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The Italian Supreme Court on the limits of pharmacy exception

Daniela Ampollini (Trevisan & Cuonzo) · Wednesday, July 28th, 2010

By a decision of 20 May 2009, the Italian Supreme Court clarified the limits of the so called pharmacy exception contemplated by Italian patent law, according to which the extemporaneous preparation by the pharmacist of units of a drug, based on a medical prescription, using a patented active substance, does not result in patent infringement. In the specific case, two pharmacists had been *inter alia* criminally charged of the offence foreseen by the then in force Art. 88 of the Italian patent law – according to which the sale of products which infringe upon a patent may also result in a criminal offence (Art. 88 of the Italian patent law was abrogated, but an almost identical provision is now contemplated by Art. 517-ter of the Criminal Code) – for having used the Merck Sharp and Dohme patented finasteride – which they had purchased from unlicensed manufacturers – in the preparation of drugs for their clients. The pharmacists claimed that, however, Italian patent law (now Art. 68 of the Italian IP Code) provides for the so called pharmacy exception, which would save them from patent infringement both civilly and criminally. In this respect the Supreme Court held that the rationale of this exception is that of allowing the preparation by a pharmacist of a patented drug with a different dosage or different excipients as opposed to those of the drug sold by the patent holder or its licensees, in view of the patient's special needs (specific therapy requirements or allergy) certified by the medical prescription. It is only in these cases that the patent rights may surrender in the face of the need to protect the health of the patient. In the case in suit, however, there was no demonstration that a different dosage or different excipients had to be administered to the patients in order to protect their health. The Court therefore held that no exception applied and the pharmacists were held liable and convicted. As regards whether the pharmacists could be held to have known that finasteride was patented – as an intentional behaviour was necessary in order for the conduct to result in a criminal offence – the Court stated that it was inferable that the pharmacists were aware of the existence of the patent, as they knew that no generic version of the MSD product was on sale. It must be noted that Art. 68 IP Code now provides that the pharmacy exception applies only if the patented active substance used by the pharmacist was not industrially produced, while the finasteride that had been used in the specific case was in fact the result of industrial-scale production. This limitation was however not present in the provision in force at the time of the conduct and the industrial-scale production of the finasteride was therefore irrelevant in the case. This decision established a very narrow interpretation of the Italian pharmacy exception, which is particularly interesting in that the limits upheld by the Court are not expressly contained in the provision of Art. 68 IP Code, nor are they directly inferable from the rationale of patent infringement exceptions in general.

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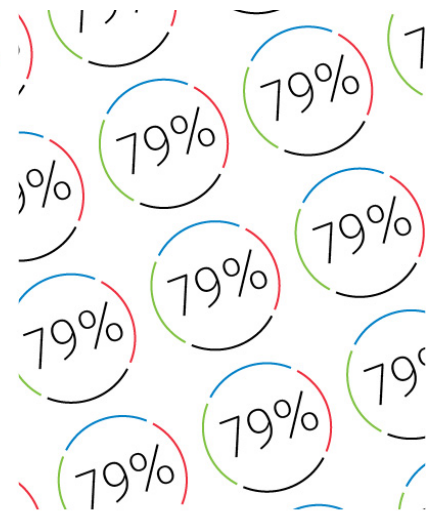
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