

Design-around biotechnology patents

An analysis of US federal circuit decisions shows the possibility of designing around biotechnology patents

Shyh-Jen Wang

Division of Experimental Surgery; Department of Surgery; Taipei Veterans General Hospital and the Institute of Hospital and Health Care Administration and Institute of Biomedical Engineering; National Yang-Ming University; Taipei, Taiwan Republic of China

In order to demonstrate the possibility of design-around for patents, we reviewed 40 no-infringement cases out of all 4,760 Federal Circuit Court of Appeals (CAFC) cases decided from 2001 to 2009. Based on this analysis, designing around a biotechnology patent first requires a thorough reading of the patent specification and prosecution history. These written descriptions offer explicit directions about claim meanings or the scope being disclaimed. By statute, claims recite and define the structure or acts of an invention, and serve as tools to determine whether or not a patent is infringed. The next procedure would include omitting a part or property from the claim, reversing the action used in the claim or changing the claim's structure or range to prevent the new design from falling within the scope of the claim. However, cases where patent infringement was found demonstrated that changing the structure or range not recited in the claim, such as enlarging the diameter, reducing concentration or alerting the shape, still falls within the scope of the patent. Although the 40 cases analyzed in this study were not related to vaccines, the thought process can serve as a guideline for patents related to vaccine development.

Introduction

The patent system is organized to encourage innovation: a government grants the patentee the right to exclude others from practicing the technical development for

a certain amount of time, in return for disclosing the innovation. The exclusive right may deter competitors from introducing technologically similar inventions, push competitors who have introduced technologically similar inventions to withdraw from the market or block competitors from patenting.¹ For example, GlaxoSmithKline, Sanofi Pasteur, Merck, Chiron and Pfizer/Wyeth respectively own 9, 17, 73, 30 and 42/41 US-issued patents related to vaccines up to October 5, 2010.

Even though big vaccine companies have owned many patents, there is always a chance to innovate. Moreover, inventors have legitimately designed around patents, building devices or devising processes similar to but not infringing on patent-protected inventions.^{2,3} Our previous investigation⁴ demonstrated that avoiding all elements of a patent claim would be the first choice for designing around a patent. The prosecution history estoppel would be the second best option for avoiding patent infringement and seeking the non-equivalent substitution of element(s) would be another alternative for designing around a patent.

However, designing a device or process to avoid all elements of a patent claim is not straightforward. In particular, one can never be sure that designing around a patent is sufficient to avoid patent infringement until a judge or jury has made that determination. Nevertheless, the courts have a precedent on these issues. The alleged device or process might not have been intended to be designed around a

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Correspondence to: Shyh-Jen Wang;
Email: wangsj@vghtpe.gov.tw

patent, but the opinion of the court serves as a good predictor of rulings on the irksome question of patent infringement. The cases where no infringement was found, therefore, serve as guidelines for an invention's development. It should be mentioned that these court cases were not related to vaccines in particular. However, the guidelines for biotechnology would be applicable for patents relating to vaccine development given that vaccines are biotechnology products, and thus offer meaningful guidance to companies in the vaccine field.

Analyzing CAFC Decisions

In order to demonstrate the possibilities of designing around a patent by avoiding all elements of a patent claim, we reviewed all 4,760 Federal Circuit Court of Appeals (CAFC) cases decided from 2001 to 2009. Among those decisions, there were 1,341 patent related cases, including infringement, invalidity, claim reconstruction and others. We further limited our analysis to the 80 out of 300 cases in which the CAFC discussed the infringement issue related to biotechnology. Analysis showed that CAFC affirmed 40 literal infringements including 28 successful design-around cases and 12 failure cases.

Analyzing these 28 successful cases, we categorized the design-around methodologies for biotechnology-related patents to include omitting a part or property from the claim, reversing the action/s used in the claim and changing the claim's structure or range.

Omitting a part or property from the claim. The literal infringement of a claim occurs when every limitation recited in the claim appears in the alleged device. Therefore, if one or more elements are omitted, the simplified design very likely does not fall within the scope of the claim.⁴

Example 1. Biagro western Sales Inc., et al. vs. Grow More Inc., (2005/9/13).

The patent was a concentrated phosphorus fertilizer comprising at least one phosphorous-containing acid or salt. The alleged product is a phosphorus fertilizer made by mixing phosphorous acid with potassium hydroxide and water. However, the final alleged product did not contain

any phosphorous acid as claimed. CAFC affirmed no infringement based on the ingredient used to make the alleged fertilizer but not actually present in the final product. Making the product without one or more elements recited the claim should not fall within the scope of the claim.

Example 2. Tap Pharmaceutical Products Inc., et al. vs. Owl Pharmaceuticals, L.L.C., et al. (2005/8/18).

The patent owners marketed a sustained-release formulation for treating prostate cancer under the trade name Lupron Depot. Not only did all of the 31 examples in the specification describe the use of particles containing a drug and a drug-retaining substance, but the specification provided that a drug-retaining substance "must be used in sufficient amount to ensure that the initial viscosity of the inner aqueous layer in the water-in-oil emulsion." The alleged product did not contain drug-retaining substance, and therefore did not infringe the patent.

Example 3. Kemin Foods vs. Pigmentos Vegetales Del Centro S.A. De C.V. (2006/9/25).

The patent in this suit included process and product claims pertaining to purified lutein that was extracted from plants. The patent specification mentioned several times that the purified lutein was required to contain no traces of any toxic chemicals. The alleged products contained traces of toxic chemicals, even though the levels of those toxic chemicals may not be high enough to cause illness or death in humans. Therefore, the alleged product did not fall with the scope of the claim.

Example 4. PSN Illinois LLC. vs. Ivoclar Vivadent Inc. (2008/5/6).

The patent claimed a method of fabricating porcelain veneers for teeth and included a term of "ready to mounting on teeth." The alleged process was to remove a sprue from the veneer and to shape the edge of the veneer. The specification disclosed the term of "ready to mounting on teeth" to be "substantially fabricated" to be "ready for mounting." The alleged process was not "ready for mounting" once the investment material was eroded, and thus the summary judgment of no infringement was appropriate.

Reversing the action used in the claim.

Reversing the action used to solve a problem would be one of the major inventive principles.⁵ From the perspective of patent infringement, the reversing an action would avoid the "all-elements rule",⁴ and could prevent the new design from falling within the scope of the claim.

Example 1. Ballard Medical Products vs. Allegiance Healthcare (2001/10/9).

The patents involved ventilating and aspirating tracheobronchial catheters. The patentee explicitly represented during prosecution that the prior art valves were "pressure valves," while the valve disclosed and claimed in the application was a "vacuum valve." The alleged devices used a pressure valve to design around the vacuum valve claimed in the patents.

Example 2. Summit Technology Inc. vs. Nidek Co., LTD., et al. (2004/3/26).

The patents involved laser eye surgical apparatuses and techniques to correct vision problems. The alleged devices adopted a bell-shaped energy distribution and thus ablated non-uniform depths of corneal tissue, rather than ablating approximately the same depth of corneal tissue as claimed. The patentee failed to present that the alleged device resulted in a substantially uniform depth of ablation across each pulse, and thus CAFC affirmed no infringement.

Example 3. Koepnick Medical & Education Research Foundation vs. Alcon Laboratories (2005/12/28).

The patent involved a surgical method with an improved microkeratome capable of cutting lamellar and lenticular shaped disks from the eye. The alleged procedures of infringement utilized a laser to ablate the tissue, which had been vaporized into a gas and therefore had no shape. The specification and prosecution history supported an understanding of the term "excising" as "cutting out," and therefore no infringement was affirmed.

Example 4. Safecare Manufacturing vs. Tele-Made (2007/8/3).

The patent disclosed a variable width bariatric modular bed that was particularly suitable for obese patients. The patent claimed deck sections for exerting a pushing force to cause the deck sections to rotate upwardly. The patent description further repeatedly emphasized that the

motor of the patented invention applied a pushing force, not a pulling force. The alleged bed was vice versa and rotated upwardly through use of exerting a pushing force.

Changing the claim's structure or range. The "all-elements rule" requirements are such that each limitation of the claim must be expressed in the alleged structure.⁴ Therefore, changing the limitation of a claim, such as the structure or range, would prevent the design-around from falling within the scope of the claim.

Example 1. Forest Laboratories vs. Abbott Laboratories, (2001/2/13).

The patents, developed as Survanta[®], disclosed a lung surfactant composition for treating respiratory distress syndrome in premature babies. Most of the claims included the term of "based on the dried weight of the material." The alleged product, Infasurf[®], was an off-white suspension. The assignee had no way of proving that the suspension contained a composition corresponding to the claimed surface active material with the percentage of water based on the dry weight.

Example 2. Biovail vs. AndrX Pharmaceuticals (2001/2/13).

The patent, marketed as Tiazac[®], was a once-a-day drug used to treat hypertension and angina. The patent claimed a wetting agent in admixture with its components. However, the alleged product comprised a sugar/starch core surrounded by a mixture of the compositions. According to the specification, the "admixture" limitation in the claim must be homogeneous. The patentee hardly contended that the alleged product was homogeneously admixed in the dry state. Furthermore, the patent owner also failed to prove by a preponderance of evidence that the alleged product forms a homogeneous admixture in the body. Therefore, the alleged product did not meet the "admixture" limitation of the claim either in the dry state or in vivo.

Example 3. Rheox vs. Entact (2001/01/08).

The patent involved to an inexpensive method of remediating lead from lead-contaminated soil by application of a composition primarily comprised of "calcium orthophosphate." The patentee disclaimed monocalcium orthophosphate and triple superphosphate during the prosecution of

the patent application. Thus, the alleged product comprising of monocalcium orthophosphate and triple superphosphate did not infringe upon the patent.

Example 4. Abbott Laboratories vs. Syntron Bioresearch Inc. (2003/7/10).

The patent involved devices and methods for performing chemical analysis related to the immune system and its reactions. The patent claimed a labeled antibody specific for, and bound to, an analyte or reaction product. However, the reactant employed in the alleged devices binded identically with the analyte. CAFC concluded that the jury could have reasonably determined that the reagent did not meet the recitation as construed by the district court in the instructions and affirmed by the verdict of non-infringement.

Example 5. Abbott Laboratories vs. Novopharm (2003/3/20).

The patent, under the trade name TRICOR[®], claimed a composition containing a co-micronized mixture of particles of fenofibrate and a solid surfactant. The alleged product involved pre-micronizing fenofibrate and in the absence of solid surfactant. Based on the explicit definition in patent specification and the all-elements rule, CAFC affirmed that the district court did not err in granting a summary judgment of non-infringement.

Example 6. Biogen vs. Berlex Laboratories (2003/1/31).

The patent related to recombinant DNA technology and the production of human interferon. The patent claimed IFN β from Chinese hamster ovary cells and in the amount of 150,000–600,000 IU/ml of medium. The final interferon concentration of the alleged composition exceeded 1,200,000 IU/ml. CAFC agreed with the district court's correct claim interpretation and affirmed the summary judgment of non-infringement.

Example 7. Goldenberg, et al. vs. Cytogen Inc., et al. (2004/6/23).

The patent claimed a method for detecting and localizing tumors by targeting "intracellular marker substances" that were produced by or associated with tumor cells. The alleged product, prostate specific membrane antigen, was a transmembrane antigen, and thus did not fall within the scope of the patent.

Example 8. Novartis Pharmaceuticals Corp., et al. vs. Eon Labs Manufacturing Inc., (2004/4/2).

The patent discovered a formulation for administering cyclosporin as a hydrosol, an important immunosuppressant drug typically administered to organ transplant patients to reduce the risk of rejection. The specification and prosecution history defined the term "hydrosol" to be limited to a medicinal preparation consisting of a dispersion of solid particles in a liquid colloidal solution prepared outside the body. The alleged capsules that contained cyclosporin dissolved in a small amount of ethanol, and therefore were outside the scope of the patent.

Example 9. Glaxo Wellcome Inc., vs. Impax Laboratories Inc. (2004/1/29).

The patent, marketed as Wellbutrin[®]SR for treatment of depression and as Zyban[®] for smoking cessation, claimed a sustained release tablet containing an admixture of bupropion hydrochloride and hydroxypropyl methylcellulose. The alleged composition was hydroxypropyl cellulose, and thus did not literally infringe the patent due to the failure to present a recited claim limitation. Furthermore, the prosecution history estoppel bared the infringement under the doctrine of equivalents.

Example 10. Janssen Pharmaceutica, N.V., et al. vs. Eon Labs Manufacturing Inc. (2005/6/13).

The patent, marked as the antifungal drug SPORANOX[®], involved to "beads" that were individual sugar cores coated with an antifungal drug and then seal-coated with a polymer layer. The patent included the parenthetical in its claim and described cores labeled 25–30 mesh at the time of manufacture and classification, and having a particular diameter, about 600–700 μm . The alleged product had a diameter in the range of 710–850 μm , and therefore did not meet the limitation "about 600–700 μm (25–30 mesh)" either literally or equivalently. The awkward claim, drafted with superfluous wordings, is easy to design around.

Example 11. Ortho-McNeil Pharmaceutical vs. Caraco Pharmaceutical Laboratories Ltd. (2007/1/19).

The patent involved a pharmaceutical composition comprising of certain weight ratios of two known drugs,

tramadol and acetaminophen and claimed that the ratio of the tramadol material to acetaminophen was a weight ratio of about 1:5. The patent specification suggested that the qualifier “about” was narrow, because if found otherwise, it could potentially render meaningless another claim’s limitation. The alleged product contained the composition with an average weight ratio of tramadol to acetaminophen of 1:8.67, and did not infringe upon the patent.

Example 12. Medtronic Navigation vs. Brainlab Medizinische Computersysteme GMBH (2007/2/5).

The patents in suit involved image-guided surgery products that enabled the precise localization of surgical instruments used during surgery. The specification mainly described acoustic systems and only in one sentence referenced an optical tracking system. Thus, the alleged product, adopting an optical tracking system, was not within the scope of the patent. The claim certainly can not cover the right without sufficient description in the specification, which is the very basic principle of patenting.

Example 13. Abbott Laboratories vs. Sandoz Inc. (2009/5/18).

The patent, marketed under the trade name Omnicef, claimed crystalline cefdinir, used its chemical name, and defined its unique characteristics with powder X-ray diffraction angle peaks. The patent claimed priority from the Japanese application, which disclosed Crystal A and Crystal B. However, the patentee only claimed Crystal A in the US patent. The alleged compounds were Crystal B, and most relevantly cefdinir monohydrate, which fell outside the scope, literal or equivalent, of the patent claimed cefdinir anhydrate. It is easy to design around the claim by referring to the disclosure disclaimed.

Failure Cases

From 2001 to 2009, CAFC affirmed 12 infringement cases related to

biotechnology. As mentioned, these alleged products or processes might not have been intended to be designed around the patents. However, retrospectively from the point view of design-around, these cases that affirmed infringement can serve as models for what needs to be avoided during an invention’s development.

Our analysis showed that all of the 12 alleged products or processes attempted to alter the patents’ structure or range. However, neither the structure nor range was recited in the claims, nor did the patentee disclaim the rights in specification or during prosecution. For example, diameter enlargement or concentration reduction could not avoid infringement for the claims that did not recite the ranges. A product that purified erythropoietin from human cells still fell within the scope of a patent that claimed purification from mammalian cells. Moreover, the alleged product, even with removing a single hydrogen atom, contained the sequence of amino acids that defined human erythropoietin in claims, and thus infringed the patent.

Conclusion

Designing or building a device or process that is similar to, but does not infringe on an invention protected by the patent, is admissible.^{2,3} However, designing a device or process to avoid all elements of a patent claim is not straightforward. In particular, one can never be sure that designing around a patent is sufficient to avoid patent infringement until a judge or jury has made that determination. Nevertheless, the courts have a precedent on these issues. The alleged device or process might not have been intended to be design around a patent, but the opinion of the court serves as a good predictor of rulings on the irksome question of patent infringement. The cases where no infringement was found, therefore, serve as a guideline for an invention’s development.^{6,7}

In order to build up the guideline, we reviewed 40 no-infringement cases out of

all 4,760 Federal Circuit Court of Appeals (CAFC) cases decided from 2001 to 2009. Based on this analysis, to design around a biotechnology patent first requires a through reading of the patent specification and prosecution history. The meaning of particular claim terms or scope being disclaimed can be found in the written description that supports a claim.⁸ The patent specification offers explicit directions about claim meaning, and the patentee may act as his/her own lexicographers to give specialized definitions of claim terms.⁹ Next, a device or process can be built by omitting a part or property from the claim, reversing the action used in the claim or changing the claim’s structure or range. Although these 40 cases analyzed in this study were not related to vaccine, the thought process can still serve as a guideline for vaccine development.

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