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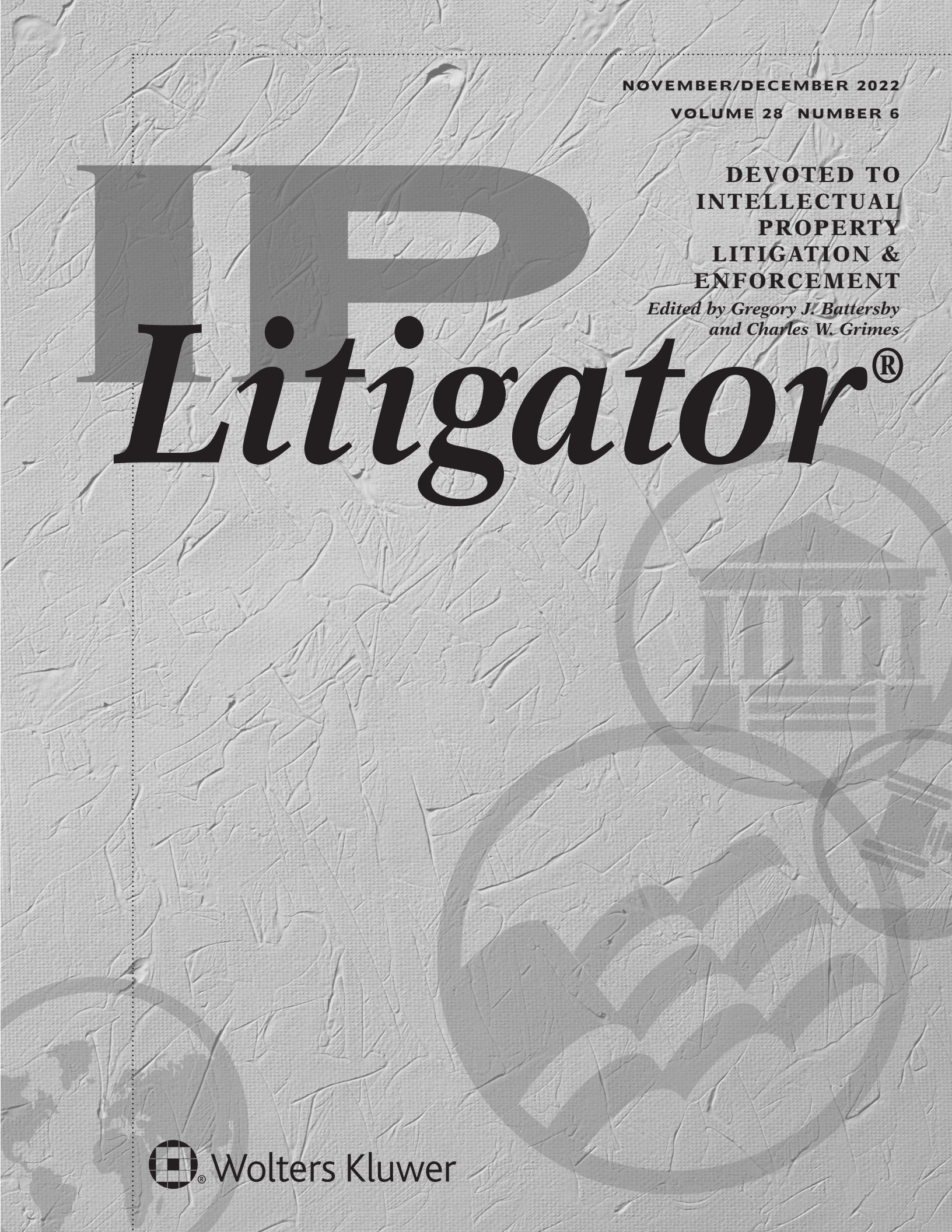

Wolters Kluwer

Pharmaceutical Litigation

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Declaratory Judgment Jurisdiction Over Skinny Label Applications

On September 27, 2022, Judge Richard Andrews of the District of Delaware granted Novartis's motion to dismiss declaratory judgment ("DJ") counterclaims raised by two generic drug manufacturers in the ongoing litigation regarding Novartis's heart failure medication, Entresto® (sacubitril/valsartan). *In re: Entresto (Sacubitril/Valsartan) Patent Litig.*, Case No. 1-20-md-02930, D.I. 844 (D. Del. Sep. 27, 2022). The decision provides guidance to ANDA applicants seeking to maintain a case or controversy for DJ counterclaims under the Hatch Waxman Act.

In September 2019, several generic drugmakers, including Hetero USA Inc. and Torrent Pharma Inc., filed ANDA applications for generic versions of Entresto®. Subsequently, in September 2021, Novartis sued the ANDA applicants alleging infringement of US Patent No. 11,096,918 (the "'918 patent"). Hetero and Torrent filed answers which included counterclaims seeking declaratory judgment of invalidity and non-infringement for not only the '918 patent, but also four additional patents that Novartis listed in the Orange Book more than a year after Hetero and Torrent filed their respective ANDA applications.[1] After the patents were listed, Hetero and Torrent supplemented their ANDA applications to include Section viii statements carving out the protected indications from their labeling. However, Defendants never pursued Paragraph IV certifications for these four patents.

Novartis moved to dismiss the counterclaims, arguing that Hereto and Torrent were barred by statute because they did not serve any Paragraph IV notice on Novartis as required by 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5). Although Judge Andrews disagreed with Novartis on this point, he nonetheless dismissed the counterclaims, holding that an ANDA applicant that submits a Section viii statement does not create an "actual controversy" because there is no cause of action. The Hatch Waxman Act allows generic manufacturers to limit the scope of regulatory approval they seek—and thereby forego Paragraph IV certification and a § 271(e)(2) infringement suit—by excluding patented indications from their ANDAs using Section viii statements. "Thus, an ANDA applicant that submits a Section viii statement for a patent does not face the imminent threat and actual controversy of an infringement action . . . for that patent." D.I. 844 at 12.

Based on this case, courts may find that preemptively carving out of an ANDA label the subject matter of a patent which has not been asserted does not provide standing for the ANDA applicant to seek declaratory judgment of noninfringement for that unasserted patent. ANDA applicants can avoid this situation by filing a Paragraph IV certification of non-infringement along with the label carve out under Section viii.

Although there is no equivalent of Section viii in the BPCIA, biosimilar applicants can choose to carve out certain indications or conditions of use from the label of the reference product sponsor (RPS) for patent reasons.[2] A biosimilar applicant wishing to engage in prelaunch litigation of an RPS patent claiming a method of use directed to the carved-out indication can engage in the Patent Dance by providing its aBLA and accompanying information to the RPS. 42 U.S.C § 262(l)(2)(A). If the RPS does not include the relevant patent on its "3A list" of patents that could reasonably be asserted, the biosimilar applicant can include the patent in its responsive "3B list." 42 U.S.C. § 262(l)(3). This procedure allows the biosimilar applicant to propose the patent for inclusion in the "first wave" litigation, and if it is not included, the biosimilar applicant may file a declaratory judgment action after service of its notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A).

With a degree in chemical engineering and intern experience at one of the world's largest pharmaceutical companies, Vivian Tian, an Associate at Rothwell Figg, assists companies in the biological, chemical, and pharmaceutical industries with patent prosecution and patent litigation matters. Vivian received her J.D. from The George Washington University Law School and her S.B. in chemical engineering with a minor in biology from the Massachusetts Institute of Technology (MIT).

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1. The four additional patents are U.S. Patents No. 9,517,226 (the "'226 patent"), 9,937,143 (the "'143 patent"), 11,135,192 (the "'192 patent"), and 11,058,667 (the "'667 patent").
2. *See* Food and Drug Administration, Guidance for Industry: Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed (February 2020).