

# Drug Patents May Fare Better Than Other Technologies In IPR Proceedings



**JUNE 12, 2017**

**Corinne E. Atton** and **April M. Breyer**

On March 31, 2017, the United States Patent Trial and Appeal Board (“PTAB”) released updated statistics<sup>1</sup> showing the fate of resolved *inter partes* review (“IPR”) proceedings. These statistics show that a total of 4,563 IPR petitions were resolved as of March 31, 2017 including 1,577 final written decisions. In 81% of these final written decisions (27% of the total number of petitions filed), at least some instituted patent claims were found unpatentable. This statistic has contributed to concerns that PTAB is a patent “death squad.”

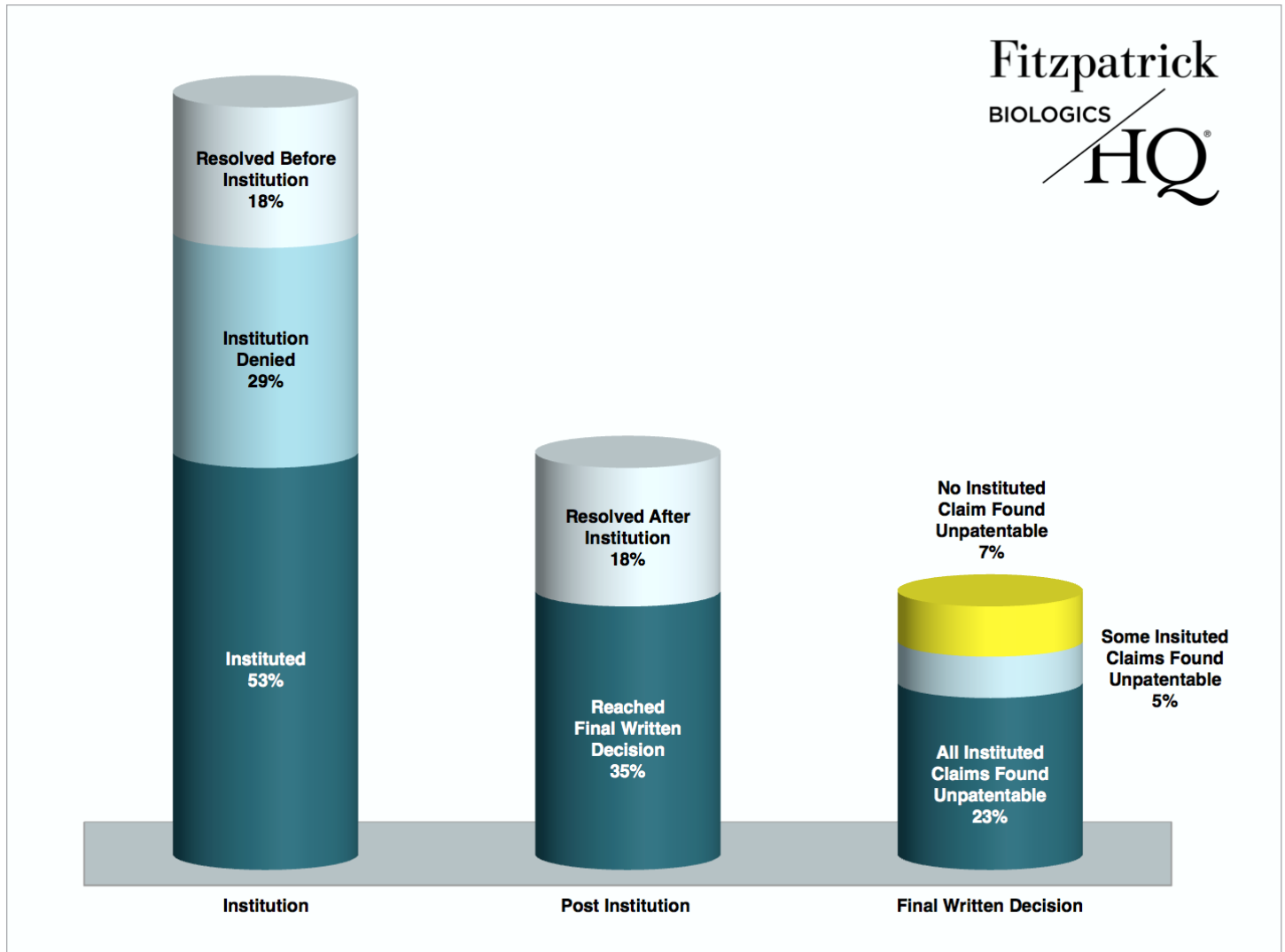
Fitzpatrick’s BiologicsHQ reports that such concern is not justified for drug patents. On the contrary, IPR statistics for this subset of patents are significantly more favorable: a smaller percentage of drug patent IPRs are instituted; and of those that reach a final written decision, a higher percentage of patents survive with at least some claims remaining patentable. This is welcome news to the pharmaceutical industry.

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## ACROSS ALL TECHNOLOGIES, 53% OF IPRS WERE INSTITUTED, 35% REACHED FINAL WRITTEN DECISION, AND ALL CLAIMS REMAINED PATENTABLE IN 19% OF FINAL WRITTEN DECISIONS

The March 2017 PTAB Statistics show that across all technologies 53% of resolved IPRs were instituted, and 35% reached a final written decision. No instituted claim was then found unpatentable in 19% of final written decisions (in 7% of the total number of resolved IPRs); some instituted claims were found unpatentable in 16% of final written decisions (in 5% of the total number of resolved IPRs); and all instituted claims were found unpatentable in 65% of final written decisions (in 23% of the total number of resolved IPRs).

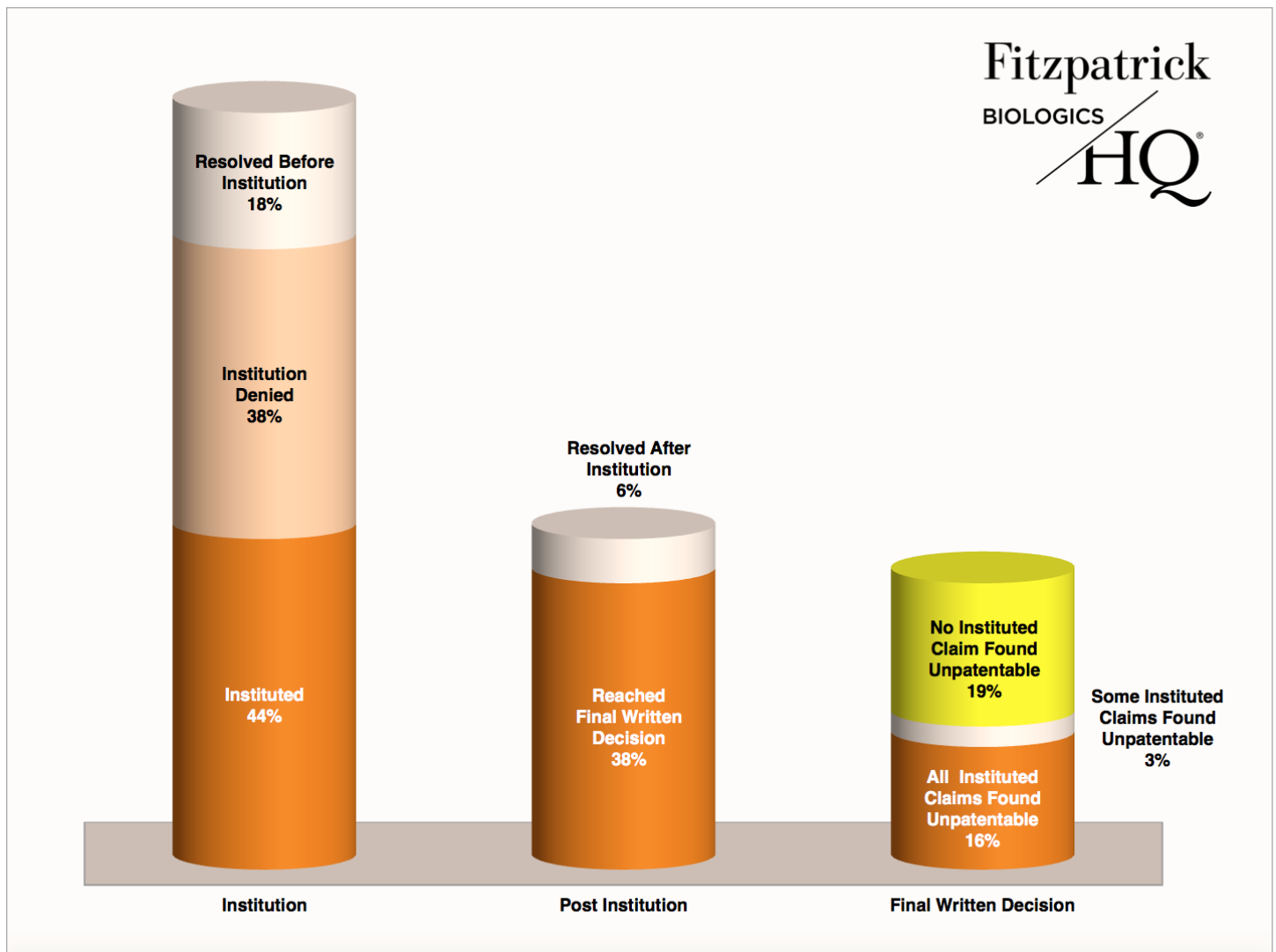


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## FOR ORANGE BOOK PATENT IPRs, 44% WERE INSTITUTED, 38% REACHED FINAL WRITTEN DECISION, AND ALL CLAIMS REMAINED PATENTABLE IN 50% OF FINAL WRITTEN DECISIONS

Of the 4,563 resolved IPR petitions, 222 petitions (5%) concerned patents that were listed in the U.S. Food and Drug Administration Orange Book (“Orange Book IPRs”). Focusing on just these Orange Book IPRs, 44% were instituted, and 38% reached a final written decision. No instituted claim was then found unpatentable in 50% of final written decisions (in 19% of the total number of resolved Orange Book IPRs); some instituted claims were found unpatentable in 7% of final written decisions (in 3% of the total number of resolved Orange Book IPRs); and all instituted claims were found unpatentable in 43% of final written decisions (in 16% of the total number of resolved Orange Book IPRs).

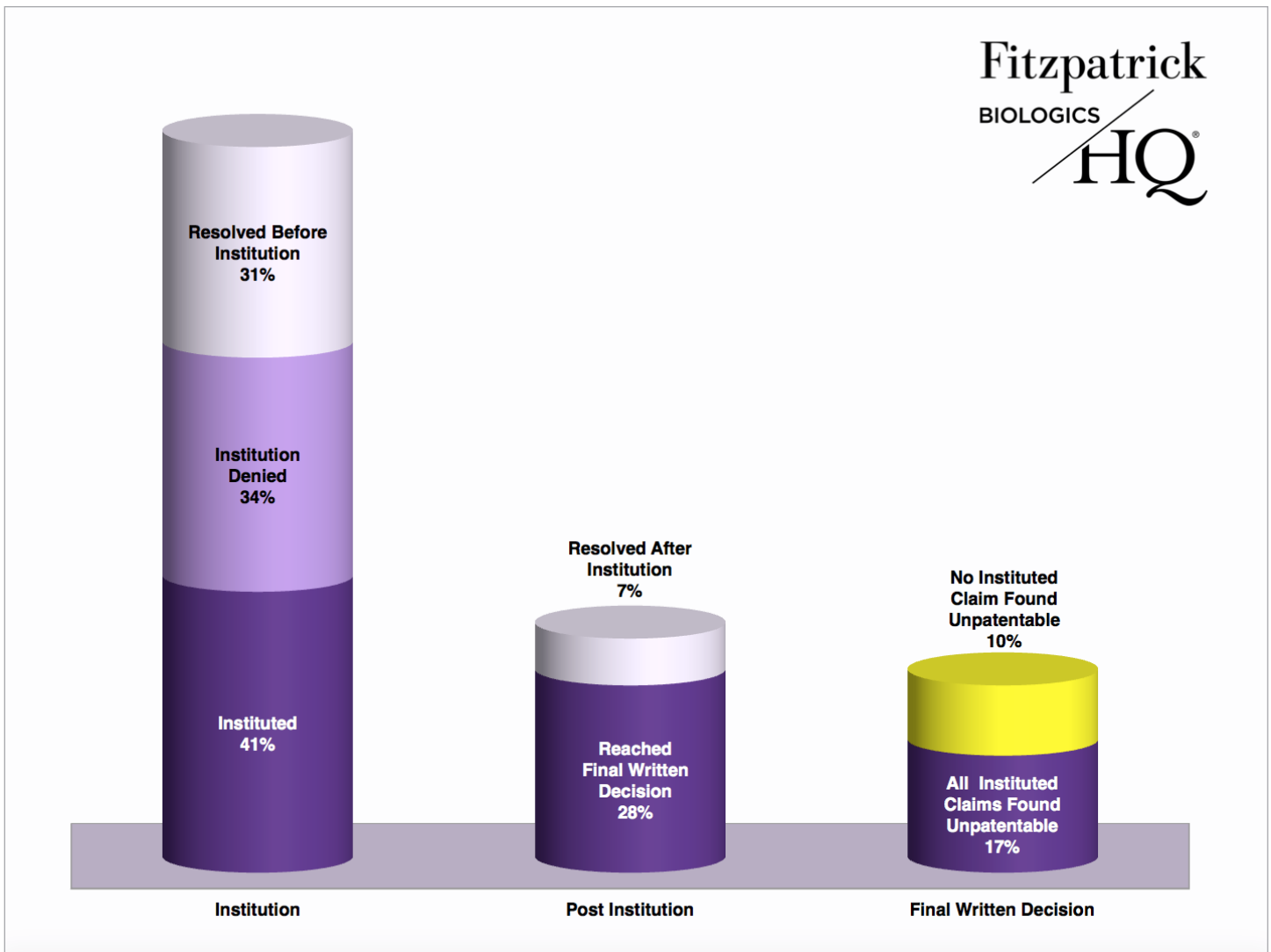


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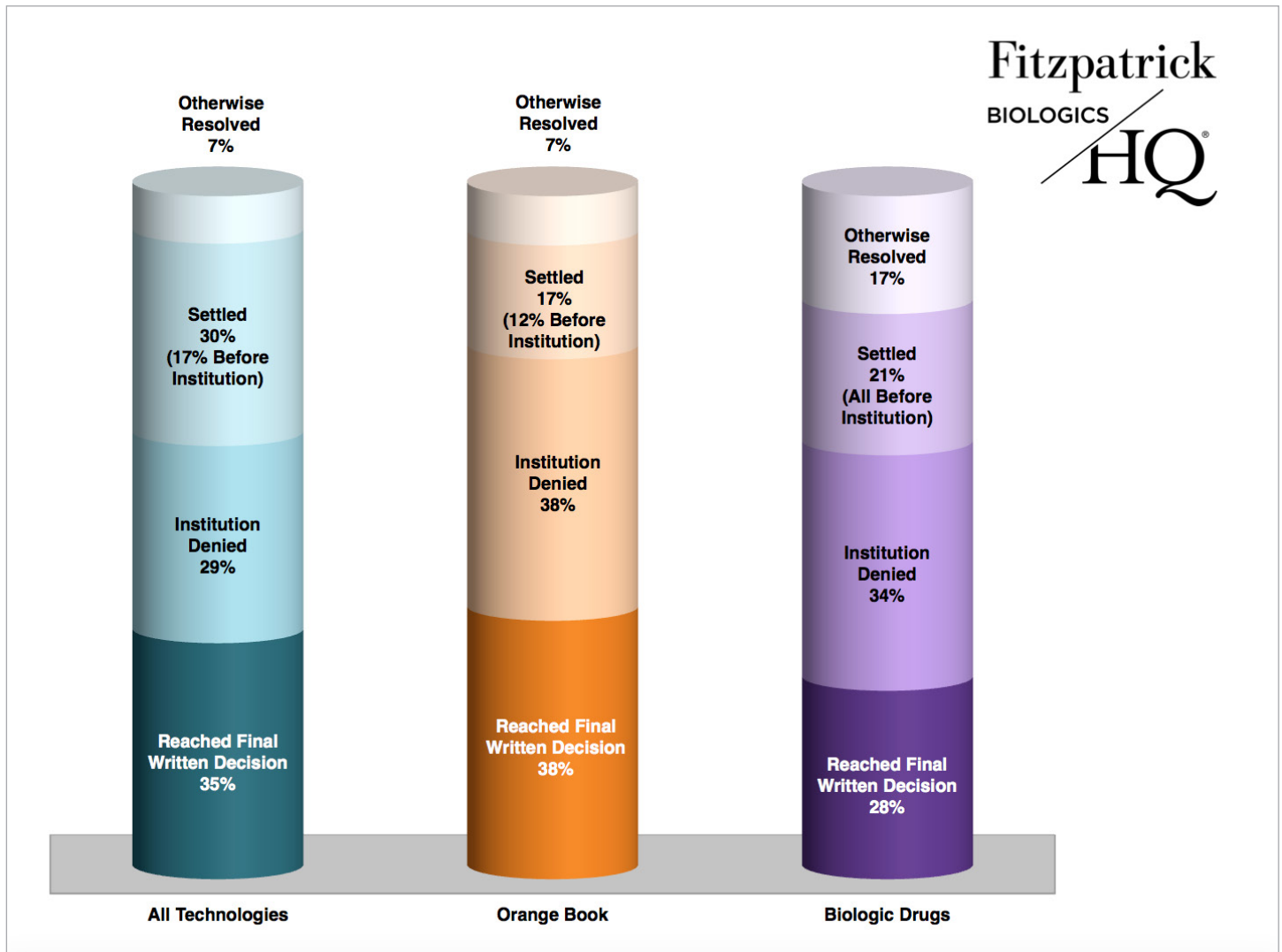
## FOR BIOLOGIC DRUG PATENT IPRs, 41% WERE INSTITUTED, 28% REACHED FINAL WRITTEN DECISION, AND ALL CLAIMS REMAINED PATENTABLE IN 37.5% OF FINAL WRITTEN DECISIONS

Looking instead at the 29 IPR petitions (0.6% of the total number of resolved IPRs) challenging patents that have been identified as reading on CDER-listed biologic drugs (“Biologic Drug IPRs”),<sup>2</sup> Fitzpatrick’s BiologicsHQ reports that 41% were instituted, and 28% reached a final written decision. No instituted claim was then found unpatentable in 37.5% of final written decisions (in 10% of the total number of resolved Biologic Drug IPRs); and all instituted claims were found unpatentable in 62.5% of final written decisions (in 17% of the total number of resolved Biologic Drug IPRs).



## A HIGHER PERCENTAGE OF BIOLOGIC DRUG IPRs SETTLED BEFORE AN INSTITUTION DECISION

While the dataset for Biologic Drug IPRs remains very small, to date, a smaller percentage of Orange Book and Biologic Drug IPRs have been instituted as compared to IPRs across all technologies (44% and 41%, as compared to 53%). Also, a higher percentage of Biologic Drug IPRs settled before an institution decision—21%, as compared to 12% for Orange Book IPRs, and 17% across all technologies—and a higher percentage of Orange Book and Biologic Drug IPRs were denied institution (38% and 34%, as compared to 29% across all technologies).

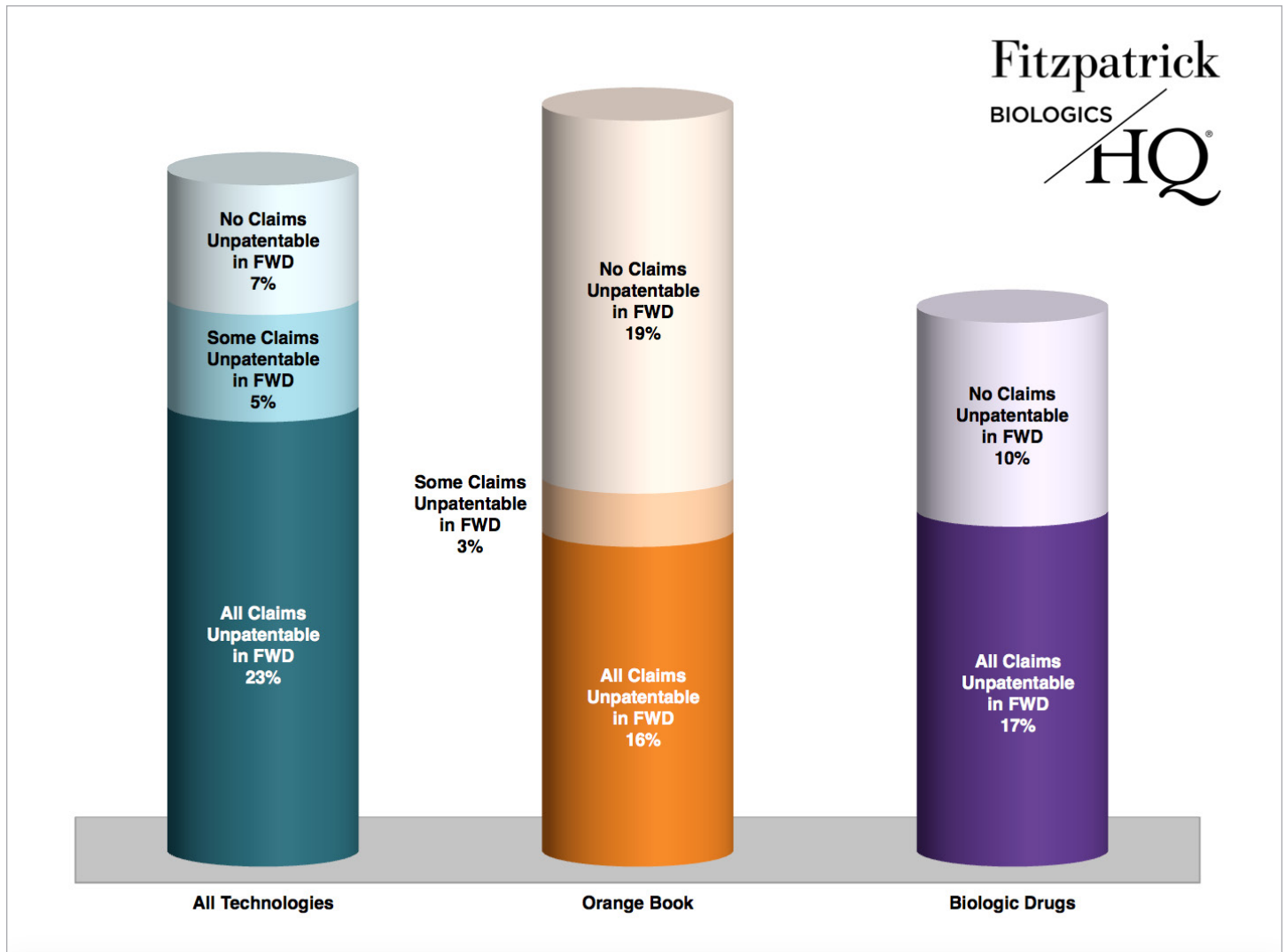


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## HIGHER PERCENTAGES OF ORANGE BOOK AND BIOLOGIC DRUG IPRS SURVIVE FINAL WRITTEN DECISIONS UNSCATHED

Another notable difference between Orange Book and Biologic Drug IPRs, and IPRs across all technologies is the number of final written decisions in which all instituted claims were found unpatentable. For Orange Book IPRs, all instituted claims were found unpatentable in 16% of final written decisions. This percentage is 17% in Biologic Drug IPR final written decisions, as compared to 23% across all technologies.

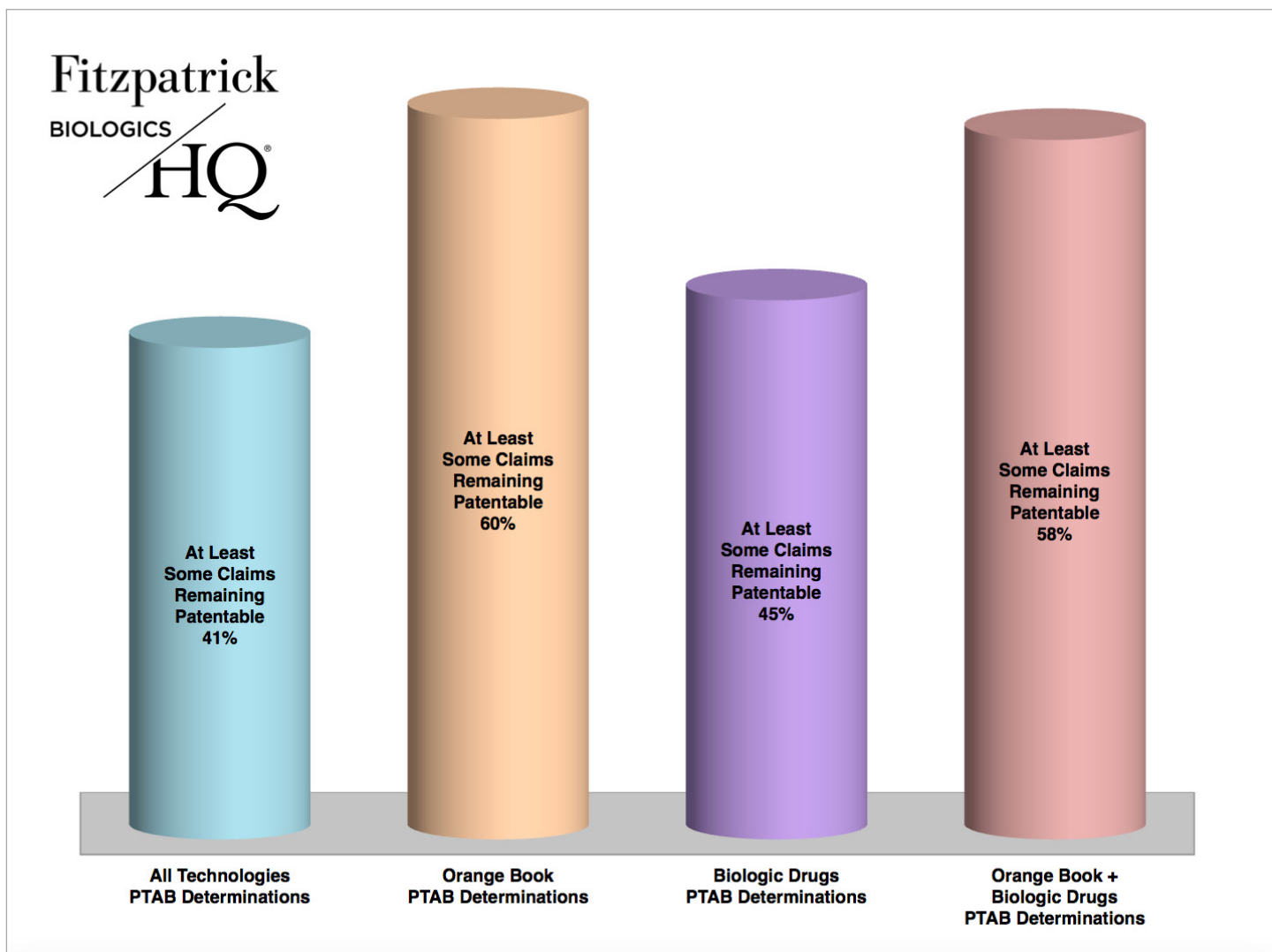


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## HIGHER PERCENTAGES OF ORANGE BOOK AND BIOLOGIC DRUG IPRS SURVIVE INSTITUTION AND FINAL WRITTEN DECISIONS WITH AT LEAST SOME CHALLENGED CLAIMS INTACT

Finally, higher percentages of both Orange Book and Biologic Drug IPRs survive institution and final written decisions with at least some of the claims that were challenged in the petition intact. Considering just institution decisions and final written decisions, i.e. PTAB determinations—and omitting determinations made by the parties, for example to disclaim challenged claims, or to resolve a challenge by settlement—60% of Orange Book IPRs survive with at least some challenged claims remaining patentable. This compares to 45% of Biologic Drug IPRs, and 41% of IPRs across all technologies. Pooling the data for Orange Book and Biologic Drug IPRs to consider drug patents as a category, this number is 58%, as compared to 41% across all technologies.



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## CONCLUSION

In short, PTAB is not a “death squad” for Orange Book-listed patents and patents that have been identified as reading on CDER-listed biologic drugs. On the contrary, these patents have fared notably better than the data disclosed by PTAB across all technologies. This is welcome news for the pharmaceutical industry.

As the number of Biologic Drug IPRs continues to increase—currently more than 30 are pending—Fitzpatrick’s BiologicsHQ will track their progress and report on trends. For up-to-date information and metrics concerning these challenges and other patent proceedings filed against Biologic Drug patents, click here: [www.BiologicsHQ.com](http://www.BiologicsHQ.com).

<sup>1</sup> [https://www.uspto.gov/sites/default/files/documents/AIA%20Statistics\\_March2017.pdf](https://www.uspto.gov/sites/default/files/documents/AIA%20Statistics_March2017.pdf)

<sup>2</sup> In determining the statistics for “Biologic Drug IPRs,” the Authors did not include IPRs filed against manufacturing patents that potentially read on multiple CDER-listed biologic drugs, for example IPRs concerning U.S. Patent No. 6,331,415 (a “Cabilly” patent).

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## CONTACT US

For More Information On:  
[www.BiologicsHQ.com](http://www.BiologicsHQ.com)

**April M. Breyer**  
(212) 218-2561

**Corinne E. Atton**  
(212) 218-2212

Fitzpatrick’s Biotechnology/  
Biologics Group:

**Robert S. Schwartz, Ph.D.**  
(212) 218-2298

**Brendan M. O’Malley, Ph.D.**  
(212) 218-2249

Business Development  
& Marketing:

**Linda Ficano**  
(212) 218-2284