Kluwer Patent Blog

Report from Rio (2): Personalised Medicine

Brian Cordery (Bristows) · Wednesday, October 14th, 2015

by Dominic Adair

Day 2 of AIPPI's 2015 Global Congress in Rio brought with it the Pharma Sessions: trade marks, personalised medicine and two sessions with a local flavour – technology transfer under the Brazilian Government's PDP programme (promoting local laboratories) and whether the practice of Brazil's regulatory authority (ANVISA) to challenge patents prior to patent office examination is compliant with TRIPS.

The personalised medicine session was chaired by João Luis Vianna of Kasznar Leonardos, Brazil, and dealt in turn with 4 key issues in personalised medicine: (i) the impact of the US *Myriad* case on patent eligibility; (ii) IP protection other than patents; (iii) R&D productivity; and (iv) promoting future investment. The speakers were: Adrian Looney (Pfizer, Inc. – USA), Wen Cao (NTD attorneys – China) and Hugo Caro (Ferrer International S.A. – Spain).

In relation to *Myriad*, and the US Supreme Court's decision excluding patents on products of nature, all panellists agreed that in the US, the case is having a chilling effect on the patenting of tools that are potentially useful to personalised medicine, such as biomarkers. More widely, in relation to oncology, Adrian Looney pointed out that since 1940, around 175 oncology products have been developed, 45% of which are products of nature – for example, taxol, a derivative of the yew tree. However, outside the US, *Myriad* has less impact. Wen Cao explained that isolated and synthetic genes are still patentable in China. China will not permit patents on methods of treatment or diagnosis but Ms Cao provided some helpful drafting tips to avoid the exclusion. Hugo Caro summarised the EPO position with reference to the Enlarged Board decision in G02/08, holding that the novelty of a second medical use claim may be based on the definition of an administration regimen, a new technical effect or the treatment of a sub-group of patients. He introduced an example of a recent patent granted to Ferrer International for a capsule containing tiny coated tablets of aspirin, a statin and an ACE-inhibitor, thereby allowing tailoring of the therapy to the patient.

On the question of non-patent IP protection, the panellists were also united in their view that the next best thing to patent protection was to maintain the innovation as a trade secret, albeit that this could have considerable disadvantages in the event of a breach of confidence, or the independent innovation of a competitor resulting in a blocking patent. Wen Cao summarised the recent Chinese case of *Eli Lilly v Huang* (2013) in which Lilly successfully restrained with an injunction a former employee who had downloaded 21 confidential documents to a memory stick.

As to R&D, Adrian Looney explained how the industry is moving towards a mixed model of in-house and external research partnerships. Using language that he acknowledged bore the mark of a consultant, he explained Pfizer's focus on "strengthening its research core, strategic externalisation and differentiated innovation thereby creating an engine for sustainable innovation". In plain terms, Pfizer is partnering with academic institutions to create "Centres for Therapeutic Innovation". This requires re-thinking traditional policies on IP, with an increased emphasis on sharing. Wen Cao provided some statistics to demonstrate that R&D is supported by a rapidly maturing patent system in China – patent filings having dramatically increased (from 1,427 in 1986 to 2,377,061 in 2013) and the court system has become more specialised with the introduction of IP courts in Beijing, Shanghai and Guangzhou in late 2014.

Finally, on the question of attracting investment, the speakers pointed to the need for governments to continue to find incentives for research. Adrian Looney had explained at the outset that Pfizer spends 7 billion dollars on R&D and, typical of the field, its oncology products in development suffer a 95% failure rate. Personalising medicine by tailoring the therapy to the patient's genome should improve the 5% success rate but only if the investment is incentivised, the R&D productive and the IP protection secure.

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