to the originator. Then within 60 days after receipt of the biosimilar application, the originator shall provide a list of relevant patents covering the biologic and a list of any patents it is prepared to license to the biosimilar. The biosimilar applicant, within 60 days of receiving the patent list from the originator, shall then explain why it believes these patents are either invalid or will not be infringed by its biosimilar. Alternatively, it may assert that it will not enter until the expiration of the patents.

Next, within 60 days, the originator must explain why it believes certain patents are valid and will be infringed by the biosimilar. The originator and biosimilar applicant are then supposed to negotiate over the list of patents in dispute that may be infringed. The pioneer then has 30 days in which to file an infringement suit. Failure to do so within the 30-day period will result in only reasonable royalties being available in a subsequent suit. An originator's failure to list a patent will preclude it from a subsequent suit on that patent. Finally, the biosimilar firm must notify the originator 180 days before it intends to market the biosimilar (Vatiand et al., 2010).

The patent disclosure and negotiation process is obviously intended to narrow the area of dispute. However, discussions and communications between competitors are fraught with concerns that the public could be harmed. For example, the originator and biosimilar could both potentially gain by delaying entry of the biosimilar. This is the so-called pay for delay that has been a very contentious issue in the generic market (Blackstone and Fuhr, 2006).

Antitrust concerns are likely to ensue from such exchanges of information and communications. Further, the originator could conceivably gain some competitive advantage by the information exchanges, making competition more difficult for the biosimilar. For example, the originator may become aware of the trade secrets of the biosimilar applicant who is probably using the latest technology and gives the originator some important information about this technology.

Concerning the patent dance, which is being contested in *Amgen vs. Sandoz*, the issue revolves around the meaning of the word "shall." The court has to decide if "shall" means that the patent dance is mandatory or if the biosimilar applicant has the option to refuse to dance and thus have the court decide the validity or infringement of any patents. On March 19, 2015, the district court denied Amgen's motion for an injunction to stop the sale of Zarxio. In May 2015, the Federal Circuit gave Amgen a temporary injunction to stop the marketing of Zarxio. The injunction hearing began on June 5, 2015. The district court also concluded that Sandoz had the option to not engage in the patent dance.

Some have questioned why the patent dance even exists since it does not in the generic market. One explanation is that Congress believed that the patent dance could resolve patent issues before the 12-year market exclusivity expired. The law allows a biosimilar to apply after 4 years to the FDA (at the end of data exclusivity), and thus there is an 8-year window to resolve any patent issues. This is the reason for the dance. It is unlikely that an applicant would file as early as 4 years, but even if the applicant were to file in year 9 and receive approval in year 10, there would still be around 2 years to resolve any patent issues through the rules of the so-called patent dance and thus be able theoretically to enter after the 12-year exclusivity expired. Although the goal or intent is admirable, the unintended consequences may make the patent dance problematic.