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Fordham Conference 2015 – Biosimilars

Daniel Byrne (Bristows) · Thursday, April 9th, 2015

Penny Gilbert from Powell Gilbert LLP explains the position of biosimilars in the pharmaceutical industry. Biosimilars are essentially generic versions of biologics. Traditional generic compounds are chemical reproductions of the patented compound which makes regulatory approval more straightforward. Biological compounds (proteins or antibodies which are produced from genes) are not identical with one another and have higher hurdles in terms of achieving regulatory approval. The cost of bringing it to market is significant. Doctors may be less willing to prescribe biosimilars as compared to generic chemical compounds when considering the alternatives to the originator's product. Undertaking a clearance search and identifying relevant patents is not straightforward, but the generic interested in biosimilars will otherwise be at risk of an interim injunction.

She believes that blockbuster biologics are a potentially valuable market, but the stakes are high and there is ample incentive to litigate (either to clear the way or to preclude a launch). In light of a potential patent cliff up to 2020 she wonders whether the first cases in the UPC will be biosimilar cases.

Eric Stone (Paul Weiss) explains that it has been 5 years since the US Biologics Price Competition and Innovation Act ('BPCIA') was passed and there has been 1 approved product (and 6 lawsuits). The BCPIA created a (subsection 'k') pathway for approval of a Biologics License Application with provisions for expediting the license and a list of patents which are relevant to the applicant. The applicant can then decide its position in relation to those patents and a good faith negotiation might ensue for licensing. Failing that, the patentee must sue the applicant within 30 days otherwise they lose the ability to ever recover anything but a reasonable royalty (no injunction). Notice of first commercial marketing must be given by the applicant in advance and the patentee can seek a preliminary injunction in relation to patents which were listed but not previously sued upon (although it is not clear to this blogger how that fits with the 30 days bar to remedies over and above a reasonable royalty).

'Who', 'what' and 'when' is what the litigation is about.

Who does the statue apply to? Is it the reference product sponsor only (and not the patent owner); is it the applicant only (or the marketing partner)? Is giving notice before filing the BLA allowed if the notice just states that it will be marketed and it will take more than 180 days to get the license, so the product sponsor is on notice? The court has already said no, you have to have filed a BLA to give notice.

Is the remedy patent infringement or is there another way to enforce the act? [Note from the

blogger: this was a lot of information in a short time frame (9 minutes), so apologies to Eric Stone for any errors or omissions in this report].

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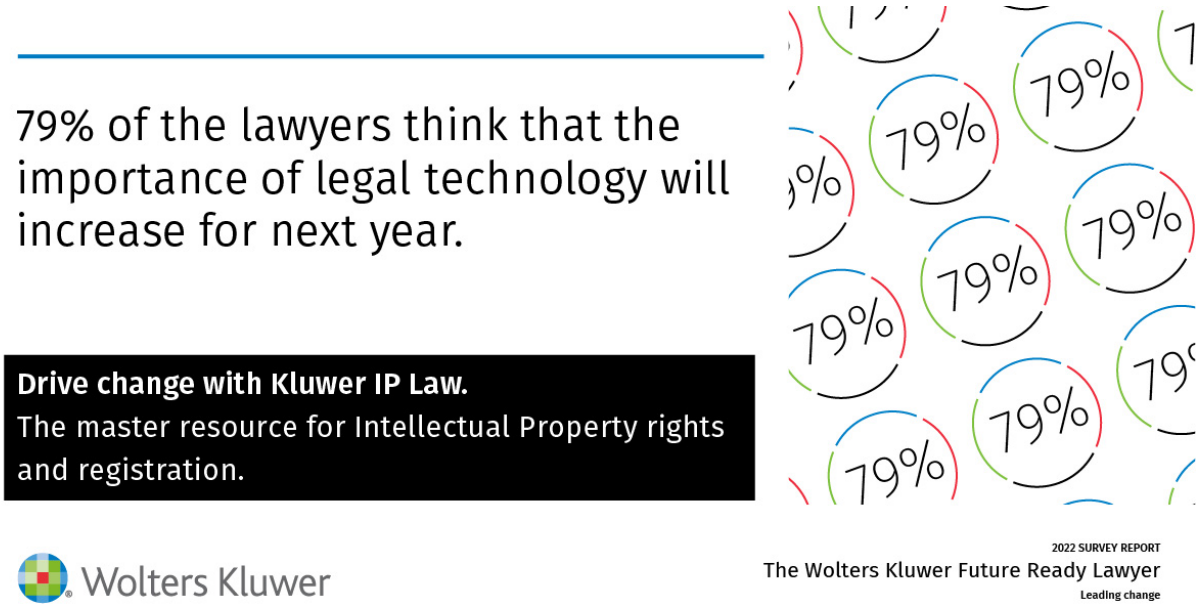

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