FDA's Proposed Performance Goals for Biosimilar Applications May Provide Some Certainty for Biologics Companies

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The Food and Drug Administration (FDA) recently issued a Federal Register Notice in which it set forth its proposed FY 2013-2017 user fee and performance goals for biosimilar and interchangeable applications (§ 351(k) applications) under the Biologics Price Competition and Innovation Act (BPCIA).[1] The Notice may remove some of the uncertainty facing biologics Reference Product Sponsors (RPSs) as to when a patent challenge might arise under the BPCIA, which sets forth the regulatory and patent litigation framework for biosimilar and interchangeable drug products.

Category 1 Versus Category 2 Applications

The FDA's Proposed Performance Goals for reviewing § 351(k) Applications for FYs 2013 through 2017 recognized two distinct categories of applications: (1) those submitted 10 years or more after the date the reference product was first licensed, and (2) those submitted between 4 and 10 years after the date the reference product was first licensed. While Category 1 applications would be eligible for approval in 2 years or less, Category 2 applications would not be eligible for approval for more than 2 years and up to 8 years. Because of the long period of time before Category 2 applications could be approved, the FDA expressed concerns about allocating resources now to review those applications only to have to conduct supplemental reviews and inspections of facilities just prior to approval. Accordingly, the FDA proposed performance goals for reviewing only Category 1 applications and is seeking public comment, due by June 9, 2011, for establishing performance goals for Category 2 applications.

Category 1 Applications Go to the Front of the Line

For Category 1 applications, the FDA proposed for FY 2013 that it would review and act on 50 percent of original applications seeking biosimilarity or interchangeability determinations within 10 months of the 60-day filing date. The FDA would also review and act on 50 percent of resubmitted applications seeking biosimilarity or interchangeability determinations in response to a complete response action within six months of receipt. The percentage of original applications seeking biosimilarity or interchangeability determinations reviewed and acted upon by the FDA within 10 months of the 60-day filing date would increase to 60 percent in FY 2014, 70 percent in FY 2015, 80 percent in FY 2016, and 90 percent in FY 2017. Those same percentage increases for FYs 2014-2017 also apply to resubmitted applications.

Predicting Patent Challenges

Although the Hatch-Waxman Act provides innovators of traditional small molecule drugs with the ability to predict, within a narrow period of time, when a generic drug company might file an abbreviated new drug application (ANDA), the BPCIA does not provide the same level of predictability to companies that develop new biological drugs. Assuming, however, that the FDA's proposed performance goals are accepted, RPSs could use the FDA's timelines as a measure to predict when they may face patent

challenges. Section 351(k) applicants are more likely to prioritize applications directed to biosimilars in Category 1 rather than invest the time and resources into filing applications directed to a Category 2 biosimilars that have the potential of sitting, un-reviewed, at the FDA for several years. Thus, RPSs with biologics that fall within Category 1 are more likely to face patent challenges in the near future and need to plan accordingly by conducting the necessary due diligence to identify the relevant patents owned, licensed-in, or held by third-parties that need to be listed during the BPCIA patent exchange process. Because the FDA wants to complete its review of Category 1 applications in a timely manner, RPSs with Category 1 biologics will also be under added pressure to litigate quickly to maintain their ability to obtain an injunction under the BPCIA, which can only be obtained with the filing of a timely lawsuit that proceeds to a final judgment from which no appeal can be taken. In addition, the FDA must not have approved the § 351(k) application because of the twelve year exclusivity period. RPSs will therefore need to identify district courts where they have the opportunity to complete trial in an expedited manner.

Strategic Planning Opportunities for Category 2 Products

While patent challenges for Category 2 biologics might not occur in the near future, RPSs should not delay analyzing these products because additional strategic options might be available. For instance, an RPS that can modify the structure of its reference product such that the structural modification results in a change in the safety, purity, or potency of the product as compared to the previously approved biologic may be able to obtain another twelve years of exclusivity. Based on the FDA's Notice that it does not intend to immediately review Category 2 applications, sufficient time may exist for RPSs with Category 2 biologics to conduct such an investigation into structural modifications that may lead to additional exclusivity. This option might not be feasible for Category 1 biologics due to the review priority placed on these drugs by the FDA.

Endnotes

[1] Biologics Price Competition and Innovation Act of 2009; Options for a User Fee Program for Biosimilar and Interchangeable Biological Product Applications for Fiscal Years 2013 Through 2017; Request for Comments, 76 Fed. Reg. 27062 (May 10, 2011).