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Turkey: Determination Of Non-Infringement Action Is To Be Rejected If Marketing Authorisation Is Not Granted Yet

(<http://patentblog.kluweriplaw.com/2019/09/24/turkey-determination-of-non-infringement-action-is-to-be-rejected-if-marketing-authorisation-is-not-granted-yet/>)

Selin Sinem Erciyas (<http://patentblog.kluweriplaw.com/author/selin-erciyas/>) (Gün + Partners (<https://gun.av.tr/>)) / September 24, 2019 (<http://patentblog.kluweriplaw.com/2019/09/24/turkey-determination-of-non-infringement-action-is-to-be-rejected-if-marketing-authorisation-is-not-granted-yet/>) / 2 Comments (<http://patentblog.kluweriplaw.com/2019/09/24/turkey-determination-of-non-infringement-action-is-to-be-rejected-if-marketing-authorisation-is-not-granted-yet/#comments>)

As per Article 154 of the Turkish IP Law any person who has a legal interest can file an action to have the Court determine that his acts do not constitute an infringement of the intellectual property rights of a rights owner.

For a quite long time patent owners were squeezed between conflicting approaches in the implementation of, on the one hand, the legal interest condition in determination of non-infringement actions (DNI), and, on the other hand, the Bolar exemption in patent infringement actions. In both cases the marketing authorisation (MA) application of the Gx Company is pending. In accordance with established case law on the interpretation of the Bolar exemption, the IP Courts immediately reject any patent enforcement attempt of a patent owner if the MA application of the defendant is still pending, emphasizing that experimental acts for the purpose of the MA are exempted from patent rights. However, the IP Courts used to accept and deal with the determination of non-infringement actions of Gx companies that are filed while the MA application is still pending. The objections of patent owners that the MA application is exempted from patent rights and therefore the plaintiff does not have any legal interest in filing the DNI were not heard.

In 2013 for the first time an IP Court in Turkey decided to reject a DNI action on the grounds that the plaintiff had no legal interest in filing this action because the MA application was still pending. The reasoning of the Ankara (2). IP Court in its decision of 27 November 2013, case number 2012/248 E.; 2013/223K., was as follows:

“The plaintiff has no legal interest in filing the declaration of non-infringement action. However, while bringing the so called Bolar exemption provision, the legislator aims to prevent both the MA application owner and patent right owner from intervening in the MA procedure before the Ministry of Health.

Besides, during the MA application procedure, the chemical properties and characteristics of the pharmaceutical subject to the MA application may be changed as per requirements of scientific boards of the Ministry of Health. Therefore, even if the Court evaluates that there is infringement at a certain point of the MA procedure it can be changed until finalisation of the procedure. Consequently it becomes unclear which stage of the MA procedure was subject to the decision of the Court and if the decision is still valid in the light of the final content of the MA dossier.

Finally, as the legal provision (the so-called Bolar exemption) already determines that a pending MA application is exempted from patent rights and therefore does not constitute patent infringement, it is unnecessary for the IP Court to re-evaluate if such an act constitutes infringement or not.

In this respect, as long as the MA application is pending, the patent owners cannot file patent infringement actions against owners of the pending MA applications and the owners of the pending MA applications cannot file declaration of non-infringement actions.”

The 11th Chamber of the Courts of Appeal upheld the decision of the Ankara (2). IP Court without any further supportive argument in the appeal decision (decision 2014/6103 E., 2014/11843K.).

An unreasoned CoA decision which simply confirms the first instance decision does not make a convincing precedent. Some IP Courts therefore continued to deal with DNI actions while the MA application was pending and rejected defences based on lack of legal interest.

However, in a new decision of 11th Chamber of Courts of Appeal numbered 2016/14642 E. 2018/6811 K., the CoA overruled the decision of the first instance court due to lack of legal interest of the plaintiff. The CoA ruled that, irrespective of the status of the MA application at the date of the final decision of the first instance court, if the MA application is still pending at the filing date of the DNI action, the plaintiff has no legal interest in filing such an action. This is because the Bolar exemption provision already exempts MA application acts from patent rights.

The reasoning of the CoA is important as it clearly and definitely puts an end to DNI actions of Gx Companies that are filed before the Gx MA is granted.

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2 comments



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This is a blow against legal certainty. If a company decides to invest in developing a product and applying for an MA, after the 20 to 25 years of patent protection expired, it would be a wise decision to get legal certainty about the potential infringement status in light of secondary patents of the commercialised product. Denying the generic industry the important tool of DNI the companies are forced to either launch their products at risk, or to stay away from developing innovative products until the last patent of the originator is expired or invalidated. Hence this move will be highly welcomed by those who want to keep their monopolies and keep the off-patent industry at bay.



SELIN SINEM ERCIYAS (<https://gun.av.tr/tr/>)

SEPTEMBER 25, 2019 AT 12:23 PM ([HTTP://PATENBLOG.KLUWERIPLAW.COM/2019/09/24/TURKEY-DETERMINATION-OF-NON-INFRINGEMENT-ACTION-IS-TO-BE-REJECTED-IF-MARKETING-AUTHORISATION-IS-NOT-GRANTED-YET/#COMMENT-35858](http://patentblog.kluweriplaw.com/2019/09/24/turkey-determination-of-non-infringement-action-is-to-be-rejected-if-marketing-authorisation-is-not-granted-yet/#comment-35858))

Thank you for your comment.

“Legal Interest” condition is one of the backbones of Turkish law system and it must exist in any kind of legal act or action. In that sense “Legal Interest” condition is superior to protection of patent rights as well as to providing Gx an early launch.

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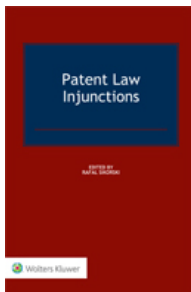
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