a third party may request reexamination of a granted patent at the Canadian Patent Office. The outcome of reexamination could be maintenance of the same claim scope, narrowed patent claim scope, or patent refusal. The patentee has the option to submit amended claims, if necessary, to try to salvage its patent. The person requesting reexamination must provide printed prior art and show its pertinency and the existence of a substantial new question of patentability. Reexamination is not commonly used to try to revoke a patent because the challenger is not allowed to participate beyond its first submission of comments on relevance. The patent owner may then engage in multiple rounds of argument and claim amendments with the Patent Office. So reexamination is typically risky for the challenger unless the prior art is very close and likely to defeat novelty.

14.4 THE US BIOSIMILAR APPROVAL PROCESS

The US federal government has created a specially designed, abbreviated biosimilar approval pathway. The Biologics Price Competition and Innovation Act (BPCIA) was part of the Patient Protection and Affordable Care Act (aka "ObamaCare") (H.R. 3590, 111th Congress, 2010) and created the regulatory process by which competitive versions of a previously licensed biological product could be brought to market (see § 7002). Prior to the BPCIA system, certain biosimilar manufacturers could attempt to obtain biosimilar approvals through Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act or a standard new biologic license application (BLA) (Public Health Service Act—Regulation of Biological Products, Section 351). These avenues are still open, but the BPCIA is expected to become the primary process for biosimilar approval.

As amended, Section 351(i) of the Public Health Service (PHS) Act defines *biosimilarity* to mean "that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components" and that "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." It was not until March 2015 that the first biosimilar, Sandoz's filgrastim (Zarxio), was approved in the US by the BPCIA pathway. The product did not launch, however, until September 2015 as a result of litigation with Amgen, discussed below. The FDA assigned the product a temporary generic name "filgrastim-sndz" and still developing its policies on biosimilar naming. It recently issued a draft guidance on the naming of biosimilars (US FDA, 2015a) that proposes to use an arbitrary, four-letter suffix on the names of biosimilars to distinguish them from their reference product counterparts.

Although more properly characterized as the absence of a reward or incentive rather than the presence of a risk, it is nonetheless worth noting that under the BPCIA the first biosimilar to market does not receive any period of marketing exclusivity, unlike a generic drug. Rather, the BPCIA gives a 1-year exclusivity only to a follow-on biologic that qualifies as interchangeable with the reference product (42 U.S. Code § 262—Regulation of biological products).

The BPCIA laid out the biosimilar pathway in general terms. The FDA then issued guidance documents elaborating on the pathway in April 2015 (US FDA, 2015b,c,d). The FDA published scientific guidance, quality guidance, and a list of