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Federal Circuit Issues a Key Decision About Biosimilars and the BPCIA

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Biosimilars continue to be a **topic to watch** in 2015 as the law around biosimilar products evolves. In March 2015, **CMS released guidance addressing Medicare and Medicaid coverage** for biosimilar drug products, shortly after the FDA's approval of a biosimilar version of Amgen's drug Neupogen®. Then, in April 2015, FDA **released final versions of three key biosimilar guidance documents** under the Biologics Price Competition and Innovation Act (BPCIA).

Most recently, as my colleague Thomas Wintner discussed in an **Intellectual Property Alert** ("Article"), the Federal Circuit Court of Appeals issued a key decision regarding the meaning of various provisions of the BPCIA. *See Amgen Inc. v. Sandoz Inc.*, *Fed. Cir. Case No. 2015-1499*. The appeal had been fast-tracked because of the potentially imminent marketing of Sandoz's biosimilar version of Neupogen®.

As explained in the **Alert**, the Federal Circuit's decision focused on two issues, both of which had been decided largely in Sandoz's favor during the district court proceedings:

1. Whether the BPCIA's patent exchange provisions – specifically, 42 U.S.C. § 262(*l*)(2)-(6) – are mandatory (Amgen's view) or optional (Sandoz's view), and what the consequences of non-compliance or "opting out" of these exchange provisions should be; and
2. Whether the 180-day pre-launch notice required under 42 U.S.C. § 262(*l*)(8) may be given immediately upon FDA's acceptance of the biosimilar application (Sandoz's view) or only upon FDA's approval of the biosimilar product for licensure (Amgen's view).

On the first issue, the Federal Circuit agreed with Sandoz's interpretation and held:

> [E]ven though under paragraph (*l*)(2)(A), when read in isolation, a subsection (k) applicant would be required to disclose its aBLA and the manufacturing information to the RPS by the statutory deadline, we ultimately conclude that when a subsection (k) applicant ***fails*** the disclosure requirement, ***42 U.S.C. § 262(l)(9)(C) and 35 U.S.C. § 271(e) expressly provide the only remedies*** as those being based on a claim of patent infringement. Because Sandoz took a path expressly contemplated by the BPCIA, it did not violate the BPCIA by not disclosing its aBLA and the manufacturing information by the statutory deadline.
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> Maj. Op. at 15 (emphasis added).

On the second issue, the Federal Circuit sided with Amgen and held as follows:

> We … conclude that, under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing ***after the FDA has licensed*** its product. The district court thus erred in holding that a notice of commercial marketing under paragraph (*l*)(8)(A) may effectively be given before the biological product is licensed….
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> Maj. Op. at 18 (emphasis added).

The **Alert** analyzes the decision in detail and interprets what the Federal Circuit's decision (1) means for the parties, and (2) means for the BPCIA.

As the biosimilar landscape evolves, we will continue to monitor and report on pertinent developments.

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