Kluwer Patent Blog

Fordham Conference 2015 – Second Medical Use Patents

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

Marleen H J van den Hors (BarentsKrans in the Netherlands) dealt with the interesting question of enforcement of second medical use patents and suggested that regulatory changes might be required to facilitate enforcement. She pointed out that there has been different interpretations of Swiss-style claims in the Netherlands and the UK leading to a different basis for enforcing, for example in relation to direct and indirect infringement.

Generics can carve out the patented indication from their marketing authorisation and should avoid promoting the product for that indication. The generics could also send warning letters to health authorities, prescribers, pharmacies and end-users. It is difficult to see what remedies the generics companies would have against customers, but patentees can sue the generic. Evidence takes on prime importance particularly where knowledge or intention is an issue. One indication is to look at the size of the market where it might be possible to presume that the generic knows that its product is over-supplying the legitimate market, but does this amount to adequate evidence?

Nicola Dagg (Allen & Overy) reminds us that second medical use patents exist to prevent competitors selling products for the patented purpose. The reality in relation even to products which have been carved out is that there is generic prescribing, prescriptions dont contain the indication and pharmacists are incentivised to cross-supply. She thinks that indirect infringement is the most important consideration, particularly for swiss-style claims. Any interpretation of a second medical use claim should bear in mind the public policy. She stated that generics cannot sit back and consider it someone else's problem, she thinks that generics can either seek to invalidate the patent or seek a DNI prior to launch of a 'skinny label' product. Although this blogger does not really see why the generic should need to do this if it does not intend the product be used for the patented indication. She also suggests that the generic could seek changes in practice in the way drugs are commissioned or prescribed. She also suggests that the generic can launch at reduced risk by using a removable label indicating that the product should not be prescribed for a particular indication (although it is unclear to this blogger if this will fall foul of regulatory hurdles).

Jurgen Dressel (Novartis) referred to thalidomide which was developed for morning sickness and later found to be useful for leprosy and multiple myeloma. There is a concerted action by pharma companies to explore other uses for medicines, but there needs to be protection to sustain the incentive. A second medical use patent will almost, by definition, extend protection beyond the term of the original indication. This is why carve out of indications is fair for generics. However, what may happen is cross label use which violates the second medical use patent, but is hard to enforce. One proposed solution (which has been ordered in the Netherlands) is for the reimburser

to make reimbursement conditional on being indication-specific.

Shimiko Kato (Abe, Ikubo & Katayama in Tokyo, Japan) points out that Japan is a large market for pharmaceuticals. Second medical use patents are available in Japan. A number of court decisions, including Supreme Court decisions (as early as 1999) deal with issues surrounding these patents. She essentially recommends that a Swiss-style claim be included in any patent (in addition to a purpose-limited product claim) in light of the case law she reviewed.

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