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## Biologics & Biosimilars: Innovator vs Competitor

Dominic Adair (Bristows) · Thursday, March 1st, 2018

The afternoon of the first day of C5's Pharma & Biotech conference in Amsterdam (27 February 2018) concluded with a lively panel session on biosimilars. Chaired by Bristows partner Dom Adair, the panel comprised Dr Corinna Sundermann (Senior Vice President, IP, Fresenius Kabi), Dr Lorenz Kallenbach (Corporate Patent Counsel, Merck) and Brian Coggio (Of Counsel, Fish & Richardson). All views expressed were personal.

The scene was set with reference to recent sales figures showing that the overwhelming majority of the world's biggest selling drugs are now biologics, and then a look at the number and variety of biosimilar products approved by the European Medicines Agency. Interestingly, and perhaps not surprisingly, the greatest number of antibody approvals relate to Humira (adalimumab), the biggest selling drug. The panel discussed the balance of interests between originator and biosimilar. With the level of investment much higher with biosimilars than small molecule generics, does this mean that biosimilars are more or less prone to litigation? The consensus view from the panellists from industry was that certainty on IP rights is more important than ever, so we can expect biosimiliars to adopt patent clearance strategies at an early stage. Inevitably, however, this has its own potential downsides if regulatory approval takes longer and one biosimilar clears the path only for another to enter the market first. Dr Sundermann emphasised that the balance of litigation risk usually favours the patent owner when it comes to provisional measures; typically, the damages paid to compensate a competitor for a wrongfully-granted preliminary injunction are significantly outweighed by the patent owner's profits made on its own product during the period of the preliminary injunction.

Also on the balance of interests, the panel discussed the proposal in Europe to have an SPC manufacturing waiver. This was where the debate became the most vigorous. Dr Sundermann summarised the arguments in favour: allowing manufacture within Europe during SPC term for export to non-SPC countries puts Europe on a more equal footing with other manufacturing countries, for example in Asia, and should serve to slow down loss of skilled jobs. It also puts biosimilar companies in a fairer market position in Europe: stockpiling during SPC term allows a day-one launch, post expiry. Anything longer affords a windfall of extra protection to the rights holder. As to the risk that product exported abroad might leak back to the EU, Dr Sundermann explained that drug products are a highly regulated market and product movement can be controlled. Dr Kallenbach provided the counter arguments: SPC waiver would erode originator patent rights and undermine R&D investment into new drugs. In particular, the manufacturing

waiver would complicate matters when it comes to enforcing SPC rights. Additional investigations may have to be made, including the identity of the market for which a certain EU-produced generic or biosimilar product is really targeted. Also, the overall economic benefit for the EU is questionable. Oftentimes European generic manufacturers compete particularly well with (European) originator products in countries outside the EU, which effectively leads to a replacement of higher value originator product with lower value generic product in these countries and an overall net loss in the EU export value. A straw poll amongst the audience indicated that the majority were against the manufacturing waiver, but the minority in favour was significant.

Against the backdrop of the recent Arrow declarations case law in the UK, and *Fujifilm v AbbVie* in particular, the panel then proceeded to discuss filing strategies and clearance strategies. Is there something about biologic products that attracts greater patent protection? Is that why dense portfolios of patents arise for products like Humira? Or is this just serendipity? AbbVie didn't break the EPO rules in setting up the patent estate around Humira that was the subject of the recent UK litigation. Are the rules fit for purpose? Whereas Dr Sundermann is in favour of more restrictive rules, Dr Kallenbach held that there are many legitimate reasons for filing divisional divisional applications and that the patent community as a whole should not suffer because of a few users stretching the rules. Instead, one should try to counteract behaviour, which Courts regard as abusive, by other means, such as the issuance of Arrow declarations. As for clearance strategies and the Arrow declaration itself, the panel were unsure whether such a declaration would be of greater value than a revocation decision when it came to persuade other judges in foreign courts. Would it be viewed as an oddity? Only time will tell.

The session concluded with an excellent presentation by Mr Coggio (also adjunct professor at Fordham Law School), running through the US patent dance procedure for biosimilar approvals under the BPCIA legislation and taking in recent case law decisions, including the US Supreme Court in *Amgen v Sandoz*. The procedure was contrasted with the more established Hatch-Waxman litigation for small molecules. One interesting difference between the two is that BPCIA allows for the assertion of process patents – something that could result in significant litigation given the complex manufacturing technology in biologic drug production.

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