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SPONSORED POST: MANDATORY POST-APPROVAL BIOSIMILAR NOTICE IMPLICATES MILLIONS

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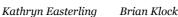
The Federal Circuit recently held that makers of biosimilars must always notify brand-name rivals six months before commercial product launch. Brian Klock and Kathryn Easterling of Fitzpatrick Cella Harper & Scinto report

The Federal Circuit <u>recently held</u> that, after receiving an FDA licence, makers of biosimilars must always notify their brand-name rivals six months before commercially launching their products.

Previously, in <u>Amgen v Sandoz</u>, the Federal Circuit held that the notice is mandatory and must be provided *after* an FDA licence is granted. Sandoz, however, had not followed certain pre-licence procedures for exchanging information with the brand-name maker.

The recent case clarifies that such notice is required even when the biosimilar maker follows those procedures.





Impact of the notice

Brand-name makers enjoy a 12-year exclusivity period. Since the mandatory 180-day notice must be given after FDA approval, some commentators opine that this requirement provides the brand-name maker with an additional six months of exclusivity, potentially worth millions of dollars.

What are these pre-licence procedures?

Biosimilar drugs display similar efficacy and safety as previously approved therapeutic biological products. The Biologics Price Competition and Innovation Act (BPCIA) provides a shortcut to biosimilar approval, similar to the Hatch-Waxman Act shortcut for generic small-molecule pharmaceuticals. A biosimilar maker may rely for approval on data generated by the innovator maker, but the original biologic drug receives 12 years of regulatory exclusivity.

To comply with the BPCIA, a biosimilar maker must follow certain reporting requirements, sometimes called the <u>patent dance.</u>

Under 42 USC § 262(*l*)(2)(A), the two makers exchange information that may be involved in future litigation, such as the biosimilar maker's application for FDA approval and manufacturing process details, and the brand-name maker's identification of relevant patents.

Why was this case different?



Biosimilar maker Apotex applied for FDA approval of a biosimilar of Amgen's drug Neulasta (active ingredient pegfilgrastim, pictured left), which is given to chemotherapy patients to stimulate production of certain types of white blood cells.

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Apotex performed the patent dance and exchanged the required information with Amgen. (That fact distinguishes Apotex's case from *Sandoz*, wherein Sandoz declined to engage in the patent dance with Amgen.)

When Amgen sought a preliminary injunction requiring Apotex to provide the required post-licence notice to Amgen, <u>Apotex argued</u> that its compliance with the BPCIA patent dance should allow it to opt out of the commercial-launch notice requirement.

<u>Amgen disagreed</u>, relying on *Sandoz* and arguing that the 180-day notice is meant to allow brand-name manufacturers sufficient time to seek preliminary injunctive relief against the commercial launch of an infringing biosimilar product.

The <u>district court granted</u> Amgen's requested preliminary injunction, finding that fulfilment of the BPCIA notice requirement was mandatory, with no exceptions. <u>Apotex appealed</u>.

The Federal Circuit affirmed the district court, holding that "the commercial-marketing provision is mandatory and enforceable by injunction even for an applicant in Apotex's position". Coming off the heels of *Sandoz*, where the Federal Circuit held that notice can only be given after the biosimilar product has been FDA-approved, this ruling appears to extend the 12-year exclusivity period by an additional six months.

Attempting to address the concerns raised in *Sandoz* about potentially delaying the launch of biosimilar products, the Federal Circuit stated that it "[h]as been pointed to no reason that the FDA may not issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date".

While that *dicta* seems to be the Federal Circuit's attempt to assuage concerns about such a potential delay, it is unclear whether the FDA will be able to take advantage of the Federal Circuit's suggestion to tentatively license a biosimilar product before the 11.5 year mark, or whether a biosimilar maker can provide effective notice of its intent to launch its biosimilar product with only a tentative licence.

What's next?

Sandoz has filed a <u>petition for certiorari</u>, and Apotex might do the same. For now, it appears the period of exclusivity has been extended.

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