Kluwer Patent Blog

AIPPI Milano – Similar but different

Vanessa Rieu (Bristows) · Tuesday, September 20th, 2016

Panel session 2 of the second day of the Congress was a discussion session about biosimilars. Moderator Dominic Adair (Partner, Bristows (UK)) led his panellists Fritz Reiter (Regulatory CMC Team Leader, Sandoz GmbH (AT)), Prof. Mei-Hsin Wang (National Yunlin University of Science and Technology (TW)) and Bryan Zielinski (Vice-President, Assistant General Counsel, Pfizer (US)) through a number of topics including data exclusivity, substitution and interchangeability, post grant patent challenges and a review of US and European case law. The panellists gave a broad range of perspectives from the technical, legal and regulatory viewpoint and covering the US, European and Asia-Pacific regions.

Some of the most interesting points arising during the discussion concerned the way in which the legal and regulatory frameworks for biologic products differ from small molecule products. In part, the panel agreed that this reflects the higher investment made into biologic reference products. In the US for example, the regulatory data protection (RDP) period is 12 years for biologics, versus 5 years for new chemical entities. However, in the EU, Japan and Australia, the RDP regimes are the same, whether for chemical molecules or biologics.

The higher level of investment into biosimilars was said to be a driver for certain features of commercial and litigation strategy. Biosimilars take twice as long to develop as chemical generics and the development process is between 50 and 100 times more expensive. This greater investment is likely to mean 2 things: biosimilars maybe more risk averse than small molecule generics when if comes to avoiding litigation, and injunctions in particular, and secondly there are likely to be fewer competitors in the marketplace.

Commercial factors play into interchangeability and substitution. Interchangeability is a US standard under the BPCIA legislation and it has yet to be attained. Nobody yet knows what will be required to achieve it but the panel were agreed that clinical trial switching studies between patients on the reference and biosimilar products were likely to be necessary. It was also suggested that with the passage of time will come greater comfort with the use of biosimilars and thus a higher likelihood that interchangeability will be granted. Interchangeability does not require any greater product purity or more detailed characterisation; it is purely a regulatory question rather than a technical one. It is, however, the ultimate commercial objective. Interchangeability unlocks the potential for a biosimilar to replace all sales of reference product because existing patients on the reference product can be given the biosimilar rather than only new patients as would otherwise be the case.

Pharmacy-level substitution was discussed. This is rare across the Asia-Pacific region, Professor Wang noting that countries such as Japan and Korea are naturally cautious. However, the Pharmaceuticals Benefits Advisory Committee in Australia has may “a-flag” products for substitution. With reference to slides showing maps of the US and the EU, the panel discussed the patchwork position on the question of whether substitution is acceptable. Generally the answer is no, but there are some countries such as France where substitution is being embraced, probably relating to limited healthcare budgets. In fact, the limited nature of any healthcare budget was said by the panel to be a reason why an equilibrium position should exist in the market penetration of biosimilars. If limited healthcare budgets must be able to fund the next generation of expensive innovator products, some money must be saved on older biologic products by the prescribing of biosimilars.

Finally, the panel discussed post-grant challenges and patent litigation cases to date, mainly by reference to the US and the EU. Bryan Zielinski discussed the pros and cons of inter partes review proceedings in the US compared with EPO opposition proceedings in Europe. Being relatively cheap, both procedures are being widely used to cut through the dense thickets of secondary patents protecting the world’s best selling products. Mr Zielinski also discussed the learnings to date from the BPCIA patent dance litigation in the US between Sandoz and Amgen. Although the case is now pending before the Supreme Court to decide certain procedural issues, the decision from the Court of Appeals for the Federal Circuit indicates that the patent dance is not mandatory, but if not used, it is mandatory to give 180 days notice of commercial marketing – acting, in effect, as an extended period of exclusivity for the reference product.

Dominic Adair finished the session by describing the latest developments in biosimilar litigation in the UK with reference to the Fujifilm v Abbvie proceedings. In these proceedings the biosimilar has requested that the court grant a declaration that the biosimilar products are already known or are obvious variants when compared to the state of the art at the priority date of certain patent families. Such a declaration, if made, would give the biosimilar products lifetime freedom from infringement risk under any pending divisional patent in the same family. It is too early to tell whether the court will grant such a declaration but so far the case has survived a strike out challenge so will proceed to trial next year. Dr Adair noted that the idea for granting such declarations dates back to the Arrow Generics v Merck case, concerning alendronate, about 10 years ago. The English case settled but in parallel litigation in the Netherlands concerning alendronate, the Dutch court did grant a declaration in favour of the generic, and in the terms sought.

Kluwer IP Law

increasingly global practice of IP law with specialized, local and cross-border information and tools from every preferred location. Are you, as an IP professional, ready for the future?

Learn how **Kluwer IP Law** can support you.

This entry was posted on Tuesday, September 20th, 2016 at 10:03 am and is filed under Biologics
You can follow any responses to this entry through the Comments (RSS) feed. Both comments and pings are currently closed.