to pay reasonable compensation for its activities for the period between publication and before patent grant. (For an example of such a law, see the Canadian case, *Baker Petrolite Corp. vs. Canwell Enviro-Industries Ltd*., 2002.) In some countries, such as Canada and the UK, the patent owner can elect between damages and an accounting of profits (i.e., disgorgement of infringer's profits). The accounting of profits is an unusual remedy in that the patent owner can take the infringer's profits arising from the infringement, regardless of whether the patent owner suffered any damages. Punitive damages may be requested, but the likelihood of such an award varies between jurisdictions. The US courts can award punitive damages up to three times the assessed amount of damages for willful infringement (35 U.S. Code § 284—Damages). Punitive damages are infrequently awarded in Canada and are relatively insubstantial compared to the US (*Bell Helicopter Textron Canada Limitée vs. Eurocopter*, 2013).

An injunction and delivery up to the patent owner of the infringing drug may also be ordered after a trial. An injunction may also be requested before trial but is unlikely to be granted in the US, Europe, or Canada in pharmaceutical patent cases. Injunctions are infrequent because pharmaceutical cases are complex, and the damage caused by infringement is usually compensable by damages so unlikely to cause irreparable harm to the patent owner.

The biosimilar company may challenge the validity of a patent, for example, that the patent claims lack novelty, inventiveness, or support. A patent is presumed valid during litigation, and the onus is on the challenger to invalidate a patent. Each country has different laws and standards on patent validity issues. At least a couple of years (often much longer) elapse before there is a trial decision on infringement and validity.

14.2.4 Linkage of Patents to Biosimilar Approval Process

Biosimilar approval by a regulatory agency can be linked to patent issues in some jurisdictions. "Linkage" rules require biosimilar drug companies to establish freedom-to-operate (clearance) with respect to certain patents as a *precondition* to market authorization. A patent owner with a product on the market can sue to try to stop the biosimilar manufacturer from getting its marketing authorization.

This is in sharp contrast to conventional patent enforcement litigation, which typically begins only *after* marketing authorization is granted and a competitor drug is launched on the market. The focus of conventional patent litigation is not blocking the government from issuing the marketing approval, but suing for patent infringement and requesting remedies such as an injunction and damages.

14.2.5 Settlement

Companies may settle patent issues between themselves, without litigation. For example, the biosimilar developer may enter an agreement with the reference product sponsor in which the reference product sponsor agrees not to challenge the entry of the biosimilar into the market. The parties are free to make a settlement agreement, subject to compliance with antitrust laws (*FTC vs. Actavis, Inc*., 2013).