reference pricing and a rebate system as well as biosimilar quotas for both regional sickness funds and physicians. Under reference pricing, patients must pay out of pocket the difference between the price of the drug chosen and the reference level. Additionally, if physicians exceed 125% of their budget they need to repay the amount above 115% unless the excess can be justified.

The large insurance companies (sickness funds) are paid in a capitated fashion and negotiate for discounts; thus, they have an incentive to choose the biosimilar to be on the formulary. Germany's Federal Healthcare Committee has encouraged the use of biosimilars and is able to bargain for rebates. Sandoz, for example, in 2007 increased its Binocrit discount from 15% to 33% and obtained 30% of the market (IMS, 2014). Another potential reason for high biosimilar penetration may be the fact that several of the biosimilar companies produce in Germany.

16.21 MARKET OPPORTUNITIES

Partly as a result of high development costs, biologics are often among the most expensive drugs. Five of the top ten revenue-producing drugs in 2012 were biologics, an increase from two of the top ten in 2008. Biotech drugs comprised only 7% of the top ten selling treatments in 2001, increasing to 71% in 2013 (Loo, 2015). This represents 18% of the global pharmaceutical industry revenues in 2012. Revenues for biologics are growing at twice the rate of global drug revenues overall. Some estimates have biologics reaching 50% of pharmaceutical sales. US sales in 2014 were around $200 billion and grew over 10% in 2014. Biotechnology products are expected to account for 51% of the top 100 drugs in 2018, an increase from 39% in 2012 and 15% in 2000 (Loo, 2014). The US comprises around 50% of the biologics market. Many biologics have sales of over a billion dollars. Over 30 biologics have lost or will soon lose patent protection. It is estimated that a total of $80 billion in US biological sales are going off patent by 2020. High prices and sales provide an incentive for biosimilar entry once patents expire. This incentive is also indicated by the higher gross margins, which are high because of the great cost of drug development.

The gross margin for the seven biological firms in the S&P 500 index in 2010–2014 ranged from 77.1% to 95.6%, among the highest of any industry (Loo, 2015). The great economic advantage of biosimilars is that a manufacturer only needs to re-create the idea that is already shown to work (Harris, 2011). Biosimilar producers can avoid much of these development costs incurred by originators. Despite the considerable barriers to entry, given the potential market opportunities, an influx of biosimilars into the market is expected. The future for many pharmaceutical firms is in biologics and biosimilars. As S&P states: "With conventional R&D yielding below-par returns, biotechnology is now viewed as the new frontier in breakthrough therapies" (Loo, 2014).

16.22 DUE DILIGENCE

There are tremendous opportunities in the biosimilar market, but there is also tremendous risk. Many companies are developing biosimilars for the same reference product. In 2013, it was reported that 21 firms were developing biosimilars