

'Rules of Game' For Medicinal IP in EU

BY JOHN FARR*



Resolving issues when authorities in multiple countries differ only in treatment

Under European rules, a medicinal product may obtain a marketing authorisation (MA) either from the European Commission after its safety, efficacy and quality have been evaluated by the European Medicines Evaluation Agency (EMEA) or from national authorities.

The grant of a MA for a given product by any national authority when the same product is in the process of being evaluated or has already been evaluated by another national authority creates the problem of so-called duplicate MA applications. In a duplicate application, the original product and the duplicate one are the same product. The differences between them are limited to the trademark and to the name of the marketing authorisation holder (MAH). The contents of the dossier and of the SPC is therefore basically the same.

Duplicate applications are normally the result of an agreement between the company that developed the product and a local company willing to put such product in the market under a license. Agreements of this kind are deeply rooted in the European Union. They are commonly known as co-marketing agreements.

The issue, which the so-called new rules of the game for marketing authorisation procedures relate to these agreements, is a leading subject of discussion in Europe, especially as a result of the Communication published by the EU Commission in July 1998 and of some more recent documents made public by the Mutual Recognition Facilitation Group. Although, many questions are still floating in

the air, and there exists a large and undefined degree of legal uncertainty regarding this matter.

► Misconceptions ►

The origin of the problem is to be found in two deep misconceptions. The first one deals with how licensing and co-marketing agreements are perceived by some authorities. The second one deals with how these authorities view the role the European law and regulatory bodies should play in the challenging game of building and maintaining the single European market. This controversy is limited to the second of these misconceptions. The first one deals more with historical issues, marketing strategies and competition law. Going through these aspects of licensing and co-marketing would probably require more time and space.

If we focus the analysis on the second misconception, I would start from the fact that it has not been uncommon to hear from some authorities that European law should promote in an active manner a harmonization of the SPC of each medicinal product. This would ensure, it has been said, free circulation of medicinal products within the Community.

Based on that idea, the fact that the same product may be placed on the market by two different companies, under licensing arrangements, and that these respective firms could in theory follow different paths (perhaps the licensee decides to make a variation as a marketing tool that would allow it to compete in a more efficient manner in the market, or perhaps the licensee invents billions in developing a new indication that does not want to give to the licensee its full, had been regarded as a threat

to the fundamental objectives of the Community.

I think this approach is wrong, and I also think that because of devoting too much time and effort to this misconception, the European market still does not exist, for medicinal products, in many of us would like to see it.

The fundamental objective of European law in this area is to ensure that once a product has been authorized in the Community, either this product may circulate freely (this is valid for products authorized through the centralized procedure), either the ability of national authorities to raise objections to such product entering their own territory is materially restricted because of mutual recognition being imposed on such national authorities on a general basis.

► Circulation issues ►

Indeed, European law must ensure that the original product may circulate from one Member State to the other and that the licensed product may also circulate from one Member State to the other. As regards regulatory issues, this is the responsibility of DGII and of national authorities.

As regards competition issues, this is the responsibility of DGIV and also of national authorities. On the contrary, neither DGII nor DGIV have been entrusted with the task of securing that the original product and the licensed product are identical, and this is without prejudice of the fact that in practice, in most cases, such identity exists. The only differences between the original product and the licensed one are their trademark and the

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name of the marketing authorization holder.

It is curious to see that if one reads the legal texts under three stars it cannot be said they are incomplete (or "wrong").

Under Regulation EEC/2008/93, nothing prevents one active ingredient from being the object of more than one marketing authorization, provided that the name of each medicinal product is different in order to ensure that no problems regarding their identifications exist. No rule of law prevents these two marketing authorizations being held by one entity or by two different ones. No rule of law prohibits the marketing authorization holder to grant distribution rights for one of such products in favor of a third party under a contract that shall need to observe competition rules just as any other contract needs to do. All of it, of course, needs to be understood without prejudice of the legal position of the marketing authorization holder, who is responsible vis-à-vis regulatory authorities for compliance with all obligations imposed on it by European law.

The same happens if we read again and take a close look at EC

Directives as they were amended in 1993. An applicant for a marketing authorization is under the obligation to provide the authority to whom it submits its petition with copies of authorizations already obtained for the relevant medicinal product and a list of Member States where the application has been filed.

One point that could perhaps need clarification was raised by the Commission Communication:

The Commission understands that the term "the relevant medicinal product" means any medicinal product the composition in active substances and pharmaceutical form is the same as the product for which a marketing authorization is sought. Once this aspect is cleared, it seems that no provision of EC Directives would prevent the licensee who applied for a marketing authorization from a national authority to benefit from the right granted to it by EC Directives in the sense that the national authority should examine its application under the constraints imposed by the mutual recognition procedure, and this right of the licensee should not be affected by the fact that the licensee may have also applied for a marketing au-

thorization to the same national authority for the same relevant medicinal product. My opinion is that EC Directives should not be read in a manner that imposes licensees to exercise rights that EC Directives have granted to them in a precise manner.

Further, if we consider that in most cases the manufacturing of the original product and of the licensed one is centralized in one site of Europe, we can easily conclude that the exercise of such rights by licensees contributes to make free movement of goods a reality and therefore to integrate markets.

On the other hand, it does not seem that any higher interest connected with the protection of public health should be invoked to restrict the licensor's and licensee's rights, especially if the legal position of the marketing authorization holder is well defined by the legislation, as it happens to be. At the end of the day one should not forget that European regulatory norms do not exist to make the life of public administrators easier but to protect consumers and to ensure free movement of goods within the Community.