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Can FDA Implement Biologics Price Competition and Innovation Act As Federal Circuit Suggested?

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In *Amgen v. Apotex*, the ***Federal Circuit*** held that under the ***Biologics Price Competition and Innovation Act ("BPCIA")***, "an applicant must provide a reference product sponsor with 180 days' post-licensure notice before commercial marketing begins." The court dismissed concerns that its holding would extend the originator's 12-year exclusivity period by 6 months, reasoning that the ***FDA*** could signal approval of a biosimilar before the 12-year exclusivity period has run, but is that correct?

The *Amgen v. Apotex* Decision

For a detailed description of the Federal Circuit decision in *Amgen v. Apotex*, please see this article, *Federal Circuit Requires 180 Day Notice For All Biosimilars, Even After Patent Dance*.

A major crux of Apotex's argument against a blanket application of the 180-day notice requirement of the BPCIA was that such notice prolonged the originator's 12-year exclusivity period by 6 months, contradicting the intention of the statute. In addressing this argument, the court posited an unconventional role for the Food and Drug Administration (the "FDA") in biosimilar approvals. In particular, the court stated:

[W]e have 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—a possibility suggested by § 262(k)(7)(A)'s language about when the FDA approval may "be made effective."

While this may seem like a simple suggestion, in making it the court may have overlooked a key fact: the FDA has never given early approval for a license before a license's effective date. Does the FDA have the authority to grant pre-effective date license approvals in the manner the court suggested? Does the FDA have the mechanisms to do so?

Current FDA Approval Mechanisms

The FDA has never approved a license before the license was effective–its final approvals always are effective upon issuance. While there have been two approvals under the BPCIA to date, those approvals came long after the original licensed product's 12-year exclusivity period had expired. Thus, the court's suggestion raises an open and interesting issue.

The concept of a “tentative” approval does exist, and is common in the context of generic drugs being approved under the Abbreviated New Drug Application (ANDA) process. The FDA has issued “tentative approvals” to ANDA applicants when the application is approvable prior to the expiration of any patents or exclusivities accorded to the reference listed drug product. While this mechanism sounds somewhat similar to what the court proposed under the BPCIA, a “tentative approval” comes with one major caveat: The applicant has to reapply for final approval 90 days prior to the date the application is eligible for final approval even if no changes are made to the product. Therefore, in granting a “tentative” approval, the FDA is not granting an approval at a date earlier than the effective date of the license. Instead, the FDA grants only an early affirmation which must be replaced at a later date by a final approval.

The Federal Circuit does not appear to have been contemplating this two-stage “tentative” approval process, but rather appears to have been suggesting an early approval process that would be inconsistent with past and current FDA drug approval practices.

Does FDA Have Authority To Implement Court’s Approval Strategy?

While the court knew “no reason” why the FDA could ***not*** “issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date”, the FDA may be more concerned with identifying a reason why it ***could*** issue such a pre-effective date approval. Neither the Federal Food, Drug, and Cosmetic Act nor the Public Health Service Act explicitly grants the FDA authority to issue an approval that is effective at a later date. Rather, the statutes appear to be silent on this issue. Accordingly, it seems that the FDA would have to exercise one of two options to effectuate the court’s suggestion:

- Initiate a long rule-making process to create a mechanism to grant pre-effective date approvals for biosimilar applications

- Begin to grant pre-effective date approvals for biosimilar licenses without any regulations in place.

The first option would not be timely. The rule-making process likely would take years, and there is no guarantee that the final approval mechanism would resemble what the court envisioned.

The second option also is not realistic. If the FDA were to grant a pre-effective date approval without regulations in place, it likely would be immediately sued by the original license holder. Additionally, the FDA historically has been uncomfortable taking any action that is inconsistent with FDA approval policies and procedures for other products.

Thus, it may not be as easy for the FDA to grant pre-effective date approvals under the BPCIA as the Federal Circuit assumed.

What Will The FDA Do?

Even if a pre-effective date approval mechanism is the correct “solution” to the “problem” of the BPCIA’s requirement for 180 days’ post-licensure notice before commercial marketing, it is unlikely to be implemented by the FDA. No language in the statute expressly authorizes the FDA to grant approval of a biosimilar product before the product’s license is effective. While such authority might be found under a broad reading of the statute, a long rule-making process would prevent the FDA

from immediately implementing a pre-effective date approval mechanism, and the FDA is unlikely to proceed without regulations in place. The FDA also may be reluctant to adopt the court's suggested approach because it would create additional administrative burdens on the government. Indeed, it appears that the court proposed an implementation of the FDA's authority under the BPCIA without regard to statutory limitations on the scope of the FDA's regulatory mandate as intended by Congress or the FDA's actual practices.

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