

Kluwer Patent Blog

NL – Second Medical Use – Too little, too late

Rik Lambers (Brinkhof) · Tuesday, June 6th, 2017

Second medical use cases have been making their way through patent courts around the world. In the *Novartis / Sun* litigation the Hague Court of Appeal (PI decision) and District Court (interlocutory merits decision) already provided their thoughts on indirect infringement in 2015. The Court of Appeal concluded that Sun did indirectly infringe Novartis' patent, while the District Court concluded Sun did not (see [this earlier post](#)). Now, in the same litigation, the Dutch Supreme Court (judgment 14 April 2017), and District Court (final judgment 5 April 2017) have provided food for some more thought.

The facts underlying the *Novartis / Sun* litigation will be well-known by now. In short, Novartis' patent relates to the (second medical) use of zoledronic acid in the preparation of a medicament for the treatment of osteoporosis (a Swiss type claim). Sun marketed its generic version of zoledronic acid for the treatment of Paget's disease and requested a carve out for the indication for osteoporosis. However, Sun won a tender from a health insurer, making no distinction between Paget's disease or osteoporosis. Sun's generic product was not only prescribed for Paget's disease (an expected 2,7% of the market), but also for osteoporosis (an expected 97,3%).

The Supreme Court confirmed the Court of Appeal's decision that Sun indirectly infringed Novartis' patent. The Supreme Court considered that uncontested was the Court of Appeal's finding that it was virtually ruled out that Sun's product was not also delivered and used for osteoporosis and that Sun therefore should know that its product, at the end of the vertical chain, would be delivered for the patented indication. The Supreme Court further considered:

“The Court of Appeal rightfully decided that – assuming indirect infringement of a [‘Swiss-type claim’] is legally possible – under such circumstances the conditions for indirect infringement [...] have been met. The Court of Appeal did not decide that Sun can be held accountable for third party behaviour on which it has no influence [...] What Sun can be accused of, according to the Court of Appeal is that it has done nothing – except for [a carve-out and e-mail to wholesalers and hospital pharmacies] to prevent that its product would be delivered for the treatment of osteoporosis. [...] It is not up to the court to indicate which measures a party to the proceedings such as Sun should have taken in a case like this. To the contrary, it is up to the party itself to show what it has done to prevent infringement. [...] Sun's asserted impossibilities to prevent the use of its product for the treatment of osteoporosis were not disregarded by the Court of Appeal. The Court of Appeal only charged Sun that it did not

sufficiently used the possibilities that were at Sun's disposal.”

The Supreme Court provided its judgment, in *PI* proceedings, a week after the Hague District Court had provided a *final* decision in the *merits* proceedings. In its 2015 *interlocutory* decision the District Court had decided that infringement of a Swiss type claim is legally impossible. The Supreme Court considered that the rule that a court in *PI* proceedings should align its decision with a merits court's decision does not apply in supreme appeal proceedings. The Supreme Court did (therefore) not go into the District Court's reasoning that indirect infringement on a Swiss type claim is legally impossible (but decided on the Court of Appeal's *assumption* that it was possible).

The District Court – having dismissed indirect infringement in its interlocutory decision–concluded in its final decision that Sun directly infringed Novartis' patent.

The District Court first considered relevant decisions from the German courts (LG Hamburg 2 April 2015, *Warner-Lambert v A Pharma*; OLG Düsseldorf 1 December 2015, *KKH v Pfizer*), and UK court (England and Wales Court of Appeal 28 May 2015 and 13 October 2016, *Warner-Lambert v Actavis*). The Hague District Court especially relied on the UK Court of Appeal judgments (e.g. incorporating paragraphs 113-133 of the 2015 judgment *ad verbatim*).

The District Court considered:

“The District Court is, in agreement with the parties and the above mentioned English case law, of the opinion that a Swiss type claim's term ‘for (the treatment of)’ includes a certain mental element of knowledge or foreseeability regarding the conscious use of the drug for the patented indication. This criterion is therefore taken into consideration in the further assessment.”

Sun asserted that only the knowledge or foreseeability of the actual manufacturer, and not of the (subsequent) trader / reseller, is relevant. Since not Sun but another entity (Sun India, not a party to the proceedings) was the manufacturer of the active ingredient, while Novartis did not assert the knowledge or foreseeability of this other entity, Sun did not directly infringe (still according to Sun).

The District Court dismissed Sun's argumentation. The District Court considered that the actual knowledge/foreseeability of the actual manufacturer is not (always) decisive. A patentee would be left empty handed if a party (trader/reseller) could instruct a third party to manufacture a product and then point to the absence of knowledge/foreseeability of this third party. Also in view of Sun's role in the trade of the generic product, the District Court considered Sun's intention relevant.

The District Court concluded that Sun had the relevant knowledge/foreseeability that its generic product would be used for osteoporosis. Considered circumstances were Sun not only having a marketing authorization for Paget's disease, but also for osteoporosis; Sun's knowledge of the practice that drugs are not prescribed on the basis of the indication; Sun's knowledge that the patented indication was not carved-out from the SmPC available from the Medicines Agency's online database; Sun not restricting its registration for a tender from health ensures to off-patent indications only; the market for Paget's disease being negligible; sales figures should have made Sun aware that its generic was not only prescribed for Paget's disease;

Having established Sun's knowledge/foreseeability that its generic would be prescribed for the patented indication, the District Court considered whether Sun "did everything in its power to prevent this use". The District Court concluded Sun did not, and summarized its actions as "too little, too late". Novartis claim for an injunction was granted.

The District Court's test ("did everything in its power to prevent this use") echoes the UK Court of Appeal's (par. 206 – 208 13 October 2016 judgment):

“206. (...) From an objective standpoint one would normally regard a person to intend what he knows or can reasonably foresee as the consequences of his actions. That is the test which I formulated in *Warner-Lambert CoA*.

207. If that is the basic test to be adopted, what is sufficient to negative the existence of intention? [...]

208. Viewed in this way I think the answer becomes clear. The intention will be negative where the manufacturer has taken all reasonable steps within his power to prevent the consequences occurring. In such circumstances his true objective is a lawful one, and one would be entitled to say that the foreseen consequences were not intended, but were an unintended incident of his otherwise lawful activity. (...)”

As to what everything (all reasonable steps) within the power of a party might be, the Dutch Supreme Court has made one thing clear: it is not up to the court to indicate which measures should (have been) taken, but to the party to show what it has done to prevent infringement.

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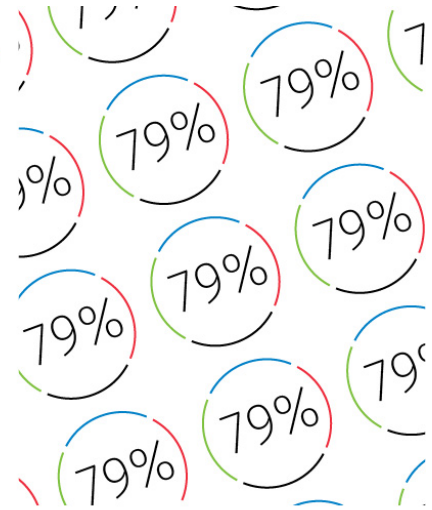
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