Federal Circuit hinders ability of pharmaceutical companies to claim broad antibody classes

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To incentivise the free flow and exchange of innovation, the patent system awards public disclosure of a novel invention with the right to exclude others from making or using the disclosed invention for a limited period. An important aspect of the public disclosure prerequisite includes a written description sufficient to convey that the applicant possessed the claimed subject matter at the time of filing. However, showing possession can often be a difficult hurdle, particularly when the claimed invention includes a large family or genus of pharmaceuticals directed to a single biological target. This requirement becomes even more onerous if the patent discloses only a limited number of members or species within the larger family of therapeutics.

In *Amgen v Sanofi* the US Court of Appeals for the Federal Circuit further confounded the process of claiming a broad genus of therapeutics – namely, the court allowed for the admission of post-priority date evidence to evaluate whether the specification discloses a representative number of species sufficient to support a claim to the entire genus. Further, the court held that simply characterising the antigen to which the claimed genus of antibodies bind is often insufficient to meet the statutory requirements of disclosure, especially when claiming a diverse genus.

Facts

Amgen owns US Patents 8,829,165 (the '165 patent) and 8,859,741 (the '741 patent), which generally claim a genus of monoclonal antibodies that bind to certain amino acid residues of a protein called PCSK9. In so biding, the therapeutic antibodies neutralise PCSK9 activity to facilitate the clearance of low-density lipoprotein cholesterol from the bloodstream. Amgen sued Sanofi, claiming that Sanofi's product fell squarely within the broad genus claim of Amgen's patents. In response, Sanofi argued that Amgen's patents had failed to provide an adequate written description. Specifically, Sanofi asserted that the '165 and '741 patents did not provide a sufficient number of species to show possession of the entire claimed genus of antibodies.

Although Amgen's patents claim a specific genus of antibodies, the language of the independent claims failed to recite structural features of the antibody itself. Rather, the claims functionally described the antibody as being capable of binding to any one of the recited amino acid residues of PCSK9. Therefore, the claims described what the antibody does (bind to PCSK9) rather than what the antibody is.

Amgen disclosed the structure of only two antibodies in the asserted patents. While Sanofi's product fell within the scope of Amgen's claims, the product's structure was markedly different than the structures disclosed in the '615 and '741 patents. This suggested that Amgen's claimed genus was fairly broad, potentially encompassing thousands of antibodies. Consequently, Sanofi sought to introduce the structure of its product in court as evidence that Amgen's disclosure of only two structurally distinct antibodies was insufficient to show possession of the entire claimed genus. However, since Sanofi's product was produced after the priority date of Amgen's patents, the district court excluded Sanofi's evidence.

Federal Circuit decision

The Federal Circuit held that, although the entry of post-priority date evidence is not allowed to show the state of the art at the time of patent filing, such evidence may be introduced for the purpose of showing that a patent failed to disclose a representative number of species. Here, Sanofi proffered the evidence of its compound's structure for just such a purpose: to highlight that the claimed genus was so diverse that disclosure of only two structural examples was insufficient to meet the written description requirements. The Federal Circuit held that the district court had improperly excluded such evidence, which created new precedent for the admission of post-priority date evidence in patent infringement lawsuits.

Further, Sanofi appealed the lower court's decision to allow the jury to rely on the "newly characterized antigen" test in evaluating the adequacy of the written description. Under this test, when functionally claiming an antibody (eg, an antibody that can bind to a specific protein), sufficient written description can be achieved by fully characterising the protein to which the antibody binds (the antigen).

On appeal, the Federal Circuit held that reliance on this test, particularly when such a diverse array of antibodies falls within the claimed genus, is improper. According to the court, reliance on such a test "allows patentees to claim antibodies by describing something that is not the invention, i.e. the antigen". Therefore, the newly characterised antigen test "contradicts the statutory '*quid pro quo*' of the patent system where one describes an invention, and, if the law's other requirements are met, one obtains a patent".

Comment

This decision is important for life sciences intellectual property and could significantly impact pharmaceutical compound patenting. Under this holding, existing claims to a large genus of antibodies are far more likely to be invalidated for lack of written description if challenged. Further, the strategy of drafting broad patent claims in an effort to cover a wide array of drugs that target a specific biological process will likely be inadvisable, particularly if the genus is made up of a diverse population of species. Therefore, in drafting patent applications to monoclonal antibodies, applicants should create a few 'picture claims' that incorporate a genus with specific structural limitations (eg, sequence identifications or complimentary-determining regions) that include the product that the company wishes to market. For those still interested in cornering the entire market, such claims could be made to depend on the broader genus-type claim, which would insulate against complete patent invalidity while providing some scope to cover species that may not be identical, but are similar to the patentee's product.

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