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Patents

Inter Partes Review Process May Overtake District Court as Place to Challenge Patents

How companies handle patent disputes involving drugs may change, with use of the inter partes review (IPR) process replacing litigation in a district court as the standard operating procedure, an attorney experienced in IPR procedures told Bloomberg BNA.

''We're very close to a tipping point where this is going to be standard operating procedure and the default choice in any patent infringement case,'' Joseph E. Cwik, a partner with Husch Blackwell LLP in Chicago, said in a July interview.

Cwik represents Gnosis SpA, which in June won favorable rulings from the Patent Trial and Appeal Board (PTAB) in four separate IPR proceedings related to four separate patents owned by Merck & Cie and the South Alabama Medical Science Foundation (SAMSF) (*Gnosis S.P.A. v. South Alabama Medical Science Foundation,* PTAB,Nos. IPR2013-00116-00119, 6/20/14). The PTAB invalidated all 58 of the patent claims that Gnosis had challenged.

SAMSF owns three of the patents Gnosis challenged, which are licensed to Merck & Cie. Merck & Cie also owns the fourth patent relating to natural folates in combination with other ingredients. The patents are licensed for use in several prescription medical foods by Pamlab LLC.

''This is, to our knowledge, the first inter partes review involving pharmaceutical-related patents to go to final opinion,'' Cwik said.

In the decisions, the U.S. Patent and Trademark Office found that many claims of the medical food-related patents challenged by Gnosis were unpatentable as obvious.

''It's a great example of the IPR process working the way it was intended,'' Cwik said. ''Statistically, it's been very effective.''

Other pharmaceutical companies will now likely take a close look at the PTAB's final decisions issued in the *Gnosis* case, Cwik said. The decisions could indicate how the PTAB will approach pharmaceutical patents in the IPR process under the America Invents Act (AIA), Cwik said.

IPR Faster, Cheaper Than Federal Court. ''It's cheaper, faster and statistically more successful'' than district court litigation, Cwik said. ''The advantages far outweigh the disadvantages.''

The panel's decisions are binding and constitute the final decision of the PTO, although there is a direct right of appeal to the U.S. Court of Appeals for the Federal Circuit.

One of the chief advantages of using the IPR process is speed, Cwik said.

Prior to the adoption of the inter partes review tool in September 2012 as part of the America Invents Act (AIA), pharmaceutical companies seeking to challenge other companies' drug patents had to bring those challenges in federal district court. Citing statistics from the PricewaterhouseCoopers 2013 Patent Litigation Study, Cwik said that the median time to trial in a federal court is 2.5 years. And, in the district courts of Delaware and New Jersey, which have dockets overloaded with pharmaceutical patent litigation, the median time to trial in civil cases is even longer—34.6 and 37.6 months, respectively, he said.

By contrast, in the IPR process, final written decisions must be issued within 18 months from the time of first filing, absent unusual circumstances.

According to Cwik, the average cost of an IPR proceeding ranges from $500,000 to $900,000. In contrast, district court patent litigation can cost anywhere from $813,000 to $3.8 million, according to 2013 statistics from the American Intellectual Property Law Association.

One reason the IPR process is cheaper than typical federal court patent litigation is because IPR discovery is much narrower.

In the IPR process, discovery is generally very limited, making the proceedings much less costly. Automatic or routine discovery before the PTAB is limited to:

- the production of any exhibit cited in a paper or testimony;
- the cross-examination of the other side's declarants; and
- non-privileged relevant information that is inconsistent with a position advanced during the proceeding.

In contrast, in federal court, discovery is allowed on any evidence or depositions that are relevant or could lead to relevant evidence.

In addition, patent challengers may have a greater chance of invalidating a patent in the IPR process than in federal court because of differing invalidity and claim construction standards. In IPR proceedings, the PTAB gives claim terms their broadest reasonable interpretation, making it easier to invalidate a patent. In addition, in IPR proceedings, unlike in district court, patents aren't presumed valid. Moreover, the evidentiary standard required to invalidate a patent in an IPR is lower than in district court. In an IPR proceeding, a chal-

lenger only has to prove that the ''preponderance of the evidence'' shows that the patent is invalid. In district court, ''clear and convincing'' evidence is required to invalidate a patent.

Companies Reluctant to Use IPR at First. Pharmaceutical companies were reluctant to sign on to the new IPR procedure at first because it wasn't the ''tried and true way of doing things,'' Cwik said. Although inter partes review first became available in September 2012, pharmaceutical companies didn't start using it until the following year.

But, now, nearly two years after its introduction, clients are increasingly turning to the new tool as a cheaper, quicker and more effective way of challenging patent validity, Cwik said. In addition to speed and cost savings, another reason to turn to the IPR process is the background of the administrative patent judges who hear the cases.

Panels hearing IPR challenges consist of three administrative patent judges who generally have extensive technical and scientific expertise and are knowledgeable about patent law concepts.

''It's very helpful to have that level of expertise,'' Cwik said. ''You get really qualified people to take a second look at these patents.''

And he said, because there's some question as to how the Federal Circuit is going to look at IPR opinions, it helps that ''there are very high quality opinions coming out of the PTO from very qualified judges,'' he said. So far, Cwik said, he isn't aware of the Federal Circuit having yet ruled on any IPR decision appeals.

But, he said, ''We're getting more and more data points'' on the usefulness of the new IPR procedure.

Why Choose District Court? But there may still be times when a patent challenger may want to choose district court over the IPR proceeding, Cwik said.

IPR challenges are limited to anticipation and obviousness grounds and may only be filed on the basis of prior art consisting of patents and printed publications. So, for an attorney who wants to keep all options open, district court may be less limiting. Also, IPR petitioners are estopped from raising in district court, the International Trade Commission (ITC) or the USPTO the same patent issues it raised or reasonably could have raised in the IPR. In district court, a challenger can raise more pieces of prior art and assert more theories than could be raised in an IPR.

District court, while generally costly and time-consuming, keeps all your options open, Cwik said.

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The four IPR opinions in the Gnosis case are available at http://op.bna.com/hl.nsf/r?Open=deln-9mgr6s; http://op.bna.com/hl.nsf/r?Open=deln-9mgrma; http://op.bna.com/hl.nsf/r?Open=deln-9mgrmy and http://op.bna.com/hl.nsf/r?Open=deln-9mgrnh.

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