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Italian Patents Revisited

Thomas Graf (Cleary Gottlieb Steen & Hamilton LLP) · Monday, March 12th, 2012

Steffano Grassani wrote a thoughtful response to my post on the Italian Pfizer decision. His discussion helps to crystallize some of the key issues raised by the case that merit some further consideration. Clearly, Steffano is right that misleading patent authorities is not the only possible patent related abuse. However, it must also be true that mere use of lawful patent instruments, such as divisional filings or applying for an SPC, cannot in itself constitute an abuse. Additional elements are needed that justify treating such conduct as unlawful under competition rules.

In the case of a refusal to license, high legal hurdles must be met for applying Article 102 TFEU. In the case of the provision of misleading patent information, the dominant company uses improper means to secure patent protection to which it is in fact not entitled. Its conduct therefore steps beyond the exclusivity delineated by the patent system. Other forms of patent related conduct must meet similar criteria to qualify as abusive. Otherwise, legal certainty is impaired and intellectual property rights are undermined.

If the conduct at issue consists of nothing more than the use of patent measures, then a challenge under Article 102 TFEU amounts to imposing a de facto duty to license. This is because such a challenge reduces the exclusivity provided by the patent system. This is illustrated well by the Italian Pfizer case.

By treating Pfizer's reliance on the Xalatan SPC that it had obtained based on a divisional patent as an unlawful act, the Italian authority in effect suggested that the scope of Pfizer's exclusivity for Xalatan should be construed more narrowly. It thus negated a portion of Pfizer's property rights. Yet, it remains unclear what the legal basis was for taking such a step.

Steffano suggests that the authority's central objection was that Pfizer had filed the divisional patent for "*no other purpose*" than obtaining the SPC (which Pfizer could no longer obtain under the parent patent). As counsel for the complainant, Steffano knows the case much better. But from the public decision, this is not so evident (the divisional patent was filed in 2002 — seven years before application for the SPC — and the Italian authority does not appear to cite internal documents from the relevant 2002 period).

Importantly, however, even if Pfizer did file the divisional patent for "no other purpose" than obtaining the Xalatan SPC, it is questionable that this should suffice for a finding of abuse. It is not correct to say that Pfizer was "*time-barred*" in the absolute from seeking the SPC. The application period had only expired for the parent patent. The application period had not expired for the divisional patent and the patent system allows relying on such divisional patents for SPCs. By

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taking a divisional patent as the basis for the SPC application, Pfizer was therefore not extending exclusivity beyond what the patent system provides for.

Steffano points to the finding of the Italian authority that the divisional patent did not embody any additional innovation. But, as noted in my original post, this reflects a misunderstanding by the Italian competition authority about the nature and purpose of divisional patents. Divisional patents cannot and should not include new innovative subject matter beyond that of the parent patent. Divisional filings serve procedural purposes.

In fact, an important function of divisional filings is to protect applicants against formal errors. The patent system is subject to many technicalities and formalities. If the parent patent is refused because of a formal shortcoming, a divisional patent can help to save the invention from loss of patent protection by healing that mistake. It is therefore common for companies to file divisional patents as a form of "insurance" against such formal mistakes. Importantly, however, this only works if the innovative substance of the patent is sound and deserves protection. The point of a divisional patent is therefore not that it involves additional innovation beyond the parent patent but that it embodies innovation covered by the parent that is worthy of protection. In such circumstances, divisional patents simply ensure the survival of valid claims that protect the invention in question.

A suggestion that divisional patents cannot be used to heal procedural or formal shortcomings would therefore be quite troubling. It would threaten a widespread and common practice with findings of illegality, and it would deprive inventions of patent protection even though their innovative substance is sound and meets the conditions of patentability.

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