

News



Potential Impact of the Affordable Prescriptions for Patients Act Patent Limit on BPCIA Litigations

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On March 17, 2025, Senators Chuck Grassley (R-IA), John Cornyn (R-TX), Richard Blumenthal (D-CT), and Richard Durbin (D-IL) [re-introduced](#) the “[Affordable Prescriptions for Patients Act](#)” (“APPA”), which previously passed the U.S. Senate as [S.150](#) in the 2024 Congressional session, but was not passed by the House. On April 3, 2025, the Committee on the Judiciary ordered the bill to be reported favorably without amendment. The text of the 2023 APPA and the 2025 re-introduced APPA bill (“bill”) are identical, except for a clause related to a Medicare Improvement Fund that was included in the Senate-passed 2023 APPA that is not included in the 2025 bill. Like the 2023 APPA, the 2025 bill limits the number of patents that can be asserted by a reference product sponsor (“RPS”) against a biosimilar manufacturer in Biologics Price Competition and Innovation Act (“BPCIA”) litigations under 35 U.S.C. § 271(e).

Overview of the APPA

The APPA, if passed into law, puts an upper limit of 20 patents, but only of certain types of patents (see below), that can be asserted in a BPCIA litigation (the APPA does not affect ANDA litigations). It does not limit the total number of patents that can be asserted in these litigations because patents are only counted against the 20-patent limit if they satisfy each of the following criteria:

- They “claim the biological product that is the subject of an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) (or a use of that product) or a method or product used in the manufacture of such biological product”;
- They are included on the list of patents given by the RPS to the biosimilar during the patent dance; and
- They have a filing date of more than 4 years after the date on which the reference product was approved, OR *include* a claim to a method in a manufacturing process that is *not* used by the reference product sponsor

Additionally, no more than 10 of the 20 patents may have issued or have been exclusively licensed after the RPS provides its initial patent list to the biosimilar applicant during the patent dance.

Patents that are not counted against the 20-patent limit also include “any patent that claims, with respect to a biological product, a method for using that product in therapy, diagnosis, or prophylaxis, such as an indication or method of treatment or other condition of use.”

The provisions of the [APPA](#) *only* apply if the biosimilar applicant completes certain provisions of the patent dance, including:

- Providing the RPS with a copy of the aBLA and “other information” that describes the manufacturing process for the biosimilar within 20 days after FDA aBLA acceptance (42 U.S.C. § 262(l)(2)(A));
- Providing a detailed statement describing the basis for invalidity, unenforceability, or non-infringement for each patent claim, or a statement that the biosimilar will not be commercially marketed prior to expiration of the patents (42 U.S.C. §§ 262(l)(3)(B)(ii) and (7));
- Exchanging patent lists if there is no agreement on which patents should be litigated (42 U.S.C. § 262(l)(5));
- Providing the Secretary with a copy of the complaint not later than 30 days after its service (42 U.S.C. § 262(l)(6)(C)(i)); and
- Providing 180-day notice of commercial marketing to the RPS (42 U.S.C. § 262(l)(8)(A))

The 20-patent limit may be increased in the interest of justice or for good cause, which includes the biosimilar applicant failing to provide information during the patent dance that would enable the RPS to form a reasonable belief with respect to whether a claim of infringement could reasonably be asserted.

While it is not entirely clear from the text of the bill (and may be subject to future litigation should the bill pass), there are numerous patent claim types that have been asserted in BPCIA litigations that potentially do not fall under the 20-patent limit, including those with packaging, device, diagnostic, kit, and design claims. It is also not entirely clear how patents with multiple claim types would be treated when determining whether the patent as a whole falls under the 20-patent limit, particularly if only some claims are asserted in the litigation.

Potential Impact of the APPA, if Enacted



We found that the APPA's impact would have been quite limited, potentially only affecting at most three of the 58 BPCIA litigations filed by RPS's to date, but likely not affecting a single case.

We sought to determine the potential impact the APPA could have on streamlining biosimilar litigations. To do this, we reviewed the impact the APPA would have had on the BPCIA litigations that have been filed as of March 17, 2025, and found that its impact would have been quite limited, potentially only affecting at most three of the 58^[1] BPCIA litigations filed by RPS's to date, but likely not affecting a single case.

Of the 58 BPCIA litigations, 25 (43.1%) asserted more than 20 patents, and could have been impacted by the provisions of the APPA. Because biosimilar disputes often involve more than one case filing, the 25 cases represent 19 of 45 (42.2%) unique disputes.

Because the APPA includes a provision stating that manufacturing patents filed earlier than four or more years after the reference product's approval (“pre-4 year manufacturing patents”) can be included in the 20-patent limit if they include a claim to a method in a manufacturing process that is not used by the RPS, and because the manufacturing methods used by the RPS are not public information, we performed two separate analyses. First, we analyzed the impact if none of these manufacturing patents were included in the 20-patent limit (which assumes the RPS does use all of the claimed methods). Next, we analyzed the impact if all of the manufacturing patents were included in the 20-patent limit (which assumes the RPS does not use any of the methods).

Potential Impact of the APPA when Pre-4 Year Manufacturing Patents Are Not Included in the 20-Patent Limit

In our first analysis (not including the pre-4 year manufacturing patents), we found that as many as seven BPCIA litigations (six disputes) may have been impacted by the bill's 20-patent limit based on the number of patents asserted, with the legislation decreasing the number of patents that could have been asserted by one to 14 (for a total number of patents asserted of 32-47 instead of 34-61).

However, based on the Complaints filed, only one of these biosimilar applicants completed the steps of the patent dance at the time of the Complaint filing (one additional Complaint has been redacted and it is not clear whether the patent dance was completed), which is a condition to applying the 20-patent limit. And even in that Complaint, deficiencies in the production of “other” manufacturing information were alleged, which may have prevented the limit from applying. It is unknown whether the parties would have chosen to complete the necessary provisions of the patent dance if there had been the additional incentive of the APPA’s 20-patent patent limits at the time of those litigations.

Potential Impact of the APPA Including Pre-4 Year Manufacturing Patents in Limit

In our second analysis (including all of the pre-4 year manufacturing patents), we found that as many as 18 litigations (15 disputes) may have been impacted by the APPA’s limits, with the legislation decreasing the number of patents that could have been asserted by one to 14 (for a total number of patents asserted of 22-47 instead of 27-61). Based on the Complaints filed, only three of the biosimilar applicants completed the patent dance at the time of the Complaint filing (not including one redacted Complaint). In each of these Complaints however, it was alleged that there were deficiencies in the production of “other” manufacturing information, which may have prevented the 20-patent limit from applying.

Provisions of the APPA That May Be Most Impactful

Perhaps one of the most impactful of the APPA provisions may end up being the impact on discovery resulting from the inclusion of pre-4 year manufacturing patents in the 20-patent limit if the RPS is not using any of the claimed methods. If the RPS chooses to assert more than 20 patents that could be included in the 20-patent limit, any of which have manufacturing claims and were filed less than four years after the RPS’s approval, it could open up the RPS to more discovery on the reference product’s manufacturing methods, because without that discovery it would be very difficult to know whether the RPS is in fact practicing those claims.

The language in the legislation relating to the RPS’s use of manufacturing methods is also quite vague, and it does not specify whether the use of the methods needs to be for the reference product at issue or could be for other products owned by the RPS. This could open the RPS up to even more discovery into other products beyond the one at issue in the litigation, or at the least could add another point of contention between the parties that could increase litigation resources and expenditures.

In our analysis of the BPCIA litigations to date, we found that the vast majority (79.4%) of patents asserted in litigations where more than 20 patents were asserted, were filed four or more years after approval of the reference product, so setting the cutoff for the patents subject to the 20-patent APPA limit is likely to be impactful. The assertion of this type of patent (4+ years after RPS approval) varied based on reference product; for example, in the Avastin® (bevacizumab) litigations it represented 40% of asserted patents, whereas in the Humira® (adalimumab) litigations it represented 95% of the asserted patents.

Reference Product	Patents Asserted in All Litigations with 20+ Patents, Filed 4+ Years after RPS Approval[2]	Percentage
Overall	223[3] of 281	79.4%
Humira® (adalimumab)	58 of 61	95.1%
Eylea® (aflibercept)	68 of 74	91.9%
Tysabri® (natalizumab)	23 of 28	82.1%
Herceptin® (trastuzumab)	33 of 47	70.2%
Rituxan® (rituximab)	28 of 42	66.7%
Prolia®/Xgeva® (denosumab)	29 of 47	61.7%
Avastin® (bevacizumab)	14 of 35	40%

Therefore, depending on the size of the patent portfolios and timing of patent application filing, the 20-patent limit may have more impact on some drug products than others. For example, products with larger portfolios will likely be more impacted, as will those with more patents filed after RPS approval.

The APPA Provisions Do Not Limit BPCIA Litigations to 20 Patents and May Not Bring Down Litigation Costs

In our analysis of the BPCIA litigations to date, we found that the 20-patent limit, as proposed in the APPA, would not have limited BPCIA litigations to 20 patents. Instead, it would have resulted in between 32 and 47 patents (not including pre-4 year manufacturing patents) being asserted, or to between 22 and 47 patents (including pre-4 year manufacturing patents) being asserted. Excluding method of treatment patents from the 20-patent limit is the largest factor in preventing a decrease in the total number of patents being asserted, with upwards of 20 method of treatment patents that were filed more than four years after the reference product’s approval being

asserted in a single litigation. The APPA provision that adds pre-4 year manufacturing patents to the 20-patent limit also has the potential to decrease the number of patents asserted, depending on whether the RPS is using the asserted methods, and, as discussed above, whether the RPS chooses to limit the number of patents asserted to avoid discovery into its manufacturing methods.

It is also questionable if the 20-patent APPA limit will actually decrease litigation costs and bring biosimilars to market more quickly. First, the 20-patent limit only affects the actual litigation, not activities taking place prior to litigation. Because the entire patent dance needs to be followed for the 20-patent limit to be applicable, the biosimilar applicant will still need to provide invalidity, unenforceability, and non-infringement contentions for every patent on the RPS’s list, and the RPS will need to respond with its validity, enforceability, and infringement positions, minimizing any APPA impact at this stage of the litigation. Also, because the RPS can choose to assert 20 patents (and likely many more, as discussed herein), the biosimilar applicant will still need to avoid infringement of many potentially-assertable patents, regardless of whether those patents are actually asserted in litigation. And the RPS will still be able to assert its strongest patents after knowing the biosimilar applicant’s litigation positions from the patent dance.

Further, Courts frequently limit the number of patents that reach trial to far less than 20, so limits are already being put in place without the need for additional legislation. For example, in the *Regeneron v. Mylan* litigation (Case No. 1:22-cv-00061 (N.D.W. Va.) / MDL 1:24-md-03103 (N.D.W. Va.)) related to *Eylea*® (aflibercept) biosimilar *Yesafili*™ (aflibercept-jbvf), while 24 patents were initially asserted, an expedited trial was ordered on just three of them. One of these patents was found to be valid and infringed and a permanent injunction was issued. Another example is the *AbbVie v. Alvotech* litigation (Case No. 1:21-cv-02899 (N.D. Ill.)) related to *Humira*® biosimilar *Simlandi*® (adalimumab-ryvk), that initially asserted 61 patents. Within about three months of filing the Complaint, the judge limited the trial to 10 patents. By comparison, the APPA provisions would have potentially allowed 47 patents to be asserted (if all other requirements were met).

Would the 20-Patent Limit Ever Apply?

Nearly all of the BPCIA Complaints filed to date have alleged that the biosimilar applicant failed to adequately provide the “other information” that describes the biosimilar’s manufacturing process to the RPS during the patent dance. Therefore, the requirement that this information be provided in order for the 20-patent limit to apply may be a frequent source of contention and could significantly hinder the application of the 20-patent patent limit. At the least, this will add another issue to be litigated; what and how much “other” information is enough to fulfil the patent dance requirement?

Conclusion

Based on our analysis of the 58 BPCIA cases filed to date, it appears that the impact of the APPA on BPCIA litigations, if enacted into law, would be limited if the bill is enacted in its current form. While the APPA may result in some decrease in the number of patents asserted in some cases, our analysis suggests it is unlikely to produce a significant change – at least because of its provisions requiring completion of the patent dance for the 20-patent limit to apply, and the exclusion of patents with method of treatment claims from the 20-patent limit.

While the 20-patent limit may be an incentive for more biosimilar applicants to complete the patent dance, the overall impact in practice may still be limited because of the frequency of Courts requiring the narrowing of cases to fewer than 20 patents. The legislation may also lead to more disputes over whether the biosimilar adequately completed the patent dance to trigger the application of the 20-patent limit.

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[1] There have been three additional declaratory judgment lawsuits filed by biosimilar manufacturers under the BPCIA that were dismissed for lack of subject matter jurisdiction that are not included in our analysis because they are not relevant to the APPA.

[2] Filing dates based on data from Google Patents.

[3] Many of the same patents were asserted in litigations relating to *Herceptin*® (trastuzumab), *Rituxan*® (rituximab), and *Avastin*® biosimilars. Four of the 222 patents were filed 4+ years after approval (“post-4 year patents”) in some of these litigations and filed less than 4+ years after approval (“pre-4year patents”) in others. These have been counted as post-4 year patents.

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