The Potential Power of Method Claims

This article provides a discussion of the recent judgement (5 July 2011) in the Patents Court in MedImmune Limited v Novartis Pharmaceuticals UK Limited and Medical Research Council (MRC) (*MedImmune v Novartis [2011] EWHC 1669 (Pat)*), concerning the alleged infringement of twopatents containing claims to antibody phage display screening methods by the antibody product ranibizumab (Lucentis). The judgement is long and detailed, however this article will aim to focus on some particular points of interest and some possible practical implications.

Interestingly, this judgement is the first to issue in a series of disputes between the parties around Europe (reportedly including France, Germany, the Netherlands and Switzerland). The UK judgement may well influence the outcome in other countries. However, this remains to be seen.

The pharmaceutical product ranibizumab is a monoclonal antibody product which is produced in the US by Genentech and sold by Novartis (under the trademark Lucentis) in Europe. Sales of Lucentis (which is used for the treatment of age-related macular degeneration, a condition involving retinal damage) reportedly generated around $1.5 billion for Novartis last year.

MedImmune alleged that sales of ranibizumab in the UK were an infringement of two related patents EP(UK)774511 ("511") and EP(UK)2055777 ("777"), jointly owned by MedImmune and the MRC. The claims in issue were claims 5-8 of 511 and claim 1 of 777, which are method claims which relate to a screening technique called phage display, which was used to screen libraries of antibodies to identify antibodies with desired binding properties. Importantly, for the question of infringement, claim 8 of 577 and claim 1 of 777 included further steps requiring the production of the antibodies.

As the patents did not contain product claims and ranibizumab was made outside the UK, this meant that MedImmune could only allege infringement under section 60(1)(c) of the UK Patents Act 1977, which provides for infringement of process claims by "any product obtained directly by means of that process". Thus, for there to be infringement under this section, ranibizumab had to have been made in accordance with the claimed process, and to be a product *obtained directly* by the claimed process.

Novartis disputed the alleged infringement and counterclaimed for revocation of the patents. In deciding on the question of validity the Judge, Mr Justice Arnold, had to consider the issues of priority, obviousness, sufficiency and added matter. On these points, the Judge found against MedImmune in respect of priority and obviousness. Regarding infringement, the Judge held that ranibizumab did not infringe the patents as it was not produced by a process falling within the scope of the claims. The Judge, however, indicated clearly that the product would have infringed the patents as a direct product of the claimed processes under section 60(1)(c) of the UK Patents Act 1977, had it been produced in accordance with the claimed process.

In connection with the issue of priority, although no explicit reasons were given, MedImmune accepted that the patents were invalid if they were not entitled to claim priority from one particular priority application. The claims were found not to be entitled to this priority date and thus both patents were held invalid.

Despite this finding of invalidity on the priority point, the obviousness attack was considered by the Judge in full. Two prior art disclosures were key in this consideration, both of which occurred before the first priority date and were therefore available as prior art irrespective of whether the patents were priority entitled. The first was a published scientific paper, over which the patents were found to be not obvious. The second was a talk given by Professor Smith (an author on said scientific paper) in which he encouraged the carrying out of methods in accordance with the claims, over which the patents were held to be obvious.

It is noteworthy that with regard to the issue of obviousness, the Judge relied heavily on the expert evidence which was available to him in accordance with UK procedure, notably from Professor Smith himself. Indeed, the Judge noted that the availability of such expert evidence was what allowed him to reach a different conclusion on obviousness than had previously been reached by the EPO Opposition Division on a related European Patent in which Professor Smiths's talk had been cited as prior art, but the EPO did not have the benefit of evidence from Professor Smith. The issue of evidence may be relevant when the parallel proceedings in other European countries are decided, as not all countries deal with expert evidence in the same way as the UK courts.

Regarding infringement, the Judge's construction of the claims (again aided by expert evidence) meant that the process by which ranibizumab was produced did not fall within the scope of the claims. Thus, there was no infringement as ranibizumab could not then be held to be a product obtained directly by the claimed process.

However, a point of interest is the Judge's clear indication that "if ranibizumab was produced by a process falling within claim 8 of 511 and claim 1 of 777, it would be a product obtained directly by means of that process. On that hypothesis, Novartis would have infringed those claims ....".

Thus, in this case, despite the absence of product claims, the method claims, which were essentially directed to a screening method by which antibodies could be identified, with final steps (included either in the subclaim 8 of 511 or in the main independent claim 1 of 777) which related to steps of producing the antibodies, were potentially enough for a finding that ranibizumab infringed the claims. The final steps in the relevant claims were key to the position on infringement. The invention, if any (bearing in mind the finding of invalidity) did by no means lie in these final steps; it lay in the phage display screening technique and the final production steps were acknowledged to be routine. However, the inclusion of these steps made the difference between the ranibizumab product being a potential infringement or not.

In determining whether ranibizumab might be a product obtained directly by the process, the Judge endorsed the application of the loss of identity test in *Pioneer v Warner ([1997] RPC 757)*. Novartis had apparently accepted that, had there been a finding that the process for producing ranibizumab was within the claim scope, then ranibizumab could be described as a product obtained directly by the process of claim 8 of 511 and claim 1 of 777, if the loss of identity test was applied. Novartis argued however that it was not right to apply this test without qualification for claims such as these, where, as discussed above, it is only as a result of the inclusion of non-inventive manufacturing steps that infringement could be alleged. Although the Judge indicated that this argument was attractive, his finding was that he could not accept it and that he was bound by *Pioneer v Warner*.

This case serves to illustrate that method claims, in this case screening method claims, can potentially be powerful and might result in highly useful protection. Here, claims directed to a screening technique could have been found to cover a commercially valuable antibody product identified using that technique.

Ultimately, the patents were held to be invalid and the Judge construed the claims such that the methods used to produce ranibizumab were different enough to the claimed steps to mean that there was no infringement. However, if these differences had not been present, the clear indication is that the method claims would have been infringed by the antibody product.

This case does thus serve as a reminder to practitioners when drafting patent applications to take into account the fact that in many jurisdictions a process claim confers protection to the "direct product" of that process. To maximise such protection, it is however important to ensure that claims are included with steps that result in the production of the final commercial product.

Thus, as a hypothetical example, if the invention resides in a new and useful transgenic plant, the seeds of which, when processed, provide an oil with useful nutritional properties, then, to maximise protection for the commercial products (such as the oil), dependent claims referring to extracting the oil from the seeds could prove highly useful. In cases (such as the present one) of an invention relating to a screening method, it is advisable to include steps in at least one claim which effectively transforms the information output of the screening process into a physical or manufactured product to ensure that any commercial product is obtained directly by the claimed process.

As regards the future of this dispute, it is reported that MedImmune will be seeking permission to appeal. Thus, it is likely that this Patents Court decision is by no means the last word on this case in the UK. The judgement also indicates that another hearing is to be scheduled to hear further questions regarding issues of priority entitlement.

MedImmune may face further hurdles. Both 511 and 777 expired in July 2011, but there is an Opposition pending on 777 at the EPO (filed by Novartis). Although the Opposition Proceedings are at an early stage, it is thus still possible that the EPO could revoke the 777 patent. Further, any Decision of the Opposition Division may be appealed. Central revocation by the EPO would have the effect as if the patent never existed in each of the EPC contracting states in which it was validated. As an added point of commercial interest, although 777 has now expired, there is a granted SPC in the UK (and possibly in other countries) in respect of ranibizumab extending any protection conferred by the 777 patent in respect of ranibizumab (should the patent be in force) to 2016. As the validity of the SPC is tied to that of the patent, the fate of 777 (and in turn its SPC) is potentially important to future as well as past sales of ranibizumab.

For all these reasons, it appears that we will be following this case with interest for some time to come.

Deborah Owen, Partner
First published in Intellectual Property Magazine, November 2011

United Kingdom

Dehns
St Bride's House
10 Salisbury Square
London
EC4Y 8JD

T: +44 (0)20 7632 7200
F: +44 (0)20 7353 8895
E: mail@dehns.com

Dehns
Aspect House
84-87 Queens Road
Brighton
BN1 3XE

T: +44 (0)1273 244200
F: +44 (0)20 7353 8895
E: brighton@dehns.com

Dehns
Willow Court
West Way
Oxford
OX2 0JB

T: +44 (0)1865 305100
F: +44 (0)20 7353 8895
E: oxford@dehns.com

Germany

Dehns
Singlspielerhaus
Sendlinger Str. 29
80331 Munich

T: +49 89 2422 8130
F: +49 89 2422 8140
E: munich@dehns.com

www.dehns.com