Dutch Patent Office limits protection of antibody patent in SPC case

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Peter Burgers (Brinkhof)

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In a decision of 7 September 2010, the Dutch Patent Office (NL Octrooicentrum) on appeal confirmed its earlier decision to not grant a supplementary protection certificate (SPC) for the medicinal product tocilizumab, a humanized monoclonal antibody against the human interleukin-6 receptor, which is approved as a human rheumatoid arthritis drug.

The applicant had requested an SPC based on a basic patent claiming "a monoclonal antibody to human interleukin-6 receptor". The Patent Office refused to grant an SPC because in its opinion the product tocilizumab was not protected by the basic patent under Article 3 (a) of the SPC Regulation, because it was not part of the "subject-matter" of the basic patent. Although the wording of the claims reads "a monoclonal antibody", and it was not in dispute that tocilizumab is in fact a monoclonal antibody, the Patent Office was of the opinion that the claim term "monoclonal antibody", read in the context of the patent description and examples, should be interpreted as being limited to monoclonal antibodies of murine origin. The reason for this being that the patent merely discloses examples of murine antibodies and a process for the production of antibodies involving hybridoma cell lines producing murine antibodies. The patent does in the opinion of the Patent Office not disclose a humanized monoclonal anti-interleukin-6-receptor antibody and therefore such a humanized antibody cannot be "protected by" this basic patent. The Patent Office referred to another case, on the application of an SPC for another humanized antibody, trastuzumab, in which the SPC was refused because the basic patent was limited to murine antibodies.

On appeal, the applicant argued that any monoclonal antibody against the human IL-6 receptor, so also a humanized antibody, would by literal wording fall within the claim, which reads on "monoclonal antibodies". The trastuzumab case was not a case in point because the claims of the basic patent in that case, unlike in the case at hand, were literally limited to murine antibodies. Moreover, the applicant argued that the Patent Office used the wrong test for Article 3(a), as it should have assessed the scope of protection under Article 69 EPC and not the "subject-matter" of the patent. Moreover, a relevant fact according to the appellant was that the SPC was granted in a number of other countries, among which the UK and Germany.

The Patent Office denied the appellant's arguments largely by repeating its earlier viewpoints. It added reference to the objective of the Regulation, i.e. to compensate a patentee for the time and effort involved in developing an approved pharmaceutical product. In this context it referred to a later patent (different patentee) which disclosed humanized anti-interleukin antibodies for which an SPC was indeed granted. This fact would concur with the objective of the Regulation because the patentee in that case had gone through the effort of producing a humanized antibody (which was approved, whereas a murine version of this antibody was apparently never approved for human use), which is something the applicant did not do.

Many comments can be made on this decision. A few of them are in order in the scope of this case comment.

In the first place, it appears that the Patent Office refuses to use the "infringement test", i.e. determining the scope of protection under Article 69 EPC (as this test was for instance used by Justice Kitchin in the matter of the Gilead SPC application – 31 July 2008 [2008] EWHC 1902 (Pat)). The test that the Patent Office purports to use resembles more closely the test used by Justice Jacob in Takeda – 2 April 2003 [2003] EWHC 649 (Pat) the "is-it-disclosed?"-test). This matter has proven to be controversial and of particular interest in the case of combination products vs. basic patents claiming only one of the components of the combination. On appeal from Justice Kitchin's decision in Medeva's SPC application, the court of appeal decided to refer questions to the ECJ as to what test should be used to determine whether a product is protected by the basic patent – 23 June 2010 [2010] EWCA Civ 700). However, going from the wording of the above Patent Office decision, the applicable test may not have been decisive, because the Patent Office considers that the claims read in the context of the patent specification should be interpreted as being limited to murine antibodies; a result it could just as well have reached applying Article 69 EPC.

Secondly, the Patent Office, in referring to the later patent in the name of different party, disclosing a humanized anti-IL-6 receptor antibody, which party was in its view rightfully awarded with an SPC, seems to link the efforts and time involved in developing a medicine to entitlement to an SPC. This is remarkable in view of the fact that the SPC can only be granted to the owner of the basic patent, whereas the developer and manufacturer of a human medicine is more often than not a third party, as is the market authorization holder. Many granted SPCs are owned by parties that have never developed a pharmaceutical product.

Thirdly, this decision of the Patent Office differs from earlier decisions in which SPCs were granted for humanized or human antibodies invoking a basic patent that merely discloses murine antibodies and the "traditional" production of antibodies by hybridoma cell lines. The latter practice seems fair because patents applied for in the pioneering days of monoclonal antibody research in the 1980s, usually only disclosed murine antibodies, and not methods of humanization of antibodies because murine antibodies were common in research at that time. It would seem unfair when the applicants of a whole generation of pioneering patents would be denied SPC protection because later developments improved monoclonal antibodies by humanizing them.