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A global pharmaceutical company filed a patent infringement action against a local generic pharmaceutical company on the grounds that the generic company had been granted an abridged marketing authorisation referring to the original pharmaceutical's dossier. The generic company also applied for inclusion on the Social Security Institution (SSI) reimbursement list. The originator company claimed that its original pharmaceutical was protected via a patent, and thus there was a danger of patent infringement. The generic company claimed that the grant of marketing authorisation fell within the scope of the Bolar exemption set out in Article 75(f) of the Patent Decree-Law.

The IP courts often broadly interpret the scope of the Bolar exemption. However, in some decisions it has ruled that the grant of marketing authorisation is insufficient to find that the Bolar exemption can no longer apply; the generic pharmaceutical must also have been granted sales permission and/or included on the SSI reimbursement list.

Court of appeal case law states that patent cases must be considered by experts, so the IP courts often refer patent cases to a court-appointed expert panel because IP court judges are not technical experts. Therefore, in the case at hand, the IP court was expected either to reject the case under a broad interpretation of the Bolar exemption or to refer the case to a court-appointed expert panel.

Decision

Surprisingly, the IP court accepted the patent infringement action. Its reasoning diverged from precedent as it held that the generic company's obtaining of marketing authorisation and application for inclusion on the SSI reimbursement list constituted actions of patent infringement.

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First, the court held that the act of applying for inclusion on the SSI reimbursement list was an 'offer for sale' and an attempt to actually sell the generic pharmaceutical. Thus, the court concluded that it was impossible to consider such action to fall within the scope of the Bolar exemption.

Going a step further, the court held that since filing an application for inclusion on the SSI reimbursement list was deemed to be an attempt to actually sell the generic pharmaceutical, such action should be evaluated under Article 136/1(a), which states that the manufacture or partial manufacture of an infringing product is an act of patent infringement. If the generic product was not manufactured at all, there would be no application for inclusion on the SSI reimbursement list.

The court also ruled that it was sufficient that an application has been filed with the SSI, even if it had not been accepted. The court based this finding on Article 151 of the Patent Decree-Law, which deals with the conditions for seeking a precautionary injunction, and found that under the decree-law, serious and effective preparations to use a patent in Turkey constitute patent infringement. Therefore, the court held that filing an application for inclusion on the SSI reimbursement list should be considered to constitute serious and effective preparations to use the patent in Turkey, and thus constituted infringement.

The court justified its decision not to refer the case to a court-appointed expert panel on the grounds that the generic company had stated that the generic pharmaceutical at issue was the same as the original patented pharmaceutical, and the generic company had based its defence on the Bolar exemption rather than the issue of non-infringement.

As a result, the court upheld the case by ordering that the pharmaceutical could not be included on the SSI reimbursement list, manufactured or launched on the market.

Comment

The IP court's decision marks the first interpretation of the Bolar exemption with such a narrow scope and the first time that an application for inclusion on the SSI reimbursement list has been considered an attempt to actually sell the product. Although all pharmaceutical companies manufacture a certain amount of a drug before applying for inclusion on the SSI reimbursement list, the courts had previously considered this to fall within the scope of the Bolar exemption.

However, considering the appeal court case law, it is highly likely that the IP court's decision will be overruled based on the lack of expert examination. It remains to be seen whether the appeal court will agree with the IP court's reasoning for not referring the case to an expert panel.

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