

PATENTS

A statistical analysis of inter partes review proceedings before the Patent Trial and Appeal Board shows that the PTAB is not a “death squad” for patents.

## Trends in Inter Partes Review of Life Sciences Patents



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### I. Introduction

First available in September 2012 under the America Invents Act, petitions for inter partes review have become a popular and relatively inexpensive staple in patent litigation.

The number of filings was small at first but steadily climbed, and invalidation rates started out and have remained high.

In fact, around the first anniversary of the proceeding, Randall Rader, the former chief judge of the U.S. Court of Appeals for the Federal Circuit, lamented that the administrative law judges at the Patent Trial and Appeal Board adjudicating IPRs were “acting as death squads, . . . killing intellectual property rights.”

James D. Smith, who was then chief judge at the PTAB, did not exactly deny this allegation, instead stating that “[i]f we weren't . . . doing some ‘death squadding,’ we would not be doing what the statute calls on us to do.”

So is the PTAB a death squad? Was that label ever justified? And how have IPRs of biopharma and medical device patents fared in particular?

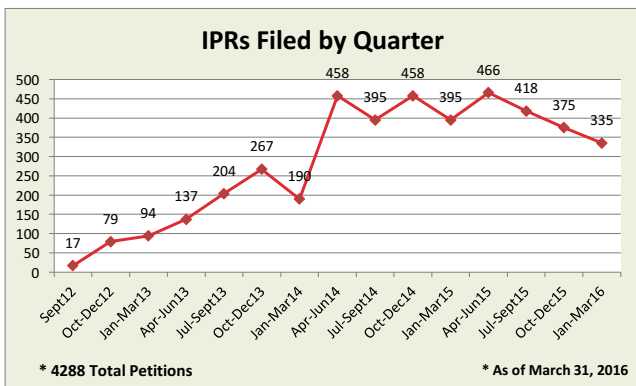
Here we use data mined from legal analytics tool Lex Machina to examine points of interest to the life sciences community, focusing on a comparison of IPR filing, institution, and invalidation rates for patents overall to those for biopharmaceutical patents, including patents listed in the FDA's approved drug "Orange Book."

We also discuss these outcomes for medical device IPRs and IPRs filed by hedge funds challenging life sciences patents.<sup>1</sup>

## II. Comparing Biopharma IPRs to IPRs for All Technology Centers

### IPR Filings

Through the end of March 2016, petitioners have filed 4,288 petitions for inter partes review. The chart below reflects the number of filings for each quarter, starting with the partial quarter of Sept. 16-30, 2012.



As can be seen from the chart, the number of petitions filed rose steadily through 2013, the first full year in which petitions were available.

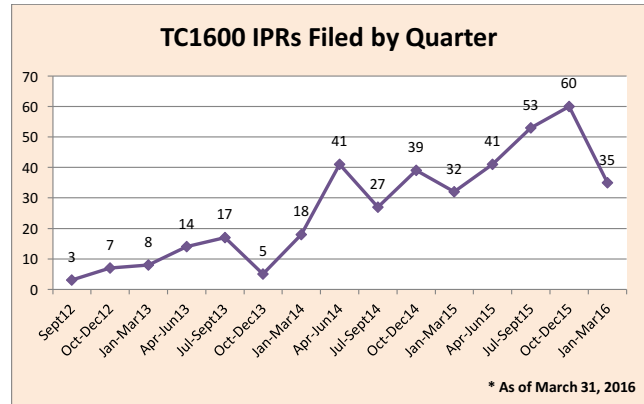
By Q4 2013, the number of filings had nearly quadrupled to 267, from the 79 that were filed in Q4 2012.

Although this increase can be attributed to the typical reluctance to adopt a new proceeding before data about the proceeding has been accumulated, it is interesting to note that the number of filings shot up dramatically thereafter, from 267 in Q4 2013 to 458 in Q2 2014, an increase of 71 percent over six months. From Q2 2014 through Q4 2015, the number of filings has averaged 424 per quarter, well above the peak of the 2012-2013 ramp-up period.

So how have life sciences patents—specifically those in the PTO's technology center 1600 for biotechnology and organic chemistry—compared to the overall

<sup>1</sup> This article does not address any post-grant proceedings other than IPRs.

trends? The chart below reflects IPR filings in TC1600 per quarter:



As the above chart shows, petitions challenging TC1600 patents also experienced a steady increase through Q3 2013.

The number of petitions then rose sharply from 18 in Q1 2014 to 41 in Q2 of that year. Petitions rose even more dramatically in 2015, spiking at 60 in Q4 2015.

In the same period that total filed IPRs averaged a high 424 per quarter (April 2014-December 2015), TC1600 IPRs averaged 41 per quarter, more than double the number filed in the quarter immediately preceding that period (January-March 2014).

TC1600 IPR filings have also been on the rise as a percentage of total IPRs. In 2013, those filings were only 6 percent of the total, but increased to 8 percent and 11 percent in 2014 and 2015, respectively.

Although the number is only 10 percent through March 2016, it will likely increase by year end.

### Institution Rate

The increase in IPR filings has undoubtedly been bolstered by the success rate of IPR petitions, attributable at least in part to the lower standards for finding claims unpatentable in the PTAB than for invalidating claims in district court.

Petitioners are also aided by the "broadest reasonable interpretation" claim construction standard and the relatively low cost of IPR proceedings.

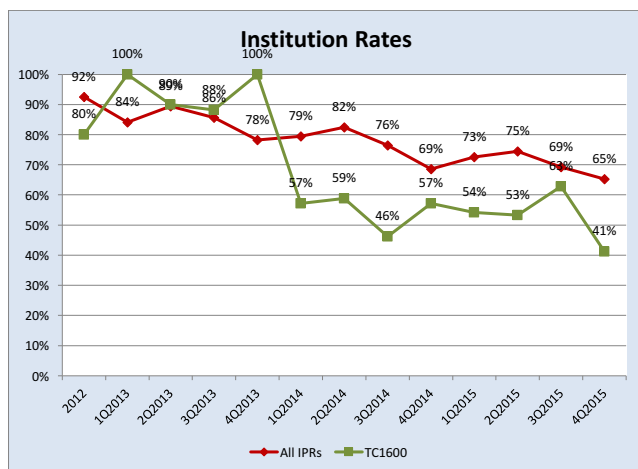
Of the 3,722 petitions filed through March 2016 that have either been terminated or reached a decision on institution (DI)—60 percent (2,231) were instituted and only 18 percent (682) were denied.

However, when only those 2,913 that have reached DI are considered—i.e., excluding the 15 percent (544) of petitions that were settled before DI and another 7 percent (264) that did not reach a DI for other reasons—the institution rate climbs to 77 percent, or 2,231 of 2,913 petitions filed through March 31, 2016.

The institution rates for TC1600 patents tell a somewhat different story. The percentage of total petitions by quarter filed through March 2016 that have reached

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DI and were instituted, as compared to that of TC1600 petitions, is shown below:



No petitions filed in 2016 have yet reached DI. For the 250 TC1600 petitions filed that have reached DI, 62 percent (155) were instituted.

This lower institution rate may be due to the patentability of new compositions claimed in biotechnology and organic chemistry patents, making them more difficult to challenge than patents in technologies for which there exists closer prior art.

Lower quality petitions, stronger patent owner responses, or both may also have played a part in the lower institution rate for TC1600 petitions than for overall IPRs.

The institution rate for all petitions has been on a downward trend, as shown in the chart above. This downward trend may be due to an increase in the number and quality of patent owner preliminary responses.

In contrast, the TC1600 rate has only recently taken a sharp downturn, dropping to 41 percent in Q4 2015. Otherwise the TC1600 institution remained steady beginning in 2014, and it is too early to determine whether the rate will continue downward for those petitions.

### Invalidation Rates

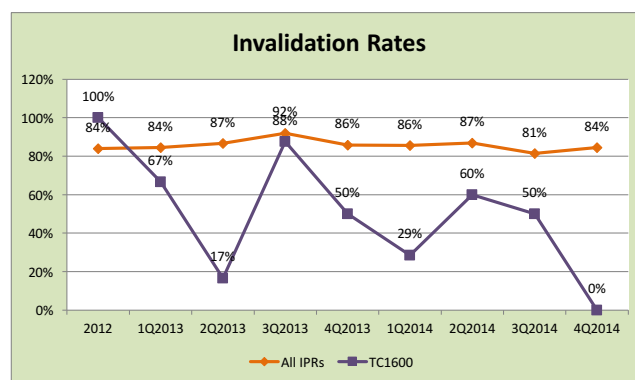
Of the 790 petitions filed through March 2016 that have reached final written decision, 73 percent (576) resulted in a finding that all claims were unpatentable, and 13 percent (100) resulted in some claims found unpatentable.

In other words, once a petitioner makes it to the institution decision, odds are very good for invalidating some or all claims.

The following chart compares the invalidation rate for all tried petitions—i.e., the percentage of petitions in which some or all claims were found unpatentable out of the petitions that were tried—in the quarter in which the petitions were filed, as compared to the same data for TC1600 petitions:

As the chart indicates, no petitions filed after 2014 have yet reached a final written decision.

The difference between TC1600 petitions as compared to all petitions is stark: The invalidation rate for all petitions is over 80 percent for the two years for which final written decision data exists and has remained remarkably steady, whereas the invalidation rate for TC1600 petitions for the same period averages



just 45 percent and varies widely from quarter to quarter.

The relatively small sample of TC1600 petitions can account for the variations between quarters, and the novelty and nonobviousness of compounds and formulations claimed in some biotechnology and organic chemistry patents may account for the lower invalidation of TC1600 claims.

### Orange Book Patents

IPRs challenging so-called Orange Book patents, i.e., those patents covering drug products that have been approved by the Food and Drug Administration for safety and efficacy, are a subset of TC1600 patent and warrant a separate analysis.

The table below shows a breakdown of IPR outcomes for these patents as of April 19:

Orange Book IPR Statistics	
Awaiting institution decision	49
Terminated by agreement pre-institution	23
Not instituted	56
Instituted:	108
Settled	11
Requested an Adverse Judgment	2
Proceeded to final written decision	20
All Instituted Claims Found Unpatentable	8
Some Instituted Claims Found Unpatentable	0
All Instituted Claims Found Not Unpatentable	12

Of the 164 petitions that have reached DI, 65 percent (108) have been instituted. This institution rate is consistent with the institution rate for all TC1600 patents. Only 40 percent (8) of final written decisions have found all claims unpatentable, which is comparable to all TC1600 patents.

Overall, like all TC1600 patents generally, Orange Book patents are less likely to be instituted than IPRs as a whole, and far less likely to be invalidated.

### III. Medical Devices

Medical devices are another category of interest to the life science technology community, but are more difficult to analyze because no one specific Technology Center exists for them.

As a proxy, we chose the six U.S. medical device manufacturers having the most patent application filings and analyzed how those companies have fared in IPRs.

Those companies are Medtronic, Johnson & Johnson, Boston Scientific, Stryker, Becton Dickinson, and Smith & Nephew. The breakdown of the 110 IPR petitions involving these companies, depending on whether they are petitioner or patent owner, is as follows:

	Petitioner	Patent Owner
Awaiting institution decision	17	5
Settled pre-institution	18	4
Procedurally dismissed / Patent owner disclaimed	6	0
Denied	22	1
Instituted	37	0
Open	6	
Settled	2	
Procedurally dismissed / Patent owner disclaimed	6	
Joined to other trial	1	
All Instituted Claims Upheld	1	
Some Instituted Claims Unpatentable	2	
All Instituted Claims Unpatentable	19	

As shown above, the institution rate for those patents that reach the institution decision stage is 62 percent, well below the average for all types of petitions and the same as for TC1600 patents.

The invalidation rate of 86 percent, however, is consistent with the numbers for all IPRs.

The medical device manufacturer is the patent owner in 10 of these IPRs: four Medtronic, four Stryker and two Becton Dickinson. Five of these petitions remain open.

Of the five that have been terminated, four were settled and one denied institution—a 100 percent win for the patent owners.

The sample size is quite small, however; it is early to draw conclusions on IPR outcomes for this category.

The medical device companies were more often the petitioner: 37 filed by Medtronic; 15 filed by Johnson & Johnson; nine by Boston Scientific; 14 by Stryker; one Becton Dickinson; and 24 Smith & Nephew.

The institution rate is 61 percent of petitions with DI—again, more consistent with the TC1600 institution rate than the institution of all IPRs—but the invalidation rate of 95 percent is higher than that for all IPRs. Twenty petitions have settled.

In sum, so far these medical device manufacturers have enjoyed a 100 percent success rate as patent owners, and a 65 percent success rate in invalidating some or all claims as petitioners.

#### IV. Hedge Fund IPRs

Hedge fund founder Kyle Bass has taken a novel approach to IPRs, namely, shorting stock of pharmaceuti-

cal companies and then filing IPRs on those companies' patents.

As of April 19, he has filed 35 IPRs in his individual capacity or through his company Coalition for Affordable Drugs. Although none has reached a final written decision and it is too early to determine the merits of this strategy, he has had some success: 18 of the IPRs have instituted (50 percent), while two are still pending.

A number of IPRs have been filed by other hedge funds or entities that appear to have been created for the purpose of challenging patents via IPRs and that have ties to hedge funds:

- *Ferrum Ferro Capital, LLC v. Allergan Sales, LLC*, IPR2015-00858 (filed Sept. 21, 2015).
- Neptune Generics LLC, a generic pharmaceutical company that launched in 2014, has challenged several pharmaceutical patents in the following four IPRs: IPR2015-01313; IPR2016-00049; IPR2016-00237; and IPR2016-00240. IPR2015-01313 is the only IPR that does not involve a patent currently listed in the Orange Book. Neptune Generics indicated in a filing before the PTAB that it “utilizes inter partes review (IPR) proceedings to challenge invalid patents.” See *Neptune Generics, LLC v. Auspex Pharmaceuticals, Inc.*, IPR 2015-01313, Ex. 1017, Declaration of Ashley Keller (Sept. 1, 2015).
- IPR2016-00471 filed by Rosellini Scientific LLC and nXn Partners LLC.
- IPR2016-00191 filed by Graybar Pharmaceuticals LLC.
- IPR2016-00204 and IPR2016-00544 filed by Argentum Pharmaceuticals LLC.
- IPR2016-00297 filed by GeneriCo LLC and Flat Line Capital LLC.
- IPR2016-00379 filed by Lower Drug Prices for Consumers LLC.

These IPRs were recently filed and therefore have no decisions on institution. They are worth watching.

#### V. Takeaway

So is the PTAB a death squad as Rader had charged? In a word, no.

Although the overall invalidation rate looks high when only IPRs that have reached final written decision are considered, it is worth remembering that of all IPRs filed and terminated through March 2016, only 22 percent have resulted in a finding that some or all claims are unpatentable.

In addition to the 22 percent that are denied institution, a significant number settled—18 percent pre-institution decision and 13 percent post-institution—and another 8 percent were procedurally dismissed pre-institution, all of which are considered patent owner wins.

The outlook is even better for biopharmaceutical patents: of all petitions filed and terminated through March 2016, only 11 percent have resulted in unpatentable claims.