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Patents

Like High Court, Drug Industry Divided on Patent Claim Standards

The Supreme Court April 25 seemed as divided about whether the patent board and a federal district court can give different meanings to claim terms as generic drug companies and biopharmas were in their amicus briefs and comments (*Cuozzo Speed Technologies, LLC v. Lee*, U.S., No. 15-00446, *oral arguments* 4/25/16).

The high court must decide whether under the 2011 America Invents Act (AIA), the Patent and Trademark Office's Patent Trial and Appeal Board (PTAB), in reconsidering the validity of a patent, can continue to use the ''broadest reasonable interpretation'' (BRI) standard instead of the ''plain and ordinary meaning'' of disputed terms that is employed by federal district courts.

Brian Matsui, of Morrison & Foerster LLP, Washington, in an April 26 phone interview told Bloomberg BNA that during the prior day's oral arguments, there was support from some justices, especially from Justice Elena Kagan, for the PTO's argument that Congress knew that the PTAB was using the BRI for other proceedings and didn't instruct the PTO to change it for newly established-AIA dispute resolutions such as inter partes review (IPR), which allows challenges to existing patents.

''On the other hand, [Chief] Justice John G. Roberts Jr.'s criticism of the 'very extraordinary animal in legal culture [that has] two different proceedings addressing the same question that lead to different results' may resonate with the other justices,'' Matsui said.

Groups: Access to Generics at Stake. The Generic Pharmaceutical Association and America's Health Insurance Plans supported the PTAB's use of the BRI, and in an April 25 e-mail to Bloomberg BNA, a GPhA spokesman reiterated the position expressed in the organizations' amicus (friend of the court) brief: It is critical that any changes to current law avoid reducing or delaying patient access to more affordable generic drugs and biosimilars.

In their brief, the organizations wrote, ''We believe that the IPR process is largely working as intended by providing a more cost-effective avenue to challenge weak patents. Further, we believe that the IPR process is a critical consumer protection against abusive patent extensions that limit patient access to more affordable treatment options, delay market entry of less expensive generic therapies and drive up drug costs.''

In their separate briefs, the Biotechnology Innovation Organization (BIO) and the Pharmaceutical Research and Manufacturers of America (PhRMA), which represent biotechnology and pharmaceutical companies, both supported the position that, rather than the PTAB using the BRI, the same ''plain and ordinary meaning'' standard should be used by both the federal courts and the PTAB.

Hans Sauer, BIO's deputy counsel for intellectual property, told Bloomberg BNA in a phone interview, ''The issues before the court have a lot to say about the relationship between the federal courts and the PTAB and the balance between them in shaping patent law. It doesn't surprise me that the Supreme Court would be interested in relationship questions, especially as they relate to power. We don't think there's any justification for the argument that what the PTO is doing is what Congress had in mind.''

Competing Views of Statute. The patent at issue in the case before the court is U.S. Patent No. 6,778,074. It's titled ''Speed limit indicator and method for displaying speed and the relevant speed limit.'' But the case has generated interest among generic and brand drug manufacturers, especially because it is the court's first opportunity to review IPR.

For much of the oral arguments about the PTAB's use of the BRI standard, the court appeared to adhere to Justice Stephen G. Breyer's ''partial Groundhog Day statute'' theory of the AIA's intent, referring to the 1992 movie in which a man finds himself living the same day again and again until he changes his approach to life. Under that approach, Breyer said, the PTO could establish whichever rules best deal with wrongly issued patents, because Congress said: ''You'll do it again until you get it right.''

But Roberts pressed the ''little district court proceeding'' view of the AIA: that the PTAB's IPR patent proceeding should function as a cheaper, efficient substitute for a court's patent validity analysis. With that goal in mind, he said, it would be ''bizarre'' for Congress to have intended that the two tribunals use different standards and not have their conclusions be binding on one another, as is the case now.

That potential for conflicting results can't be right ''under a statute designed to make the patent system more reasonable and more expeditious in reaching judgments,'' Roberts said.

He suggested where his line of inquiry was heading during his questioning of Cuozzo's attorney. Garrard R. Beeney of Sullivan & Cromwell LLP, New York, noted that district courts stay 70 percent of the cases where an IPR petition is filed. Roberts called that ''a little burdensome to the district court.''

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Curtis E. Gannon, assistant to the solicitor general and representing the PTO, returned to the ''partial Groundhog Day statute'' theory to argue that Congress wanted district courts to stay litigation while IPR proceedings play out so that the PTAB can ask, ''Is this one of those patents that we really oughtn't to have issued in the first place?''

Which way the court decides will depend on how many justices Roberts is able to bring along to his view, former PTO director Q. Todd Dickinson told Bloomberg BNA after the argument. Dickinson, now at Polsinelli P.C. in Washington, said that only Roberts seemed to ''get it'' but that Justice Sonia M. Sotomayor seemed to share his concern.

Biopharmas Say PTO Causing Uncertainty. Sauer expanded on what BIO stated in its amicus brief, telling Bloomberg BNA that a recurring theme in the PTO's arguments is the PTAB's need for unfettered discretion, independence and flexibility.

''The problem is that there are cases where the PTAB has over-ridden the federal courts on validity. The patent owner has to win every time and only has to lose once for the patent to lose its validity,'' Sauer said.

As to the PTO's argument that the IPR wasn't meant as an alternative to litigation and so could have different standards than the federal courts, Sauer said, ''That's news to us. We thought Congress intended them as providing more efficient and quicker patent dispute resolution in a more expert forum.''

Sauer asked, ''If the PTO is right that their processes were meant to be independent, as opposed to the court and the PTAB using the same thought processes to reach the same outcome, what is the point of having the district court involved at all?''

A PhRMA spokesman in an April 26 e-mail referred Bloomberg BNA to the group's amicus brief, in which it said, ''The Federal Circuit's error is further laid bare by the fact that the currently distorted version of IPR has introduced considerable uncertainty in the construction of patent claims, increased the risk of conflicting invalidity decisions and subjected patent holders to the cost of defending against such challenges. As such, the PTO's regulation has undercut a central reform that Congress enacted to strengthen the U.S. patent system, thereby allowing flaws of the pre-AIA patent system to continue unabated and, arguably, be exacerbated.''

The court is expected to issue its decision by the end of June.

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The generic industry group and health insurance group's joint amicus brief is at http://www.gphaonline.org/media/cms/GPhA_Amicus_Brief_--_Cuozzo_v_Lee_03_29_16_FINAL_.pdf.

PhRMA's brief is at http://www.bloomberglaw.com/public/document/Cuozzo_Speed_Technologies_LLC_v_Michelle_K_Lee_Under_Secretary_of/1.

BIO's brief is at http://www.bloomberglaw.com/public/document/Cuozzo_Speed_Technologies_LLC_v_Michelle_K_Lee_Under_Secretary_of/2.

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