

In Italy, a local law prevents manufacturers of generic products from submitting a request for marketing authorization prior to the second to last year before patent expiry on a reference drug product. In 2012, the EC called on Italy to comply with the EC view of the European Union rules on marketing authorization of generic drugs (European Commission, 2012). The EC view is that the processing of a submission for marketing authorization can be carried out without being affected by patent rights (European Parliament and Council, 2001), as long as the generic drug company is not allowed to place a product on the market before patent expiry. The request took the form of a “Reasoned Opinion” under EU infringement proceedings. Italy modified its law to remove the law of concern to the EU and then passed another law preventing reimbursement of a drug until the relevant patent expires (Galli, 2012).

14.5.2 RISK MITIGATION: POSTGRANT PATENT OFFICE CHALLENGES IN EUROPE

A granted European patent may be opposed by third parties (European Patent Office, 2015). Irrespective of whether the opposition procedure is initiated, it is open to a third party to challenge the validity of a patent in the court of an individual country. An opposition is currently the only way to revoke a patent in all states where the patent is validated. The time limit for filing an opposition is 9 months of the grant being published in the European patent bulletin. The opposition must state the ground of opposition, which can be one or more of the following: lack of novelty or inventiveness, lack of patentable subject matter, insufficient disclosure, or added subject matter beyond the content of the application as filed.

The Opposition Division examines the grounds for opposition and invites the patent owner to respond by setting out why the patent should be maintained. The patent owner can make amendments to the application and claims if it wishes. Typically, an oral hearing is held, after which the Opposition Division will either maintain the patent as is, maintain the patent in amended form, or revoke the patent. An appeal can be filed by either side to the independent Appeal Board. If the Appeal Board maintains the patent as granted or as amended, validity of the patent may still be individually challenged on a country-by-country basis in local courts. If the patent is revoked by the Appeal Board, there is no further appeal. If the Appeal Board overturns the Opposition Division decision to revoke the patent, the opposition may be remitted back to the Opposition Division for further consideration of any outstanding grounds.

14.6 CONCLUSIONS

The biological patent landscape should be proactively assessed by both patent owners having a biologic on the market and subsequent-entry biosimilar manufacturers. Patent owners should consider bolstering patent protection through new filings on improvement inventions and taking advantage of patent term extensions. Biosimilar manufacturers may consider launching early patent challenges in court or at the patent office, particularly in regions where there are linkage regulations that can delay market entry while patent issues are reviewed.