Wisdom
International Patent & Law Office
維新國際專利法律事務所

Wisdom News

Volume 37 (3 February 2021)

Wisdom News brings you the latest patent and trademark trends around East Asia

China

Bayer anti-cancer drug Nexavar® patent was challenged by YaoPharma, and finally declared invalid by CNIPA

Bayer manufactures Nexavar® (active ingredient sorafenib), which is used all over the world as a cancer treatment. The disputed patent no. CN200680007187.1 "Pharmaceutical composition comprising an omega-carboxyaryl substituted diphenyl urea for the treatment of cancer" held by Bayer, is the corresponding patent of Nexavar® (sorafenib tosylate tablet) in China.

Case Fact and Decision Summary

A Chongqing-based pharmaceutical company, YaoPharma filed invalidation requests against the dispute patent twice before the China National Intellectual Property Administration (CNIPA). Finally, on 21 September 2020, the CNIPA declared that all the claims of the disputed patent were invalid due to lack of inventive steps.

The invalidation decision no. 46292 is summarized as below:

Compared to the closest prior arts, the distinguishing features of the disputed patent are the (1) high drug loads of at least 75%, (2) micronized forms of the active agent and (3) specific types and content of excipients. However, it is known that the administration dosage of sorafenib is high, and thus a skilled person would obviously select high drug loads and smaller size tablets to improve patient compliance.

Further, based on the disclosure of prior arts, it appears that producing tablets with active agents in a concentration over 75% can be easily achieved. Also, due to slow dissolution of sorafenib tablet in the gastrointestinal tract, it is general knowledge to micronize the active agent to increase surface area. The types and content of excipients are also taught in the prior arts, and fail to show any unexpected effects. In conclusion, all the claims in the dispute are obvious and can be expected by a skilled person, and thus do not involve any inventive step.

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Key Takeaways

It will be interesting to see how new drug manufacturers like Bayer corresponds to patent invalidity challenges in China. It is also worth noting that the competition for generic drugs of sorafenib is getting fiercer in China. More than 20 pharmaceutical companies in China have filed Abbreviated New Drug Applications (ANDA) for sorafenib, including YaoPharma, Jiangxi Shanxiang Pharm, Jiangsu Hansoh Pharmaceutical Group, CTTQ Pharma, Qilu Pharmaceutical, etc.

The full invalidation decision can be read here:
http://reexam-app.cnipa.gov.cn/reexam_out2020New/searchdoc/decidedetail.jsp?jdh=46292&lx=wx.

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