The Future of Patentability in International Law According to CAFTA

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While discussions stagnate at the WTO over access to medicines, protection of indigenous knowledge and technology transfer, the United States and other developed countries multiply bilateral 'TRIPs-plus' treaties with developing countries. This article compares patentability provisions under the recently-concluded US-Central American Free Trade Agreement (CAFTA) with those of Article 27 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

Arguably, bilateralism allows the United States to bypass the dead-end debates at the TRIPs Council and to consolidate key elements of multilateral intellectual property (IP) treaties.[1] A closer look at the differences between the CAFTA and the TRIPs Agreement gives a good indication of the possible evolution of international IP law and of the additional weight bilateral negotiations confer to the United States when compared to multilateral approaches.

Although most of the provisions of the controversial Article 27 on patentability are integrated without changes in the CAFTA, we have identified five significant changes:

- the industrial application requirement is defined;
- a grace period for inventors is added;
- the plant protection regime is reinforced;
- the non-discrimination rule is omitted; and
- a ceiling to the disclosure requirement is introduced.

The industrial application requirement is defined

The TRIPs Agreement stipulates that an invention is patentable "provided that it is new, that it involves an inventive step and that it is capable of industrial application". However, these requirements are not defined and their interpretation therefore differs from one country to another. The CAFTA is one of the first agreements to specify that: "Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility".

US case law is usually less rigorous when interpreting the industrial application requirement: "All that the law requires is that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society".[2] In comparison, the language "specific, substantial, and credible utility" is more restrictive and is likely to close the door to the patentability of several inventions, especially in the field of biotechnology. In this sense, it is undoubtedly more acceptable to Central American countries, generally in favour of stricter patenting limitations than the traditional understanding resulting from US jurisprudence. Nevertheless, the CAFTA definition is drawn from the US patent regime. It was not elaborated by Congress or the courts, but is rather contained in the *Utility Examination Guidelines* adopted on 5 January 2001 by the US Patent and Trademark Office to guide patent examiners. Curiously, the CAFTA propels this administrative definition into international law.

Although adopted in a bilateral context, the definition of the requirement for industrial application must be read in the light of the multilateral negotiations conducted at the World Intellectual Property Organisation (WIPO). Indeed, for some months, negotiators of the upcoming Substantive Patent Law Treaty have debated a harmonised definition of "industrial application". By exporting its own definition through a bilateral treaty, the United States is building alliances in view of the multilateral negotiations at WIPO.

A grace period is added

Contrary to the TRIPs Agreement, the CAFTA provides a grace period to inventors:

> *Each Party shall disregard information contained in public disclosures used to determine if an invention is novel or has an inventive step if the public disclosure was (a) made or authorised by, or derived from, the patent applicant and (b) occurs within 12 months prior to the date of filing of the application in the Party.*

The United States is one of the few countries that offer a grace period of twelve months prior to the filing of a patent application during which an inventor can use, sell and disclose his or her invention without compromising its "novelty". During this period the inventor may search for financing or test the market for his/her invention before initiating the costly and complicated steps to patent the invention. In most countries, any disclosure annuls the novelty characteristic of an invention. If a US inventor wants to obtain protection abroad, s/he cannot take advantage of the grace period offered under US law and must only publish his/her invention after filing a patent application. To make the US approach more effective, the United States must export its norm abroad, as it has done through the CAFTA.

The plant protection regime is reinforced

According to Article 27.3(b) of the TRIPs Agreement, WTO members can exclude plants and animals from patentability but "shall provide for the protection of plant varieties either by patent or by an effective *sui generis* system or by any combination thereof". At the TRIPs Council, African countries, on the one hand, are seeking to modify this provision to exclude plant varieties (and other living organisms) from patentability on ethical, environmental and agricultural grounds. The US, on the other hand, considers that even the *sui generis* exception is useless and that plants should be patentable in order to create incentives for biotechnological innovation.

The CAFTA represents a compromise between TRIPs Article 27.3(b) and the US proposal for its review. It encourages – but does not impose – plant patents: "Any Party that does not provide patent protection for plants by the date of entry into force of the Agreement shall undertake all reasonable efforts to make such patent protection available". Besides, the CAFTA provides for a mechanism that prevents any back-sliding: "Any Party that provides patent protection for plants or animals as of, or after, the date of entry into force of this Agreement shall maintain such protection".

CAFTA countries are still free to exclude plants from patentability. In such a case, plant varieties must be protected "by an effective *sui generis* system" as provided by the TRIPs Agreement and reiterated in the CAFTA. However, WTO members still disagree on the meaning of this language. The system in force in most OECD countries is that of the International Union for the Protection of New Varieties of Plant (UPOV Convention). UPOV certainly is an "effective *sui generis* system" but is it the only acceptable one? Could a WTO member design a system better adapted to the needs of small farmers?

The CAFTA resolves this debate by requiring all the signatories to accede to the 1991 UPOV Convention before 1 January 2006, with three exceptions. The first exception grants Costa Rica, which has already drawn up draft legislation on the protection of plant variety, an additional year to join UPOV 1991. Nicaragua, which acceded to a previous version of the UPOV Convention to meet the requirements of an earlier bilateral treaty signed in 1998 with the United States, is granted a delay of four years. The third exception provides that countries, which follow the US example and accept the patentability of plants, shall only "make all reasonable efforts" to accede to UPOV 1991. In other words, the countries that first conform to the US position subsequently benefit from longer transition periods.

The non-discrimination rule is omitted

Article 27.1 of the TRIPs Agreement introduced a new rule in the international patent regime: "Patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced". The CAFTA, like most US bilateral treaties, omits this rule of non-discrimination.

How can one explain this omission? One possible explanation resides in the fact that US law contains several measures that could be considered *de facto* or *de jure* discriminatory by an international panel of arbitration. These include the procedures of the US International Trade Commission pertaining to foreign inventions; the fast-track examination procedures for biotechnologies; the exclusion of oral communication outside the United States in considering prior art; and the exceptional rights granted to pharmaceutical inventions.

It must also be said that the omission of the non-discrimination rule seems to reflect not only the US position but also a latent consensus among negotiators of the international patent regime. Indeed, many WTO Members discriminate according to the place of origin of the invention, the field of technology, or as to whether or not the product is imported or of national origin. In addition, a tactical game of reciprocal threats prevents the application of the non-discrimination rule by the WTO's dispute settlement system. For example, when the United States asked for the establishment of a panel to rule on the discriminatory nature of Brazilian patent law, Brazil immediately retorted by filing a request for consultation in connection with US law. A few weeks later, the United States and Brazil announced that they had reached an agreement on these issues. The omission of the rule of non-discrimination in the CAFTA thus sanctions the ineffectiveness of this TRIPs provision.

A ceiling to the disclosure requirement is introduced

In exchange for their exclusive marketing rights, patent holders must fully disclose their inventions. This classic requirement is contained in every national IP law and in the TRIPs Agreement. However, none of the bilateral treaties signed by the US prior to 2004 reiterates this obligation. It reappears, substantially modified, in the CAFTA: "A disclosure of a claimed invention is considered sufficiently clear and complete if it provides information that allows the invention to be made and used by a person skilled in the art, without undue experimentation […]".This wording is more consistent with US law than the original provision of the TRIPs Agreement. For instance, the expressions "to be made and used" and "without undue experimentation" are directly imported from US law.[3]

Contrary to the provision of the TRIPs Agreement, the CAFTA equivalent seems to have been drafted to limit disclosure requirements rather than for ensuring full disclosure. Indeed, it appears to forbid countries from asking for more than "information that allows the invention to be made and used" in order to accept a disclosure as sufficiently clear and complete.

Biodiversity-rich countries, such as those of Central America, see mandatory disclosure of origin of genetic resources as a tool for monitoring the sharing of benefits arising out of the use of genetic resources. While some European countries support the idea of mandatory disclosure of origin, the United States remains firmly opposed to any multilateral treaties requiring – or even explicitly allowing – the disclosure of origin of genetic resources. Through the CAFTA, the US seems to have been able to limit the ability of Central American countries to require the disclosure of the origin of genetic resources used in the development of biotechnological inventions.

The ceiling on disclosure provided in the CAFTA could also have some effects on US law. Indeed, US law requires that a patent application disclose not only how to make and how to use the invention, but also "the best mode contemplated by the inventor of carrying out his invention". However, the business and IP communities have been questioning the usefulness of this 'best mode' requirement for some time. In 1992, the *Advisory Commission on Patent Law Reform* even recommended its elimination. By establishing a new ceiling to the disclosure requirement, the US Administration has opened the door to an amendment to US patent law.

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Conclusion

Our comparative analysis shows that bilateralism allows the US to consolidate existing multilateral treaties, such as the TRIPs Agreement and the UPOV Convention, and to strengthen its negotiating position for future multilateral treaties, such as the WIPO Substantive Patent Law Treaty. These dynamics between bilateralism and multilateralism are also observable in other bilateral treaties recently concluded by the United States.

Most provisions included in US bilateral treaties are TRIPs-*equivalent*, that is to say literally duplicated from the TRIPs Agreement. Others, such as the definition of the industrial application requirement, go beyond TRIPs provisions and can be described as TRIPs-*plus*. These are mostly copied from US law – or even on US Patent and Trademark Office policies not yet submitted to Congress – and exported to trading partners. Only a few provisions, like the omission of the non-discrimination rule, can be labelled as TRIPs-*minus*! Be that as it may, for those who oppose patents on genetic material in Central America, the CAFTA is a bad trip.

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ENDNOTES

[1] Jean-Frédéric Morin, 'Le droit international des brevets: entre le multilatéralisme et le bilatéralisme américain', *Études internationales*, Vol. 34, No 3, December 2003, p. 537-562.

[2] Lowell v. Lewis, Circuit Court, D. Massachusetts, 1817. 15 F.Case 1018

[3] United States Code, Title 35, Section 112. See also *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991).

The Dominican Republic and and the US concluded bilateral FTA negotiations on 15 March. The agreement is modelled on the CAFTA and will eventually be 'docked' in the subregional pact, which already counts Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua as members. The Dominican Republic essentially accepted all CAFTA disciplines, (see Bridges Year 8 No.2, page 13).

US–SACU Talks Hit Snag on Services

Fundamental differences with regard to services market opening have emerged between the five-member South African Customs Union (SACU) and the US in their free trade agreement negotiations. Other unresolved sticking points include agricultural subsidies and trade remedy rules.

The two sides are scheduled to meet on 4-8 May to discuss services, as well as investment, intellectual property, government procurement, and labour and the environment. The US continues to insist on a 'negative list' approach under which all services sectors except those explicitly carved out would be opened to competition. In contrast, SACU wishes to retain the 'positive list' approach used in the WTO's General Agreement on Trade in Services (GATS), which includes only those sectors that are explicitly offered. Reflecting its sanguine attitude to opening services markets, the US routinely imposes the negative list approach in bilateral services negotiations, in which it which usually most aggressively targets the insurance, banking, telecommunications and express delivery sectors.

Civil society organisations such as the Treatment Action Campaign and the AIDS Law Project have raised several concerns about the areas to be addressed in May. For instance, they have warned that the FTA could undermine the financing and provision of health care services in SACU countries, stressing that "the investment chapter would provide the back door for a pharmaceutical company, for example, to sue a SACU member state for failing to amend its legislation in line with the chapter on intellectual property". They have also noted that "rules on procurement may unfairly preclude necessary and urgent action, such as procurement of essential medicines for dealing with a health emergency, such as a cholera outbreak".

Major differences also remain on 'first phase' topics such as agricultural subsidies and trade remedy provisions (i.e. anti-dumping and countervailing rules). SACU countries would like to address both issues in the FTA negotiations, but the US has so far remained adamant that they can only be dealt with in the WTO. In addition, South Africa continues to have important reservations about tariff elimination in sensitive industrial sectors.

After the May meeting, negotiations will take place at six-to-eight week intervals, with a final 'super round' starting on 18 December in hopes to meet the proposed year-end deadline for closing the deal after only 18 months of negotiations.

FTAA Negotiations Still Suspended

Hopes for the conclusion of the Free Trade Area of the Americas negotiations by next January were further dimmed when 12 vice trade ministers from the region decided in early March to postpone reconvening the full Trade Negotiations Committee (TNC) until late April.

The vice ministers met in Buenos Aires to explore flexibilities in view of resuming the TNC meeting suspended in February due to insurmountable differences over the scope of common obligations and plurilateral agreements (Bridges Year 8 No.2, page 15.) It soon became clear that a TNC meeting in late March would fail. Mercosur and the US continued to square off on domestic agricultural support, with the US resisting any FTAA disciplines and Mercosur calling for "mechanisms to neutralise the distorting effects of domestic agriculture programmes" in the core obligations. Some progress was made in bridging the divide on tariffs, but the two sides still disagree on whether the 'entire tariff universe' should be covered by the common set of obligations or whether countries participating in plurilateral agreements could also benefit from higher tariff cuts.

The twelve countries were to meet again in late March with a view of resuming the full TNC session on 22-23 April in Puebla, Mexico.