Mixed Results as IPR Petitions for Biosimilars Soar

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Inter partes review proceedings for biosimilar products are soaring. Biosimilar makers are taking advantage of IPR proceedings to challenge patents protecting some of the world's most important biologic medicines due to the advantages that these proceedings offer: no standing requirement, no presumption of validity, a lower burden of proof and potentially broader claim construction. More than half of the IPR petitions challenging these patents were filed in fiscal 2017. But the results are mixed, with the Patent Trial and Appeal Board denying a high percentage of the petitions. Many of these patents are ultimately litigated in district court under the U.S. biosimilar statute, the Biologics Price Competition and Innovation Act of 2009 (BPCIA). The challenged patents are referred to as BPCIA patents in this article as they are patents that would be litigated under the BPCIA.

IPR Petitions on the Rise

Of the 85 IPR petitions filed by biosimilar makers as of mid-November, most were filed in fiscal 2017 (which ends in September for the PTO). Only one biosimilar maker filed a petition in fiscal 2013 and none were filed in 2014. The number of petitions jumped to eight for fiscal 2015. Biosimilar makers filed another 17 petitions in 2016. Petitions more than tripled in number in fiscal 2017, for a total of 53. Another 6 petitions have been filed in fiscal 2018 as of mid-November.

The Supreme Court's June 12, 2017 decision in *Sandoz Inc. v. Amgen Inc.,* 137 S. Ct. 1664 (2017), the first to interpret the BPCIA, has had no impact on the rise of IPR

petitions for biosimilars. The Court held that the BPCIA's pre-suit patent dispute resolution procedures were not enforceable under federal law. Although some viewed obtaining patent certainty in IPR proceedings prior to the events triggering the BPCIA's procedures as a mechanism of potentially avoiding them, the ruling has not reduced the filing of petitions for IPR. Indeed, more than a third of the 85 petitions (29) for biosimilars were filed in the five months after the Supreme Court's decision.

Patents, Products and Players

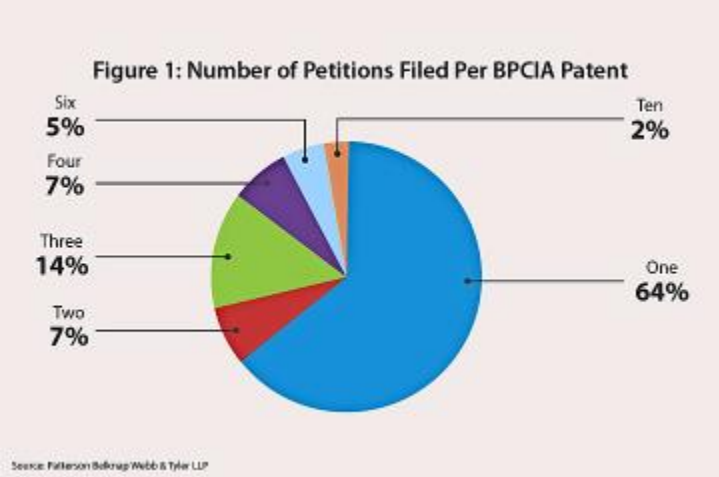
Biosimilar makers are turning to IPRs to challenge all types of patents protecting blockbuster biologics. Of the 85 petitions, 55 challenge claims directed to methods of treatment, such as claims to dosing regimens and combination therapies. 13 challenge claims to formulations of the biologics products. But claims protecting the biologic products are also being challenged. A total of 10 IPR petitions were filed by a number of biosimilar makers, Mylan, Celltrion, Pfizer, Samsung and Boehringer Ingelheim, challenging a Genentech patent covering certain humanized antibodies, including Herceptin (IPR2016-01693, IPR2016-01694, IPR2017-01373, IPR2017-01374, IPR2017-01488, IPR2017-01489, IPR2017-02031, IPR2017-02032, IPR2017-02139, and IPR2017-02140). Coherus recently filed an IPR petition challenging claims protecting Amgen's Enbrel (IPR2017-02066). Biosimilar makers are also using IPRs to challenge patents that protect methods of manufacturing biologics.
Since biosimilar makers are focused on biosimilars of a few blockbuster biologic products, most of the IPR petitions are focused on patents protecting those products. 88% (75) of the petitions target three of the world's best-selling biologics: Genentech's Herceptin, Genentech's Rituxan and AbbVie's Humira. 30 IPR petitions are directed to patents protecting Herceptin (with 9 patents challenged). Rituxan drew 23 petitions from biosimilar makers (with 9 patents challenged). Biosimilar makers filed 22 IPR petitions challenging 14 of the patents protecting Humira.

The biosimilar makers bringing these challenges are also repeat players. Pfizer and its subsidiary Hospira filed a total of 24 petitions. Celltrion is second in line with a total of 17 petitions. Coherus and Sandoz are a close third and fourth with 12 and 10 petitions, respectively, followed by Boehringer Ingelheim (7) and Samsung (5).

Tackling the Same Patents

The PTAB recently reported that overall patent owners are not being “gang tackled” by multiple petitioners challenging the same patent. In a study of nearly 4,000 patents across technology areas, the PTAB found that 88% of the patents are challenged one or two times (PTAB Judicial Conference—June 29, 2017, available at https://www.uspto.gov/sites/default/files/documents/PTAB%20Judicial%20Conference%20June%2029%202017.pdf). For BPCIA patents, however, multiple challenges appear to be more frequent (Fig. 1). 42 BPCIA patents were challenged in the 85 IPR petitions. 71% of those patents were challenged one or two times. The number of patents challenged three, four or six times was greater in the BPCIA context (14%, 7% and 5%,

respectively) than for patents in general (6%, 3% and 1%, respectively). Notably, one BPCIA patent was challenged 10 times.



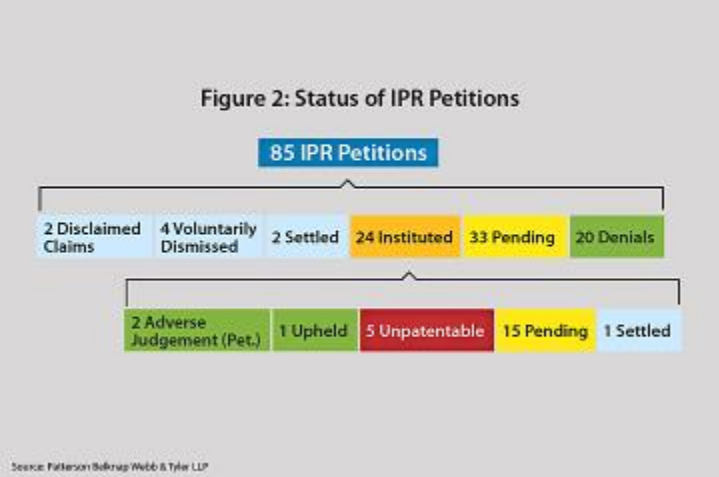
Timing of Challenges

The timing of challenges to BPCIA patents is also distinct. Most IPRs involve parallel district court litigation. The same is not the case for IPR petitions for biosimilars. Here biosimilar makers typically file petitions prior to any case or controversy allowing for district court litigation. Of the 85 petitions, for 81 of them (95%) there was no parallel district court litigation when the petitions were filed. Only one petition involved pending district court litigation between the same parties, and three petitions involved pending district court litigation between the patent owner and different biosimilar makers. Indeed, many biosimilar makers filed IPR petitions while clinical trials were still underway, well prior to seeking regulatory approval for their biosimilar products from FDA. Since it takes 18 months from the filing of an IPR petition to obtain a final written decision from the PTAB, biosimilar makers can time their petitions to obtain a decision by the time of FDA approval for their biosimilar products.

Mixed Results

While IPR challenges to clear a path for biosimilar products are soaring, the results of the challenges are mixed (Fig. 2). Of the 44 petitions where the PTAB has issued a decision on institution, institution has been denied approximately 45% of the time (55% of the time IPR is instituted). Given the sample size, the rate of institution may not be significantly different from that observed for biotech/pharma patents in general (61% instituted) but it is lower. The results for most of the instituted IPRs are still unknown. Decisions for 15 of them are still pending. One resulted in a final written decision upholding the patent claims (IPR2015-01537), and five of the IPRs resulted in all challenged claims of the patents being cancelled (IPR2016-00172, IPR2016-00188,

IPR2016-00189, IPR2016-00408, and IPR2016-00409).



The fact that institution decisions are pending in 39% (33) of the petitions reflects that biosimilar makers are turning to IPR proceedings given the many advantages that they offer despite mixed results.

Lessons So Far

Although the numbers of IPR petitions for biosimilars are still relatively limited, a number of trends have emerged. While the results of challenges continue to be mixed, the number of challenges is greatly increasing. Biosimilar makers are challenging all types of patents in IPR proceedings—from antibodies to processes for making them—to clear the path for their biosimilar products. Although biosimilar makers can avoid the BPCIA's pre-suit procedures after the Supreme Court's decision in *Sandoz* with or without IPRs, biosimilar makers continue to actively pursue IPRs due to the procedural and substantive advantages they offer and because they allow them to challenge the validity of patents before they have standing to do so in district court. But given the mixed results to date as well as the number of patents protecting important biologics, biosimilar makers are unlikely to avoid district court litigation entirely with IPRs.

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