

- The proceedings are less expensive, in part because discovery is limited.
- The proceedings are typically shorter than court litigation, lasting at most 18 months from the filing of a petition to initiate a proceeding.

A reference product sponsor faced with an *inter partes* or postgrant review petition could potentially argue that in the biosimilars context the BPCIA's litigation provisions are exclusive and thus preclude resort to either an *inter partes* review or a postgrant review proceeding. Only time will tell whether such an argument will succeed.

There have been *inter partes* review challenges to biologic patents. The Patent Trial and Appeal Board denied two requests by Amgen for reviews of two AbbVie patents (US Patent Numbers 8,916,157 and 8,916,158) covering the blockbuster biologic, Humira, just months after Amgen had asked the FDA for permission to market a biosimilar version of the autoimmune disease drug (*Amgen Inc. vs. AbbVie Biotechnology Ltd.*, 2015a,b). In both cases, the PTAB found that Amgen had not shown that it was reasonably likely that at least one claim of the patents was invalid. Eli Lilly recently filed an IPR challenging a University of Pennsylvania patent (*Eli Lilly vs. University of Pennsylvania*, 2016).

Even if a patent office challenge is underway, in some cases, where there is an imminent patent threat, it is possible that a declaratory judgment action may be again argued as an available court option to seek to avoid a potentially applicable patent based on noninfringement, invalidity, or unenforceability.

14.5 THE EUROPEAN BIOSIMILAR APPROVAL PROCESS

Biologics are reviewed and approved by the EMA, which has authority to approve drugs for the entire European Union. The EMA implemented a biosimilars approval pathway in March 2004, which took effect the following year (EMA, 2005). Since then, the EU has led the way in first-world biosimilar regulation and approvals. Approved products include somatotropins, erythropoietins (epoetins), granulocyte-colony stimulating factors (filgrastims), and a monoclonal antibody (infliximab). The EMA has developed extensive guidance for industry, approved complex biosimilars such as antibodies, and also approved the most biosimilars. The Committee for Medicinal Products for Human Use (CHMP) at the EMA published a series of general and product-specific guidelines in 2005 (European Medicines Agency, 2005).

14.5.1 NO LINKAGE OF EUROPEAN COMMUNITY PATENTS TO BIOSIMILAR APPROVAL PROCESS

There are no European Community (EC) linkage regulations. Certain countries, such as Italy, Hungary, Portugal, and the Slovak Republic do have a national system that, in some way, links patent rights to marketing approval (Bhardwaj et al., 2013) or reimbursement.

It appears that the EC's view is that linkage regulations that delay regulatory review are not permitted at an EC level and may not be permitted at a country level.