

Endo may face enablement and non-infringement obstacles in defending Lidoderm patent litigation against Watson - attorneys BioPharm Insight

- Endo's patent susceptible to invalidity challenge on enablement due to broad Markush groups
- Company's patent lacks detailed formulation claim specific to commercial formulation
- **Endo may face new prior art, but has strong data to defend against obviousness challenge**

Endo Pharmaceuticals (NASDAQ:ENDP) may face enablement issues concerning the validity of its patent for Lidoderm in an ongoing ANDA litigation with **Watson Pharmaceuticals** (NYSE:WPI), as well as a strong non-infringement challenge, patent attorneys said.

On 19 February 2010, Endo and **Teikoku Seiyaku** and **Teikoku Pharma USA** sued Watson in federal court in the district of Delaware for patent infringement, pursuant to Watson's Paragraph IV ANDA for Lidoderm. On 31 January 2011, Endo announced receipt of a Paragraph IV ANDA notification from **Mylan** (NASDAQ:MYL) to produce a generic version of the Lidoderm Patch. Endo has 45 days to sue Mylan after receipt of the Paragraph IV notification.

There are four patents listed in the FDA's Orange Book for Lidoderm, but the litigation concerns only US Patent No. 5,827,529, which is listed as expiring in October 2015. The other three patents expire in 2012 and 2014.

A spokesperson for Endo said, "We intend to pursue all legal, business and regulatory avenues in defense of Lidoderm, while we also intend to vigorously defend Lidoderm intellectual property rights against infringement."

Watson did not respond to a request for comment.

The '529 patent is a "relatively broad" formulation patent that uses Markush Groups and numeric weight ranges for different chemical excipients in the formulation, noted George Xixis, a partner at Nutter McLennan & Fish. Markush groups are a way of drafting a patent claim to cover an element, which are selected from a list of options.

Because the ranges are so large, this could present Endo with a problem for establishing enablement of the claims since there may not be enough support in the specification for such wide excipient ranges and combinations, Xixis explained. In addition, he noted that it is possible that all of the different combinations of excipients and weight ranges may not function as contemplated by the specification since the limited number of examples provided in the specification only contemplate certain combinations and ranges.

In addition, the example formulations in the patent are all relatively the same with respect to the amount of each type of excipient, said Jennifer Fox, head of the life sciences and biotechnology group at Coats & Bennett. Accordingly, she noted that Endo may face challenges with respect to proving enablement.

Connie Wong, an intellectual property partner at Lee & Hayes, added that Endo only provides three examples in the specification, which may not be enough to enable the entire scope of the claim. Enablement is the strongest ground for Watson with respect to attacking the validity of the patent at issue, she noted. The Markush groups and broad excipient ranges could further open up the patent to enablement attack, since Endo does not have a specific dependent claim for the marketed formulation that it is using commercially.

The lack of a specific claim to the formulation for the commercial product is "surprising," said Brian O'Shaughnessy, a partner at Buchanan Ingersoll. He explained that the patent examples do not need to embody the entire claim, but it is a good idea to embody as much of the claim as possible,

and the claim could face enablement challenges.

Yet Robert Siminski, a partner at Harness Dickey & Pierce, noted that the claim uses the language “consisting essentially of” -- which makes the claim a “close ended claim,” limiting its scope. Therefore, he added that the claim is not necessarily extremely broad, and that the ranges of the Markush groups do not alone create an enablement problem.

The case is scheduled for a Markman, or claim construction, hearing in June. Xixis noted that because the claims do have specific numeric limitations and use Markush groups to define the scope of the claimed formulation, there is probably not a lot of variability for the upcoming claim construction.

Bob Breisblatt, an intellectual property partner at Katten Muchin & Rosenman, added that Judge Sleet, the district court judge presiding over the case, is likely to do a “quick” claim construction that will reflect the “plain and ordinary meaning” of the claim terms.

Fox agreed that there is “not much room to play” with claim construction as there is not a lot of ambiguity in the claim language. She added that the claims do not contain much “functional” language, which is often the subject of controversy during Markman hearings.

Xixis noted that the patent could be vulnerable to an obviousness validity challenge because of the broad ranges and numerous potential combinations of excipients and the potential range of prior art that might be used to invalidate the patent.

With respect to obviousness as further grounds for invalidity, Wong noted that during the patent’s prosecution, Endo tried to highlight “unexpected results” of the claimed formulation. Endo also ran experiments comparing the closest prior art with the claimed formulation to defend against the Patent & Trademark Office’s obviousness rejection, she added.

This is a very strong way for Endo to have defended against obviousness, Wong noted, and puts Endo in a strong obviousness position against Watson. Such side-by-side experimental comparisons are the best way to defend against obviousness, although Watson will certainly see if these experiments can be replicated during the course of the litigation, Wong noted.

O’Shaughnessy agreed that the breadth of the Markush groups could give Watson a lot of leeway in finding prior art for obviousness.

Siminski added that a patent attorney would be able to construct a viable obviousness challenge to the ‘529 patent from a prior art search, which should start by looking for prior art relating to topical lidocaine applications.

Fox also noted that Watson asserts that it does not infringe any valid and enforceable claims of the ‘529 patent. If Watson indeed has created a formulation where one or more of the excipients are in an amount outside of the ranges claimed, Endo will have a hard time overcoming Watson’s non-infringement position absent of convincing the court to construe the ranges to include amounts more or less than those specifically indicated, she said.

Fox noted that she would “not be surprised” if Watson were able to design such a non-infringing formulation by changing the amount of one or more of the excipients. Certainly one other possibility is that Watson’s assertion of non-infringement is simply due to the fact that it also asserts that none of the claims are valid and enforceable, she said.

Xixis agreed that there may be a “reasonable” non-infringement argument for Watson because the claims may have to be construed narrowly to be valid at all.

O’Shaughnessy agreed that non-infringement will depend on Watson’s specific formulation, but noted that there are a lot of ways that Watson could have come up with a non-infringing formulation based on the breadth of Markush groups included in the claims. Non-infringement may also depend on arguments made by Endo during patent prosecution, he said.

Siminski added that a design around by changing one of the excipients is possible, but it is unclear



if it would be as effective as Endo's formulation.

Yet Wong noted that the broad claims may be beneficial to Endo from a non-infringement perspective if they survive validity challenges, although this will depend on the formulation Watson is using.

Xixis noted that if Watson defeats the '529 patent at trial or reaches a settlement with Endo, it would be able to market the drug a year or two earlier, after the other patents covering the product have expired.

by Sasha B. Coffiner