STRATEGIES IN INTER PARTES REVIEW PROCEEDINGS FOR BIOTECH/PHARMA PATENTS

BY: ROBERT H. RESIS
In October 2013, about one year after inter partes review (IPR) proceedings became available, the chief judge of the Federal Circuit called the Patent Trial and Appeal Board (PTAB) a “death squad.”1 Certainly, a high percentage of early IPR petitioners enjoyed success getting the PTAB to hold patent claims invalid, and the number of IPRs filed has steadily climbed.2 Biotech/pharma patents, however, have a greater success rate in surviving an IPR than patents in other technologies. First, almost 40 percent of IPR petitions have been denied for patents in Tech Center 1600 (Biotechnology and Organic), whereas about 21 percent of IPR petitions for all technologies have been denied.3 Second, even when an IPR is instituted, biotech/pharma patents have all challenged claims survive about 33 percent on final PTAB decision versus about 23 percent for all technologies. Of 18 final PTAB decisions for biotech/pharma patents, the patentee had all challenged claims survive in six,4 and no challenged claims survive in ten,5 and some, but not all challenged claims, survive in two.6 Particularly useful strategies for petitioners and patent owners are discussed below.

STRATEGIES FOR PETITIONERS

1. Argue the Primary Prior Art Document Favorably References a Secondary Prior Art Document that Discloses Claimed Feature(s) Not Found in the Primary Prior Art Document.

In Illumina v. Trustees of Columbia University (IPR2012-00006), the challenged patent involved sequencing DNA by incorporating a base-labeled nucleotide analogue into a primer DNA strand, and then determining the identity of the incorporated analogue by detecting the label attached to the base of the nucleotide. Illumina argued that claims were obvious in view of Tsien and Prober I. Specifically, Illumina contended that Tsien’s reference to Prober I’s fluorescent nucleotides would have provided a person of ordinary skill in the art (POSITA) with a reason to substitute the nucleotide and lead to a POSITA to conclude that they were suitable for the “sequencing DNA by synthesis” purpose described by Tsien.

2. Argue Inherency.

In Ariosa v. Juj (IPR2013-00022, IPR2012-00250 joined), the challenged patent involved prenatal detection methods using non-invasive techniques to detect foetal nucleic acids in serum or plasma from a maternal blood sample. The patent taught that the claimed methods may be used to screen for Down’s syndrome and other chromosomal aneuploidies, to detect other conditions. The PTAB held that the same claim construction from its institution decision applied, i.e., all that was required by the amplification step of claim 1 was a step of amplifying nucleic acid from a serum or plasma sample from a pregnant female, such as by PCR, as such amplified nucleic acid necessarily includes paternally inherited nucleic acid. Further, the PTAB held that the detecting step did not require that the detected nucleic acid specifically be identified as being inherited from the father or even as being from the fetus, only that it be identified as containing some level of nucleic acid, which would include, necessarily, nucleic acid from the fetus that was inherited from the father. The PTAB held that the Kazakov reference anticipated the claimed methods because it inherently detected paternally inherited nucleic acid of fetal origin. The PTAB held that the cases cited by his did not support its position that because experimental mistakes may have been made in Kazakov, Kazakov could not, under the law of inherency, anticipate the claimed methods.

3. Demonstrate Motivation of POSITA to Pursue Development Despite Potential Hurdles.

In BioMarin v. Genticine (IPR2013-000534), the challenged patent involved treatment of Pompe disease using a claimed enzyme (GAA) biowise. BioMarin demonstrated that a POSITA would have understood that to treat Pompe disease effectively using GAA, sufficient quantities of enzyme would have to reach the patient’s muscle cells, which could potentially require high doses that could determine the relative amounts of non-random polynucleotide sequences from a chromosome suspected of being aneuploidy, and from a reference chromosome or a chromosome region, in a cell-free sample from a pregnant woman. Verinata argued that a “tagging” method of one reference would not have been combinable with another reference’s use of restriction digestible primers. The PTAB found that although the petition and accompanying declarations point to disparate elements in the three references, and attempt to reach the patient’s muscle cells, which could potentially require high doses that could introduce safety and efficacy hurdles resolvable only with human clinical trials.

STRAIGHTWAYS IN INTER PARTES REVIEW PROCEEDINGS FOR BIOTECH/PHARMA PATENTS

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In Amnual v. Supernus (IPR2013-00348), the patent involved sub-antimicrobial formulations of doxycycline. The claimed formulations could be used to inhibit activity of collagen destruction enzymes associated with human diseases, such as rosacea, without provoking undesired side effects attendant to an antibacterial dose. The PTAB credited the declaration testimony of Supernus’ expert that inclusion of a water-soluble polymer coating of the secondary reference’s secondary loading portion results in release of the drug promptly after administration, and that Amnual did not cite credible evidence to refute that testimony. The PTAB noted that although Supernus’ expert conceded that there must be some lag while the polymer hydrates, it further credited his testimony that this lag, essentially the time required to wet the material, would not be considered a “delay” in connection with the construed claim term. The PTAB agreed with Supernus that the secondary reference did not disclose a “delayed release” portion. Thus, the PTAB held that the challenged claims were not unpatentable.

CONCLUSION

As shown above, the PTAB should not be considered a “death squad” for biotech/pharma patents. The exemplary biotech/pharma IPRs above demonstrate that there are successful strategies for both petitioners and patent owners.