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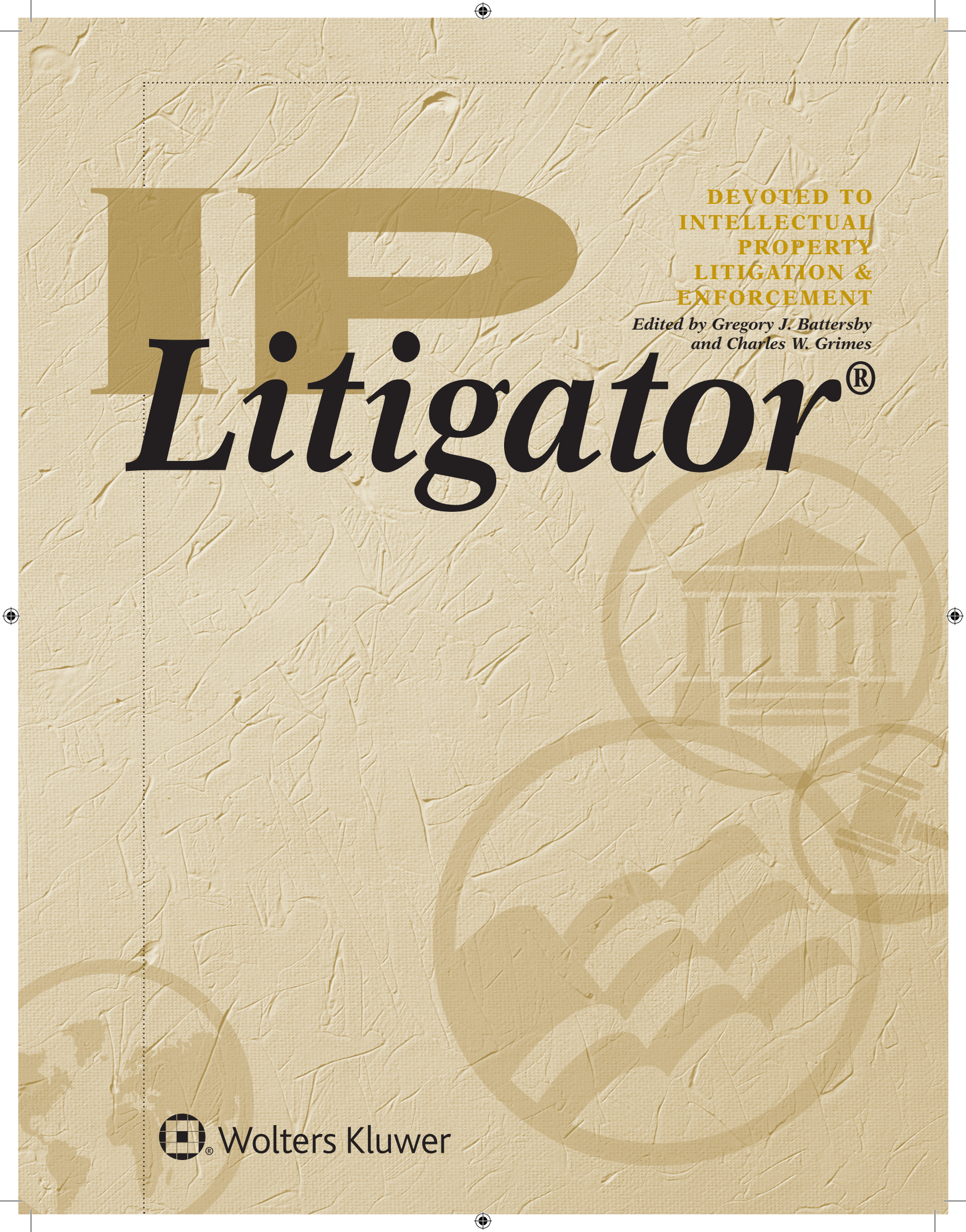
Edited by Gregory J. Battersby and Charles W. Grimes



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IP Litigator, Patent Litigation, (Jan. 1, 2025)

Michael Siekman and Huiya Wu

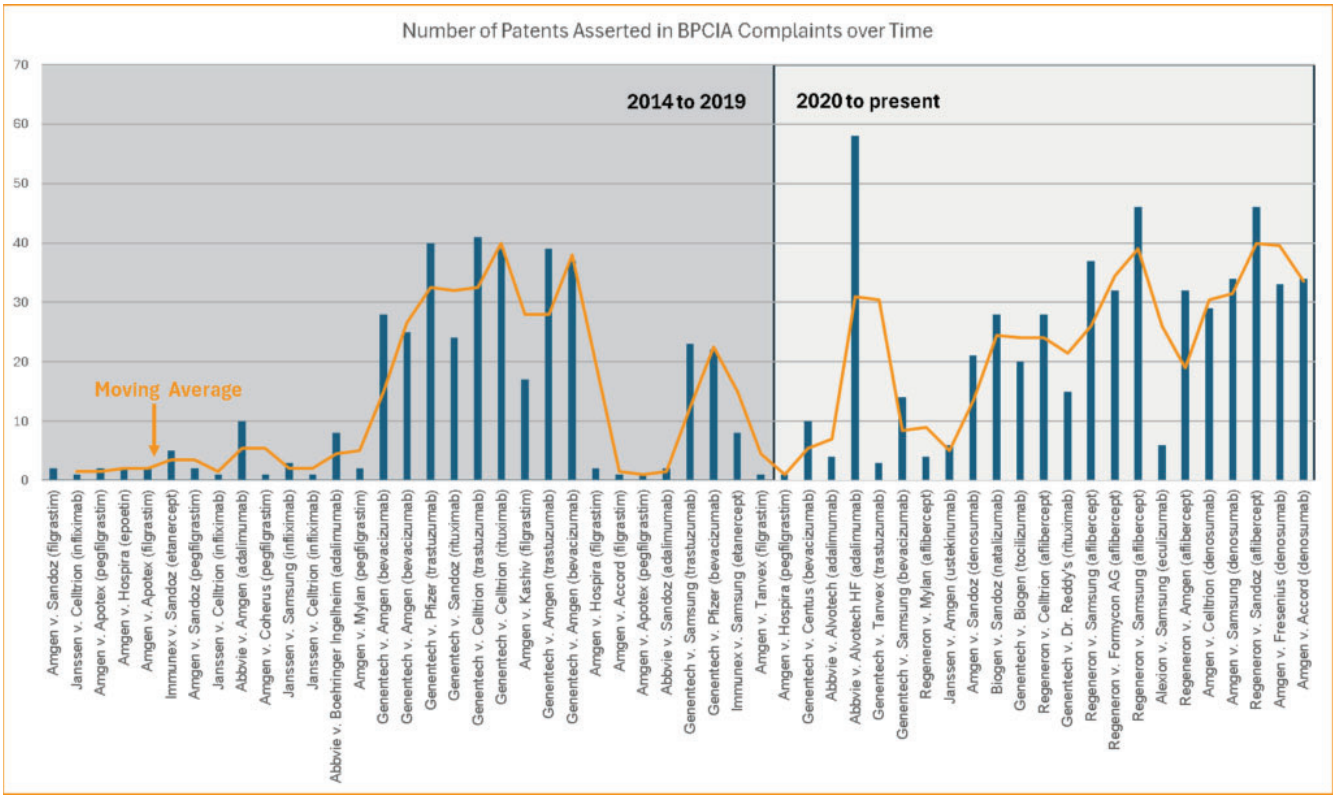
A partner in Goodwin's Life Sciences group and Intellectual Property practice, Michael Siekman focuses his practice on intellectual property matters, including patent prosecution, licensing and post-grant proceedings and litigation. Leveraging over 25 years of experience, Michael has built in-depth patent portfolios, particularly advising clients in the biotechnology and pharmaceutical industries. Michael has extensive experience with biosimilars and has written and presented often on the topic.

Huiya Wu, a partner in Goodwin's IP Litigation practice, has spent more than 25 years litigating and trying cases in both federal and state courts, and has appeared before the Patent and Trademark Office (PTO), the Patent Trial and Appeal Board (PTAB), as well as the International Trade Commission (ITC). She has represented pharmaceutical clients including in litigation under the Biologics Price Competition and Innovation Act. Additionally, Huiya is an Editor-in-Chief of the Big Molecule Watch blog, an award-winning resource for daily updates and analyses of regulatory issues, litigation, legislation, and other news in the world of biologics, biosimilars, and related technologies.

Are Reference Product Sponsors Asserting More Patents in BPCIA Litigation?

On October 24, 2014, Amgen initiated the first litigation under the Biologics Price Competition and Innovation Act (BPCIA), asserting infringement of two patents. Over the last two calendar years, Amgen, Biogen, Genentech, and Regeneron have all filed BPCIA complaints (sometimes several) asserting 20 or more patents. Does this reflect a trend of Reference Product Sponsors (RPS) asserting more patents as they have gotten more experience with BPCIA litigation over the last decade since Amgen filed the first BPCIA complaint asserting just two patents?

To answer this question, we reviewed the complaints filed in all 54 BPCIA litigations monitored by the Big Molecule Watch blog and tallied the number of patents asserted. On average, 17 patents were asserted per BPCIA litigation, but that average does not appear to be representative of the current trends. An average of 13 patents were asserted in the 31 BPCIA complaints filed from 2014 through 2019, while an average of 24 patents were asserted in the 23 BPCIA complaints filed from 2020 through 2024. While there is some noise in the numbers—notably a temporary increase in the number of patents asserted in late-2017 to mid-2018—there has been a clear increase over time in the number of patents asserted in BPCIA litigation:



In each of the first eight BPCIA litigations, the RPS asserted less than 10 patents, and it was not until the 15th BPCIA litigation in late 2017 (*Genentech v. Amgen* ((bevacizumab)) that an RPS asserted more than 20 patents. In contrast, only one of the 15 BPCIA complaints filed in 2023-2024 has asserted less than 10 patents (*Alexion v. Samsung* (eculizumab)), and only one other asserted less than 20 patents (*Genentech v. Dr. Reddy's* (rituximab)). Thus, it does appear that there is a trend for an RPS to assert more patents in BPCIA litigation, as also illustrated by the moving average line in orange above.

What accounts for the increasingly large number of patents being asserted in BPCIA complaints? Interestingly, it does not appear to be due to an increase in the number of manufacturing patents asserted. Manufacturing patents constitute over 66% of all patents asserted in BPCIA complaints; that percentage decreases slightly to 63% for the 13 BPCIA complaints filed in 2023-2024.

Similarly, while RPSs continue to prosecute patents relating to their biologics including after FDA approval, the increase over time in the number of patents asserted does not appear to be due to the RPS obtaining new patents for portfolios already involved in BPCIA litigation. For example, Amgen asserted eight patents in its second etanercept complaint, three more than the five patents asserted in its first etanercept complaint, but all the patents asserted in the second complaint had issued well before Amgen filed its first complaint. Similarly, while Amgen asserted more patents in its later denosumab complaints compared to its first denosumab complaint, almost all the additional patents Amgen asserted in its later complaints had already issued at the time of its first complaint. No other RPS asserted a clear increase in the number of patents across their BPCIA litigations for a Reference Product once BPCIA litigation had commenced.

Rather, there might be two factors driving this trend across all BPCIA complaints from the RPS side. First, as RPSs have become more experienced with BPCIA litigation, they appear to be actively increasing their patent portfolios *before* litigation commences. They recognize that larger patent portfolios have proved valuable in delaying biosimilar competition. They also recognize that possessing a diversity of the types of patents that can be asserted is likewise valuable. More recently, RPSs have asserted device patents, and even design patents, for example, in *Regeneron v. Sandoz*. Second, with most BPCIA litigations being resolved through settlement,

many RPSs appear to recognize the value in asserting as many patents as possible in the original complaint, and not engaging in second-wave litigation envisioned by the BPCIA.

Of course, the biosimilar manufacturer ultimately controls the number of patents asserted in BPCIA litigation via 42 U.S.C. § 262 (l)(5)(A) and (B)(ii). As the Supreme Court repeatedly noted in *Sandoz Inc. v. Amgen Inc.*, the BPCIA provides biosimilar applicants with "substantial control" over the scope (*i.e.*, the number of patents) and the timing of both phases of litigation. 582 U.S. 1, 9, 10, 16 (2017). Having gained more experience with BPCIA litigation, biosimilar manufacturers also may be seeing the value of front-loading the BPCIA process, by seeking resolution and certainty for all asserted patents, rather than having the patent issues adjudicated in a piecemeal manner. Their experience with BPCIA litigation has also taught them that challenging patents at the PTAB via *inter partes* or post-grant review successfully are useful tools in obtaining a settlement.

For Reference Product Sponsors, the takeaways from this trend of more patents being asserted in BPCIA complaints are similar to those for Hatch-Waxman litigation, where there has also been a clear trend over the last several years to list more patents in the Orange Book. Asserting more patents up front narrows the potential pathway to success for a biosimilar manufacturer, as it does in Hatch-Waxman litigations. RPSs should therefore continue to invest heavily in growing their patent portfolios, including across different categories of patents. Having more patents available to assert in BPCIA litigation increases an RPS's leverage in settlement. Moreover, especially as proposed biosimilars increase, often using different approaches in their cell culture media, manufacturing processes, and/or formulations for the same Reference Product, an RPS has to be prepared to assert different patents against different biosimilar manufacturers in BPCIA litigations.

For biosimilar manufacturers, the trend of more patents being asserted in BPCIA complaints requires more up-front work to evaluate and avoid patent infringement, in order to secure a favorable settlement down the line. Many biosimilar manufacturers begin their design-around efforts years before filing an aBLA and must navigate around complicated patent portfolios. With the increasing number of patents being asserted in BPCIA complaints, the biosimilar manufacturers who have a plan to deal with the impending patent issues are most likely to secure a favorable settlement and avoid the costs of a full-blown BPCIA litigation.

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