

questions and answers. Much remains to be learned about the regulatory pathway. Some recent court decisions, discussed below, are starting to fill in gaps as to how the regulatory regime will interact with patent issues.

14.4.1 LINKAGE OF US PATENTS TO BIOSIMILAR APPROVAL PROCESS

The BPCIA includes several provisions directed to resolving patent disputes through either settlement or litigation. The BPCIA has some conceptual similarity to the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch–Waxman Act), which provides a path for market entry to generic small-molecule pharmaceuticals. Patent issues were not previously linked to the biologic regulatory approval system, so this is a significant change of the new law. There are also very distinct differences in the patent litigation pathways under the BPCIA and the Hatch–Waxman Act. For example, there is no Orange Book for listing patents under the BPCIA. Instead, there is a process for a complex, private exchange of information between competitors. The patent owner may be informed of at least a portion of the biosimilar company’s confidential manufacturing process, and the biosimilar manufacturer is informed of the innovator’s patents. This process also produces patent litigation options, as discussed in more detail below.

The BPCIA litigation provisions contain several “patent” ambiguities in key areas, particularly whether various lists of patents to be litigated are exclusive. Courts will have to resolve these issues.

Some review of the litigation provisions is necessary to understand the more important areas of contention. The Act prescribes a rather elaborate interaction, informally referred to by some in the industry as a “dance,” in which reference product sponsors and biosimilar applicants (referred to as “subsection (k) applicants” based on the subsection of the statute that creates biosimilar applications) may engage before commencing any patent infringement litigation (42 U.S.C. § 262(l), 2013). The dance can begin when the applicant submits to the FDA an application for approval of a biosimilar drug. The statute states that “[w]hen a subsection (k) applicant submits an application” to the FDA, the applicant will give a copy of the application to one in-house lawyer for the reference product sponsor and to outside counsel for the sponsor, subject to certain confidentiality restrictions. Later, the statute states that the copy of the application “shall” be provided to the sponsor “[n]ot later than 20 days after the Secretary [through the FDA] notifies the subsection (k) applicant that the application has been accepted for review.” In addition, at that point the applicant must also provide “such other information that describes the process or processes used to manufacture the biological product that is the subject of the application.”

Although the language appears to require disclosure of the application, a Court recently decided that it was optional. In *Amgen Inc. vs. Sandoz Inc.* (2016), Sandoz offered to provide portions of its abbreviated biologics license application (aBLA) for Zarxio to the reference product manufacturer, Amgen. In reply, Amgen demanded the entire application. Amgen and Sandoz did not agree on the extent of disclosure of the aBLA required by the BPCIA. The Court decided that disclosure of the aBLA was not mandatory. The word “shall” in paragraph (l)(2)(A) was not read in isolation, and when read in the context of the statute, it did not mean “must.” The Court stated