

A Question of Timing: Negative Declaratory Relief in Pharmaceutical IP Practice

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Istanbul's First Instance IP Court recently dismissed a negative declaratory action (the "Case") against our client citing plaintiff's lack of standing because the pharmaceutical at issue was unlicensed as of the when the action was started. The ruling is noteworthy because it appears to confirm the precedential force of similar Court of Appeal decisions.

For pharmaceuticals in particular, negative declaratory relief is considered as an effective market-clearing tool. Anyone with an interest in a pharmaceutical product sufficient to confer standing, may petition a competent court for a declaratory ruling that current and future use of the product is, or, as the case may be, is not, infringement. These actions are initiated both by pharmaceutical and non-pharmaceutical entities as a means of avoiding prospective infringement actions and, concomitantly, of securing rights before entering a market.

As illustrated by the Case, timing of the petition is crucial. This is particularly so for pharmaceuticals both in light of the process for bringing a drug, particularly a competing generic, to market; and of Article 85/3-c of the Turkish Industrial Property Law numbered 6769, referred to colloquially as the Bolar exemption, which provides a safe harbor for non-rights holders to use patented pharmaceuticals for clinical trials without infringing on the patent owner's rights.

The Bolar exemption is interpreted and applied without uniformity by Turkey's intellectual and industrial property courts. Accordingly, pharmaceutical companies and IP lawyers have lacked the clarity of a unifying pronouncement of the limits of the Bolar exemption. However, the Court of Appeal has consistently held that an unlicensed pharmaceutical is not subject to IP enforcement.

Under Turkey's Code of Civil Procedure numbered 6100, standing to file an action requires a sufficient legal interest. Where standing is lacking courts must, *ex-officio* or upon motion, dismiss the case. In the Case, negative declaratory relief was sought against our client's registered patent rights. We argued that dismissal was required under the Bolar exemption because the product in question was not licensed and, therefore, the plaintiff lacked standing, and, because the product license dossier might change during the licensing process, it would be impossible, prior to licensing, for the court to rule on the merits of the claim.

The court ruled in favor of the patent holder, and dismissed the case. It is reasonable, then, in light of the outcome of the Case, to consider the question of timing settled in accord with the Court of Appeal.

The Case confirms the settled practice of the Court of Appeal and according to the settled practice, in case of negative declaratory actions, timing is important, as the actions might be refused due to lack of legal interest. Considering this settled approach, it is advisable to file a negative declaratory action close to the anticipated time of the pharmaceutical license approval to avoid dismissal of the case. e.

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