

INITIAL DATA SHOWS THAT
PTAB IS NOT A 'DEATH SQUAD' FOR

BIOLOGIC DRUG PATENTS

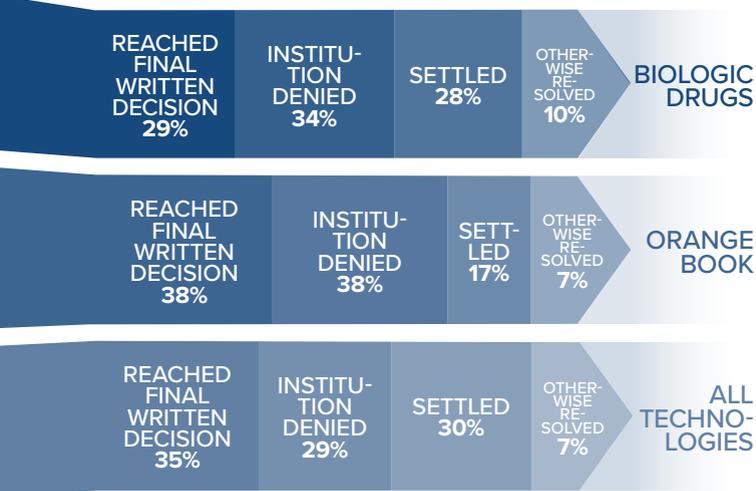
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The March 2017 statistics issued by the United States Patent Trial and Appeal Board (PTAB) report that across all technologies, all challenged patent claims are found patentable in only 19 percent of *inter partes* review (IPR) final written decisions.¹ This is an improvement over a low point of in only 13 percent of decisions between late 2015 and early 2016,² but this percentage does little to assuage concerns that PTAB is a patent “death squad.”³ But there is good news for the pharmaceutical industry. The data concerning drug patents is more favorable: a smaller percentage of drug patent IPRs are instituted, and a higher percentage of drug patent IPRs survive final written decisions with all instituted claims intact. The initial data for IPR challenges to patents that are identified as reading on CDER-listed Biologic Drugs (Biologic Drug IPRs) is also looking promising. While the dataset remains very small, Biologic Drug patents are holding up in institutions and in final written decisions.

As of March 31, 2017, PTAB reports that there were 4,563 resolved IPRs.⁴ Of these, 222 concerned patents were listed in the U.S. Food and Drug Administration Orange Book (Orange Book IPRs) and 29 concerned biologic drug patents.⁵ Looking at the total number of resolved IPRs, 53 percent were instituted and 35 percent reached final written decision. For Orange Book IPRs, these numbers are 44 percent and 38 percent; Biologic Drug IPRs are 41 percent and 28 percent.

that at least some challenged claims were patentable (in that PTAB did not institute IPR on these claims or PTAB found instituted claims not unpatentable in a final written decision) in 41 percent of the total number of resolved IPRs. This number marks the most significant difference between the data across technologies. The comparative number for Orange Book and Biologic Drug IPRs is 60 percent and 45 percent respectively, comprising a combined total of 58 percent. It is also noteworthy that a higher percentage of Biologic Drug IPRs settled before an institution decision: 21 percent of the total number of Biologic Drug IPRs, compared to only 12 percent of the total number of Orange Book IPRs.⁶ In other words, proportionately fewer Biologic Drug IPRs reached an institution decision.



ALL TECHNOLOGIES PTAB DETERMINATIONS AT LEAST SOME CLAIMS REMAINING PATENTABLE **58%**

ORANGE BOOK PTAB DETERMINATIONS AT LEAST SOME CLAIMS REMAINING PATENTABLE **45%**

BIOLOGIC DRUGS PTAB DETERMINATIONS AT LEAST SOME CLAIMS REMAINING PATENTABLE **60%**

ORANGE BOOK + BIOLOGIC DRUGS DETERMINATIONS AT LEAST SOME CLAIMS REMAINING PATENTABLE **41%**

Considering just these two stages of PTAB determination— institution decisions and final written decisions—PTAB found

In short, the statistics concerning drug patent challenges are optimistic. Orange Book and Biologic Drug patents are faring better in IPRs than patents across all technologies, and the initial data for Biologic Drug IPRs is looking promising: a higher percentage of challenges have settled before an institution decision, and a higher percentage of challenged claims have survived IPR unscathed as patentable. ●

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¹ https://www.uspto.gov/sites/default/files/documents/AIA%20Statistics_March2017.pdf

² See September 2015 through February 2016 PTAB statistics at <https://www.uspto.gov/patents-application-process/appealing-patent-decisions/statistics/aia-trial-statistics>.

³ See Randall Rader, C.J., Fed. Cir., Address at the American Intellectual Property Law Association Annual Meeting (Oct. 25, 2013), (“You’ve got an agency with 7,000 people giving birth to property rights, and then you’ve got, in the same agency, 300 or so people on the back end ... acting as death squads, kind of killing property rights.”)

⁴ https://www.uspto.gov/sites/default/files/documents/AIA%20Statistics_March2017.pdf

⁵ Data relating to Orange Book and Biologic Drug IPRs is obtained from proprietary databases maintained by Fitzpatrick Cella Harper and Scinto. Data relating to Biologic Drug IPRs is available here: <http://www.biologicshq.com/>.

⁶ A further 7 percent of the total number of Biologic Drug IPRs settled after institution, resulting in a total of 28 percent that settled prior to a final written decision. A further 5 percent of the total number of Orange Book IPRs settled after institution, resulting in a total of 17 percent that settled prior to a final written decision.