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PATENTS

Emerging Trends in Biopharma IPR and PGR Proceedings



By Rubén H. Muñoz, Melissa R. Gibson and Jonathan J. Underwood

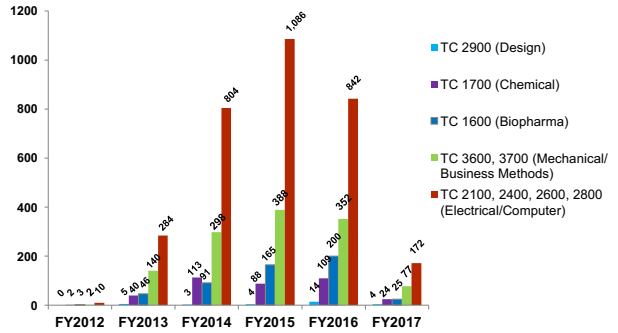
The America Invents Act (AIA), which was signed into law on Sept. 16, 2011, introduced several changes to U.S. patent laws. Among those changes were the introduction of two administrative proceedings that have emerged as particularly relevant for challenging patents in the biotechnological and pharmaceutical sciences (biopharma) before the U.S. Patent and Trademark Office (PTO): inter partes review (IPR) and post-grant review (PGR). These proceedings were introduced to provide cheaper and more time efficient mechanisms for challenging patents than litigation in federal court.

The PTO classifies each patent based on the technical subject matter of its claims, and each patent is assigned to a technical center. The PTO publishes on its website statistical information for IPR and PGR proceedings for five groups of technical centers, namely, ''electrical/computer,'' ''mechanical/business methods,'' ''chemical,'' ''biotechnology/pharma'' and ''design.'' *See, e.g.*, Patent Trial and Appeal Board Statistics, USPTO (Nov. 30, 2016). This paper explores trends in IPR proceedings for biopharma patents, which are assigned to PTO Technical Center 1600 (TC1600), analyzes the interplay of concurrent Hatch-Waxman litigation with biopharma IPR petitions and provides an overview of the PGR process (as relevant to biopharma), which is currently in its infancy.

Rubén H. Muñoz is a partner, Melissa R. Gibson is counsel, and Jonathan J. Underwood is an associate in the intellectual property practice at Akin Gump Strauss Hauer & Feld LLP in Philadelphia. The authors focus their practice on patent litigation and related matters, particularly in the biotechnology and medical device sectors.

Figure 1

IPR Petitions filed by Technical Center per Fiscal Year
(current as of 11/30/2016)



Overview of IPR and PGR Proceedings

Both IPR and PGR are litigation-like proceedings held before the PTO's Patent Trial and Appeal Board (PTAB). Although there are some similarities between

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IPR and PGR proceedings, there are also key differences (*see* Table 1). *See* 35 U.S.C. § § 311 and 321; *see also* Major Differences between IPR, PGR, and CBM, USPTO (Aug. 15, 2014).

Table 1. Basic differences between IPR and PGR petitions

	Petitioner	Patent	Unpatentability Grounds	Availability
IPR	■ Not the patent owner ■ Has not filed civil action challenging validity and has not been served with complaint alleging infringement more than 1 year prior to filing petition	■ ''first-to-invent'' (i.e. all claims have priority to before March 16, 2013) ■ ''first-inventor-to-file'' (i.e. at least one claim has priority to March 16, 2013 or later)	■ 35 U.S.C. § § 102 and 103, only on the basis of prior art consisting of patents and printed publications	■ ''first-to-invent'': any time after grant or reissue of the patent ■ ''first-inventor-to-file'': after the later of either i) 9 months following grant or reissue of the patent, or ii) the termination of any PGR of the patent
PGR	■ Not the patent owner ■ Has not filed civil action challenging validity	■ ''first-inventor-to-file'' (i.e. at least one claim has priority to March 16, 2013 or later)	■ 35 U.S.C. § § 101, 102 (including, for example, prior use), 103 and 112	■ ''first-inventor-to-file'': up to 9 months after the date of the grant of the patent or of the issuance of a reissue patent

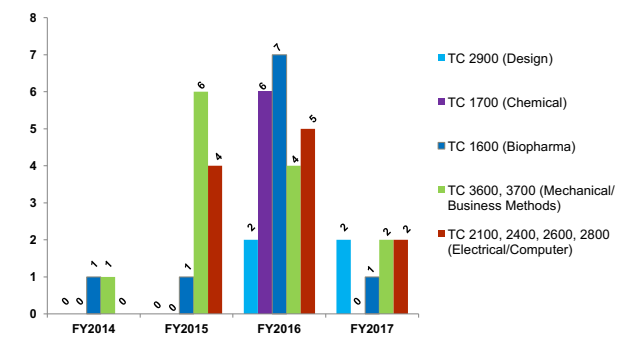
The number of IPR petitions filed has risen steadily since the AIA became effective on Sept. 16, 2012 (*see* Figure 1), but the first PGR petition was not filed until April 2014. This considerable lag is primarily due to the requirement that at least one claim of the challenged patent have an effective filing date of March 16, 2013, which is the effective date of the AIA ''first-inventor-to-file'' laws. Pub. L. No. 112-29 § 3(n)(1) (2011); *see also Inguran, LLC v. Premium Genetics (UK) Ltd.*, PGR2015-00017, at 10-11 (P.T.A.B. Dec. 22, 2015) (Paper 8). This requirement also explains why, as of Nov. 30, 2016, the total number of PGR petitions (43) is dwarfed by the total number of IPR petitions (5,446). Although there are far fewer PGR petitions, the number of PGR petitions filed each fiscal year continues to rise (*see* Figure 2).

Lower Institution Rate and Higher Claim Survival Rate in Biopharma IPR Petitions

According to the PTO grouping of technical centers, the majority of IPR petitions challenge patents classified as ''electrical/computer'' (TCs 2100, 2400, 2600, and 2800) and ''mechanical/business methods'' (TCs 3600 and 3700). However, there has been a steady rise in the number of IPR petitions challenging biopharma patents. In fact, during the 2016 fiscal year, IPR petitions challenging ''electrical/computer'' and ''mechanical/business methods'' patents decreased, whereas IPR petitions challenging biopharma patents increased (*see* Figure 1).

Figure 2

PGR Petitions filed by Technical Center per Fiscal Year
(current as of 11/30/2016)



This continuous rise in the number of biopharma IPR petitions may be due to an increased comfort by patent challengers in this field with the IPR process as well as confidence in obtaining the desired outcome. As IPR proceedings become more popular with those wishing to challenge biopharma patents, an understanding of the trends in the outcomes of these IPR proceedings becomes increasingly important.

Of the 5,446 IPR petitions filed as of Nov. 30, 2016, biopharma patents account for 530 of those petitions. The PTAB has issued an institution decision for 374 biopharma petitions; the other 156 petitions are pending or were terminated before institution (*see* Figure 3). For the 374 petitions that reached an institution decision, 37.2 percent were denied, 49.4 percent were granted on all challenged claims, and 13.4 percent were granted-in-part (*see* Figure 3).

In sum, 62.8 percent of biopharma IPR petitions that reached an institution decision were instituted in whole or in part. In contrast, 71.3 percent of all other petitions that reached an institution decision were instituted in whole or in part (*see* Figure 4). Thus, the institution rate of IPR petitions is lower for biopharma compared to all other technical centers combined.

In addition, the number of instituted claims that survive following a final written decision is significantly higher for biopharma (44.9 percent) than for all other technical centers combined (17.9 percent) (*see* Figure 5). One possible explanation for the higher survival rate of biopharma patent claims is the inherent unpredictability of the subject matter. That is, it may be more difficult to establish that a claim is ''obvious'' where the

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Figure 3

Institution Status of Biopharma IPR Petitions (TC 1600)
(current as of 11/30/2016)

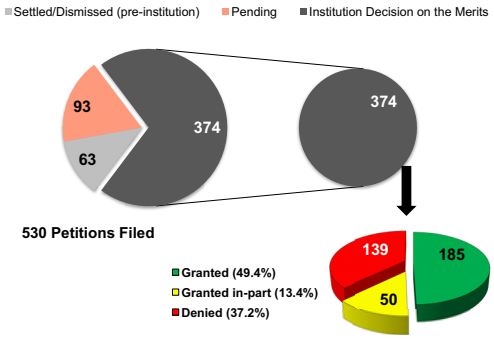
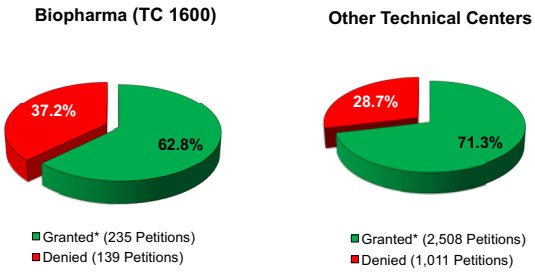


Figure 4

Outcome of Institution Decisions
(current as of 11/30/2016)



* A petition is considered granted if at least one petitioned claim is instituted.

art is unpredictable, particularly without the full scope of discovery allowed in district court litigation. Whatever the reason for the resilience of biopharma claims, many more claims reached a final written decision on obviousness grounds (1,154 claims) than on anticipation grounds (272 claims), and these claims had a better survival rate against obviousness grounds (49 percent) than anticipation grounds (37 percent).

The institution rate for biopharma IPR petitions is approximately 8.5 percent lower than for all other technical centers combined, but the claim survival rate for biopharma IPRs is approximately 27 percent higher. Thus, it appears that biopharma IPR petitions may be instituted less frequently than all other petitions, and that the chance that the instituted claims will survive the final written decision is greater for biopharma IPR petitions than for all other petitions.

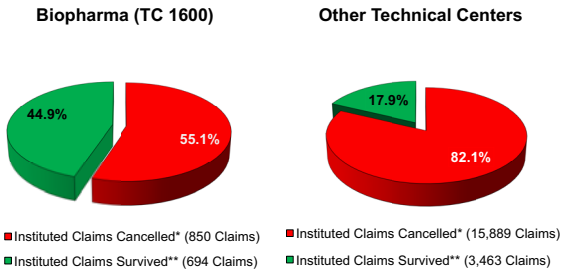
A possible reason for this observed trend is the ability of the patent owner to submit expert testimony post-institution, which may be a more persuasive tool in the unpredictable arts to rebut the petitioner's obviousness arguments. Notably, prior to May 2, 2016, petitioners were permitted to file an expert declaration with their petition, but patent owners could not file an expert declaration to support the preliminary response. Therefore, prior to issuing an institution decision, the PTAB could only consider the petitioner's expert testimony for the key factors considered in an obviousness inquiry—namely, the scope and content of the prior art, the differences between the claimed invention and the prior art, the level of ordinary skill in the art and the objective indicia of nonobviousness; the PTAB would only be given the opportunity to consider a patent owner's rebuttal expert testimony after an institution decision was made through the patent owner's response.

However, effective May 2, 2016, the PTO issued a rule change that allows patent owners to file expert declarations with the patent owner's preliminary response. *See* Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 81 Fed. Reg. 18,750, 18,766 (Apr. 1, 2016) (to be codified in 37 C.F.R. § 42.107(c)). Since this rule change went into effect, there have only been 32 institution decisions; thus, there is only limited data to ascertain if the patent owner's filing of an expert declaration decreases the institution rate. Based on the data available, the institution rate for petitions in which the patent owner has filed an expert declaration is 61.5 percent, which is not significantly different from the overall institution rate for biopharma patents (62.8 percent). Therefore, it will be important to examine how the institution rate changes over the coming months as more petitions subject to this rule change reach an institution decision.

Despite the higher survival rate of biopharma claims after a final written decision, there does not appear to be a significant difference in the settlement rate between biopharma and all other technical centers. Nonetheless, while the settlement rate *before* institution is substantially the same for biopharma and all other technical centers (11.9 percent and 11.7 percent, respectively), the settlement rate *after* institution is marginally lower for biopharma (6.8 percent) compared to all other technical centers (9.6 percent) (*see* Figure 6).

Figure 5

Outcome of Final Written Decisions
(current as of 11/30/2016)



* Number of instituted claims cancelled in the final written decision either on the merits by PTAB or at the request of patent owner.
** Number of instituted claims that survived or were amended in the final written decision

Figure 6

Termination Rate – Before vs. After Institution
(current as of 11/30/2016)

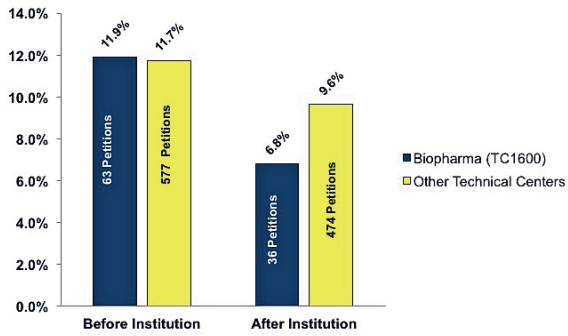


Figure 7

Number of IPR Petitions Filed per Fiscal Year
(current as of 9/30/2016)

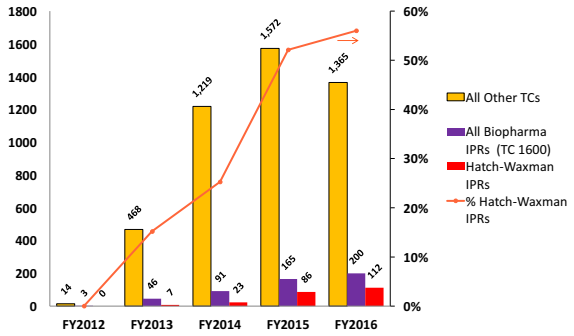
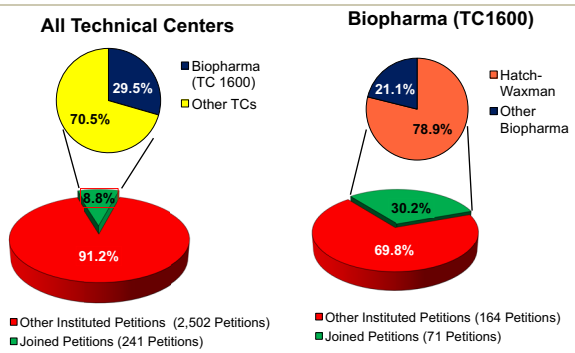


Figure 8

Biopharma & Hatch-Waxman IPR Petitions – Joined Petitions
(current as of 11/30/2016)



In summary, although there is an increase in the number of biopharma patents that are being challenged through IPR proceedings, these patents have experienced a lower institution rate and a higher claim survival rate after institution compared to patents in other technical centers. Furthermore, it is possible that as patent owners take advantage of the new rule permitting them to file an expert declaration with their preliminary response, the institution rate may decrease even further.

Hatch-Waxman Litigation and Related Biopharma IPR Petitions

A common type of district court litigation in the biopharma industry relates to a patent infringement action against a generic drug manufacturer that files an application with the U.S. Food and Drug Administration (FDA) seeking authorization to market a generic drug prior to the expiration of patents that cover the brand-name drug. Under the Hatch-Waxman Act, the generic manufacturer provides written notice to the patent owner that it is seeking FDA approval to market a generic drug before patent expiration. By filing an infringement action within 45 days of receiving this notice, the patent owner temporarily stays the entry of the generic drug onto the market.

The number of biopharma IPR petitions that challenge the patentability of patent claims involved in Hatch-Waxman litigations has steadily increased each fiscal year (*see* Figure 7). In FY2016, the number of Hatch-Waxman IPR petitions increased from 86 to 112, despite a decrease in the total number of petitions from 1,737 to 1,565 during that same period (*see* Figure 7). Furthermore, the percentage of Hatch-Waxman IPR petitions relative to all biopharma petitions increased from 15.2 percent in FY2013 to 56.0 percent in FY2016 (*see* Figure 7). Although this upward trend appears to be leveling off, it is apparent that Hatch-Waxman IPR petitions make up a significant portion of biopharma IPR petitions and substantially shape the trends for biopharma IPR petitions.

Hatch-Waxman IPR petitions also contribute to the high percentage of joinders in biopharma IPR petitions compared to petitions filed across all other technical centers. Although biopharma IPR petitions only account for 9.7 percent of all IPR petitions filed, biopharma IPR petitions constituted 29.5 percent of all petitions that were joined following institution (*see* Figure 8). And although the average rate of joinder for all IPR petitions combined was 8.8 percent, the average rate of joinder for biopharma petitions was 30.2 percent (*see* Figure 8). Notably, Hatch-Waxman IPR petitions account for 78.9 percent of all biopharma IPR petitions (*see* Figure 8). Therefore, there is a higher probability that upon institution, a Hatch-Waxman IPR petition will be joined with other petitions related to that same patent.

Multiple Biopharma IPR Petitions

The filing of multiple petitions against the same patent, either by the same or different petitioners, appears

Figure 9

Breakdown of Challenges to Biopharma Patents by Number of Petitions
(current as of 11/30/2016)

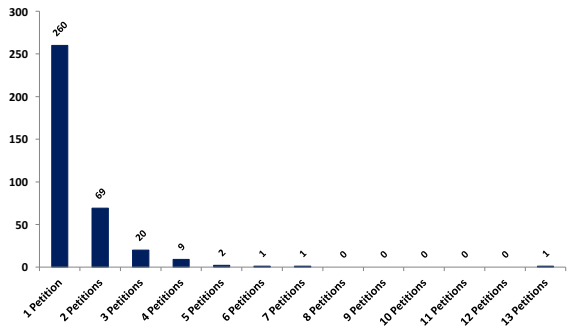
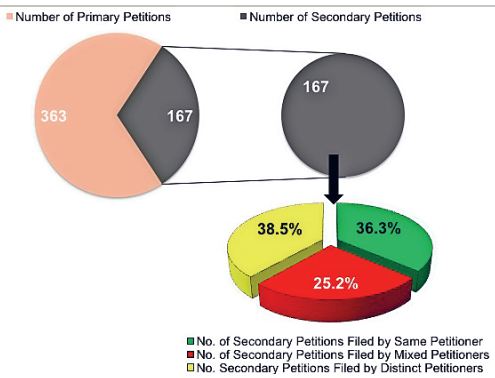


Figure 10

Biopharma IPR Secondary Petitions – Petitioner Information
(current as of 11/30/2016)



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to be a prevalent practice in biopharma IPR proceedings. Of the 530 biopharma IPR petitions filed, only 363 unique biopharma patents were challenged. Therefore, 31.5 percent of the biopharma IPR petitions were secondary petitions on the same patent.

Although the vast majority of those biopharma patents were challenged by two petitions, one particular biopharma patent was challenged by 13 separate petitions (*see* Figure 9). These multiple petitions result from a mix of secondary petitions filed by the same petitioner (38.5 percent), separate petitioners (36.3 percent) and a combination of separate and same petitioners (mixed petitioners) (25.2 percent) (*see* Figure 10). Of the secondary petitions filed against biopharma patents, over 61 percent are Hatch-Waxman IPR petitions.

Some petitioners file multiple petitions directed to the same patent to increase the likelihood that their petitions will be instituted. Petitions directed to nine biopharma patents were successfully instituted upon filing of a secondary petition when the primary petition had been denied in whole or in part. The secondary petitions for six of those nine patents were filed after the institution decision in the primary petition and involved the same claims as the primary petition.

Therefore, the petitioners who filed those secondary petitions were afforded an opportunity to improve the arguments made in the primary petition to help persuade the PTAB to grant institution. Notably, of those six secondary petitions that enjoyed a second bite at the apple, three were Hatch-Waxman IPR petitions.

Overview of PGR Petitions Filed Against Biopharma Patents

PGR proceedings make up a small number of the petitions filed following the enactment of the AIA. As of Nov. 30, 2016, petitioners have filed 10 biopharma PGR petitions challenging eight distinct patents. Of these 10 petitions, three were granted institution, in whole or in part, three were denied institution and four are still pending or settled before institution. One of the instituted petitions has reached a final written decision, in which all 13 instituted claims survived the patentability challenge.

A PGR petitioner may assert grounds of unpatentability that are not available to an IPR petitioner such as, for example, unpatentability under 35 U.S.C. § § 101 and 112. However, the PTAB has yet to issue a final written decision on the merits of a challenge under Section 101 or Section 112 for a biopharma patent. In this regard, the PTAB denied institution on the sole Section 101 challenge, and granted institution for two petitions on Section 112 grounds—one settled and the other is still pending.

Given that biopharma patents appear to be faring better than non-biopharma patents in IPR proceedings, future challengers may opt to pursue the additional grounds available in PGR if the window to file a PGR petition is still open. As more PGR petitions are filed and resolved, it will be important to monitor trends in PGR proceedings to determine how the PTAB handles the additional grounds available in PGR, and how well biopharma patents survive those challenges.

Conclusion

The outcomes for biopharma patents in IPR proceedings are distinct from patents in other technical centers. Biopharma patent claims have had a lower institution rate and a higher survival rate, meaning that these claims have tended to better withstand unpatentability challenges.

However, the institution and survival rates may change as time progresses, not least because biopharma patents appear to continue to account for a higher proportion of patents subject to multiple IPR challenges, which potentially allow for petitioners to assert additional or more polished unpatentability grounds.

Finally, although the paucity of biopharma PGR petitions makes current trends difficult to discern, PGR proceedings could become an important part of biopharma litigation. Patent owners and challengers would be well advised to monitor developments for biopharma patents in both IPR and PGR proceedings.