Patent Obscura: The Use Of Obscure Patent Doctrine In Biomedical Science Cases

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Abstract

The vast majority of patent law doctrine has been established through judicial interpretation and establishment of precedents that serve to guide the decisions of future courts. Despite the fact that many of these doctrines have fallen out of consistent use by courts, obscure patent doctrine can yield tremendous benefits to attorneys with the foresight to assert them. Patent law and the biotechnology, biomedical engineering, and pharmaceutical sectors in particular represent fertile grounds for utilizing rare doctrines because these disciplines are continuously evolving and require new legal constructs to accommodate such rapid change. This paper analyzes four obscure patent doctrines; obviousness-type double patenting (OTDP), the Kessler doctrine, the printed matter doctrine, and the ensnaring the prior art defense; and discusses the impact that these doctrines have had in specific court cases involving biomedical sciences. The paper also advocates for use of obscure patent doctrine by attorneys and describes why such an approach is appealing.

Introduction

The Patent Act of 1790, which defined the subject matter of a United States patent as "any useful art, manufacture, engine, machine, or device, or any improvement there on not before known or used," was designed to set the congressional framework for patent law in the U.S.[1] The language of the act was broad, concise, and structurally has not changed significantly since its enactment over two centuries ago.[2] As such, it has become clear that throughout the years, Congress has relied on the courts to fill in the numerous gaps in U.S. patent law architecture left by the 1790 law and by subsequent legislative efforts.[3] In fact, the vast majority of patent law doctrine has been established through judicial interpretation and establishment of precedents that serve to guide the decisions of future courts.[4]

Despite the fact that most patent doctrines trace their origins to judge-made common law, all patent doctrines are not created equally in terms of the prevalence of their use in the U.S. patent law landscape. Many patent doctrines are obscure and rarely see the light of day in any legal brief or courtroom. However, such arcane patent law principles can have significant impact on modern-day patent case law. Obviousness-type double patenting (OTDP), the Kessler doctrine, the printed matter doctrine, and the ensnaring the prior art defense are examples of obscure patent doctrines that have taken center stage in patent litigation involving biotechnology, biomedical, and pharmaceutical sciences and that have had enormous monetary consequences for the litigants involved. Patent law and the biomedical sector in particular are fertile grounds for utilizing rare doctrines because the disciplines are continuously evolving and require new legal constructs to accommodate such rapid change.

Obscure Patent Doctrines

Obviousness-Type Double Patenting: Janssen Biotech v. Celltrion Healthcare

OTDP essentially states that a patent covering the same subject matter as a previously existing patent should not have a patent life that is longer than the original patent.[5] OTDP is a rare, judicially-created doctrine that was created as an equitable remedy to address gaps left by previous statutes and doctrines.[6]

In *Janssen Biotech v. Celltrion Healthcare,* Janssen was the owner of multiple patents related to the biologic Remicade, a therapeutic antibody which is used for the treatment of chronic pain.[7] In 2016, Janssen brought legal action against Celltrion under the Biologics Price Competition and Innovation Act of 2009 claiming that Celltrion's biosimilar infringed on its patents.[8] In this case, Janssen's patent relating to antibodies that target TNF, a protein related to inflammatory response, issued on September 4, 2001, and was set to expire on September 4, 2018.[9] As a result of changes to patent terms outlined in the Uruguay Rounds Agreements

1. Patent Act of April 10, 1790, ch. 7, 1 Stat. 109 (establishing the United States Patent Act).

2. Nard, C.A. "Legal Form and the Common Law of Patents," *Boston University J.L. 90*, 51 (2010).

3. *Id*. At 53.

4. *Id*.

5. David P. Halstead, "Balancing Inequities: Overcoming Double Patenting in Today's World," *Bloomberg Law Reports Blog* (last visited August 30, 2018 1:58 PM), *http://www.foleyhoag.com/-/media/files/foley%20hoag/publications/articles/2014/david%20halstead/doublepatentingbalancinginequities.ashx?la=en.*

6. *Id*.

7. *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, 210 F. Supp. 3d 244 (2016).

Act of 1994, Janssen's other antibody patent related to TNF issued on September 14, 2004 and expired on July 11, 2011 and was determined by the courts to not be patentably distinct from the original patent.[10] The court ruled that the claims of the later expiring patent were invalid under the doctrine of OTDP as a result of being described in the later issued and earlier expiring patent.[11] At the time of the case, annual sales of Remicade totaled four billion dollars and the judgment is expected to cost Janssen roughly one billion dollars a year.[12]

Kessler Doctrine: Brain Life, LLC v. Elekta Inc.

The Kessler doctrine, which has been sparsely relied upon by courts throughout the years in patent cases, first arose from a 1907 case involving infringement of an electric lighter patent.[13] The Kessler doctrine fills gaps in existing law and bars claims that are not barred by either of two other doctrines, claim preclusion and issue preclusion.[14]

In general, claim preclusion prevents re-litigation of a cause of action that has been decided on the merits whereas issue preclusion prevents re-litigation of an issue of law or fact that has previously been litigated.[15] These doctrines were designed to prevent defendants from being subjected to repeated lawsuits by a single plaintiff relating to a single cause of action.[16] A party must raise all grounds for recovery that arise from a single transaction in a single lawsuit.[17]

The Kessler doctrine is at the forefront of the 2014 *Brain Life, LLC v. Elekta Inc.* case. In 1997, Medical Instrumentation Diagnostics Corporation (MIDCO) sued Elekta, a manufacturer of equipment for the diagnosis of brain cancer, for infringing MIDCO's patent describing a method and apparatus for generating a video image using various scanning technologies.[18] In this case, MIDCO focused on the apparatus claim and allowed the method claims to be dismissed.[19] The district court entered a final judgment that Elekta did not infringe the apparatus claims.[20]

Brain Life later licensed the MIDCO patent, and in 2009, sued Elekta for infringement. Brain Life argued that Elekta's ERGO++ radiotherapy technology infringed on the method claims described by the patent.[21] Elekta asserted a claim preclusion defense and argued that the lawsuit should be dismissed because the method patent claims were dismissed in the previous lawsuit against MIDCO.[22] However, the court ruled that claim preclusion did not apply because the ERGO++ product did not exist until after the MIDCO case was decided and that the alleged infringement postdated the dismissal of the method claims.[23] Additionally, it was ruled that the method claims could not be dismissed based on issue preclusion because while the methods claims were a subject of the original MIDCO case, those claims were not fully litigated to finality.[24]

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With claim and issue preclusion not being available to Elekta as a defense, the court turned to the Kessler doctrine to fill in the gaps left by these two doctrines and Brain Life's lawsuit was dismissed, saving Elekta tens of millions of dollars by allowing the company to continue selling its radiotherapy products.[25]

Printed Matter Doctrine: AstraZeneca LP v. Apotex, Inc.

The non-statutory and relatively obscure printed matter doctrine has its roots in the 1931 Russell case, which involves technology for indexing names in directories.[26] The basic premise of the doctrine is that patentable weight should not be given to information simply because it is arranged on paper, in a book, or on other printed media.[27]

In *AstraZeneca LP v. Apotex, Inc.*, Apotex was attempting to launch a generic version of AstraZeneca's

8. *Id*. at 245.
9. *Id*. at 248.
10. *Id*.
11. *Id*. at 245.
12. Sharon Roberg-Perez, "How an Obscure Patent Doctrine Can Cost You $1 Billion a Year…," *Robins Kaplan Trial Attorneys Blog* (September 7, 2016, 2:01 p.m.), *http://blog.robinskaplantrialattorneys.com/2016/09/07/obscure-patent-doctrine-can-cost-1-billion-year%20/*.
13. Brain Life, LLC v. Elekta Inc., 746 F. 3d 1045 (2014).
14. *Id*. at 1056.
15. *Id*. at 1052.
16. *Id*. at 1056.
17. *Id*.
18. *Brain Life, LLC v. Elekta Inc.*, 746 F. 3d 1049 (2014).
19. *Id*. at 1050.
20. *Id*.
21. *Id*.
22. *Id*. at 1051.
23. *Id*. at 1052.
24. *Brain Life, LLC v. Elekta Inc.*, 746 F. 3d 1055 (2014).
25. *Id*. at 1056.
26. Rebecca Harker Duttry, "What Is the Printed Matter Doctrine?"—*In re* DiStefano, *JD Supra Blog* (February 10, 2016), *https://www.jdsupra.com/legalnews/what-is-the-printed-matter-doctrine-in-51289/*.
27. *Id*.

(AZ) drug respiratory disease drug budesonide.[28] AZ's patents related to the drug included methods to administer the drug and product claims directed to a kit for treating respiratory disease.[29] The kit claims describe a budesonide composition and a label describing once daily administration of the drug by nebulization.[30] Although AZ's patents were directed to once daily administration, the actual instructions in the label described once or twice daily administrations.[31] Apotex's generic drug involved twice daily use, which was described in AZ's label, but not claimed in their patents.[32]

Under the printed matter doctrine, printed matter is generally not considered patentable subject matter.[33] The exception to the rule is that printed matter may be used to distinguish an invention from the prior art if a "functional relationship" exists between the printed matter and the medium on which it is printed.[34] AZ argued that the kit claims should not be invalidated by the printed matter doctrine because the drug and its label are so closely intertwined and that one cannot be approved without the other.[35] The court rejected this argument stating that a claim which describes information on a label should not be given patentable weight because instructions that simply explain how to use the product do not constitute a "functional relationship."[36] If the opposite ruling were made, new material could be added to the patent simply by adding new instructions.[37]

The end result of this case was that AZ's kit claims were rejected based on the printed matter doctrine.[38] The significance of this ruling is evident in the fact that in the year prior to the case being decided, AZ's U.S. sales of Pulmicort, the brand name for budesonide, were $982 million, 90 percent of which came from the drug form that was the subject of the lawsuit.[39]

28. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1046 (Fed. Cir. 2010).

29. *Id*. at 1045.

30. *Id*. at 1048.

31. *Id*.

32. *Id*. at 1047.

33. *Id*. at 1064.

34. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1064 (Fed. Cir. 2010).

35. *Id*.

36. *Id*. at 1063.

37. *Id*. at 1065.

38. *Id*.

39. AstraZeneca Sues Apotex Over Generic Asthma Drug, Reuters UK (2009, April 3), *https://uk.reuters.com/article/astrazeneca-apotex/astrazeneca-sues-apotex-over-generic-asthma-drug-idUKN0334323120090403?pageNumber=1&virtualBrandChannel=0.*

Ensnaring the Prior Art: Jang vs. Boston Scientific Corp.

Ensnaring the prior art, which originates from a 1990 case involving golf balls, is a defense to another judicially created doctrine known as the doctrine of equivalents.[40] Under the doctrine of equivalents, a party can be held liable for patent infringement even if that party's technology does not literally infringe all elements of the patent.[41] The basic premise of the obscure ensnaring the prior art defense is that a doctrine of equivalents claim against an accused infringer is invalid if the patent holder argues that their patent claims should be construed so broadly as to encompass existing prior art.[42]

In *Jang vs. Boston Scientific Corp.,* Dr. Jang assigned patents relating to a coronary stent to Boston Scientific (BSC) for $50 million.[43] BSC agreed to pay an additional $110 million in royalties if the company developed a device that infringed Dr. Jang's patent.[44] Several years later, BSC developed the Express Stent, which Dr. Jang claimed infringed on his patent.[45] The court ruled that there was no literal infringement because the Express Stent expansion columns were connected to each other in a "peak-to-valley" configuration as opposed to the "peak-to-peak" configurations of the device in Dr. Jang's patent.[46] Dr. Jang raised a doctrine of equivalents argument, which was then countered by BSC's ensnaring the prior art defense.[47]

One the of analyses used by courts to determine if the prior art has been ensnared involves having the patent holder construct hypothetical claims that are broad enough to include the accused infringing technology.[48] If the accused infringer is able to introduce prior art that reads on the hypothetical claims, the ensnaring defense is valid.[49] In this case, Dr. Jang attempted to introduce a hypothetical claim in which he deleted part of the claims relating to non-parallel connecting struts and replaced it with parallel struts that provide more flexibility.[50] The court ruled that this hypothet-

40. Ryan Davis, "Ensnarement 101: Anatomy Of An Uncommon Patent Defense," *Law360 Blog* (October 24, 2017, 2:04 PM), *https://www.law360.com/articles/976807.*

41. *Id*.

42. *Id*.

43. *Jang v. Boston Scientific Corp.*, No. 16-1280 (Fed. Cir. 2017).

44. *Id*. at 1280.

45. *Id*.

46. *Id*. at 1283.

47. *Id*. at 1285.

48. *Id*.

49. *Jang v. Boston Scientific Corp.*, No. 16-1285 (Fed. Cir. 2017).

50. *Id*. at 1286.

ical claim was impermissibly narrowed and therefore invalid.[51] Since Dr. Jang was unable to draft proper hypothetical claims, the court did not need to conduct a comparison with existing prior art. Dr. Jang's doctrine of equivalents claim was ruled to have ensnared the prior art and his nearly $200 million cause of action was dismissed.[52]

Discussion

These four cases are just a small sampling of instances in which obscure, seldomly utilized patent doctrines have had tremendous impact in litigation involving biotechnology, biomedical engineering, or pharmaceutical technologies. A number of characteristics relating to patent law and the biomedical sciences create a hospital environment for assertion of obscure patent law doctrine.

Patent Law

Patent law is a discipline that is particularly well-suited to discovering obscure doctrines that have the potential to yield significant benefit to attorneys with the foresight to utilize them. A typical patent case involves a cause of action for infringement, a defense of noninfringement or that the patent was not valid in the first place, or both, and quite often, an additional retort to the accused infringer's defense, which often represents a "doctrine-within-a-doctrine." Each of these claims or defenses is a separate, complex set of facts that requires application of different legal principles. For example, the Jang case involved an infringement action involving a cardiac stent, a successful defense that literal infringement did not occur, assertion of a doctrine of equivalents cause of action by Dr. Jang, and a successful ensnaring the prior art defense by BSC. Such a fact and law-rich environment presents numerous opportunities for attorneys to assert any number of arcane patent doctrines.

Patent law is authorized by the U.S. Constitution and federal courts have exclusive jurisdiction over patent cases. Under the Federal Rules of Civil Procedure, "a party may state as many separate claims or defenses as it has, regardless of consistency."[53] Therefore, there is little downside to utilizing an obscure patent claim or defense, even if the claim or defense is inconsistent with other causes of actions that may be asserted. Additionally, patent law is constantly changing because the field is inextricably linked to rapidly evolving technologies in all disciplines. Constantly changing laws create a fertile environment for assertion of rarely used patent doctrines because a new legal framework may allow for the application of legal concepts that have previously been rendered obsolete. In Janssen Biotech, the OTDP doctrine was only relevant to the case after the patent term extensions in the Uruguay Rounds Agreement Act of 1994 created a situation where a later-issued patent was allowed to expire earlier than the earlier-issued patent.

Biomedical Sciences

The complex, continually evolving nature of biotechnology, biomedical engineering, and pharmaceutical sciences also lends itself to assertion of obscure patent doctrines. Inherent in the fact that the disciplines involve manipulation, isolation, simulation, and analysis of naturally occurring biological processes is the idea that the doctrinal framework associated with providing a limited monopoly to inventions relating to these processes is rapidly evolving.[54] The boundaries of what constitutes a natural phenomenon and patentable subject matter is far from being clearly defined.[55] Additionally, the existing patent law framework is constantly shifting as a result of the tremendous public health potential associated with biomedical technologies. For example, the public policy goal of facilitating the development of more affordable drugs has led to the Hatch Watchman Act, and the Biologics Price Competition and Innovation Act, which set forth the legal foundation for generics-drugs and biologics by recalibrating existing notions of what constitutes infringement.

Such seismic shifts in existing legal paradigms provide excellent opportunities for patent practitioners in the biomedical sciences to look to existing, rarely used doctrines for applicability to a modern day set of facts. This situation was on display in the AstraZeneca LP and Janssen Biotech cases, which both involve utilization of obscure patent doctrines in generic drug cases. Both of these cases resulted in multimillion-dollar judgements in favor of the parties that asserted these doctrines.

Asserting Obscure Patent Doctrines

There are a number of factors that make assertion of obscure patent doctrine appealing. Obscurity can be found in both old and newer doctrine. For example, the Kessler doctrine was first put forth in 1907 while the ensnaring the prior art defense originated from a 1990 case. Additionally, patent practitioners need not wait until the litigation stage to benefit from seldomly used patent doctrines. Awareness of these doctrines can be used as a tool to draft patent claims that are not susceptible to future invalidation at the hand of

51. *Id*.

52. *Id*. at 1290.

53. Fed. R. Civ. P. 8(d)(3).

54. Adriana Benedict, "The Nature of Biotechnology Patents: A Tangled Doctrinal Web of Processes and Products That Can Catch All Genes But Save None." *Intellectual Property Brief* 5, no. 1 (2013): 37-76.

55. *Id*.

these same doctrines.[56] If Dr. Jang's attorneys contemplated the ensnaring the prior art defense when they originally drafted the patent application, they may have drafted patent claims that were as narrow as the hypothetical claims presented in court.[57]

Patent judges seem to be more than willing to resurrect obscure doctrines if they are applicable to a particular case. In general, patent judges have a vast amount of knowledge of both antiquated and current patent law doctrines. If an appropriate set of facts happen to present themselves, patent judges seem to have few reservations about demonstrating their grasp of obscure doctrinal issues and going into great depth regarding why a particular doctrine is or is not relevant to the current case.

In certain instances, the patent attorney may not even need to apply the doctrine correctly and the mere mention of a certain claim or defense may result in the judge rendering a correct application of the doctrine that serves to benefit the attorney's client. This exact situation occurred in *Brain Life* and the judge noted that "Elekta identifies the [Kessler] doctrine, but does so under the general rubric of claim preclusion… However, traditional notions of claim preclusion do not apply when a patentee accuses new acts of infringement, *i.e.*, post-final judgment, in a second suit—even where the products are the same in both suits."[58] The judge then went on to enter a judgment for Elekta after applying the Kessler doctrine correctly.

Even if a particular patent doctrine is somewhat antiquated, a judge may be willing to adjust its contours to fit a given fact pattern if the doctrine still represents valid law. For example, in *Brain Life,* the judge stated that "the continuing force of the Kessler doctrine in the face of the development of defensively applied issue preclusion may be questionable on the precise set of facts presented in the case at bar. But, the Kessler doctrine exists, and we are bound by it, even if its viability under current estoppel law may be of less value now than it was at the time it was handed down."[59] In this case, the judge found a way to apply the Kessler doctrine, despite the fact that it may have been somewhat obsolete with respect to the case at hand.

Conclusion

With respect to patent law doctrines, the frequency with which a particular claim or defense has been utilized in the past is not necessarily an indication of the success that doctrine will yield in a courtroom today. Obscure patent doctrines such as obviousness-type double patenting, the Kessler doctrine, the printed matter doctrine, and the ensnaring the prior art defense have had significant impact in the biomedical science sectors and have caused or prevented the exchange of hundreds of millions of dollars between litigants. A number of factors inherent to the discipline of patent law, such as the fact that multiple causes of action can be raised by patent holders and accused infringers, the application of federal law and the ability to assert multiple, inconsistent claims or defenses, and the rapid evolution of the field make this strategy particularly beneficial. Additionally, the fields of biotechnology, bioengineering, and pharmaceutical sciences, like patent law in general, are continuously changing and require novel legal architecture to accommodate these changes. Such transition creates opportunities for application of patent doctrines that are still valid law, but that have fallen out of consistent use by courts.

Patent litigators would benefit immensely from scouring the wide-breath of patent law opinions in all disciplines to familiarize themselves with obscure patent doctrines in the event an appropriate situation to assert such a doctrine presents itself. Hidden doctrinal gems can be found in both older and more current case law and can be utilized prophylactically to draft the strongest patent claims possible. Additionally, patent law judges may be eager to reward those who pay respect to all available valid precedent and assert less common claims and defenses. Patent law in the biomedical sciences is rapidly changing and the best patent practitioners are the ones that are most competently able to adapt to these changes. However, the ability to examine the role that antiquated and obscure doctrines have in a changing environment and to effectively seek out and apply a wide spectrum of legal doctrine to an appropriate set of facts could end up paying large dividends for those vigilant enough to implement such a strategy. ■

Available at Social Science Research Network (SSRN): *https://ssrn.com/abstract=3317032*.

56. Alan Wang, "Ensnarement as Defense Against Infringement," *Law360 Blog* (October 27, 2017), *http://www.haynesboone.com/articles/ensnarement-as-defense-against-infringement.*

57. *Id*.

58. *Brain Life, LLC v. Elekta Inc.*, 746 F. 3d 1056 (2014).

59. *Id*. at 1058.