costs and damages for delaying biosimilar drug entry into the market. The NOC Regulations have been extensively litigated in the context of conventional, small-molecule pharmaceuticals. The NOC Regulations will become an important patent protection tool as biosimilar development increases.

An early biosimilar NOC Proceeding involved Teva's biosimilar version of filgrastim (*Amgen Canada Inc. et al. vs. Teva Pharmaceutical Industries Ltd. et al*., 2012). Amgen had the first approved filgrastim product in Canada, under the brand name Neupogen, whose patent expires on July 31, 2024. Amgen started an NOC Proceeding in an attempt to block Teva's biosimilar filgrastim. In defense, Teva had alleged that claims of the Amgen patent in issue were either invalid, infringed, or not relevant. The case was settled in August 2013. The terms of the Canadian settlement are unknown since neither company appears to have issued a press release on its terms. In particular, it was not publicly stated whether Teva agreed to keep its filgrastim product off the market for a period of time. In the US patent litigation on the filgrastim product (which is completely independent from the Canadian litigation), Teva had earlier admitted in a settlement that certain Amgen US patent claims were infringed, valid, and enforceable, and a court injunction was issued that would keep Teva off the market until December 2013. Teva did not have its Canadian NOC as of April 1, 2016. Apotex won its NOC Proceeding with Amgen and has its NOC for filgrastim and launched its product (*Amgen Canada Inc. vs. Apotex Inc*., 2015). Amgen Canada Inc. and Samsung Bioepis Co., Ltd. are currently in an NOC Proceeding regarding Samsung's enteracept, which involves infringement and validity issues (*Amgen Canada Inc. et al. vs. Samsung Bioepis Co., Ltd. and the Minister of Health*, 2015).

14.3.4 Interaction of NOC Regulations with Conventional Patent Infringement Lawsuit

The NOC Proceeding is not a patent infringement or validity action; rather, it is a summary application proceeding, the outcome of which is a decision on whether or not the biosimilar manufacturer may get its NOC and enter the marketplace prior to patent expiry. Patent issues are taken into account in the NOC Proceeding, but there is no final determination of infringement or validity. The Canadian government intends to amend laws to turn NOC Proceedings into full actions.

A conventional patent infringement lawsuit may be brought by a patent owner, irrespective of whether it has engaged in an NOC Proceeding. The patent owner can commence the patent infringement lawsuit in Federal Court, even if it loses in an NOC Proceeding. Likewise, the biosimilar company may lose in the NOC Proceeding but later establish at a trial that the patent is invalid or not infringed. Canadian patent infringement litigation is more extensive and permits discovery and trial testimony.

14.3.5 Risk Mitigation: Postgrant Patent Office Challenges in Canada

The grounds to oppose a patent application or patent are quite limited in Canada. Printed prior art publications may be filed any time during the pendency of an application, along with a statement of pertinency (Patent Act, s. 34). Another basis of challenge is reexamination (Patent Act, s. 48.1 to 48.5). Either the patent owner or