Regulatory activities and infringement of pharmaceutical patents in Sweden – what is the connection?

The EU IP Rights Enforcement Directive makes interlocutory injunctive relief available where infringement has been attempted or where preparations for infringement have been made. So, can the act of seeking and obtaining marketing authorisation or price approval for a generic product qualify as an attempt to infringe or prepare for infringement?

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It is vital for pharmaceutical companies which hold patents for valuable drugs or specific formulations of such drugs to monitor the market for potential infringements and to act proactively in both the regulatory and patent law areas. This article considers the extent to which regulatory measures taken by a potential infringer can give rise to cause of action and liability under patent law.

One of the first issues for the patentee to consider is when action to stop an infringement can be taken. Early action is important in order to mitigate the damage caused by infringement, not least in countries such as Sweden, where the system of mandatory generic substitution means that the launch of a low-price generic can have an immediate and dramatic impact on sales of the original product.

In 2009, it was established law in Sweden that none of the acts of obtaining marketing authorisation and subsequent price approval for a generic medicinal product in themselves constituted an act of patent infringement. Since injunctive relief – including interlocutory relief – requires the existence of infringement, this meant that the patentee had to wait until the launch of the generic product before effective measures could be taken.

On 1st April 2009 the EU IP Rights Enforcement Directive (2004/48/EC) was implemented in Sweden. Among other things, the directive makes interlocutory injunctive relief available where infringement has been attempted or where preparations for infringement have been made. In this light, the question arises: can the act of seeking and obtaining marketing authorisation and/or price approval for a generic product qualify as an attempt to infringe or prepare for infringement?

In the absence of developed case law in this area, it is not possible to reach firm conclusions in this respect. However, if the facts of a given case suggest that the marketing authorisation and/or price approval has been obtained for the purpose of launching a product during the term of a patent, it could well be argued that this

constitutes a preparatory act for infringement and hence warrants interlocutory relief.

Where the applicant (ie, the potential infringer) has refused to confirm that it will not launch during the term of the patent and/or undertake to provide reasonable notice to the patentee prior to a launch, this fact could prove useful in arguing that the marketing authorisation or price approval involves preparatory steps for infringement.

Where the potential infringer has made statements that the patent will be revoked or contested that the product in question infringes the patent, this will constitute strong circumstantial evidence to suggest that preparations for infringement have taken place. Further, where an application for marketing authorisation has been filed long before the patent term will lapse, this fact could support the notion that relevant preparations for infringement exist.

In its judgment of 11th June 2010 in Case T 16665-04, the Stockholm District Court found a number of pharmaceutical companies guilty of infringement of a supplementary protection certificate held by MSD Overseas Manufacturing Co and Merck Sharp & Dohme by marketing and selling medicaments which contained alendronate as the active substance.

One issue before the court was the extent to which a marketing authorisation holder is liable for the marketing by another entity of products covered by the authorisation. In the case before the court, as in many other cases involving generics companies, a foreign parent company had applied for and been granted a marketing authorisation to sell the products in Sweden. The foreign company was also responsible for the preparation of the summary of product characteristics and the product insert leaflet. As the entity performing the actual marketing and sales of the medicament was a Swedish entity (a subsidiary), it was of interest to ascertain the extent of responsibility borne by the foreign parent company. The district court established that the mere fact that the name of a marketing authorisation holder appears on the summary of product characteristics and the product insert leaflet will not, as such, constitute infringement by offering for sale. This is because the summary of product characteristics and product insert leaflet are submitted to the Medical Products Agency when the marketing authorisation application is filed.

The district court found that the Swedish subsidiary had sold alendronate products to Apoteket, the Swedish pharmacy chain. It could therefore be assumed that the summary of product characteristics and product insert leaflet not only had been prepared in order to obtain a marketing authorisation, but also had been distributed to customers. The court further drew attention to the fact that the subsidiary sold the products under the parent company's marketing authorisation. According to the district court, these combined circumstances led to the conclusion that the parent company participated in the marketing of the medicament and was thus responsible for the infringement.

In passing, the district court held that it could be possible to consider an application for price approval as an attempt to infringe or preparation for infringement. However, since the parent company had already been found liable for infringement due to its participation in the marketing and sale of the infringing products, the court stated that the parent company should not be liable for having prepared to infringe.

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The judgment has been appealed to the Svea Court of Appeal.

Following the implementation of the EU IP Rights Enforcement Directive in Sweden, there should be possibilities to argue strongly that applications for and the obtaining of marketing authorisations and/or price approvals should be considered as attempts to infringe or preparations for infringement, thereby warranting interlocutory relief – at least where other supporting circumstances exist. ■

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