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Beyond 'Patent Quality': Basic Concepts of the Patent System Need To Be Reviewed

By Carlos M. Correa

A proposal has been made to initiate a debate on 'patent quality' at the World Intellectual Property Organization (WIPO). The expression 'patent quality' ambiguously alludes to a growing problem, faced in both developed and developing countries alike: the overwhelming majority of patents are applied for and granted over incremental developments on existing technologies. Although the patent system is supposed to reward inventiveness, in many cases patents cover minor improvements or trivial ideas.

Although the intrinsic value of the technology protected under such patents is low, they are often strategically used to generate or keep monopolistic positions that affect competitors and consumers. Thus, the proliferation of patents that do not make a genuine technical contribution limits legitimate competition and undermines innovation. An investigation conducted by the European Commission on the pharmaceutical industry, for instance, concluded that:

- Filing numerous patent applications for the same medicine (forming so called "patent clusters" or "patent thickets") is a common practice... to delay or block the market entry of generic medicines.
- ...individual medicines are protected by up to nearly 100 product-specific patent families, which can lead to up to 1,300 patents and/or pending patent applications across the Member States.
- patent litigation cases increased by a factor of four between 2000 and 2007; generic companies prevailed in 62% of 149 litigated cases that lasted from six months to more than six years.
- European governments and consumers paid around 3 billion Euros in excess between 2000 and 2007 (in relation to 219 drugs) due to abuses in the exercise of patent rights.

The acquisition of a large number of patents around a single technology has become common practice. Contrary to the ordinary belief that one product will deserve one patent, a single medicine may be covered by hundreds of patents. Thus, a WIPO study identified around 800 patents on ritonavir, an important component in the treatment against HIV/AIDS. In order to preserve a monopolistic position after the expiry of basic patents, pharmaceutical companies routinely apply (and often obtain) patents on derivatives, dosage forms, new uses, etc. of existing medicines thereby 'evergreening' the original patents.

Information and communication technologies have also become a patent battle field. Thousands of patents granted on computer programs and other technologies are used to block competitors or to keep them out of the market through the threat of costly litigation. Companies that do not have large patent portfolios can hardly survive. Google paid U\$12.5 billion to take over Motorola Mobility and get hold of its around 17.000 patents that could be used to harass mobile-device makers using Google's Android mobile operating system.

A number of factors explain the proliferation of patents with low or no inventive contribution. Two of them are of particular relevance. On the one hand, large companies devote significant resources to pursue patent strategies that deliberately aim at limiting the competitors' room to operate. They include "*Blanketing*" (creating a jungle or a minefield of patents), "*Flooding*" (taking out multiple patents, major as well as minor, in a field), "*Fencing*" (acquiring a series of patents that block certain lines or directions of research and development) and "*Surrounding*" (an important central patent is fenced by other less important patents).

On the other, patent offices in many countries apply lax standards to assess what is inventive and tend to consider patent applicants as 'clients' that must be properly served. For instance, while in the 1940's a patent would be considered valid in the USA when the invention revealed 'a flash of creative genius' (Judge Douglas in *Cuno Engineering Corp.*, 314 U.S. 84, 51 U.S.P.Q. 1, 1941), in the 1980's it became sufficient to show some degree of novelty to get a 'valid' patent. Growing concerns about this trend led the US Federal Trade Commission to rightly state, in 2003, that the patent office should function 'as a steward of the public interest, not as a servant of patent applicants. The PTO must protect the public against the issuance of invalid patents that add unnecessary costs and may confer market power...'.

Patent offices in developing countries have followed similar patterns regarding the patentability criteria. Technical assistance programs, intense advocacy and business lobbying, have been effective in creating pro-patent practices that transform the patent system in a convenient mechanism of market control and exclusion. In most cases, patent activity by foreign companies does not encompass any investment in production (since markets are mainly supplied through imports) nor a real transfer of technology to the countries where protection is sought.

A research conducted in five developing countries (Argentina, Brazil, Colombia, India and South Africa) on patenting in the pharmaceutical field revealed several aspects of the functioning of the patent system that raise significant concerns. Some of the findings of the study were as follows:

- Pharmaceutical patents are overwhelmingly concentrated in the hands of foreign companies (with the exception of India).
- The introduction of product patent protection has had no impact in terms of promoting local innovation in pharmaceuticals.
- There is a significant proliferation of patents over minor technical changes that are often used to create undue constraints on legitimate competition that negatively affect access to medicines.
- A large proportion of granted patents are based on the so-called 'Markush claims'; if 'selection patents' are later on allowed on elements already disclosed in such claims, market control may be maintained through 'evergreening' of the original patent.
- Many patents and patent applications do not mention the International Nonproprietary Name (INN) of known drugs, thereby making patent searches and oppositions extremely difficult and costly.

Importantly, the TRIPS Agreement leaves considerable room to define how the standards of patentability may be applied. Stipulating rigorous criteria to assess novelty, inventive step and industrial applicability will help prevent patent abuses. This may also avoid the need to resort to compulsory licenses in cases where the patent application itself can be rejected. Based on public health considerations, for instance, Thailand, decided to grant a compulsory license on clopidogrel, a medicine used to prevent strokes and heart attacks. The patent, however, covered a polymorph (i.e., a particular crystalline form of a drug that is routinely

identified, not invented, during the crystallization process) that could have been considered not patentable under better defined patentability standards.

Once a patent is granted it is generally presumed to be valid until otherwise decided by the courts. Substantial resources (both financial and technical) are necessary to invalidate a patent. This is a difficult or impossible task for small and medium companies, non governmental organizations or individuals (e.g. patients) that may be directly affected by wrongly granted patents. In addition, invalidation procedures may take years during which the patent can be legally enforced, even if under legal challenge. For instance, invalidating the 'Enola patent' (a patent granted on yellow coloured beans obtained from Mexico by a US breeder) took nine years in the USA, a country deemed to have an efficient judicial system.

Canada and the United Kingdom submitted to the WIPO's Standing Committee on Patents a proposal to deal with the issue of 'patent quality' (SCP/16/5). It suggests to undertake work on three aspects: technical infrastructure development, information exchange on quality of patents and process improvement. The proposal recognizes the existence of a problem with the current functioning of the patent system. However, it fails to address critical issues, such as the way in which the patentability requirements and other concepts of the patent system are applied. It is also unclear whether the suggested 'process improvement' would aim at facilitating the acquisition of patents (that is, to serve the 'clients' of the system) or to protect the public from undue detracting of knowledge from the public domain.

The commented proposal seems to be clearly insufficient to address the distortions of the patent system and to ensure that it serves the interests of society and not just of patent holders. As the US Supreme Court stated almost a century ago '...the primary purpose of that law [the patent law] is not to create private fortunes, but is to promote the progress of science and the useful arts' (*MOTION PICTURE PATENTS CO. V. UNIVERSAL FILM CO.*, 243 U. S. 502 , 1917).

Important changes in the way the system is designed and operates are necessary to achieve this objective. They include:

- To integrate patent policies into national development policies, including in relation to access to medicines and to environmentally sound technologies;
- To increase the capacity available in patent offices and courts to properly examine patent applications, and introduce substantive examination where it does not exist;
- To provide patent examiners incentives to objectively examine patent applications and thereby avoid a bias towards approval;
- To ensuring that the inventive step analysis takes into account prior expert knowledge available in written documents as well as that derived from practical experience. Patents should only be granted when a real contribution to the state of the art has been made;
- To adopt measures to prevent the proliferation of patents resulting from offensive and defensive practices (e.g. patent thickets, evergreening) that may block legitimate competition and the development of a local innovative capacity;
- To review practices based on questionable assumptions or legal fictions, such as the number of documents that may be combined to establish inventive step, the evaluation of novelty in the case of selection patents, and the admissibility of Markush and Swiss claims;
- To clearly distinguish 'inventions' from 'discoveries'; if genetic materials are deemed patentable, to limit the protection to the function/s disclosed in the patent claims;
- To differentiate, as necessary, between sectors in applying the patentability standards. For instance, more rigorous standards may be applied to examine pharmaceutical patents (given their impact on access to drugs) than those in other sectors;

- To strengthen and facilitate the use of pre and post-grant opposition systems;
- To improve the transparency of the system by requiring information on the INN of drugs and the origin of claimed genetic resources;
- To empower the competition authorities to take effective action in cases of abuses of patent rights.

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