NOVARTIS v SUN PHARMACEUTICAL: A BATTLE OVER SECOND MEDICAL USE PATENTS

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In Europe, it is well established that a second medical use patent can be obtained for any second or further therapeutic use of a known drug, providing the use is novel and inventive. However, a recent judgment in the Netherlands highlights that this is a developing area of law, and that there is uncertainty.

Sun Pharmaceutical and Novartis have been in dispute over a second medical use patent, EP 1296689 ('689 patent), which relates to the treatment of osteoporosis using a specific acid, zoledronic acid. It was granted on September 21, 2005. Novartis developed a medicine with zoledronic acid as an active ingredient that is used in the oncological field. Novartis commercialises the product with zoledronic acid as the active compound under the trademark 'Zometa'.

Sun, which sells and distributes drugs, obtained a licence for generic zoledronic acid in the Netherlands on July 29, 2013. The licence covers the treatment of osteoporosis and Paget's disease, but Novartis already had a patent for the treatment of osteoporosis. At Sun's request, the indication for osteoporosis was deleted (carved out) from the summary of its product characteristics and patients information leaflet.

After the carve-out Sun participated in and won a tender organised by a health insurance company for the supply of zoledronate. The conditions of the tender forbade Sun from limiting its supply to the treatment of Paget's disease. Although Sun informed its customers that its medicine was exclusively intended for the treatment of Paget's disease and that the indication for osteoporosis was protected by Novartis's patent, Novartis started legal action.

Court rulings

In January 2015 the Court of Appeal held Sun liable in preliminary proceedings for indirect infringement of Novartis's '689 patent despite the carve-out of the osteoporosis indication from the summary of product characteristics and patients information leaflet. The Court of Appeal considered that Sun supplied too much of its zoledronate product in view of the size of the patient population for Paget's disease. Sun knew that its product was being used for the protected indication osteoporosis and had not taken sufficient action to prevent infringement further down the distribution chain.

On November 25, 2015, the District Court of The Hague disagreed with the appeal court's decision in final relief proceedings. The district court concluded that there was no indirect infringement of the Swiss-type second medical use claim. The *Novartis* case concerns purpose-limited process claims, which comprise the distinctive element "in the preparation of a medicament".

According to the district court, there is no other way to read this sentence in view of article 73 of the Dutch Patent Act. Sun's product is a so-called ready product: after Sun's supply of the medicament, no-one is actually applying the claimed process, ie, 'the preparation', since no wholesaler or pharmacist will use zoledronate to prepare a pharmaceutical composition.

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Novartis claimed that the 'preparation' should be considered the same as providing a purpose to the product. This is not the case, according to the district court, since a Swiss-type claim is considered a purpose-limited process, not like an EPC 2000 claim. Therefore, a ready-to-use product cannot be regarded as an essential component of an invention defined in a Swiss claim.

The dispute will continue with the question of whether generic suppliers can be accused of direct infringement. The district court, probably inspired by judgments of the English High Court, granted Novartis the opportunity to substantiate its claim further (the English court had decided accordingly in a similar dispute). The district court itself did not exclude the possibility of direct infringement. ■

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