The statute also does not address the procedure for seeking a preliminary injunction. Must the sponsor seek the preliminary injunction in any pending case? What if the deadline for amending the pleadings (often fairly short) has passed? Will courts conclude that the applicant's notice of intent to market satisfies the "good cause" required under Federal Rule of Civil Procedure 16 to amend pleadings after any applicable deadline, except in extraordinary circumstances? Can the sponsor start an all new suit on the patent(s) for which it is seeking a preliminary injunction? If so, does it have to be before the same court as the pending suit? If the sponsor chooses to file a new suit before a different court, will the new court transfer the case to the court handling the earlier case? The statute does not address these and other possible issues, so that task will fall to the courts.

Another question is whether the provisions on preliminary injunctive relief provide clues to the earlier question about whether the agreed list or Paragraph 5 lists of patents limit the patents that the sponsor can assert. The preliminary injunction provisions give the applicant an incentive to include on its Paragraph 5 list any and all patents that could reasonably be asserted against the proposed biosimilar. Otherwise, it would expose itself to the risk of being hit with a preliminary injunction at or near the time of its proposed launch of the biosimilar (a time at which considerable investment would have been made). This suggests that Congress may have intended the agreed list or the Paragraph 5 lists to be exclusive for any initial litigation.

On the other hand, an applicant willing to run the risk of a preliminary injunction could force the sponsor to seek such relief, perhaps on an incomplete record with limited time to prepare and/or for the hearing itself. Further, the sponsor would have to satisfy the additional evidentiary burdens of irreparable harm, the balance of the harms, and that the preliminary injunction would not disserve the public interest. The sponsor would have to post a bond, potentially quite large, to enforce the preliminary injunction. What if the court does not rule on the motion for preliminary injunction before the stated date for the applicant to begin commercial marketing?

As a result of these ambiguities, both reference product sponsors and biosimilar applicants can look forward to several years of litigation while these procedural issues are decided, along with issues going to the merits of their cases.

14.4.2 Risk Mitigation: Postgrant Patent Office Challenges in the US

Notwithstanding the risks identified above, there are reported to be many biosimilars in development. In prepared remarks to the US Congress in September 2015, an FDA official stated that "[a]s of July 31, 2015, 57 proposed biosimilar products to 16 different reference products were enrolled in the Biosimilar Product Development (BPD) Program." The same official indicated that "[s]ponsors of an additional 27 proposed biosimilar products have had a Biosimilar Initial Advisory meeting with FDA, but have not joined the BPD program to pursue the development of these products" (Woodcock, 2015).

An obvious way to avoid the uncertainty and expense of litigation under the BPCIA is to wait for any patents covering the reference product to expire. As discussed above, it appears that the patents covering several of the biggest selling biologics have already expired or will expire over the next 5 years.