Kluwer Patent Blog

Patent protection irrelevant for inclusion of generics in transparency list, says the Italian Supreme Administrative Court

Daniela Ampollini (Trevisan & Cuonzo) · Wednesday, September 8th, 2010

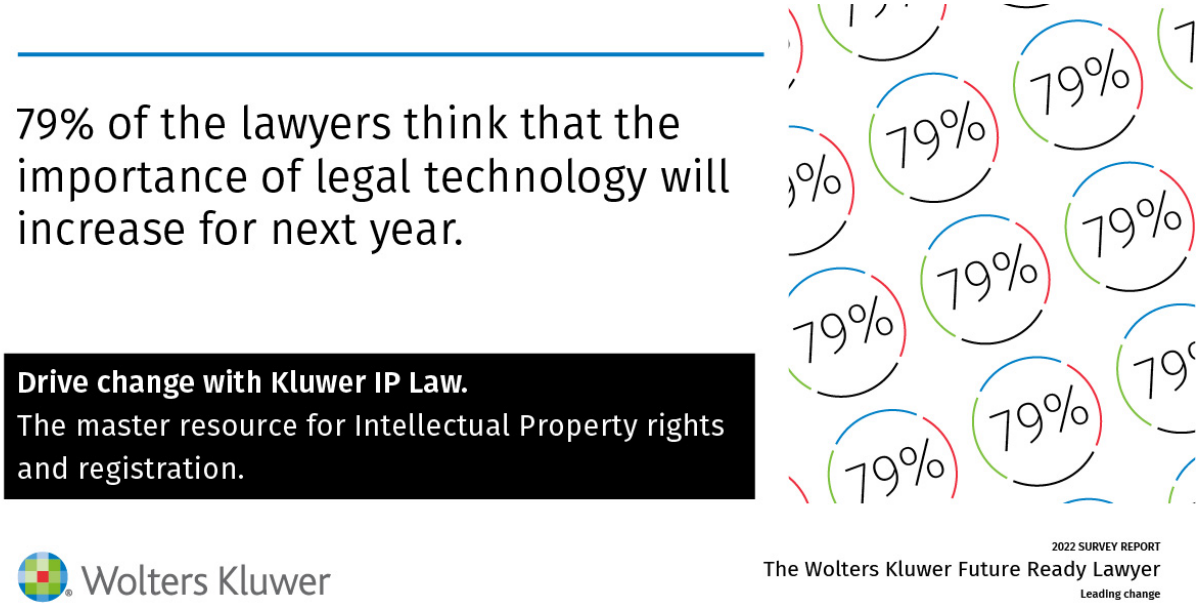
By decision of 29 July 2010, the Italian Supreme Administrative Court (Consiglio di Stato) tackled the difficult issue of whether the Italian drugs regulatory authority (Agenzia Italiana del Farmaco – AIFA) should or should not consider the existence of a patent when adopting decisions relating to the marketing authorisations of generics. In the case at issue, Pfizer had requested the competent regional administrative court (TAR Lazio) to revoke a decision whereby AIFA had included a generic of the Pfizer latanoprost based drug into the Italian transparency list, i.e. the list of equivalent drugs and their respective prices which has the purpose of allowing the application of the mechanism for the reimbursement of equivalent drugs. According to the latter, the State's health service shall reimburse a drug only up to the price of the cheapest equivalent drug on the market, and in case a more expensive product is purchased by the patient (as he chooses so or as the doctor prescribed that no generic product can be used in substitution of the prescribed branded product) the patient shall bear the difference. Pfizer had succeeded in the first instance, as the regional Court had decided to stay AIFA's decision to include the generics in the transparency list in view of the fact that the Pfizer product was still covered by a supplementary patent certificate. This had to be presumed valid, so that no generic was allowable in view of Art. 10 of the Italian Drugs Code according to which the simplified procedure for the marketing authorisation of generic drugs must be applied "without prejudice to industrial and commercial property". The Supreme Administrative Court, however, reversed the decision of first instance and, based on a detailed analysis of the wording of the various provisions contemplating transparency lists and the mechanism of reimbursement of generics, and in particular the way this wording was subsequently modified since initially adopted in 2001, stated that the existence of a patent is irrelevant to the inclusion of an equivalent drug into a transparency list. I believe there is room for criticising the reasoning followed by the Supreme Court in this case, which is very (too much) rigidly dependent on the literal language of certain pieces of legislation while disregarding the wording of other relevant provisions. This case law is however no big surprise as there are other precedents in which the Supreme Administrative Court stated that the Italian regulatory authority has no powers of assessing whether a (valid) patent exists or not on the originator, when conducting a procedure for the authorisation of a generic. On the other hand, this decision may support a case that it must be the ordinary courts to take care of the sentence "without prejudice to industrial and commercial property" in Art. 10 of the Italian Drugs Code and impose (maybe even directly on the regulatory authority) an injunction against the infringement of a patent at the very moment of conducting the authorisation procedure.

To make sure you do not miss out on regular updates from the Kluwer Patent Blog, please subscribe here.

Kluwer IP Law

The **2022 Future Ready Lawyer survey** showed that 79% of lawyers think that the importance of legal technology will increase for next year. With Kluwer IP Law you can navigate the increasingly global practice of IP law with specialized, local and cross-border information and tools from every preferred location. Are you, as an IP professional, ready for the future?

Learn how **Kluwer IP Law** can support you.



This entry was posted on Wednesday, September 8th, 2010 at 4:05 pm and is filed under Italy
You can follow any responses to this entry through the Comments (RSS) feed. Both comments and pings are currently closed.