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Are IPRs Impacting the Pharmaceutical Industry?

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The use of inter partes review (IPR) to challenge patents has grown significantly since its initiation in September 2012. In the first four months of IPRs, the United States Patent and Trademark Office (USPTO) received 97 petitions. In the parallel months of 2014, 578 new petitions were filed. As statistics go for invalidating patents, the IPR process scores high—so much so that the US Patent Trial and Appeal Board (PTAB) has had to defend itself from allegations that it is a "death squad" for patent rights (1).

IPRs are a mechanism for challenging the validity of a patent without the expense and time of bringing litigation in the federal court system. To initiate an IPR, the challenging party files a petition with the PTAB, part of the USPTO. Petitions may raise challenges based on novelty or obviousness of the patent claims in view of prior art printed publications and patents. Other validity challenges, such as written description and enablement, are not available through IPR. If the petitioner demonstrates a reasonable likelihood that it would prevail in showing the unpatentability of one or more claims, the PTAB institutes the review. The parties can then file written submissions with additional evidence; this is followed by an oral hearing before the PTAB. Within 12 months from the institution of the review, the PTAB issues a written decision on each of the challenged claims, declaring them unpatentable or upholding them as valid. The entire process generally takes 18 months and thus moves much quicker than a patent litigation. Also, a party can initiate a challenge independent of whether a controversy exists as to infringement of the patent.

From the viewpoint of a potential challenger, therefore, it would seem IPRs effectively and efficiently clear the path of potentially impeding patents. Yet only approximately 8% of petitions are in the pharmaceutical area. Why are the numbers so low?

IPRs in pharma

One reason for the low numbers of IPRs in the pharmaceutical industry may be that the Hatch-Waxman framework governing challenges to generic drugs relies on district court litigation to start the clock for approval; the framework does not take into account use of IPRs to achieve the same goal. In Hatch-Waxman litigation, the generic-drug company asserts that the branded pharmaceutical's patents are invalid or will not be infringed by the generic drug. To obtain a 30-month stay on the generic's approval, the branded pharmaceutical company must file an infringement action in district court. Subsequent court rulings then determine whether the generic-drug company can lawfully launch its drug before the patents expire and whether the first generic-drug company to file its FDA application will be rewarded with 180-day market exclusivity. This statutory framework does not include a mechanism for challenging patents by IPR, so such challenges remain in district court. A second reason for the slow start to pharmaceutical-related IPRs may be that the industry has taken a wait-and-see approach as the first IPRs make their way through the process.

The IPR process

IPRs can be divided into two stages. First, the PTAB decides whether the challenger has shown a reasonable likelihood that it would prevail in showing the unpatentability of the patent claims in view of elected prior art. If not, the IPR terminates. If this hurdle is passed, however, the IPR is instituted and proceeds to trial, where the PTAB makes a final determination on validity. **Table I** shows the status of pharmaceutically related IPRs with a filing date on or before March 31, 2015 and their status as of May 12, 2015.

Table I: Summary of pharmaceutical-related IPRs.

Status		Small Molecule Drugs	Biologics	Total
Pending	Awaiting institution decision	29	4	33
Instituted	Awaiting PTAB trial	23	2	25
	Settled after institution	8	0	8
	Patent upheld by PTAB trial	4	0	4
	Patent invalidated by PTAB trial	3	3	6
Not instituted	Time-barred	2	0	2
	Substantive denial on the merits	14	5	19
Settled	Settled before institution decision	13	2	15
Total		96	16	112

Of the challenges that have reached the institution decision point, the PTAB instituted review on two-thirds of the petitions (43 of 64 total). However, a look at the type of patent claims at issue in these IPRs adds more color to the picture.

Pharmaceutical patent claims typically fall into a few defined categories: the chemical structure of a drug; formulations of the drug; methods of administration and treatment (e.g., dosing regimens, diseases treated); and drug combinations. Generally, the latter three categories concern drugs whose chemical structures are already known. A majority of the pharmaceutical IPRs are focused on these types of claims and also constitute the majority where PTAB review is instituted. Of the 64 petitions considered for institution to date, eight concern patents for new chemical structures. The PTAB denied institution to all eight petitions (2). In contrast, the PTAB instituted the IPRs for 35 of the 56 petitions relating to patent claims for known drugs.

The overall picture suggests IPRs may have a more limited application for pharmaceuticals. For the first filer of a generic small molecule drug, the Hatch-Waxman process will continue to play out in district courts to ensure award of the 30-month stay and 180-day first filer exclusivity. It is likely only subsequent filers will use the IPR process to gain market access. Moreover, the IPR success rate on challenging patents directed to new drugs is low. Thus, it is only after these central patents expire or are invalidated in district court that IPRs become expedient to challenge follow-on patents.

Patent challenges for biosimilar drugs may be more amenable to IPRs. Currently, biosimilars are largely directed at drugs where patents on chemical structure have expired and only follow-on patents remain. Also, the first-filer market exclusivity incentive only applies to a subset of biosimilars designated as interchangeable. Currently, FDA approval is proceeding in two steps, with drugs clearing the biosimilar approval first and going back for interchangeable status only later. In this manner, the patent challenges may be already addressed in either IPRs or district court before exclusivity comes into play. Additionally, recent court battles over the process for challenging biosimilars in district court suggest IPRs may be a faster, easier route.

As more patents make their way through IPRs, the balance of how the pharmaceutical industry selects between IPRs and district court litigation will likely evolve.

References

1. T. Dutra, “Rader Regrets CLS Bank Impasse, Comments on Latest Patent Reform Bill”, *Bloomberg BNA* [2], Oct. 29, 2013.
2. UPSTO, See IPR2014-01126 (Paper 21); IPR2014-00885 (Paper 15); IPR2014-00886 (Paper 15); IPR2014-00887 (Paper 16); IPR2014-00888 (Paper 15); IPR2014-00559 (Paper 8); IPR2014-00398 (Paper 11); IPR2014-00315 (Paper 14), https://ptabtrials.uspto.gov/prweb/PRServlet/Hcl5xOSeX_yQRYZAnTXXCg%5B%5B*/!STANDARD?# [3].

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