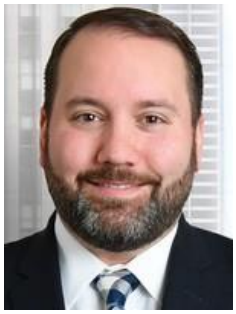
Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Trends And Predictions For Serial Biologic Drug IPR Petitions

By **Frederick Millett and Robert Schwartz** (July 31, 2018, 12:59 PM EDT)



Frederick Millett

Robert Schwartz

Two decisions over the past year could have significant implications in how serial inter partes review petitions are handled by the Patent Trial and Appeal Board going forward. The first, General Plastic Industrial Co. v. Canon Kabushiki Kaisha,[1] which laid out a seven-factor test to determine whether the PTAB will use its discretion not to review serial IPR petitions, was recently designated "precedential" by the PTAB. The second, the U.S. Supreme Court's April 24, 2018, decision in SAS Institute Inc. v. Iancu,[2] where the court held that the PTAB must determine the patentability of all challenged claims in a petition and can no longer issue final written decisions on only a partial list of challenged claims, could also have implications for how serial petitions are considered by the PTAB going forward. This article reviews how serial IPRs on patents covering biologic drugs could be affected by these decisions, based on trends over the last few years.

General Plastic and SAS Decisions

In General Plastic, the PTAB laid out a seven-factor test to determine whether a follow-on petition would be reviewed or whether the PTAB would use its discretion under 35 U.S.C. § 314(a) to deny institution:

1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;
2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it;
3. whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition;
4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition;
5. whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent;
6. the finite resources of the Board; and
7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.[3]

These seven factors aim to assess any undue inequities and prejudices to patent owners and the potential of abuse by petitioners in filing serial IPR challenges that should have or could have been raised earlier. This particular section of the decision was designated as "precedential" on Oct. 18, 2017. Pursuant to USPTO Standard Operating Procedure 2, a "precedential" designation requires a majority vote from the almost 300 PTAB administrative patent judges in support.[4]

While the PTAB denied institution in General Plastic based on an analysis of these seven factors, it did not create a per se rule against serial IPR petitions. Indeed, the PTAB stated that "there may be circumstances where multiple petitions by the same petitioner against the same claims of a patent should be permitted, and that such a determination is dependent on the facts at issue in the case."[5]

One such circumstance occurred earlier this year in Samsung Electronics Co. v. Ibex PT Holdings Co.,[6] where the PTAB granted institution to two Samsung follow-on petitions filed approximately six months after the PTAB denied institution to Samsung on two initial petitions challenging the same patent. After going through the seven factors in General Plastic, the PTAB held that since Ibex did not file a preliminary response to Samsung's initial petitions, there was less chance for abuse by petitioner Samsung, in that it could not use Ibex's preliminary response as a roadmap to create a better second challenge.[7] Further, the PTAB noted that the one-year time period between both sets of petitions was not unreasonable.[8] Together, the Samsung and General Plastic decisions demonstrate how the PTAB will look at serial IPR petitions and apply the seven factors laid out in General Plastic.

While not set up as a decision on serial IPR petitions, the Supreme Court's decision in SAS could have implications for how the PTAB permits serial petitions going forward. In SAS, the Supreme Court held that the PTAB was required to issue a final written decision that addresses the patentability of all claims challenged in a petition, invalidating a patent office regulation that permitted "partial institution" decisions that allowed the PTAB to pick and choose which claims would proceed to final written decision.[9]

SAS focused on the plain text of 35 U.S.C. § 318(a), which required that the PTAB "shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner."[10] Neither the opinion nor § 318(a) said anything about whether the PTAB was required to issue a final written decision on all grounds asserted in the petition (as opposed to all claims). However, shortly after SAS the patent office issued a guidance document stating it will interpret SAS as requiring a final written decision to address both all challenged claims and all challenged grounds in a petition.[11] Indeed, the Federal Circuit agrees with this interpretation of SAS, stating in a recent decision that "[e]qual treatment of claims and grounds for institution purposes has pervasive support in SAS."[12] One open question after this guidance is how the PTAB will deal with partial institution decisions that preceded SAS, as the guidance only stated that the PTAB "may issue an order supplementing the institution decision" in those instances.

There has been much discussion in the wake of SAS regarding how that decision might frame IPR proceedings going forward in the patent office. For example, the PTAB could decide not to institute an IPR petition that contains grounds that appear to lack merit, hinting in its denial of institution which grounds might succeed in a later challenge. While this might seem unlikely, the PTAB could use this tactic to control its docket by instituting fewer cases. And if a petitioner files two petitions on the same patent, the PTAB might choose to institute review on only one of the petitions to reduce its workload while still following SAS. This could result in a petitioner deciding to split up asserted grounds and challenged claims into multiple IPR petitions for a better chance that the PTAB will institute review of at

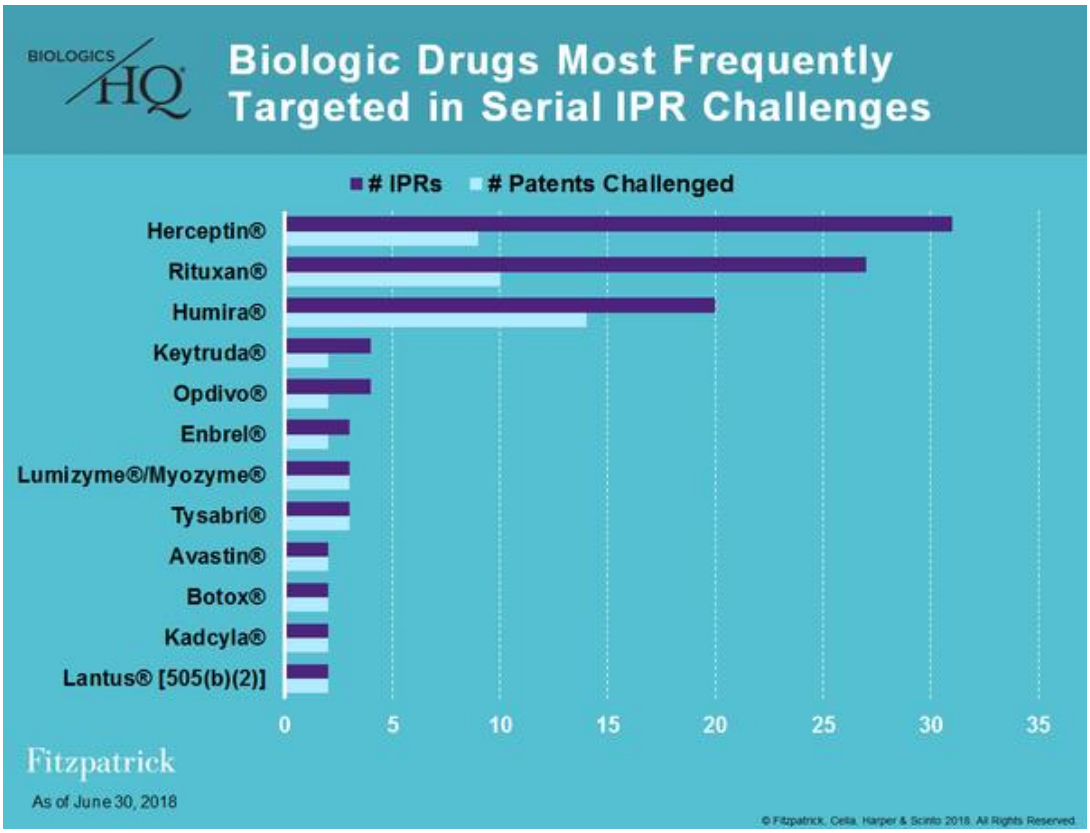
least one of the petitions. Alternatively, to satisfy the requirement of reviewing all claim challenges, the PTAB could base an institution decision on only one claim (where there are multiple claims challenged) and not separately address the merits of other challenged claims.

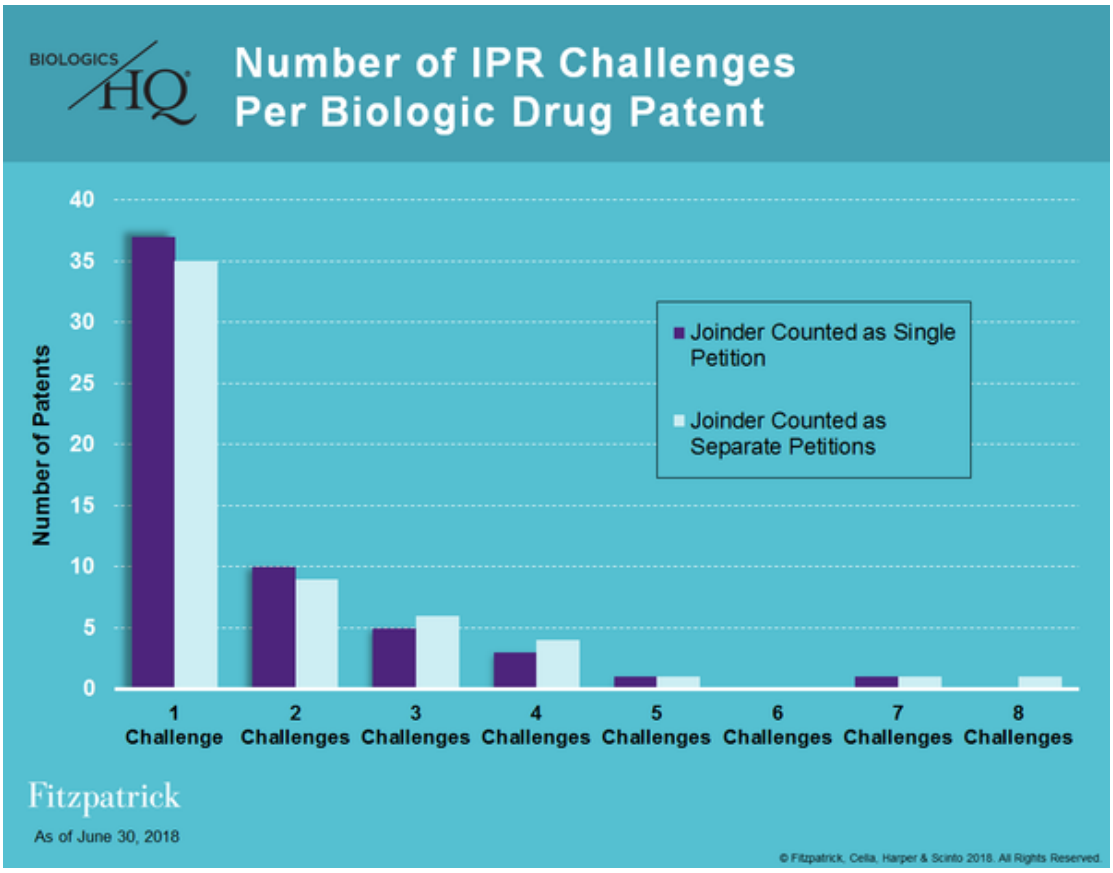
This article will review trends in IPRs on patents covering Center for Drug Evaluation and Research-listed biologic drugs over the last few years to see how the decisions in General Plastic and SAS might impact strategies for filing and defending IPRs for biologic drugs going forward.

Serial IPR Petitions Are a Popular Form of Challenge for Biologics

Our review of biologic drug IPRs shows that serial IPR petition challenges are already a popular form of challenge. As shown in the graphic below, several of the most successful biologics have had both multiple patents challenged in IPR proceedings, as well as multiple petitions filed against single patents. Thus, the precedential designation of General Plastic could have a significant impact in how serial petitions are filed for biologic drugs going forward. Because multiple petitions have been filed on a single patent, sometimes by the same party, this also shows that SAS might not have much of an impact on how petitioners file IPR petitions, as it has already been the strategy to file multiple IPR petitions against a single patent with different grounds (or challenged claims) in each petition.

Our analysis also looked at the number of IPR challenges per biologic drug and the effect of joinder. Twelve petitions out of 107 requested joinder. No petition had more than one other petition requesting joinder. Since there were so few requests for joinder, whether one counts joined petitions as one or two does not have a huge impact. Further, it appears that method of treatment patents were the most frequently subject to serial challenges, followed by composition of matter patents and formulation patents.





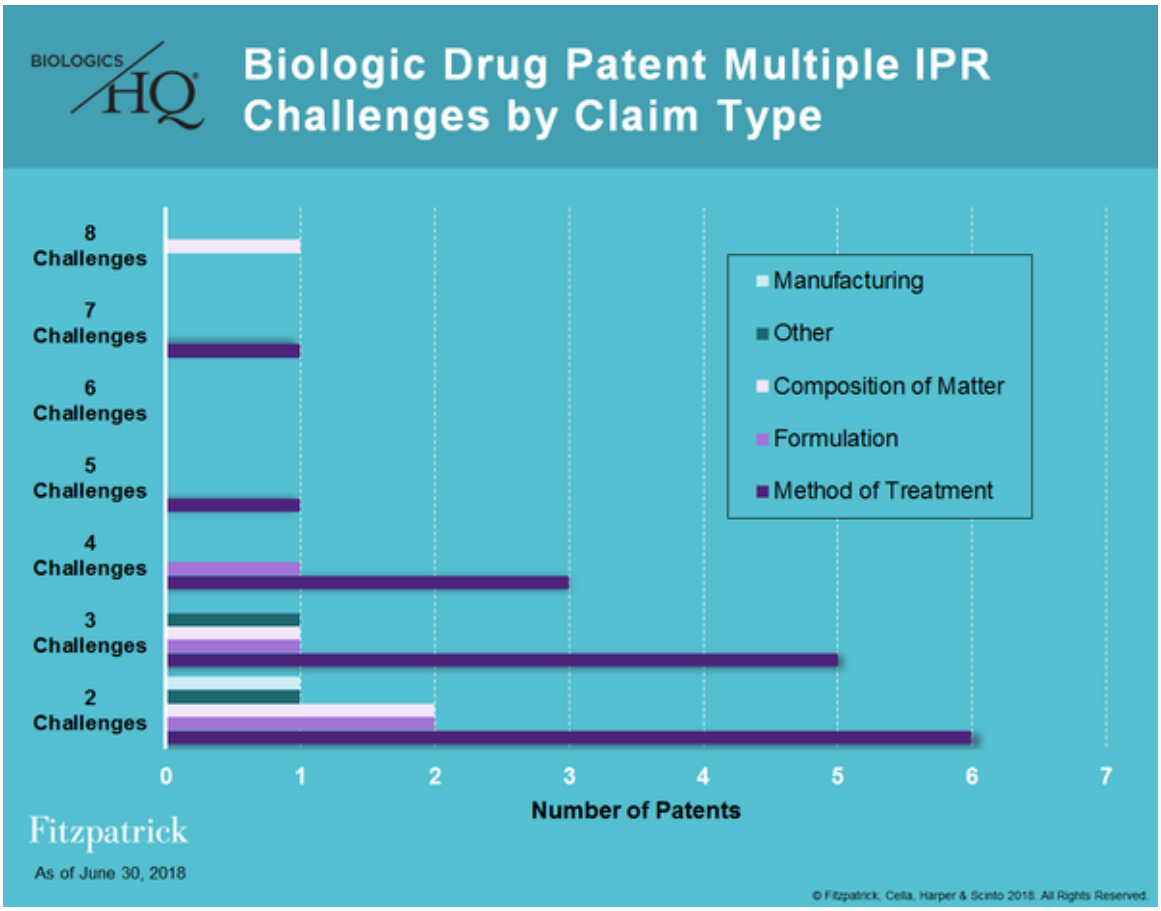
Analysis of Timing and Challenge Type of Serial IPRs

When there were multiple petitions filed against a single patent for a biologic drug, in the majority of cases the exact same claims were being challenged in the different petitions (16 of the patents). There were only two IPRs with a later-filed petition challenging a larger number of claims than the initial petition,[13] and only a handful of other petitions that challenged only a subset of the claims challenged by the initial petition (six patents). Thus, for biologics, petitions are not being filed multiple times so that they can carve up patents with large claim sets into multiple petitions. However, this means that petitioners are splitting up multiple grounds into serial petitions instead of trying to put the multiple grounds into one petition. This again shows that the impact of SAS is likely to be low for biologic drug IPRs, as biologic drug IPR petitions were already being filed with multiple grounds in separate petitions. This trend is likely to continue post-SAS.

Moreover, it is rare for a petitioner to use a previously denied biologic drug IPR petition to discover problems with arguments and then file a new petition addressing those issues, as most of the time multiple petitions are filed prior to institution decisions on the initial petitions. Indeed, in our analysis of the 15 biologics petitions on patents that have been challenged more than once that have had inconsistent institution decisions as of June 30, 2018, all but one of the initial IPR petitions were instituted, while the later filed IPRs were more likely to be denied institution (three petitions instituted after an initial institution and five petitions denied after an initial institution). Where the initial IPR was denied institution, both subsequent petitions (filed by the same parties) were instituted.[14]

Thus, the seven-factor test laid out in General Plastic is unlikely to affect the filing of biologic drug IPRs

going forward. The PTAB in General Plastic particularly noted the inequities in allowing petitioners the ability to file a subsequent IPR petition after the PTAB denied institution of the first petition or after the patent owner filed a preliminary response. For biologic drug IPRs, Petitioners have not often been using this method of filing serial petitions, instead using serial petitions to amplify the various grounds of their challenges.



It is also very rare for petitioners to use multiple IPR petitions to challenge different claim sets in the same patent because the patent has a large number of claims. This only happened in one case: IPR2017-01227 (challenging claims 23-35, 37-57) and IPR2017-01230 (challenging claims 1-13, 15-22, 58-60), both filed by Celltrion and Teva. Most of the claim sets for the challenged patents have been small (about 20 or fewer). There have only been a few patents challenged with large claim sets (60-80 claims), and for those, a subset of the claims were challenged. There was one petition that challenged 58 claims, but the rest have challenged 35 claims or fewer.

Further, it is rare for petitioners to file one petition on § 102 (anticipation) grounds only. Out of over 100 biologic drug IPRs, there have only been four petitions presenting only an anticipation challenge to the patent-at-issue. In the cases where an anticipation-only challenge was filed, the petitioner also filed a § 103 (obviousness) challenge for that patent in a separate petition.

Inconsistent Decisions With Serial IPR Petitions Are Rare

All final written decisions for serial biologic drug IPR petitions have reached the same outcomes. And there are only a handful of serial IPRs that have had different outcomes for institution decisions. In serial

IPR petitions for Herceptin and its U.S. Patent No. 7,846,441, two IPRs were instituted on obviousness grounds (IPR2017-00731 and IPR2017-01121), while a third later-filed IPR was denied institution on obviousness grounds (IPR2018-00016). For Rituxan and its U.S. Patent No. 7,976,838, in five serial challenges only two IPRs were instituted by the PTAB (IPR2015-00417 and IPR2017-01923) on obviousness grounds. The other three IPRs were denied institution. Finally, for Dupixent and its U.S. Patent No. 8,679,487, two IPRs were instituted on anticipation and obviousness grounds (IPR2017-01879 and IPR2017-01884, respectively), while a third challenge was denied institution (IPR2017-01129) on anticipation grounds.

However, most serial IPRs had the same outcomes on institution, or were still awaiting institution decisions as of June 30, 2018. Overall, it is rather unusual for a patent directed to a biologic drug to produce inconsistent institution decisions.

Impact of SAS and Patent Office Guidance on Biologic Drug IPRs

At the time the Supreme Court issued SAS, there were 29 pending biologic drug IPR petitions that were instituted on at least one ground for at least one claim. Of these 29 petitions, the majority of these institution decisions were for all challenged claims and grounds — only seven instances were "partial institution" decisions (joined petitions not counted separately):

- IPR2017-02019: Institution was granted for all challenged claims, but not on all challenged grounds. After SAS, institution was modified to include all challenged grounds.

- IPR2017-02020: Institution was granted for all challenged claims, but not on all challenged grounds. After SAS, institution was modified to include all challenged grounds.

- IPR2017-01923: Institution was granted for all challenged claims, but not on all challenged grounds. After SAS, institution was modified to include all challenged grounds.

- IPR2017-00731: Initially denied institution. On request for rehearing, institution was granted for all challenged claims, but not on all challenged grounds. After SAS, institution was modified to include all challenged grounds.

- IPR2017-01095: Initially instituted claims 5-6 under § 102 (denying institution of claims 1-4 under § 102) and claims 1-3 and 6 under § 103 (denying institution of claims 4-5 under § 103) (claim 4 not instituted under any ground), changed after SAS to institute on all of claims 1-6 under both § 102 and § 103.

- IPR2017-01489: 29 claims were challenged, 2 of which were not instituted on all challenged grounds. Nothing on the docket after SAS changing this decision.

- IPR2017-01168: Institution was granted for all challenged claims, but not on all challenged grounds. Nothing on the docket after SAS changing this decision.

As noted above, only in two instances did the PTAB decide not to change its institution decision, showing that it is using its guidance to modify previous "partial institution" decisions to cover all asserted grounds in the majority of cases. As only seven out of 29 (24 percent) pending biologic drug IPRs were affected by SAS, this further shows that SAS will likely not have much of an effect on how the

PTAB reviews biologic drug IPRs, as the PTAB was already instituting review on all challenged claims and grounds in the majority of petitions.

Conclusion

Based on an analysis of 107 biologic drug IPR petitions, the recent Supreme Court SAS decision and precedential General Plastic PTAB decision are not likely to have much impact on how IPR petitions for biologic drugs are filed by petitioners and reviewed by the PTAB. Serial IPR petitions have been commonly filed for the past several years on biologic drugs. In the serial petitions filed against the same patent by the same petitioner, the later petitions are filed to break out multiple grounds into separate petitions, instead of using an institution decision as a road map to file a later, stronger IPR challenge. Further, this practice might allow the PTAB to choose the best grounds for granting institution and allow the PTAB to deny other, weaker grounds in separate petitions to comply with the mandate of the Supreme Court in SAS. Finally, as only approximately 25 percent of pending biologic drug IPRs were affected by SAS as "partial institution" cases, SAS is unlikely to have much effect on how the PTAB determines how to institute IPRs on biologic drugs going forward.

Frederick C. Millett is an associate and Robert S. Schwartz, Ph.D., is a partner at Fitzpatrick Cella Harper & Scinto.

The authors wish to thank former associate April Breyer for her contributions to this article.

Disclosure: Fitzpatrick Cella represented Canon in the General Plastic matter.

[1] IPR2016-01357, Paper No. 19 (Sep. 6, 2017).

[2] 138 S. Ct. 1348 (2018).

[3] General Plastic, Paper No. 19 at 16.

[4] Patent Trial and Appeal Board, Standard Operating Procedure 2 (Revision 9), Publication of Opinions and Designation of Opinions as Precedential, Informative, Representative, and Routine, Sep. 22, 2014, available at: https://www.uspto.gov/sites/default/files/documents/sop2-revision-9-dated-9-22-2014.pdf.

[5] General Plastic, Paper No. 19 at 18.

[6] IPR2018-00011, Paper No. 6 (Apr. 13, 2018).

[7] Id. at 21.

[8] Id. at 20-21.

[9] 138 S. Ct. at 1354.

[10] Id.

[11] Guidance on the impact of SAS on AIA trial proceedings, Apr. 26, 2018.

[12] See PGS Geophysical AS v. Iancu , Nos. 2016-2470, 2016-2472, 2016-2474, slip. op. at 7 (Fed. Cir. Jun. 7, 2018).

[13] Initial IPR2017-00804 challenging claims 1-3, 5, 7, 9-11, 17-33, and subsequent IPR2017-01139 challenging these claims and additionally claims 13-15; Initial IPR IPR2017-00805 challenging claims 1-3, 5, 7, 9-11, 16-28, 30-40 and subsequent IPR2017-01140 challenging these claims and additionally claims 13-15.

[14] Initial IPR 2017-01129 (§ 102 only challenge) and subsequent IPRs IPR2017-01879 (§ 102 only challenge) and IPR2017-01884 (§ 103 only challenge).