Effectively resolving IP disputes in the pharmaceutical industry

Papula-Nevinpat was founded in 1975 and now has an 80-strong team in Finland of whom 30 are IP attorneys. It has offices in Finland, Russia, some of the former Soviet states and Munich with a total staff of 150 professionals of which around 50 attorneys/specialists. Director Mr Folke Johansson and Mrs Erja Partio, both European Patent Attorneys, talk to AI about IP litigation in Finland.

Finnish IP law underwent an important change in 1995 when the country joined the WTO. Until that point IP protection in the pharmaceutical industry was only available for the method of manufacture of a pharmaceutical and not the product itself. As these patents and their Supplementary Protection Certificates can be in force for 20 + max 5 years, the majority of pharmaceutical IP disputes in Finland still revolve around manufacturing methods.

Still the majority of the pharmaceutical patent litigations go about whether the manufacturing method is an equivalent to the patented method – the burden of proof lies with defendants to prove it's not within the patent scope.

"Pharmaceutical products must have market authorisation issued by the Finnish Medicine Agency Fimea or European Comission/the European Medicine Agency EMEA," explains Mrs Partio. *"Patent holders monitor applications for market authorisation to recognize potential infringing products – and the burden of proof is on the defendant to prove that a different method which is workable in industrial scale has actually been used, which may involve revealing trade secrets to the court."*

As part of the Finnish government's IP strategy, Finland's new IP court opened in September 2013. As yet, no pharmaceutical cases have been decided by it, so it is unclear whether there will be any differences in approach. However, Mr Johansson points out that it will be important for companies to invest in litigation.

"Previously IP cases were heard in the district court with appeals to the court of appeal and then the high court, although permission was rarely granted," he says. *"The new IP court only allows for appeal to the high court and it may be equally rare, so it will be important to get it right first time."*

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Pharmaceutical patent litigations are the most difficult among the patent infringement cases. This is partly due to the fact that they are strongly influenced by public interest in securing the access to low cost generic drugs as soon as possible, and partly to complicated subject matter of this kind of patents.

It is the principle that when a patent proprietor sues for infringement the generic manufacturer, this challenges the validity of the patent. In pharmaceutical disputes the scope of protection of the patent is of course the key problem, and the application of doctrine of equivalence makes the outcome difficult to predict.

The approach to the evaluation of claims could be different even among European countries. The invalidation procedure can last three or more years, so the pharmaceutical companies take substantial financial risks. Therefore it is necessary not only to determine the appropriate level of costs in relation to the patent validity claim and the costs of main proceeding, but also to take into consideration possible damages due to the defendant in case of a negative outcome of the case. Of course, this calculation depends on the procedural situation i.e. if the plaintiff obtains the preliminary relief against the alleged infringer.

In Poland the invalidation procedure takes place before the PO and the infringement dispute is resolved in a civil court. According to the Polish Supreme Court, there is no reason to suspend the proceeding on infringement until the PO has ruled on validity. Therefore it is possible that the case in court ends before the decision on validity is taken, and then it is necessary to determine the risk connected with enforcement of the court verdict.

The amicable settlements in pharmaceutical disputes are subject to close scrutiny of antitrust authorities which can rule that the agreement was unlawful, e.g. reverse payment settlement and commitment not to sell generic version until x months before the expiry of the patent term would be challenged.

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