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PATENTS

INTER PARTES REVIEW

The PTAB May Be Taking a More Balanced Approach in Biotech and Pharmaceutical IPRs

By Michael Fuller

Patent challengers were first able to file *inter partes* review (IPR) petitions on September 16, 2012. Since then IPRs have become an increasingly popular way of challenging the validity of patents. In the first three months that IPRs were available 97 petitions were filed with the Patent Trial and Appeal Board (''PTAB''). That number has now risen by over four-fold, with more than 450 petitions being filed in the last three months of 2014. As the first final decisions were released, many commenters felt that the PTAB was acting as a ''death squad,'' invalidating almost every challenged patent. Even PTAB Chief Judge James Smith mentioned at a U.S. Patent and Trademark Office Patent Public Advisory Committee that if the PTAB wasn't doing some ''death squadding'' they wouldn't be doing what Congress mandated in developing the IPR process. This naturally led to much concern that the PTAB wasn't providing the proper balance between the rights of challengers to invalidate patents in view of the prior art, and the rights of patent owners to have certainty in the strength of their intellectual property.

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However, as we start to review more decisions by the PTAB, and particularly recent cases, it appears that the pendulum is starting to swing away from invalidity of almost every case and towards more balance to the IPR process. For example, the PTAB is now instituting a noticeably lower percentage of IPRs by finding that the challenger hasn't met its initial burden of demonstrating there is a reasonable likelihood that the claims are unpatentable over the prior art. In addition to granting fewer institution decisions, the PTAB has also started to find that a greater number of challenged patents are patentable over the prior art cited by the IPR petitioner.

According to USPTO statistics, in fiscal year 2013, the PTAB granted the challenger's petition to institute trial in 87% of all filed cases. In fiscal year 2014 the PTAB instituted trial in 75% of the filed cases. That 75% number appears to be holding steady so far for fiscal year 2015, which began on October 1, 2014. Thus, while

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75% of cases are still having a trial instituted by the PTAB, that number is down from the 87% of petitions granted in 2013.

The majority of IPRs are still being filed in the electrical/computer and business method technologies. However, a review of IPRs in the pharmaceutical and biotechnology area shows the same trend towards decreasing numbers of granted petitions in institution decisions. For example, there were a total of 166 IPR petitions filed at the PTAB by the end of 2014 in the pharmaceutical/biotechnology field. Of those 166 petitions, the PTAB has come to a decision in 103 petitions. In those decisions 67 IPRs had trial instituted and 36 had trial denied resulting in a 65% institution rate. Note this is lower than the 75% institution rate for all technologies combined. But what is more interesting in looking at the actual cases is that the PTAB has begun to uphold the patentability of some or all of the claims in a greater number of IPRs within the biotechnology/pharmaceutical fields.

On March 6, 2014, in one of the first IPR decisions relating to biotechnology, the PTAB found that three patents owned by the Trustees of Columbia University were invalid as obvious.[1] The claimed technology related to nucleotides used in sequencing-by-synthesis reactions. Columbia had attempted to cancel the pending claims, and file a new set of amended claims. However, as would become a pattern at the PTAB, they did not allow Columbia to introduce the amended claims. The PTAB found that the amended claims were invalid for having a similar scope to the original claims, or were not shown to be patentable over the prior art. This decision on the three Columbia patents is now on appeal to the Federal Circuit.

Following the March 2014 decision invalidating the Columbia patents, the PTAB issued decisions on June 20, 2014, in four IPRs filed by Gnosis SpA on pharmaceutical patents owned or licensed by Merck.[2] These decisions were noted as being among the first to involve pharmaceutical products. In actuality they related to compositions of a natural folate used in the treatment of vitamin deficiencies. Because the patents covered a natural folate vitamin, the products were not required to be approved by the FDA. For that reason, some argued that these were not truly pharmaceutical IPR decisions. No matter what they were called, the result was that the challenger, Gnosis prevailed in invalidating all of the patents in the four IPRs.

On July 25, 2014, the PTAB continued its trend of invalidating patents in IPR proceedings by issuing a decision invalidating all of the challenged claims of U.S. Patent 7,057,026 owned by Illumina Cambridge.[3] This IPR related to litigation between Columbia University and its licensee IBS against Illumina. The claims of this patent related to nucleotides for sequencing-by-synthesis reactions. As mentioned above, in one of the first biotech IPR decisions in March 2014, Illumina was able to successfully invalidate three Columbia patents on sequencing-by-synthesis nucleotides. Now, in this IPR, claims relating to similar subject matter of nucleotides for sequencing-by-synthesis were invalidated at the PTAB by Columbia's licensee, IBS.

A few months later, on September 2, 2014, the PTAB found only a subset of the challenged claims of U.S. Patent No. 6,258,540 unpatentable.[4] This patent was owned by Isis Innovation, licensed to Sequenom, and related to prenatal diagnostics and methods of detecting the presence of a paternally inherited nucleic acid in an infant. According to the PTAB, the patent challenger, Ariosa Diagnostics, had proven by a preponderance of the evidence that some of '540 patent claims unpatentable as anticipated. However, the PTAB also determined that Ariosa had not proven by a preponderance of the evidence that many other claims of the '540 patent were unpatentable. With this decision, the PTAB showed that it was willing to consider each invalidity argument brought before it, and find some claims patentable over the cited prior art if the PTAB believed that the petitioner did not meet its burden to prove the claims unpatentable by a preponderance of the evidence.

In the following month, October 2014, the PTAB issued final decisions in two other IPRs filed by Ariosa Diagnostics.[5] These decisions related to U.S. Patent No. 8,318,430 owned by Verinata Health. The PTAB found that Ariosa did not meet its burden to show that the claims of the '430 patent were invalid over the prior art. This marked some of the first biotech IPRs where the challenger failed to invalidate even a single claim of the challenged patent. These IPRs further demonstrated the PTAB's willingness to issue final decisions, particularly in biotechnology/pharmaceutical cases, finding the challenged patents valid if the PTAB believed that the petitioner's burden of proof was not met.

At the end of that month, on October 28, 2014, the PTAB issued a final decision invalidating all of the challenged claims of U.S. Patent 8,158,346 in an IPR filed by petitioner Intelligent Bio-Systems (IBS) against Illumina Cambridge.[6] This was the second decision where IBS had successfully challenged a patent owned by Illumina relating to sequencing-by-synthesis nucleotides. In this IPR, the PTAB determined that all of the challenged claims were invalid over the prior art.

In November 2014, the PTAB released another decision involving Ariosa Diagnostics. This time Ariosa was able to convince the PTAB that U.S. Patent 8,296,076 owned by Stanford University, and licensed to Verinata Health, was invalid.[7] The technology of the '076 patent related to fetal diagnostic methods of detecting aneuploidies. The PTAB found that all of the challenged claims were unpatentable as being anticipated or obvious over the prior art cited by Ariosa. At this stage the petitioner Ariosa had one split decision on U.S. Patent No. 6,258,540, had lost on two challenges against U.S.

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[1] *Illumina, Inc. (Petitioner) v. The Trustees of Columbia University in the City of New York (Patent Owner)*. IPR2012-00006, IPR2012-00007, and IPR2013-00011.

[2] *Gnosis SpA et al. (Petitioner) v. South Alabama Medical Science Foundation (Patent Owner)* IPR2013-00116, IPR2013-00118, and IPR2013-00119; and *Gnosis SpA et al (Petitioner) v. Merck & Cie (Patent Owner)* IPR2013-00117.

[3] *Intelligent Bio-Systems, Inc. (Petitioner) v. Illumina Cambridge Limited (Patent Owner)*. IPR2013-00128.

[4] *Ariosa Diagnostics (Petitioner) v. Isis Innovation* Ltd. *(Patent Owner)*. IPR 2012-00022

[5] *Ariosa Diagnostics (Petitioner) v. Verinata Health, Inc. (Patent Owner)*. IPR2013-00276 and IPR2013-00277.

[6] *Intelligent Bio-Systems, Inc. (Petitioner) v. Illumina Cambridge Limited (Patent Owner)*. IPR2013-00266.

[7] *Ariosa Diagnostics (Petitioner) v. The Board of Trustees of the Leland Stanford Junior University (Patent Owner)* IPR2013-00308.

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Patent 8,318,430, and had invalidated all challenged claims of U.S. 8,296,076.

Then on December 9, 2014 the PTAB ruled in favor of the patent owner on three patents owned by Galderma Laboratories and Supernus Pharmaceuticals.[8] The PTAB determined that the patents were not invalid in view of a challenge from generics company Amneal Pharmaceuticals. The patents related to the pharmaceutical Oracea and this IPR decision was noted as one of the first where the parties to the IPR were also involved in an ANDA dispute under the Hatch-Waxman statutory scheme. Amneal was attempting to launch a generic version of Oracea and was in litigation against Galderma and Supernus when it filed an IPR challenge to the three patents in suit. However, in this case the PTAB did not side with the petitioners, and instead found that Amneal did not meet its burden to show that the challenged claims in each patent were unpatentable over the prior art.

A few months later, on February 11, 2015 the PTAB issued a third decision the ongoing dispute between IBS and Illumina Cambridge. However, unlike the prior two decisions in 2014, in this case the board upheld the validity of all of the challenged claims. The claims in this IPR related to sequencing-by-synthesis nucleotides that contained an azido protecting group. The PTAB found that IBS had not met its burden to show that the claims were obvious in view of the prior art cited in the IPR.

What can be gleaned from this brief overview of recent biotechnology/pharmaceutical IPR decisions is that the PTAB seems to be taking a more balanced review of each IPR. Trial is being instituted in about 65% of biotech/pharma IPRs. In addition, as discussed above, in several of the most recent cases, the PTAB found that the petitioner could not demonstrate by a preponderance of the evidence that most, or all, of the challenged claims were invalid over the cited prior art.

It remains to be seen whether this small sampling of recent IPR cases shows a real trend towards more of a balance of final decisions at the PTAB and if the earlier ''death panels'' will become a relic of the past. As more and more final decisions are released, we will be able to assess whether the PTAB is finding a balance between the rights of the petitioner to successfully challenge patents that are proved to be unpatentable based on the prior art, and the rights of the patent owner to maintain valid intellectual property over such challenges.

[8] *Amneal Pharmaceuticals (Petitioner) v. Galderma and Supernus (Patent Owner)*. IPR2013-00372, IPR2013-00368 and IPR2013-00371.