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Lessons From The 1st Biopharma Inter Partes Reviews

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Recently, the Patent Trial and Appeal Board issued its first set of final written decisions in three inter partes reviews relating to molecules in the large molecule biopharma space (IPR2013-00534, IPR2013-00535 and IPR2013-00537). Biosimilar companies will no doubt be looking to these decisions as a roadmap for clearing patent landscapes for their own biosimilar products in the coming years.

While all of the challenged claims in all three patents at issue in the three IPRs were found invalid, this set of decisions should be viewed in its appropriate context. While many of the claims at issue are representative of later generation molecular biology claims, this should be tempered in light of the results seen in other large biomolecule IPRs and recent trends in the U.S. Patent and Trademark Office's institution in the biotechnology space (TC1600). While there are situations where IPRs can be highly successful, there are clearly situations where careful thought should be given prior to pursuing an IPR approach.

IPR2013-00534, IPR2013-00535 and IPR2013-00537 (involving U.S. Patent Numbers 7,351,410, 7,056,712 and 7,655,226 respectively), successfully invalidated numerous claims involving the use of large biomolecules (Myozyme and Lumizyme molecules) in methods of treatment. While these were technically three different IPRs, the same panel of administrative patent judges (Lora Green, Jacqueline Bonilla and Sheridan Snedden) was assigned for all three IPRs.

The broadest claims in the ‘534 IPR and the ‘537 IPR were directed to methods of treating a patient with Pompe’s disease via administering human acid α-glucosidase. The ‘535 IPR involved an independent claim directed to treating glycogen storage disease type II, also by administering human acid α-glucosidase. The dependent claims of the ‘535 IPR and the ‘537 IPR involved claims specifying a particular disease, therapeutic amounts, protein aspects (such as being manufactured in CHO cells), administration intervals/routes, various combinations, form of the protein administered, and dosage amounts (milligrams/kilograms), which are the types of claims most frequently present in second/third generation patent portfolios. Thus, the claims successfully challenged in this series of IPRs represent later life cycle claims.

The panel’s finding that all of the challenged claims were invalid as obvious may be interpreted by some

as an invitation for biosimilar companies to consider IPRs as an option for clearing a path forward in the biotechnology space. However, there are a number of items to consider before concluding that an IPR is the optimal approach for any given biopharma patent.

First, one unique aspect of these IPRs was that a Web-based document taught key elements of the claims, and a key issue was simply the determination of the actual date the document published. Thus, once this issue was resolved, much of the analysis in this case appeared relatively straightforward. As such, many of the possible complicating issues that could be present in the large molecule space when it comes to nonobviousness, were not as central to the present set of cases.

Furthermore, while second/third tier patents (e.g., method of treatment claims) were successfully challenged in these IPRs, U.S. Pat. No. 6,118,045 was not challenged by an IPR (this '045 patent is listed in Genzyme's 2010 10-K filing as one of the patents that protects the Myozyme product). While there could be other reasons for the lack of a challenge to this patent (e.g., various strategic considerations, including differences in patent expiration, filing date, etc.), it is worth noting that the claims of the '045 patent are different in nature than the above challenged claims. In particular, Claim 18 of the '045 patent is a composition claim directed to a pharmaceutical composition comprising human acid α-glucosidase. Thus, while the IPRs were successful in invalidating claim formats typical of follow-on patent portfolios, no IPR was even attempted against a claim format that is more typical of initial pioneering discoveries (e.g., novel pharmaceutical compositions).

In addition, the above discussion has only focused on three final written decisions for biotech IPRs, and it does not take into account those IPR petitions that were filed but did not result in the IPR proceeding being instituted. Taking these aspects into account provides insight that biopharma IPRs are not automatic wins for the patent challenger.

For example, in IPR2014-00842 (U.S. Pat. No. 7,575,748), a petition was filed against claims directed to a method of treatment employing an anti-ErbB2 antibody conjugated to a maytansinoid. The board found that the petition was insufficient to institute IPR on these claims. The '842 IPR is especially informative as there was a co-pending patent for which a parallel IPR was instituted on similar subject matter (IPR2014-00676, U.S. Pat. No. 8,337,856, anti-ErbB2 antibody immunoconjugates to maytansinoid), allowing for a side-by-side comparison of these two cases. The '842 IPR was not instituted primarily because the method claims in the '748 patent recited that the subject over-expressed ErbB2 and failed to respond to ErbB antibodies. Apart from this "failed" population aspect, the claims and issues involved in the two IPR petitions were fairly similar (one involving the composition, and the other the use of the composition). This contrast provides insight that some claim elements will be more effective in avoiding an institution of an IPR than other elements.

Another possible outcome of an IPR is settlement between the patent challenger and the patent owner. This was the case for large molecule biopharma IPRs IPR2014-01269, and IPR2015-00293. Settlement terms are confidential, so it is difficult to determine the value of these IPRs to the patent challenger. Neverthless, full invalidation was never reached and the challenged patents remain in force. Thus, while the three IPRs discussed initially provide informative data points for biopharma IPRs, it is important to keep in mind that a petitioner may not even make it to a final written decision in this technology, and some patents and claim formats will be more challenging than others to address via an IPR.

In addition to the specific considerations noted above regarding the applicability of IPRs in the large molecule biopharma space, there is also a growing indication that one should not expect IPRs to be instituted as frequently as they had been in the past.

For example, during the first year or two of IPR petitions, one would frequently hear of institution rates in the 80 to 90 percent range. However, looking at institution rates over more recent time periods suggests that this value has dropped significantly. For example, in September and October of 2014, 29 percent of the petitions were fully denied institution, 19 percent of the petitions were instituted as to only some challenged claims, and 52 percent of the petitions were instituted as to all challenged claims. Thus, the institution rate over the recent past is much lower (closer to 70 percent) than it was in the early months of IPR proceedings. Furthermore, if one focuses purely on art unit 1600, as being representative of life sciences (although it does also include small molecules), the institution rates are even lower than that for IPRs generally (52 percent denied, 3 percent some claims granted, 45 percent all claims granted). Thus, there is a clear decrease in the institution rate compared to what it was a year ago, and this institution rate is even lower if one looks to the life science area in particular.

Given the above, while IPRs are still a useful approach to removing patents, even in the biotechnology space, one also has to be objective in analyzing the strengths and weaknesses of a case, especially in light of the limitations of IPRs to present a compelling case on a complex technology. The importance of this is amplified by the fact that, effectively, there may only be a single opportunity to present any given set of legal arguments. Indeed, as patent owners become more savvy in drafting claims to recite elements that are difficult to identify in the prior art, recite superior aspects over the prior art, or recite functional aspects that simply were not known to those of skill in the art, the analysis for using an IPR may change.

Despite the fact that there are numerous considerations to make in deciding whether or not to pursue an IPR to challenge a patent, many of the previous reasons for filing an IPR still hold true, if not more so, in the biotechnology space. For example, to the extent that the patent owner decides to take a position on lack of predictability in the art to assist in overcoming an obviousness argument, even if the patent owner is successful in the IPR, they may well be forced into a lack of enablement or a lack of written description problem during a subsequent litigation. Thus, a full analysis of the value of an IPR in the biotechnology space not only takes into account the likelihood of invalidating a patent through §102 or §103 based rejections based on printed art and patents, but also on the ability to help on subsequent §112 or §101 challenges, as well as strengthening noninfringement positions. As such, even if a party is seen to have “lost” an IPR challenge in one scenario, it may be that they are actually positioning themselves for a more effective attack on other grounds further down the line.

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