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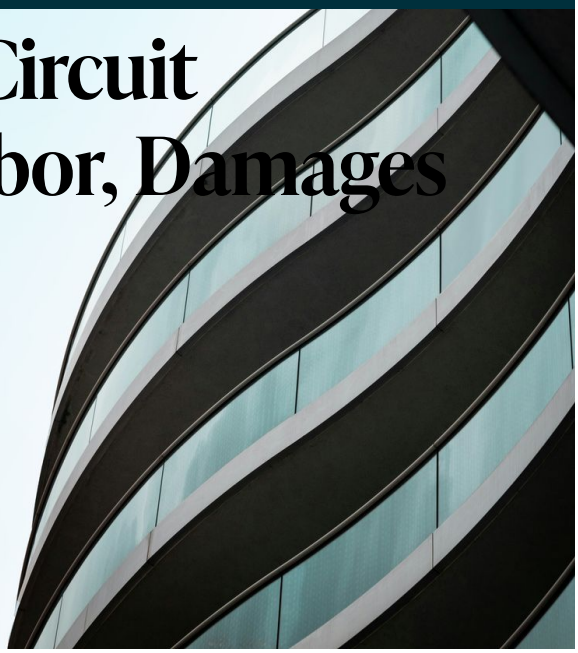
Axinn IP Update: Federal Circuit Addresses BPCIA Safe Harbor, Damages



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Axinn Update

On December 16, 2019, the Federal Circuit issued its decision in *Amgen Inc. v. Hospira, Inc.*, No. 2019-1067, 2019 WL 6834390 (Fed. Cir. Dec. 16, 2019), a rare BPCIA case involving application of the Safe Harbor defense and damages strictly for the manufacture of infringing products.

Amgen, the maker of Epogen®, asserted two patents relating to erythropoietin (EPO) isoforms and aspects of their production. Hospira contested liability, but also argued that its manufacture of twenty-one batches of the drug substance for its biosimilar product was protected by the BPCIA's Safe Harbor for activities "solely for uses reasonably related to the development and submission of information [for regulatory approval]." 35 U.S.C. § 271(e). A jury determined that Hospira (i) infringed the method-of-manufacture patent, and (ii) made fourteen commercial batches outside the BPCIA's safe harbor provision. It awarded Amgen $70 million in lump-sum royalty damages.

On appeal, Hospira argued that the district court erred in instructing the jury on the Safe Harbor by "improperly focus[ing] the jury on the reasons *why* each batch of EPO was manufactured, not *how* each batch was used." *Id.* at *6 (emphasis in original). The Federal Circuit rejected that argument, holding that "[t]he relevant inquiry … is not *how* Hospira used each batch it manufactured, but whether each act of manufacture was for uses reasonably related to submitting information to FDA." *Id.* at *7 (emphasis in original). The Federal Circuit

also held that sufficient evidence supported the jury's finding that fourteen batches of the drug substance fell outside the statutory Safe Harbor. It pointed to testimony that Hospira was not required to manufacture any additional batches for FDA approval after it made non-accused batches in 2012. Hospira's expert admitted that FDA's Complete Response Letter to Hospira did not require Hospira to produce additional batches. In view of this and other evidence, "the jury reasonably found that certain batches at issue were not protected under the Safe Harbor." *Id.* at *8.

On damages, Hospira challenged the $70 million lump-sum royalty award as unreasonable because, at the time of trial, it had not received FDA approval or sold any EPO. It pointed to a "claw-back provision" in the only other lump-sum agreement in evidence as proof that a commercially reasonable party would not agree to such a large payment without knowing whether it could obtain FDA approval. But the Federal Circuit pointed to testimony from Amgen's damages expert that the value to Hospira in obtaining a license so that it could stockpile quantities for a planned commercial launch justified the $70 million payment and affirmed the jury's damages award.

Both the Safe Harbor and damages issues point to the difficulties that follow-on biologic and generic drug manufacturers face in balancing the commercial imperatives of preparing for launch with the potential exposure attendant to an ongoing patent dispute. Similarly-situated companies need to consider whether patent exposure might justify a smaller scale (and less profitable) launch.

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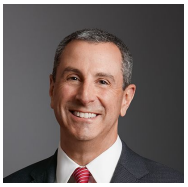

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