

# Kluwer Patent Blog

## Is the filing of an MA application for a generic drug an act of infringement for the Italian courts? (Part I)

Daniela Ampollini (Trevisan & Cuonzo) · Wednesday, April 21st, 2010

Whether patent holders marketing branded drugs may assume that the very act of filing of an MA application by generic companies result in patent infringement is one of the hottest issues at the moment being tackled by the IP Chambers of Italian district courts. The IP Chamber of the Milan Court and the IP Chamber of the Rome court have so far adopted divergent opinions.

According to the Rome Court in the preliminary proceedings between Pronova and Chiesi (decision of 23 October 2006), even when the generic drug has not been licensed yet, the filing of the MA application for the generic per se results in patent infringement as a preparatory act of marketing. This conclusion mainly derives from a provision of Italian patent law which expressly defines the filing of an MA application as an act of infringement: Art. 61(5) of the Italian IP Code (IPC) provides that

*“Companies wishing to produce pharmaceutical specialties outside patent protection may commence the procedure for the registration of the product containing the active substance one year before the expiry of the complementary patent protection over the active substance”.*

This provision is included in an article dealing with supplementary patent certificates (SPCs) and was originated by the need to mitigate the effects of the excessive length of Italian SPCs which, before the entry into force of Regulation 1768/92/EC, could extend to a maximum of 18 years in addition to patent length. The general language used in this provision, however, determines objective effects beyond the case of excessively lengthy SPCs. In stating that generic companies may file MA applications one year earlier than the expiry of the SPC protection covering the active substance, this provision also states that the same companies may not do so before as this would result in patent infringement. Further conclusions are that if there is no applicable SPC, the MA filing may only take place after the very last day of patent validity and that it is necessary to wait until after the expiry of the SPC in case the patent does not concern the *“the active substance”*, e.g. it claims a novel pharmaceutical formulation.

Based on the above, the Rome Court stated that the mere filing of an MA application by the generic company when the relevant patent is still valid results in patent infringement. The Rome Court well motivated its decision also in respect of the so called *“Bolar Exception Clause”*

contained in Art. 68(1)(a) IPC, according to which the exclusive right of the patent holder does not extend

*“to experimental activity (...) although aimed at obtaining, even in foreign countries, an authorization for the marketing of a drug and the consequent practical fulfillments including the preparation of the pharmaceutically active starting materials that are strictly necessary thereto”.*

According to the Rome Court, this provision simply clarifies that the experimental activity exception extends to the experimental activity to be carried out by the generic company in order to prepare the marketing of the generic drug, but it does not to the filing with the regulatory authority of the dossier resulting therefrom. This appears as the only interpretation of Art. 68(1)(a) IPC which would not deprive abovementioned Art. 61(5) IPC of any meaning, even more considering that Art. 68(1)(a) IPC only refers to “*experimental activity*” and that there is nothing of an experimental nature in the initiation of an administrative procedure aimed at the release of a marketing authorization.

The divergent opinion of the Milan Court in the next post!

---

*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.

---

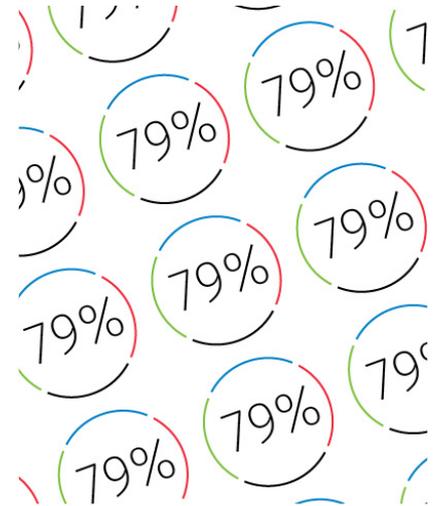
79% of the lawyers think that the importance of legal technology will increase for next year.

**Drive change with Kluwer IP Law.**

The master resource for Intellectual Property rights and registration.



2022 SURVEY REPORT  
The Wolters Kluwer Future Ready Lawyer  
Leading change



This entry was posted on Wednesday, April 21st, 2010 at 7:00 am and is filed under [\(Indirect\) infringement](#), [Biologics](#), [Enforcement](#), [Italy](#)

You can follow any responses to this entry through the [Comments \(RSS\)](#) feed. Both comments and pings are currently closed.