

Puma and the Pitfalls of the “Narrow” Exclusive License

A photograph of a modern building with a curved glass facade, showing multiple floors and windows, set against a light blue sky.

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Puma Biotechnology is the latest victim of standing requirements in patent cases that continue to wreak havoc on plaintiffs' ability to recover a full measure of damages.

In *Puma Biotechnology, Inc. v. AstraZeneca Pharmaceuticals LP*, 21-cv-01338-MFK, 2024 WL 1157120 (D. Del. Mar. 18, 2024), the court granted AstraZeneca's motion to dismiss Puma for lack of constitutional standing under Article III. Puma was a co-plaintiff with the asserted patents' owner, Wyeth LLC. It signed an agreement with Wyeth's corporate parent, Pfizer, to license the patents on an exclusive basis for certain compounds. Puma markets a cancer treatment that incorporates one such compound, neratinib, and allegedly competes with AstraZeneca's accused product. Puma subsequently received the right to enforce the asserted patents, although Pfizer retained the right to approve any settlement agreement.

Puma's problem was that the active ingredient in AstraZeneca's accused product is osimertinib, and Puma's license did not cover that particular compound. Puma thus possessed no right to exclude others from practicing the asserted patents using osimertinib, and the Federal Circuit has held that Article III standing in patent cases requires that a party must hold exclusionary rights *as to the conduct at issue*. In *re Cirba Inc.*, No. 2021-154, 2021 WL 4302979, at *3 (Fed. Cir. Sept. 22, 2021). As a result, “[d]epending on the scope of its exclusionary rights, an exclusive licensee may have standing to sue some parties and not others.” *WiAV Sols. LLC v. Motorola, Inc.*, 631 F.3d 1257, 1266 (Fed. Cir. 2010). Puma might have been able to prove an injury-in-fact

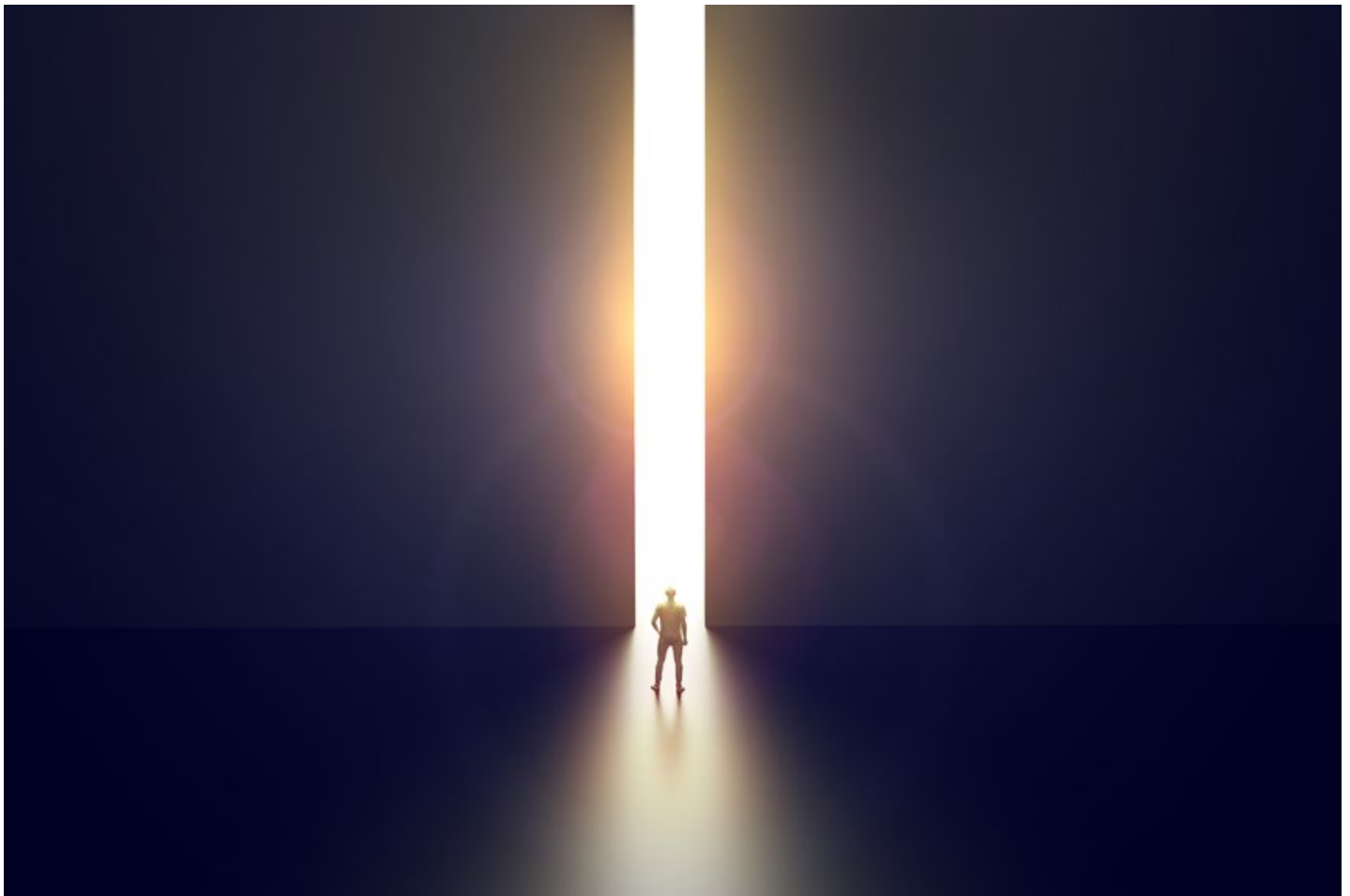
resulting from AstraZeneca's conduct, but that prospect did not confer standing without the necessary exclusionary rights in the patents.

Puma's dismissal is likely to seriously limit the case's value. With both plaintiffs in the case, Puma could seek recovery of its lost profits, and Wyeth could seek the additional royalties it would have received from Puma but for AstraZeneca's alleged infringement. Now, Wyeth can still seek its lost royalties, but those lost royalties will be substantially lower – less than 50 percent, as an educated guess – of the profits that Puma and Wyeth jointly expected to recover.

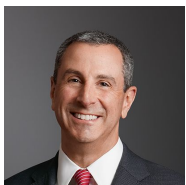
Wyeth doubtlessly had its reasons for limiting the license to only certain compounds, but that decision will come at a substantial cost if it prevails on liability against AstraZeneca. Companies seeking to enter into an exclusive license should be mindful not to unnecessarily limit the license's scope and fall into the same trap that Wyeth and Puma did here.

Importantly, Puma's exclusive license does not permit it to practice the patents-in-suit with respect to osimertinib, the compound in Tagrisso. This means that AstraZeneca's allegedly infringing activity falls outside of the scope of Puma's license. Because Puma has no right to use or exclude others from practicing the patents-in-suit with respect to osimertinib, it has no standing to sue AstraZeneca for infringement.

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