

**Boehringer's Pradaxa: Potential future generic challengers to face steep hurdle to challenge patent protection - attorneys**

**Boehringer Ingelheim's** patent for Pradaxa is strong, and potential future generic ANDA challengers are likely to face an uphill battle with respect to invalidity, patent attorneys said.

There is one patent listed in the Orange Book as covering Pradaxa, US Patent No. 6,087,380, which is presently identified as expiring in February 2018.

The patent is so strong such that generics would likely face an "uphill battle" with respect to potential challenges on structural obviousness grounds, said Larry Coury, an associate in the intellectual property department at Cravath, Swaine & Moore. The patent has both genus and species claims for the compounds it covers, he noted, adding that there are numerous examples in the specification of the patent, and consequently should not be any written description problems.

The claims look "pretty strong" in terms of validity, agreed Michael Muczynski, a partner in the biotech and chemical group at Marshall Gerstein & Borun, who added that the US Patent and Trademark Office (PTO) did not identify any relevant prior art, and that patent offices around the world granted the patentees similar claims. The presence of both genus and species claims adds stronger protection, he added, noting that the broad claims could inhibit the sale of competing drugs, while the very narrow claims that cover Pradaxa would only be invalidated on prior art grounds by earlier disclosure or sale of the same compound.

Connie Wong, an intellectual property partner at Lee & Hayes, added that the patent is "very strong" and distinguishes from generic warfarin. She added that Boehringer Ingelheim has "a lot to stand on" with respect to its patents, because clinical data set forth in the patents supports "unexpected results" of the chemical structure of Pradaxa compared to other chemical structures, such as the chemical structure for generic warfarin.

The broad compound claim in claim 1, as well as the specific compound claims in claims 6, 7 and 9 of the patent would be difficult for generics to invalidate based on structural obviousness in an ANDA challenge. She agreed that Boehringer Ingelheim would likely be able to prove "unexpected results" and "unexpected benefit" under the Supreme Court's "KSR" obviousness standard even if a similar chemical structure is found in the prior art.

Kimberly Berkowski, an organic chemist and patent agent at Marshall Gerstein & Borun, noted that the chemical structure in claim 9 of the patent is the same chemical structure as in the prescribing information for Pradaxa. She noted that the benzimidazole portion of the molecule cannot tautomerize because one of the nitrogen atoms is substituted, in this case with a methyl group.

Sam Talmassebi, an intellectual property partner at Techlaw, noted that the claim language "more tautomers thereof" was previously in the claims and was removed during prosecution due to a restriction requirement from the PTO. Thus, the marketed compound will have to be analyzed during discovery in a potential litigation to make sure that it only contains the claimed tautomer.

All of the attorneys who spoke with the news service said that despite the strength of the patent, ANDA challenges are likely after the NCE exclusivity expires because the drug is expected to be a blockbuster.

Boehringer Ingelheim did not respond to a request for comment.

by Sasha B. Coffiner