both cases, Amgen alleges that Sandoz started the patent dance by providing Amgen with its application and manufacturing information, that Amgen responded with a list of patents of which infringement could reasonably be alleged, and that Sandoz then stopped the music and told Amgen to file suit. Amgen obliged by seeking a declaratory judgment that Sandoz had violated the BPCIA, that there could be no immediate action for patent infringement until the parties had completed the patent dance, and that Amgen would still be entitled to all the remedies for patent infringement, including lost profits and injunctive relief. These cases reinforce the trend that biosimilar applicants view the patent dance procedures as a waste of time that delays the resolution of litigation and their entry into the market. Conversely, the patent owners want the procedures to be completed in full before any litigation begins.

Another section of the statute addresses preliminary injunctions. This section provides that the applicant must give the sponsor 180 days' advance notice of its intention to begin commercial marketing of the biosimilar (42 U.S. Code § 262—Regulation of biological products). Between its receipt of the notice and the expiration of the 180 days, the sponsor can seek a preliminary injunction against sales of the applicant's biosimilar based on any patent that (1) was included on a Paragraph 3 list but (2) was not included on either an agreed list of patents for litigation or a Paragraph 5 list (or, under another section of the statute, based on a patent that issued or was licensed after the sponsor created its Paragraph 3 list).

The 180-day notice of intent to begin commercial marketing does not grant standing to commence a declaratory judgment action before a biosimilar application under 262(k) submitted to the FDA is approved as complying with the requirements for licensing. This arguably provides an additional 6 months exclusivity to the reference product based on the initial court decisions discussed above. The action must meet the requirements of "immediacy and reality." There is no immediacy if the biosimilar manufacturer is still conducting Phase III trials because the product may not yet be final at this point (though it should be near-final for the trial results to be relied upon). It is also unlikely that a court would find immediate and significant impact on the biosimilar company. The biosimilar company may nonetheless try to establish standing at an earlier stage if it can rely on other conventional patent law bases for a declaratory judgment such as having been threatened with a patent infringement suit. It is not clear if the BPCIA could preclude this conventional declaratory judgment jurisdiction until after the biosimilar company had proceeded through the BPCIA framework (*Celltrion Healthcare Co., Ltd. vs. Kennedy*, 2014). The standing issue also has to be reviewed on a case-by-case basis, since merely stating ownership of patents (per *Sandoz*) or having previously asserted patents in the US and elsewhere (per *Celltrion)* against other companies may not provide standing.

An unresolved issue raised by this section is exclusivity again. Can the sponsor only seek a preliminary injunction based on a patent that falls into one of these categories? What if there is pending litigation involving the agreed or Paragraph 5 list patents? Can a patentee seek a preliminary injunction based on those also? The statute does not expressly say that the sponsor cannot. If the answer is that the patentee can seek a preliminary injunction based on such patents, however, what is the point of the provision limiting the requests for preliminary injunctions to patents on Paragraph 3 lists but not the later lists?