

Consultation on principles guiding the harmonization of substantive patent law

I have two general and one specific comments/suggestions.

General comments:

(a) The term “harmonization of substantive patent law” is a misnomer and, unfortunately, has given rise to a deep and apparently unsurmountable misunderstanding in the negotiations around the initiative. As a matter of course, the core of the harmonization is not about harmonization of “substantive patent law” but rather of “substantive patent requirements.” The difference between these two notions is enormous. Substantive patent law is perceived as comprising the principles and rules that preside over the design of the rights that stem from patents. Terms of protection, exceptions and limitations to their acquisition and enforcement, and exclusions from patentability are examples of the subject matter of substantive patent law.

By contrast, the work of the WIPO Standing Committee on the Law of Patents (SCP) has focused on patent requirements: novelty and prior art, grace period, non-obviousness, publication, utility. One item—prior user rights—has nothing to do with patent requirements, but it will be subject to a specific comment, below. Harmonization of patentability requirements is very helpful in a global perspective, namely because patentees will have more security about the validity—and the value—of their patent rights in different jurisdictions. Under a harmonized patent system, it is not probable that a patent that resists a validity challenge in one jurisdiction succumbs to a similar challenge in another jurisdiction. In other words, a successful harmonization of patent requirements will lead to some consistence in the legal and economic value of patents in different jurisdictions.

A significant number of developing countries has strongly opposed the efforts toward harmonization in the SCP because of the misunderstanding that the draft SPLT (Substantive Patent Law Treaty) was about substantive standards of patent law and therefore it would lead to the adoption of “TRIPS plus” standards. Numerous misguided academics and ngos voiced this same concern while the SCP attempted to move forward with the negotiations.

On the other hand, those few developing countries that understood the real thrust of the SPLT—to harmonize patent requirements with a view to the setting of a genuine global patent system (with the adoption of a global patent mechanism)—were concerned with the possibility of its

success and were able to derail it by resorting to two initiatives: one was the introduction in the draft SPLT of matters of substantive patent law, namely exceptions and limitations (health, environment, security, etc); the other was the submission to WIPO General Assembly of the proposal for the Development Agenda, under which there would be no new negotiations in WIPO on IP without a development dimension (in which they naturally included the SPLT).

The combination of these two factors means that the harmonization sought by Group B+ will never fly as currently proposed. This brings me to two general suggestions:

(a) Interested Group B+ countries should change the name of the initiative into “harmonization of substantive patent requirements.”

(b) The Group should change the strategy to bring developing countries on board. In a multilateral setting it will not be possible to reach an agreement on those requirements, particularly where certain countries continue taking them for substantive standards, and others fear a global patent. The suggestion is that Group B+ countries should first find consensus among them on the points regarding which they have not yet reached agreement; once the consensus is formed, Group B members could introduce the harmonized requirements into the national laws of developing countries through free trade agreements.

Specific comment

My specific comment is about the prior user exception. This is indeed a matter of substantive patent rights to the extent it concerns the curtailing of patentees’ rights to enforce their exclusivity under certain circumstances. Being a matter of substance, it does not fit in an initiative that is primarily concerned with patent requirements.

Moreover, as I explained in the book *The TRIPS Regime of Patents and Test Data*, at 384-385 (4th edition, Wolters Kluwer, 2014), the prior user exception is TRIPS incompatible, given that it is not limited, under Article 30. In general, prior users are allowed to make, use and sell, and these are the three rights of the patent bundle. There is no limit therefore. This argument is strengthened by the TRIPS provision that, in other circumstances, deals with a sort of prior user exception. It is Article 70.4, which requires prior users to pay equitable remuneration to the patent holder. In other words, Article 70.4 goes as far as granting a remunerated compulsory license to the prior user, not a royalty-free one.

Moreover, in the principles described on CIPO’s webpage, the prior user exception is not limited to a fixed quantity (by contrast, in some countries prior users are not authorized to increase the amount of production set before the date of patent application). The prior user exception has two major inconveniences: (a) where exercised by a large company against a small company or

individual inventor, it simply nullifies the value of the patent; (b) it rewards an inventor who has kept his/her invention secret and operates in detriment of another inventor who has accepted the rules of the patent game, disclosing the invention in exchange for exclusivity.

My suggestion, therefore, is that the prior user exception be either dropped or modified so as to include the payment of equitable remuneration, in particular when it unreasonably conflicts with the normal exploitation of the patent by the patentee.

Porto, February 24, 2016

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