

# Bayer / Sandoz: a step forward for Dutch patent law

Kluwer Patent Blog

June 10, 2016

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Please refer to this post as: Jan Pot, 'Bayer / Sandoz: a step forward for Dutch patent law', Kluwer Patent Blog, June 10, 2016, <http://patentblog.kluweriplaw.com/2016/06/10/bayer-sandoz-a-step-forward-for-dutch-patent-law/>

Claim construction and scope of protection are perhaps the most hotly contested topics in Dutch patent law. Over the last ten years, we have had no less than six Supreme Court decisions dealing with these matters. The latest development in this continuing saga is the Supreme Court's recent decision in *Bayer / Sandoz*, which offers an important update to the Supreme Court's earlier case law on claim construction. The case marks the first time that the Supreme Court explicitly rejected the earlier approach it had adopted in the late 1980s. As such, it is an important decision offering welcome clarification on a crucial issue of patent law. The case involved two Bayer patents, EP 0 918 791 ("EP 791") and EP 1 149 840 ("EP 840"), each claiming a process for manufacturing drospirenon (marketed by Bayer as Yasmin®), with the claims focusing on different steps in this process. In short, EP 791 specifically pertained to the step of oxidation of a certain precursor of drospirenon in the presence of ruthenium salt to obtain the intermediate compound 5β-OH-DRSP. EP 840 in turn pertained to water elimination from this 5β-OH-DRSP through addition of p-toluene sulfonic acid, or pTSA, to obtain drospirenon.

The process used by Italian company Industriale Chimica, which was responsible for manufacturing drospirenon Sandoz®, differed from the claimed methods in (at least) one aspect: instead of ruthenium salt, oxidation happened in the presence of TEMPO, an organic compound, and instead of pTSA, water elimination was performed through the addition of pyridine, a base, and water.

Both the District Court and the Court of Appeal rejected infringement. According to the Court of Appeal, the skilled person would assume that Bayer consciously chose ruthenium salt in EP 791; for that reason, the scope of protection does not extend to TEMPO. Furthermore, the interpretation of EP 840 by the skilled person would be that Bayer wanted to limit the patent to the use of the specific acid pTSA, because other ways of water elimination are disclosed but not claimed (and 'disclosed but not claimed is disclaimed'), for which reason the use of other compounds such as pyridine and water is outside the scope of protection of that patent.

It is these findings that were attacked by Bayer in Supreme Appeal. According to Bayer, the Court of Appeal should not have investigated whether Bayer made a conscious choice for ruthenium salt, but whether the skilled person would have good grounds to assume that Bayer wanted to relinquish part of the scope of protection to which it was entitled on the basis of the inventive concept underlying the invention. Moreover, according to Bayer, the rule 'disclosed but not claimed is disclaimed' can only be applied if the relevant subject-matter was disclosed in the application to the extent that it could actually have been claimed as an alternative without violating Article 123(2) EPC.

The latter argument is easily dismissed by the Supreme Court. It is the former argument that is by far the most interesting aspect of this case.

To understand Bayer's argument, one needs to be at least somewhat familiar with previous Supreme Court case law on scope of protection. As the Advocate General Van Peurse explains in his very thorough and highly readable advisory opinion to the Supreme Court, before the advent of the EPC (notably Article 69), the Dutch Supreme Court used to look at the 'essence of the invention' in order to determine the scope of protection. Scope of protection was determined by the inventive concept underlying the claimed invention. According to the Advocate General, this position lay somewhere between the 'classic' English and 'classic' German approach to claim construction, which were based on a (purely) literal reading of the claims and the *allgemeine Erfindungsgedanke* (the 'general idea of the invention'), respectively.

It was initially the position of the Supreme Court that the existing body of case law was in conformity with Article 69 EPC.

In the late 1980s, the Supreme Court had, based on this approach, formulated the rule that the inventive concept was to be considered the starting point when determining scope of protection, and that the protection could only be construed more narrowly if the description provided the skilled person with good grounds on the basis of which it could be assumed that the patentee had wanted to relinquish part of the protection to which he was entitled on the basis of the inventive concept (Supreme Court, *Meyn / Stork*).

Although the Supreme Court already determined in 1995 (*Ciba Geigy / Oté Optics*) that in the face of Article 69 EPC the inventive concept could no longer be considered the 'starting point', but only as a 'point of view' to be contrasted with the literal text of the claims, the "good grounds to assume relinquishment"-rule made a surprise (at least to some) comeback in the 2002 Supreme Court decision in *Van Bentum / Kool*. Although the Supreme Court has never referred to *Meyn / Stork* or *Van Bentum / Kool* since (while referring to *Ciba Geigy / Oté Optics* repeatedly), it never unequivocally distanced itself from these decisions either.

Although some practitioners had long thought *Meyn / Stork* and *Van Bentum / Kool* to be dead in light of more recent case law, others continued to argue that they still reflected the law; and it is the "good grounds to assume relinquishment"-rule from these decisions on which Bayer now relies in its Supreme Appeal.

Because Supreme Appeal in the Netherlands is only a legal review of the case below, parties challenging claim construction before the Supreme Court are always fighting an uphill battle. After all, claim construction is intimately related to the facts of the case. The last time the Supreme Court overturned a decision on scope of protection was in 2006 and Bayer was not able to break this streak.

The Opinion of Advocate General Van Peurse already did not bode well for Bayer: after giving an outline of the law on equivalence in all major European patent jurisdictions, he concludes that Bayer's argument does not square with claim construction according to Article 69 and the Protocol. It is no longer correct that scope of protection according to the essence of the invention can only be limited if it is relinquished. However, the Advocate General also provides an alternate route to uphold the decision of the Court of Appeals: an apparently conscious choice for ruthenium salt is a good reason to assume relinquishment of other ways to achieve oxidation.

Finally, on equivalents the Advocate General opines that Bayer has put the cart before the horse: the question is not whether the patentee relinquished equivalents, but whether the claims leave room for equivalents, taking into account a reasonable protection for the patentee and the legal certainty of third parties.

The Supreme Court's decision is mostly in line with the Advocate General's Opinion. The Supreme Court states unequivocally that insofar as Bayer's argument was that Court of Appeal failed to appreciate that in order for equivalents to be outside the scope of protection there must be a good reason on the basis of which the patentee relinquished that protection, it finds no support in the law.

The Supreme Court then goes on to say that the Court of Appeal rightly investigated whether the skilled person reading the patent would understand that the patentee made a conscious choice for ruthenium salt.

On equivalents the Supreme Court holds that the relevant question is whether the claims as interpreted by the skilled person in light of the drawings and the description leave room for equivalents, taking into account a reasonable protection for the patentee and the legal certainty for third parties. The Supreme Court adds that the will or intent of the applicant to relinquish that subject matter is not decisive in answering that question.

The Supreme Court's rejection of its earlier approach is certainly to be welcomed. As the Advocate General opined, the rule as formulated in *Meyn / Stork* and *Van Bentum / Kool* were not in line with Article 69 EPC. However, the Supreme Court's decision also raises new questions. Is investigating whether there has been a 'conscious choice' really different than what came before? Or does it really come down to the same thing, as the Advocate General suggests in his Opinion? What would be the case if the patentee *unconsciously* makes a choice for one alternative, perhaps through sloppy drafting, and how can the skilled person know the difference? And how does one reconcile the requirement of a conscious choice with the Supreme Court's statement that the will or intent of the applicant is not decisive? These and other questions will no doubt require another trip to Supreme Court to be resolved.

Notwithstanding the above, it at least seems the "good grounds to assume relinquishment"-argument can now finally be put to rest, which is a welcome development and opens a new chapter in the law on claim construction. That said, it is entirely possible that the Supreme Court will be called upon at least once more to confirm that *Meyn / Stork* and *Van Bentum / Kool* really are dead.

Full disclosure: Brinkhof acted on behalf of Sandoz in this case.