeric, karela and the neem tree, plants found in India. The European Patent Office (EPO) has revoked a patent granted jointly to WR Grace and the US Department of Agriculture for an insecticide and fungicide derived from the seed of the neem tree. The EPO revoked the patent on grounds similar to those that the US PTO used to cancel the patent on the invention relating to the ayahuasca vine. The EPO ruled that the patent claims were not novel and there was prior public use.

As a result of the divergence of interests between the North and the South, many developing countries opposed the inclusion of Article 27.3(b) in TRIPS. In addition, they resist the implementation of the provision. As will be explained below, one of the major points of contention in any future WTO negotiating round will be whether the substantive obligations in TRIPS should be reopened or whether the focus should be on the 'built in agenda'. The concept of the built-in agenda focuses attention on implementation, not renegotiation. Predictably, the US and to some extent the EC favour a focus on implementation and the built-in agenda, whilst the developing countries favour a focus on TRIPS obligations.

B. *The Built-In Agenda: Effects On Article 27.3(b)*

Article 27.3(b) provides that 'the provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.'[22] TRIPS entered into force on 1 January 1995, which means that the provisions on patentability of biotechnology were to be reviewed in 1999, as part of the WTO's so-called built-in agenda. In addition,

22 TRIPS Art 27.3(b).

TRIPS by its terms required a review of its implementation in 2000.[23] Developing countries, moreover, were required to bring their domestic laws into compliance with TRIPS on or before 1 January 2000, and least developed countries have until 2006. All WTO members, however, were required to bring their existing laws into compliance with the TRIPS most-favoured-nation and national treatment provisions by 1 January 1996.[24] The review of Article 27.b(3) was thus to take place one year before developing countries were required to implement it, and the review of TRIPs generally was to occur in the same year that developing countries were required to implement it.

Tracing the progress of the built-in agenda under these provisions brings home the distinction well known by lawyers between the words of the contract and the actual conduct of the parties in performing it. Article 27.3(b) has been under scrutiny at least since December 1998, when the TRIPS Council initiated an information gathering exercise on how WTO members were implementing the provisions.[25] In the TRIPS Council meeting in December 1998, the developed countries wanted to focus on implementation whilst the developing countries wanted to focus on substance. Developing country representatives argued that the language of Article 27.3(b) supported their position because it says that *'the provisions'* of Article 27.3(b) were to be reviewed four years after the date of TRIPS' entry into force.[26] The TRIPS Council decided that the WTO Secretariat would collect information about implementation from WTO members, in response to a questionnaire the Council would furnish.[27]

Throughout 1999, WTO member responses to the questionnaire trickled in to the TRIPS Council. WTO members, including the EC, submitted responses to questionnaires that the TRIPS Council circulated, and these responses were collated and available for general circulation. Not all WTO members responded. As of April 1999, only thirty countries had submitted information on implementation.

In summer 1999, preparations started to take on some seriousness for the WTO's Third Ministerial Conference, to be held in Seattle. It was widely contemplated that Seattle would result in the launching of a new WTO negotiating round, the so-called Millennium Round. Developing countries expressed more of an interest in the preparations

23 TRIPS Art 71.
24 TRIPS Art 65.2.
25 WTO Document IP/C/W/175.
26 *Ibid.*
27 *Ibid.*

for Seattle than in the TRIPS Council assessment of implementation. About 100 developing countries agreed to almost a dozen proposals, to be tabled in Seattle, to reform TRIPS. The gist of these proposals was that TRIPS failed to deal adequately with biodiversity and traditional knowledge. Perhaps the most influential of these proposals was that of the Africa Group, which Kenya led, submitted to the WTO General Council on 6 August 1999.[28] This submission proposed to extend the deadline to implement Article 27.3(b) in the developing countries, to ban patents on 'life', including those on microbiological organisms, and sought clarification of some of the TRIPS provisions.

Throughout late summer and autumn 1999, discussions continued in the TRIPS Council, with, as the developing countries sought initially, a focus on the substance of TRIPS rather than on its implementation. The US and the EC responded. They agreed that granting intellectual property rights in biotechnology was vital to providing proper incentives to innovate, and that the UPOV Convention provided an acceptable *sui generis* system for protecting rights in plant varieties. The EC urged all WTO members to promulgate laws that complied with the UPOV Convention. The EC was prepared to address the ethics of biotechnology patenting and to consider the sorts of protection traditional knowledge might require.[29]

The Seattle Ministerial Conference took place in late November – early December 1999. The differences in the positions of the WTO members at the Conference were significant. In Seattle, the United States did not offer a proposal on TRIPS. Instead, the US wanted to work on the built-in agenda, primarily to get developing country members to meet existing obligations when TRIPS transition periods expire.[30] The EC focused substantially on trying to convince the US to adopt a 'first to file' system for patents. The US alone uses a 'first-to-invent' system, while virtually the rest of the world uses first to file.[31] The EC was in substantial agreement with the US on the need for compliance with the TRIPS built-in agenda. The EC position was that a new round would offer an opportunity to examine areas of TRIPS for possible amendment, but by the time a new round came into operation, the transition periods for developing country implementation of TRIPS would have expired.[32] The EC Communication to the WTO General

28 WTO Document WT/GC/W/302.
29 WTO Document WT/GC/W/193.
30 Abbott, *supra* note 2; WTO Document JOB(99)/4797/Rev 3.
31 Abbott, *supra* note 2.
32 WTO Document WT/GC/W/193; WTO Document JOB(99)/4797/Rev 3.

Council on TRIPS states, among other things, that '[i]t should of course be kept in mind that the TRIPS *acquis* is a basis from which to seek further improvements in the protection of IPR. There should therefore be no question, in future negotiations, of lowering of standards or granting of further transitional periods.'[33] Contrast these positions with those of the developing countries in Seattle. The Africa Group, led by Kenya, reiterated that Article 27.3(b) by its terms provides for a review of its provisions, and that implementation is covered under TRIPS Article 71.1. Here is a summary by the WTO Secretariat of the position of the Africa Group on the problems with Article 27.3(b):

> Artificial distinctions between biological and microbiological organisms and processes:
>
> (a) The review of the substantive provisions of Article 27.3(b) should clarify the following:
>
> - Why the option of exclusion of patentability of plants and animals does not extend to micro-organisms as there is no scientific basis for the distinction.
> - Why the option of exclusion of patentability of 'essentially biological processes' does not extend to 'microbiological processes' as the latter are also biological processes.
>
> (b) The review process should clarify that plants and animals as well as microorganisms and all other living organisms and their parts cannot be patented, and that natural processes that produce plants, animals and other living organisms should also not be patentable.
>
> Clarifying the option of a *sui generis* system for plant varieties: After the sentence on plant variety protection in Article 27.3(b), a footnote should be inserted stating that any *sui generis* law for plant variety protection can provide for:
>
> (i) the protection of the innovations of indigenous and local farming communities in developing countries, consistent with the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources;
>
> (ii) the continuation of the traditional farming practices including the right to save, exchange and save seeds, and sell their harvest;
>
> (iii) preventing anti-competitive rights or practices which will threaten food sovereignty of people in developing countries, as is permitted by Article 31 of the TRIPS Agreement.
>
> Relation between Article 27.3(b) and CBD and the International Undertaking on Plant Genetic Resources: The review process should seek to harmonize Article 27.3(b) with the provisions of the CBD and the International

33 WTO Document WT/GC/W/193.

> Undertaking, in which the conservation and sustainable use of biological diversity, the protection of the rights and knowledge of indigenous and local communities, and the promotion of farmers' rights, are fully taken into account.[34]

WTO members not in the Africa Group, particularly those from Latin America, shared the concerns of the Africa Group. The US and the EC both offered various 'trade-off' initiatives to assist developing countries in building institutional capacity and improving governance structures to implement TRIPS, but these did not go to the core of what the developing countries wanted, which was a major revision of the substantive obligations in TRIPS.

The result of Seattle was that the WTO members took no significant decisions on TRIPS. Towards the conclusion of the Conference, the US Trade Representative (the Chairperson of the Seattle Ministerial Conference) and the WTO Director General both declared the Conference to be 'suspended', although the import of such language and its effects on the Seattle proposals is unclear.

Post Seattle, the Quad countries held various meetings about the future of a new WTO round. In various statements to the press, the EC has strongly supported the idea of a comprehensive new round. A good segment of the post-Seattle discussions have focused on 'confidence building' measures intended for least developed countries. In March 2000, the Quad countries proposed a plan to improve the confidence of the least developed countries. The plan included four elements: 1) zero tariffs and zero quota access to developed country markets; 2) mechanisms for addressing the implementation problems of developing countries; 3) enhanced technical assistance for least developed countries, and 4) increased transparency in WTO decision making. As part of the package, extensions requested of TRIPS implementation deadlines would be considered on a country specific basis. The WTO Director General expressed disappointment in the package, contending it did not go far enough, and it is unclear what the result of this exercise was. In June 2000, however, the momentum seemed to be in favour of focusing on implementation issues. In the 22 June 2000 meeting of the WTO General Council, a programme of meetings on implementation was agreed with the goal of concluding discussions before the next ministerial conference, to be held in 2001. The developing countries again balked, contending that they faced considerable institutional and financial problems in achieving compliance with existing WTO obligations. These battles continued through 2000.

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34 WTO Document JOB(99)/4797/Rev 3.

In a 27 November – 1 December 2000 meeting of the TRIPS Council, Brazil and India renewed efforts to seek a review of TRIPS to avoid conflict with the Convention on Biological Diversity. The Brazilian and Indian efforts represent an attempt at a major refocus on substantive policy and legal obligations. Brazil's Communication to the General Council is telling. It includes as issues to be considered technical issues relating to patent protection under Article 27.3(b) and *sui generis* protection of plant varieties, ethical issues relating to patentability of life forms, the relationship between conservation and sustainable use of genetic material and the relevance of traditional knowledge and farmers' rights.[35]

As of 16 March 2001, the WTO Chair of the General Council declared the discussions over TRIPS with developing countries to be stalled. There was a 27 March 2001 meeting, attended by delegates of 20 WTO members, including delegates from the EC, Japan and Canada. The US did not participate. From the press reports of this meeting, the EC and Japan said that they would take a harder line on implementation at the upcoming Ministerial Conference in Doha, Qatar and in any future negotiating round. The distinction made at the meeting was between countries that want to implement but cannot because of a lack of institutional capacity and those who want a different obligation. The former problem is one of 'capacity building' whilst the latter is one of 'negotiation'. Negotiation, or more properly, renegotiation, entails a change in a treaty obligation and possibly also in domestic implementing legislation. The EC and Japanese delegates took a legalistic position to the effect that the developing country delegates knew or should have known what they were agreeing to in the Uruguay Round.

The frictions between the Quad group of countries and developing countries continued in the Doha Ministerial Conference in November 2001. The Quad group of developed countries, particularly the US, sought to focus the Conference on implementation but also wanted some movement in the Conference, so as to avoid the label 'failure' that has been so persistently affixed to the Seattle Ministerial Conference. The implementation question was one of the most difficult of the Conference, bordering on intractable. The actual negotiating positions of the EC and the other Quad members did not offer substantial revisions of TRIPS obligations. The positions of the Quad versus the developing countries stood in stark contrast for most of the Conference. The Declaration of the African, Caribbean and Pacific (ACP) countries on the Conference, submitted by Kenya to the WTO before the Conference, provided in pertinent part as follows:

35 WTO Document IP/C/W/228.

> 31. We ... reaffirm that [WTO] members should develop mechanisms to allow for the disclosure of the sources of traditional knowledge and genetic resources used in inventions in order to achieve a fair and equitable sharing of benefits. The TRIPS Agreement should be supportive of, and not run counter to, the objectives of the [Convention on Biological Diversity]
>
> 32. We urge that the review of the TRIPS Agreement should clarify that all living organisms including plants, animals, and part of plants and animals, including gene sequencing and biological and other natural processes for the production of plants and animals and their parts shall not be patented.[36]

India took the lead in stridently opposing the TRIPS built-in agenda. The Indian Minister of Commerce and Industry, in a fourth session of the Doha Conference explained that while '[a]fter the setback at Seattle, all of us want Doha to be a success', but warned that '[w]e cannot be held hostage to unreasonable demands that concessions be made for carrying forward what are already mandated negotiations.'[37] The Indian position is that there 'should ... be no misappropriation of the biological and genetic resources and traditional knowledge of the developing countries.'[38]

It is difficult to say whether Doha produced any concrete agreement on the way forward on TRIPS and biotechnology. The two relevant provisions of the Doha Ministerial Declaration are the following:

> 12. We attach the utmost importance to the implementation-related issues and concerns raised by Members and are determined to find appropriate solutions to them. In this connection, and having regard to the General Council Decisions of 3 May and 15 December 2000, we further adopt the Decision on Implementation-Related Issues and Concerns in document WT/MIN(01)/W/10 to address a number of implementation problems faced by Members. We agree that negotiations on outstanding implementation issues shall be an integral part of the Work Programme we are establishing, and that agreements reached at an early stage in these negotiations shall be treated in accordance with the provisions of paragraph 47 below. In this regard, we shall proceed as follows: (a) where we provide a specific negotiating mandate in this Declaration, the relevant implementation issues shall be addressed under that mandate; (b) the other outstanding implementation issues shall be addressed as a matter of priority by the relevant WTO bodies, which shall report to the Trade Negotiations Committee, established under paragraph 46 below, by the end of 2002 for appropriate action.

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36 ACP Declaration on the Fourth Ministerial Conference, Communication from Kenya, Document No WT/L/430, 9 Nov 2001.

37 Statement by the Honourable Murasoli Maran, Minister of Commerce and Industry for India, Document No WT/MIN(01)/ST/10, 10 Nov 2001.

38 *Ibid.*

> 19. We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.

Paragraph 12 seems wholly concerned with implementation of existing WTO obligations, including TRIPS. Paragraph 19 seems more directly on point in the dichotomy between developed and developing country interests in how TRIPS should or should not regulate biotechnological innovation. Paragraph 19 directs a review of Article 27.3(b) in the context of Article 71.1. Article 71.1 has to do with the review of transitional periods for developing countries to comply with TRIPS, since they had longer periods of time in which to achieve compliance with the TRIPS obligations, and hence paragraph 19 focuses the work of the TRIPS Council on the built-in agenda and implementation. Article 71.1 provides, however, that the TRIPS Council 'may ... undertake reviews in the light of any relevant new developments which might warrant modification or amendment' of the TRIPS Agreement. Moreover, paragraph 19 of the Ministerial Declaration refers the TRIPS Council to TRIPS Agreement Articles 7 and 8. TRIPS Article 7 provides that '[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'. TRIPS Article 8 provides that WTO members may adopt measures necessary 'to promote the public interest in sectors of vital importance to their socio-economic and technological development' and that 'may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology', provided that such measures are consistent with the provisions of the TRIPS Agreement. It remains to be seen whether the Quad and the developing countries will reach a suitable compromise in any future work emanating from the Doha Round. The Round seems merely to have put matters off for the time being.

III. In Search of EC Policy Coherence on TRIPS

What are the various substantive obligations affecting the position that the EC might take in the new WTO negotiating round? I analyse European laws and international legal obligations to understand the substantive constraints on EC policy making. The EC needs to ensure that its TRIPS obligations are consistent with a host of other obligations. These obligations can be found in various international conventions, such as the UPOV Convention, and perhaps secondarily, the Convention on Biological Diversity, in regional conventions such as the European Patent Convention, and in EC law, such as the EC Biotechnology Directive and the EC Regulation on Plant Varieties.

A. *The Convention on Biological Diversity*

The United Nations Framework Convention on Biological Diversity (CBD), concluded on 5 June 1992 at the Rio de Janeiro Earth Summit, states its three main objectives as: (i) the conservation of biological diversity; (ii) the sustainable use of the components of biological diversity; and (iii) the fair and equitable sharing of benefits arising from the use of genetic resources.[39] Genetic resources are 'genetic material of actual or potential value.'[40]

The CBD is not a regional EC instrument. It is a multilateral convention. As of the writing of this paper, 180 parties have ratified the CBD. The EC and all of its member states are parties to the CBD. President Clinton signed the Convention, but the US has not ratified it. President Clinton submitted the Convention to the US Senate as is required under the US Constitution, but the Senate has not consented to it. Unlike the US, the EC is actively involved in the CBD Conference of the Parties. The Spanish and Scandinavian governments are perhaps the most actively involved European states in the Conference of the Parties, with the Scandinavian governments taking roles supportive of the concerns that developing countries express about access to biodiversity within their borders.[41]

The relationship between TRIPS and the CBD has been the subject of substantial debate, both in the WTO, in its TRIPS Council, and outside

39 CBD Art 1. The Convention on Biological Diversity can be found at http://www.biodiv.org/convention/articles.asp

40 CBD Art 2.

41 CEAS Consultants (Wye) Ltd, Centre for European Agricultural Studies & Geoff Tansey; Queen Mary Intellectual Property Research Institute, 'Study on the Relationship Between the Agreement on TRIPS and Biodiversity Related Issues, Final Report for DG Trade European Commission'.

of the WTO. Some countries, particularly developing countries, assert that TRIPS and the CBD are incompatible, and that the WTO members should amend TRIPS, particularly Article 27.3(b), to conform it to a CBD-like pattern of international obligation. In particular, some developing countries have argued that TRIPS should require authorisation for access to genetic resources within the territory of a WTO member, prior informed consent for use of genetic resources in inventions, sharing of the benefits of inventions associated with genetic resources. The WTO examined the relationship of the CBD and TRIPS on at least two occasions, in June 1995 and May 2000.[42] Not much came out of these exercises other than general conclusions of the need for further study. The EC has been involved in the debate, and tends to take the position that developing countries should air their concerns, but that implementation of existing TRIPS obligations should be the major focus of the WTO outside of any new round.[43]

Given the debate about whether TRIPS and the CBD conflict, are there any relevant treaty provisions that inform this debate? CBD Articles 15 and 16 are the key provisions relevant to intellectual property rights. Article 15 deals with access to genetic resources and Article 16 with transfer of technology. The primary obligations of countries rich in biodiversity, such as developing countries, are to provide access, and Article 15 identifies the characteristics of the laws and institutions to regulate such access. For those countries whose persons obtain access, Article 16 identifies the characteristics of the laws and institutions to regulate the transfer of technological innovation to the countries from which the genetic resources are obtained.[44]

The CBD takes a state-oriented, centralist approach to controlling access to genetic resources. States have 'the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.'[45] CBD Article 15 implements. As CBD Article 15.1 states, '[r]ecognizing the sovereign rights of States over their natural resources, the authority to determine

42 'Environment and TRIPS', WTO Document WT/CTE/W/8; 'The Relationship between the CBD and TRIPS; With a Focus on Art 27.3(b)', WTO Document IP/C/W/175.

43 Communication by the European Communities and their Member States on the Relationship Between the CBD and TRIPS, 3 Apr 2001.

44 Charles R McManis, 'The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology', (1998) 76 *Washington University Law Quarterly* 255.

45 CBD Art 3.

access to genetic resources rests with the national governments and is subject to national legislation.'[46] CBD Article 15.4 provides that '[a]ccess, where granted, shall be on mutually agreed terms and subject to the provisions of this Article' and Article 15.5 provides that '[a]ccess to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.'[47]

Various provisions of the CBD are concerned with the fair and equitable sharing of the benefits of genetic resources and the results of research and development relating to genetic resources, but provide few if any details on how to achieve such benefit sharing. Article 15.6 requires contracting parties to 'endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.'[48] Article 15.7 requires contracting parties to share in a fair and equitable way 'the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.'[49] Article 19 concerns the sharing of benefits and is to be read in conjunction with Article 15. Article 19.1 requires CBD contracting parties to 'take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.'[50] Article 19.2 requires contracting parties to 'take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.'[51]

In addition to the sharing of the benefits of research and development in genetic resources, the CBD contains various obligations governing the transfer of technologies that result from such research and development. Article 16.2 provides that the transfer of technology to developing countries 'shall be provided and/or facilitated under fair

46 CBD Art 15.1.
47 CBD Art 15.5.
48 CBD Art 15.7.
49 CBD Art 19.1.
50 CBD Art 16.3.
51 CBD Art 19.2.

and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21.'[52] Article 20 obligates developed countries to provide financial resources to developing countries to enable the developing countries to comply with the CBD. Article 21 requires the creation of a 'financial mechanism', which the CBD Conference of the Parties is to manage, to dispense these financial resources. Finally, contracting parties are required to 'take legislative, administrative or policy measures with the aim that the private sector facilitates access to, joint development and transfer of technology ... for the benefit of both governmental institutions and the private sector of developing countries ....'[53]

The CBD deals explicitly with intellectual property rights in three potentially conflicting provisions. According to CBD Article 16.5, '[t]he Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate ... subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.'[54] Under CBD Article 16.2, access to and transfer of technology to developing countries 'shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights.'[55] CBD Article 16.3 requires contracting parties to 'take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries which provide genetic resources, are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights where necessary, ... and consistent with paragraphs 4 and 5 ....'[56] These provisions are ambiguous as to whether the intellectual property rights will have to be altered to accommodate the transfer of technology to developing countries under the Convention.

Traditional knowledge is not a legally recognised form of intellectual property in its own right, at least not yet. CBD Article 8(j) sets forth a provision on traditional knowledge. It provides that CBD contracting parties 'shall, as far as possible and appropriate' and subject to national legislation:

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52 CBD Art 16.2.
53 CBD Art 21.
54 CBD Art 16.5.
55 CBD Art 16.2.
56 CBD Art 16.3.

> respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;[57]

Further, CBD Article 10(c) provides that contracting parties shall, as far as possible and appropriate, '[p]rotect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements.'[58]

The above CBD provisions are sufficiently general so as to be interpreted either as consistent or inconsistent with TRIPS. The EC and its member states have advocated various positions, typically asserting that TRIPS and the CBD are consistent with each other. The most recent submission of the EC and the member states to the TRIPS Council was on 3 April 2001, which states the proposition 'that, from a legal perspective, the CBD and the TRIPS Agreement do not conflict with each other. They have diff erent objectives, they do not deal with the same subject matter and they are of a different legal nature.'[59] The key to understanding this position is the emphasis on 'legal'. The EC position seems to be that if one were to examine TRIPS and CBD solely by their legal language, there is no conflict. The treaties do not refer to each other, nor do they deal with the same subject matter, and 'there is nothing in the provisions of either agreement that would prevent a state from fulfilling its obligations under both treaties.'[60] The Communication explains, '[i]n themselves, the provisions of the TRIPS Agreement appear neutral in terms of their impact on the objectives of the CBD.'[61]

The EC's position seems to be that, although no legal conflict exists between TRIPS and the CBD, the potential for policy conflict exists, or, in the carefully-crafted words of the EC Communication to the TRIPS Council, 'despite their difference in coverage there is considerable *interaction* between the rights referred to in the TRIPS Agreement and the subject matter of the CBD.'[62] This dichotomy between the legal

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57 CBD Art 8(j).

58 CBD Art 10(c).

59 Communication by the European Communities and their Member States on the Relationship Between the CBD and TRIPS, 3 Apr 2001.

60 *Ibid.*

61 *Ibid.*

62 *Ibid.*

and policy characteristics of the two treaties has its apparent origins in a study performed by the Centre for European Agricultural Studies, Wye College, University of London, on the EC's behalf.[63] The EC approach is to deflect concern about conflict between the two treaties by interpreting and implementing the two treaties so that they are consistent with each other. This approach finds support in the text of the CBD, where it provides that its provisions 'shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.'[64]

The EC's position is neither surprising nor controversial. The EC and its member states benefit from a 'conservative' reading of the CBD. Some European countries benefit from TRIPS in its current form because they can appropriate the rents of innovation through strong intellectual property protection at the international level.[65] Even EC member states that lose in the rent transfer could reasonably perceive dynamic benefits from a strong TRIPS, in that the benefits of TRIPS are seen as accruing to those countries over time, as their technology sectors benefit from intellectual property protection over time. The EC and its member states benefit from ratifying the CBD as well, as it enables them to signal their commitment to the protection of biodiversity and the environment without having to change national or European legislation in a significant way, since 'the provisions of the CBD tend to create obligations of a general kind.'[66] It has been argued that the CBD is a framework agreement, setting forth terms that are more general in tenor than the TRIPS, which specifies levels of intellectual property protection and seeks to harmonise the intellectual property laws of the WTO members.[67]

The EC advocates parties to the CBD to adopt national legislation to govern access and benefit sharing under the CBD, and supports the development of an international model for the legal protection of traditional knowledge. (Communication by the European Communities and their Member States on the Relationship Between the CBD and TRIPS, 3 April 2001). This is certainly a way to deflect developing

63 CEAS & Tansey 2000, *supra* note 41.

64 CBD Art 22.

65 Philip McCalman, 'Reaping What you Sow: An Empirical Analysis of International Patent Harmonization,' econ.ucsc.edu/faculty/mccalman/workingpapers/454paper.pdf.

66 CEAS & Tansey, *supra* note 41.

67 *Ibid.*

countries away from seeking amendments to TRIPS. This approach appears to be preordained by the provisions of the CBD itself, which mandates that the parties take legislative, administrative and policy measures to implement it.

B. *The European Regime for the Protection of Intellectual Property Rights in Biotechnology*

The European regime of intellectual property rights in biotechnology has undergone significant development in the past decade. This development has been contentious in Europe, with public hostility continuing unabated against genetically-modified foods and with concerns expressed about the ethics and morality of 'patenting life'. *The Economist* analogises adverse British public opinion to a genetically-modified organism: 'it seems to resist anything that might kill it, from scientific evidence to official reassurance.'[68]

The European regime of patent and *sui generis* protection is governed by four legal instruments at the multilateral or European level and a host of national laws to implement these instruments. I can only provide an overview here in the context of examining the relationship between European law on intellectual property rights in biotechnological inventions and TRIPS Article 27.[69]

1. *The Biotechnology Directive*

One of the principal European laws on the patenting of biotechnological inventions is Council Directive 98/44 on the Legal Protection of Biotechnological Inventions.[70] The Directive came into force on 30 July 1998 and EC member states had until 30 July 2000 to implement it. The Biotechnology Directive took almost ten years to bring to completion, with the European Parliament rejecting a prior draft in 1995. Some uncertainty still remains about the Directive. The Netherlands brought suit in the European Court of Justice, seeking to nullify the Directive. The suit, joined by Italy, is still pending as of the writing of this paper.[71] Notably, both the Netherlands and Italy have relatively small

68 'Who's Afraid?,' *The Economist*, 17 July 1999.

69 For detailed discussion of other major aspects of European patent law, see Gerard Paterson, *The European Patent System* (London: Sweet & Maxwell 2nd ed 2000); Ian Muir, Matthias Brandi-Dohrn & Stephen Gruber, *European Patent Law* (Oxford: Oxford University Press 1999).

70 http://europa.eu.int/eur-lex/en/lif/dat/1998/en_398L0044.html.

71 Action Brought on 19 Oct 1998 by the Kingdom of the Netherlands against the European Parliament and Council of the European Union, Case C-377/98.

biotechnology industries and therefore stand to gain relatively less from the Directive than the UK, which has the largest biotechnology industry in Europe. The law has thus had a tortuous path. There have been no rigorous studies of whether the delay in implementing the Directive has affected the growth of the biotechnology industry in Europe, although this has been suggested.[72] Policy makers have expressed concern that European laws and institutions lag behind their American counterparts, thus losing 'competitive advantage' for the European biotechnology industry. It is difficult to assess the effect of laws and institutions on the growth of a particular industry sector and thus it is difficult to verify these claims.

The Biotechnology Directive came into existence after TRIPS. The Recitals in the Directive say that it is in part designed to implement TRIPS. Recitals are important in EC law for purposes of interpreting legislative language. One of the 56 Recitals in the Directive states, as one of the reasons for the adoption of the Directive, that TRIPS, 'signed by the European Community and the Member States, has entered into force and provides that patent protection must be guaranteed for products and processes in all areas of technology.'[73]

TRIPS Article 27.1 provides that patents may be obtained on 'any technology'. Directive Article 3 implements TRIPS Article 27.1. Article 3 provides:

> 1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.
>
> 2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.[74]

The additional requirements imposed on patentability under Article 3, stated in the alternative, are reproducibility or the presence of a technical process in the invention. Under Article 3.1, inventions are patentable even if they concern a product or process that uses 'biological material'. The Directive defines 'biological material' as 'any material

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72 Donna O Perdue, 'The Changing Landscape of Patenting Transgenic Plants in Europe', CASRIP Newsletter (1999), http://www.law.washington.edu/Casrip/newsletter/news6i1Perdue.html.

73 For the text of the biotechnology directive, see the website identified in *supra* note 70.

74 *Ibid.*

containing genetic information and capable of reproducing itself or being reproduced in a biological system.'[75] Under Article 3.2, even biological material that occurs in nature may be patented if it is isolated from nature or a technical process is used to produce it.

TRIPS Article 27.3(b) contains four rules on patentability of biotechnology. First, WTO members may exclude from patentability plants and animals other than micro-organisms. Second, they may exclude from patentability essentially biological processes for the production of plants or animals. Third, they may exclude plant varieties from patentability if they provide *sui generis* protection for plant varieties. Finally, WTO members may not exclude from patentability non-biological and microbiological processes for the production of plants and animals. The Biotechnology Directive complies with all four principles found in Article 27.3(b). First, under Directive Article 4.2, inventions relating to plants or animals are patentable 'if the technical feasibility of the invention is not confined to a particular plant or animal variety'. Second, under Directive Article 4.1(b), 'essentially biological processes for the production of plants or animals' are not patentable. Third, under Directive Article 4.1(a), plant and animal varieties *per se* are not patentable, but plant varieties receive protection under Council Regulation 2100/94/EC, which implements the UPOV Convention. Finally, Directive Article 4.3 provides that the ban on patenting of essentially biological processes for the production of plants or animals is 'without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.'[76]

Directive Article 6 implements TRIPS Article 27.2. It provides that '[i]nventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.'[77] Directive Article 6 provides more detail than the TRIPS provisions by adding four specific patentability exclusions to which EC member states must adhere. They exclude patenting of processes for cloning of human beings, processes for modifying the germ line genetic identity of human beings, patents relating to uses of human embryos for industrial or commercial purposes and patenting of processes (and animals resulting from such processes) for modifying the genetic identity of animals that are likely to cause them suffering without any substantial medical benefit.

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75 Directive Art 2.1(a).
76 Directive Art 4.1(a).
77 Directive Art 6.

2. *The European Patent Convention*

The Convention on the Grant of European Patents, popularly known as the European Patent Convention, came into existence on 5 October 1973 in Munich. It has thus been in existence long before TRIPS, and, as explained in Part II above, it in part formed the basis for language used in TRIPS Article 27.3(b). The members of the Convention include the EC member states in their capacities outside of the EC system. The Convention is not part of the EC legal system. In addition, five other European states not in the EC are members of the Convention: Cyprus, Liechtenstein, Monaco, Switzerland and Turkey. With a single application to the European Patent Office (EPO) established under the Convention, an inventor can obtain patent protection in all countries that are members of the Convention. The European level Convention and its registration system co-exist with national patent laws and national registration systems. The European patent is valid in the countries that are members of the Convention, but the interpretation and enforcement of the patents are issues for national law.[78]

As explained in Part II above, Convention Article 53(b) provides that 'European patents shall not be granted in respect of ... plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.'[79] The term 'varieties' is not defined in the Convention. The *travaux préparatoires* of the Convention indicates that plant varieties were excluded from patent protection principally because *sui generis* protection existed under the UPOV Convention, then in its 1971 version, and under national laws implementing the UPOV Convention.[80]

The European Patent Convention thus excludes plant varieties from patentability. This is consistent with TRIPS Article 27.3(b). The Convention interpretation of Article 53(b) has evolved over the years, and there would seem to be a trend in the law towards harmonisation with US law. The US approach has been to permit three kinds of intellectual property rights in plant varieties: (i) patents under general patent law, available for all inventions that meet patentability criteria, also known as utility patents; (ii) plant patents under the Plant Protection Act 1930, available for patents on asexually producing plants; and (iii) PBRs under the Plant Variety Protection Act 1970, for sexually producing varieties.

78 European Patent Convention Arts 1-3, 66, 74.
79 See *supra* note 21 and accompanying text.
80 See *supra* note 5.

In Europe, the approach has been to exclude patent protection for plant varieties, but the trend is towards permitting both kinds of protection. When the European Patent Convention was drafted in the early 1970s, the UPOV Convention required signatories to use plant variety rights as the exclusive means of protection of rights in plant varieties. The UPOV Convention was amended in 1991 to freely permit countries to use patents, plant variety rights or both to protect rights in plant varieties. The Council Regulation on Community Plant Variety Rights still provides that in the EC, plant variety rights are 'the sole and exclusive form of Community industrial property rights for plant varieties.'[81] When the European Patent Convention was drafted, plants and animals were not patentable because breeding did not result in plants and animals that could be reproduced. Genetic engineering has advanced since the early 1970s to the point where the reproducibility objection no longer exists, and patenting would seem to be a feasible option for protection of inventions in plant and animal varieties.[82] The Biotechnology Directive underscores this conclusion. Recital 15 of the Directive states, 'no prohibition or exclusion exists in national or European patent law (Munich Convention) which precludes *a priori* the patentability of biological matter.'[83]

The significant event towards patent protection for plant and animal varieties in Europe was issuance of the decision of the EPO Enlarged Board of Appeal in *Novartis Transgenic Plant,* G01/98, on 20 December 1999.[84] The case concerned the patentability of plants containing foreign genes inserted into their genomes.[85] The transgenic plants produced with the claimed inventions would have characteristics that inhibit the growth of plant pathogens. One of the questions that the Technical Board of Appeal asked the Enlarged Board of Appeal was whether a patent claim relating to plants but in which specific plant varieties are not individually claimed avoids the prohibition in European Patent Convention Article 53(b) even though the patent embraces plant varieties. The Enlarged Board of Appeal ruled that Convention Article 53(b) prohibits patents for specific plant varieties but patents can be granted if varieties fall within the scope of the claims of the patent. The Enlarged

81 Regulation, *supra* note 5, Art 1.

82 Robin Nott, 'The Novartis Case in the EPO', (1999) 21 *European Intellectual Property Review* 33.

83 Directive, *supra* note 70.

84 OJ EPO 2000, 111.

85 Karen Blöchlinger, "A Variety of Interpretations of 'Plant Variety'", CASRIP Newsletter (2000), http://www.law.washington.edu/Casrip/newsletter/.

Board looked to the UPOV Convention for guidance on what constitutes a plant variety, and found that the plant variety concept embraces 'the entire constitution of a plant or a set of genetic information'.[86] Plant variety rights were designed at a time when varieties were the result of breeding processes, as in the use of selection and crossing to produce hybrids.[87] This was in contrast to the patent claim in issue in *Novartis,* which involved a plant into which a piece of recombinant DNA was inserted, which, according to the Enlarged Board, was 'not a concrete living being but an abstract and open definition embracing an indefinite number of individual entities defined by a part of its genotype or by a property bestowed on it by that part.'[88] According to the Enlarged Board, the subject matter of the *Novartis* patent claim was ineligible for protection under the UPOV Convention. Plant variety rights are granted only for specific plant varieties and not for 'technical teachings' that can be implemented in any number of different plant varieties.[89]

The Enlarged Board of Appeal issued *Novartis* under the European patent law system that the European Patent Convention establishes. It is not EC law. *Novartis* is consistent with the EC Biotechnology Directive, which provides in Article 4.2 that inventions relating to plants or animals are patentable 'if the technical feasibility of the invention is not confined to a particular plant or animal variety'. Whilst *Novartis* and the Biotechnology Directive go a long way towards expanding patent protection in Europe, pure plant varieties remain ineligible for European patent protection.

The European Patent Convention and *Novartis* are consistent with TRIPS Article 27.3(b), which permits patent or *sui generis* protection or a combination of the two. As explained in Part I above, the TRIPS exclusions in Article 27.3(b) are permissive, not mandatory. Under Article 27.3(b), WTO members 'may' 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.'[90] *Novartis* does not implicate this provision, because it permits patentability of a process that is not essentially biological. The transgenic technology involved in *Novartis* was biotechnological, not merely biological.

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86 *Ibid.*
87 Nott, *supra* note 82.
88 *Ibid.*
89 *Ibid.*
90 TRIPS Art 27.3(b).

3. *The UPOV Convention and Implementing Council Regulation*

The European countries are all members of the International Convention for the Protection of New Varieties of Plants (UPOV Convention), signed in Paris in 1961 and revised in 1972, 1978 and 1991. The Convention established the International Union for the Protection of New Varieties of Plants.[91] The US is also a signatory to the UPOV Convention. The EC has implemented the UPOV Convention with Council Regulation 2100/94 on Community Plant Variety Rights. The 1991 Convention represents a substantial revision, in that it freely permits dual protection of plant varieties, by patents, *sui generis* rights or both.[92] The original 1961 Convention required signatories to choose one form of protection for 'one and the same botanical genus or species', either patents or *sui generis* rights. The 1978 Convention relaxed this restriction to permit countries such as the US and Japan to continue to provide dual protection if they had provided it before 31 October 1979. The 1978 revision facilitated the accession of the US and Japan to the Convention. In the EC member states, however, the Council Regulation provides that plant varieties are entitled only to protection as Community plant variety rights.[93]

IV. CONCLUSION

The TRIPS Agreement is at a critical juncture in the new negotiating round launched at Doha. It will remain in its current form to the extent that the US, and perhaps the EC as well, continue to assert a leadership role over its contents. The EC and its member states have a substantial contribution to make in the ongoing work of the WTO on TRIPS, and in any new negotiating round in which the Agreement is on the agenda. It is doubtful that the EC and its member states would take positions differing radically from those of the US on matters involving intellectual property rights in biotechnology. Europe and the US share a similar stake. The European Commission Directorate for Trade has offered some general proposals in various forums for assuaging developing country concerns. It is doubtful that these proposals will result in negotiating positions antagonistic to those of the US.

One of the main areas of controversy is how TRIPS deals with rights in biotechnology. The biotechnology controversy surfaced well before

91 Timothy Millett, 'The Community System of Plant Variety Rights,' (1999) 24 *European Law Review* 231.

92 UPOV Convention Art 2.

93 Council Regulation Art 1.

the Seattle Ministerial Conference, continued unabated in successive conferences and shows no signs of abatement. The key divisive issue continues to be implementation versus renegotiation: the developing countries want a substantive review of TRIPS obligations, but it is in the interests of the US, and the EC as well, to focus on the built in agenda.

The TRIPS Agreement is not solely a debate about eliminating barriers to trade. It is about allocating property rights, which leads to an allocation of wealth to the various interested parties that have voice in the executive and legislative bodies of the WTO members. A substantial segment of the WTO members that are developing countries object fundamentally to its provisions, asserting that the TRIPS obligations are either inappropriate or too protective of categories of intellectual property that favour established interests in developed countries. The WTO members have the opportunity in the new round of trade negotiations to revise the TRIPS Agreement in a manner that will produce substantial innovation in taking the contribution of traditional knowledge and other forms of non-Western forms of innovation into account, but it is doubtful that the political will or political incentives exist to produce such innovation in the TRIPS Agreement itself.