This is especially the case for new technologies like biologics since patents tend to be fairly narrow, making them vulnerable to challenges (Sahr, 2009). Also, because of the complexity of large-molecule biologics, proving infringement may be more difficult. Differences in their manufacturing processes and their complexity may combine to yield different properties and structures even though the product is highly similar (Roth, 2013).

On the other hand, biologics tend to be protected by 50–70 patents that cover manufacturing, production, and every aspect of R&D, while chemical or small-molecule drugs are usually covered by 8–10 patents (Blackstone and Fuhr, 2012). Further, manufacturing plays a much more important role in the case of biologics than for chemical drugs, and the manufacturing processes can be kept secret, avoiding the necessity of obtaining patents at all for this aspect. In any event, the extent of effective patent protection for biologics is unclear.

In view of the uncertainties of patent protection for new biologics, it is probably desirable that additional protection be provided. Under the BPCIA, both data and market exclusivity are provided. Four years of data exclusivity begin from the date of FDA approval, which means that no studies or data from the innovator can be used for 4 years. Also, the FDA will not consider any application for a biosimilar during that time. In addition, there is a 12-year market exclusivity from the date of FDA approval of the originator biologic. This means that no biosimilar can be marketed for 12 years from FDA approval for the reference product. Thus, the FDA can approve a biosimilar after 4 years, but the biosimilar cannot be marketed until after the 12-year market exclusivity expires (Gorman et al., 2013).

Also, given that patents are granted for 20 years from the date of application and the 4-year data exclusivity and 12-year market exclusivity are granted from the date of FDA approval, there is a considerable time period, around 8–10 years from patent application through clinical trials to drug approval. In many cases, the patent will probably expire before the end of the exclusivity period.

Interestingly, most commentators discuss data exclusivity without noting the market exclusivity. It is noteworthy that data and market exclusivity cannot be challenged in court (Blackstone and Fuhr, 2013). The exclusivity is automatic once the originator biologic has been approved. Given the uncertainties of patent protection and the long period before drug approval, the market exclusivity included in the BPCIA serves as an important incentive in encouraging innovation. An additional exclusivity of 6 months is available for pediatric applications.

16.7 LENGTH OF EXCLUSIVITY AND TYPE 1 AND TYPE 2 ERROR

There was much debate over the length of market exclusivity that biologics should enjoy. The debate centered around 7 or 12 years. It is obviously difficult to determine the optimal exclusivity time period. It can and almost certainly will differ significantly by drug. Thus, there is almost inevitably going to be some error involved in determining the appropriate exclusivity period. It was eventually decided and implemented that a 12-year exclusivity period was appropriate. This raises the issue of a type 1 and type 2 error. If too short a period were to be chosen, a type 1 error, originator firms would have less time to obtain a return on investment and less incentive