

# EIP



## So when is a patent claim too broad?

In Regeneron Pharmaceuticals Inc v Genentech Inc [2013] EWCA Civ 93 the Court of Appeal dismissed the claimants' appeal, rejecting all their arguments in respect of construction, infringement, novelty, inventiveness, and sufficiency. The court preferred the first instance finding that the patent was valid and infringed. The case therefore confirms that a broad claim encompassing a large number of unexemplified embodiments can be valid and enforceable.

### **Background**

Genentech's patent (EP 1238986) described therapeutic agents for the treatment of a range of diseases by preventing excessive blood vessel growth (angiogenesis or neovascularisation). In particular, it was concerned with Vascular Endothelial Growth Factor antagonist antibodies (anti-VEGF) and the patent claims were limited to treatment of non-neoplastic diseases.

On the other hand, the claimants were planning to launch a product for the treatment of age-related macular degeneration of the eye (ARMD), called VEGF Trap Eye (VTE) – now known by its brand name "Eylea". Regeneron developed the product, and Bayer was the licensee.

### **Decision - Court of First Instance**

The Claimants decided to apply to revoke the patent (on grounds of lack of novelty, lack of inventive step and insufficiency) and also requested a declaration of non-infringement. However, Genentech, the Defendant, counterclaimed that VTE infringed their 1992 patent.

The main disputed claim

"Use of a hVEGF antagonist in the preparation of a medicament for the treatment of a non-neoplastic disease or disorder characterised by undesirable excessive

neovascularisation, wherein the hVEGF antagonist is: (a) an anti-VEGF antibody or antibody fragment; (b) an anti-VEGF receptor antibody or antibody fragment; or (c) an isolated hVEGF receptor.”

The claim covers a wide range of ailments and proposed treatments, so coupled with previous case law on inventive step and sufficiency, the claimants believed the patent was invalid because “it merely provides information about the known use of VEGF antagonists and their use for treating disorders” and because its claims are speculative and covered a “huge range of non-neoplastic diseases and disorders without the experimental work needed to support them”.

#### Lack of inventive step

This argument was based on a piece of prior art (citation: Kim 1992), which disclosed antibodies to VEGF, but it did not directly or unequivocally disclose the therapeutic application of those antibodies in the treatment of disease and it did not specify any particular medical use. This was enough for Floyd J to find an inventive step.

#### Insufficiency

The claimants sought to claim insufficiency on a number of grounds. However, Floyd J rejected all of the arguments for a number of reasons, the most salient being: “the patent discloses a principle of general application within the meaning of the authorities insofar as it claims anti-VEGF antagonism as a treatment for all non-neoplastic diseases”. This meant that whilst he considered the invention claims to be broad, they were not insufficient.

#### Infringement

Floyd J held that VTE is part of a receptor for VEGF, and thus was an effective antagonist of which could sufficiently bind to VEGF to bring about a therapeutic effect. Therefore, VTE infringed part (c) of the claim in the patent.

### **Decision - Court of Appeal**

The appellate tribunal agreed with Floyd J and dismissed the appeal.

The claimants appealed on all possible grounds. However, of most interest was their challenge of Floyd J’s ruling to construe the meaning of “a medicament for the treatment of a non-neoplastic disease or disorder characterised by undesirable excessive neovascularisation” differently from the definitions put forward by any of the three parties.

Floyd J was not attracted by the interpretation given by either party and concluded that

the words should be given their plain meaning. He held that the claim did not require that the anti-VEGF treatment must be effective to treat the disease or any of its clinical symptoms, so long as there was some effect on angiogenesis. Kitchin LJ agreed with Floyd J's interpretation.

As to the arguments put forward for insufficiency, Kitchin LJ supported Floyd J's well-reasoned judgment and further added that "A claim for an invention of broad application may properly encompass embodiments which may be provided or invented in the future and which have particularly advantageous properties, provided such embodiments embody the technical contribution made by the invention. VEGF-Trap does indeed embody the technical contribution made by the patent; it has a therapeutic effect in patients suffering from ARMD by treating the angiogenesis associated with that condition, and it does so by binding to VEGF and inhibiting its biological activity. VEGF-Trap is therefore one of those improvements which Lord Hoffmann had in mind in Kirin-Amgen".

### **Comments**

Both Courts concluded that whilst the claims were broad, they were not insufficient. Although the first instance ruling raised a few eyebrows as to whether the scope of the claims was appropriate given the actual contribution made by the inventors, Kitchin LJ was clearly of the view that it was, and in doing so, confirmed the value of claiming inventions broadly where the underlying invention permits it. We now wait to see whether there is any appeal to the Supreme Court.

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