


December 2010

Exhausted or Unlicensed: Can Field-of-Use Restrictions in Biotech License Agreements Still Prevent Off-Label Use Promotion After Quanta Computer?

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Kristal M. Wicks, *Exhausted or Unlicensed: Can Field-of-Use Restrictions in Biotech License Agreements Still Prevent Off-Label Use Promotion After Quanta Computer?*, 9 U.N.H. L. REV. 157 (2010), available at http://scholars.unh.edu/unh_lr/vol9/iss1/8

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Exhausted or Unlicensed: Can Field-of-Use Restrictions in
Biotech License Agreements Still Prevent Off-Label Use
Promotion After *Quanta Computer*?

KRISTAL M. WICKS *

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I. INTRODUCTION

In the biotechnology (biotech) industry, companies must be increasingly aware of their intellectual property and how their licensing strategies can impact their rights. When licensing patented technology, it is common practice for biotech companies to include restricted field-of-use provisions in their license agreements.¹ Such provisions permit a licensee to only use licensed technology in a defined field and restrict use or development in another field.² This licensing strategy plays an important role within the biotech industry because it allows companies to more effectively control their intellectual property and to more efficiently research and develop pharmaceutical products.³

A problem that occurs in the biotech industry is when a company promotes the “off-label” use of an already-approved drug—a use that may be covered by another’s patent, though perhaps undeveloped or unlicensed.⁴ This problem can be an unforeseen side effect of utilizing biological material to develop drugs that may have many, and often unknown, indications for disease treatments. One way to control off-label use promotion is through patent license agreements. Unfortunately, for many biotech licensors, patent licenses may not always prevent off-label use promotion. To illustrate, a licensee (or a third party downstream of the license agreement) could promote a drug approved by the Food and Drug Administration (FDA), developed from licensed technology, for an unapproved treatment covered

1. See Jeffrey P. Somers, Morse Barnes-Brown Pendleton PC, *Biotech/Patent Licensing: Key Considerations in Deal Negotiations*, http://www.mbbp.com/resources/iptech/biotech_patent_licensing.html (last visited Oct. 27, 2010).

2. BRIAN G. BRUNSVOLD & DENNIS P. O’REILLY, *DRAFTING PATENT LICENSE AGREEMENTS* 39 (5th ed. 2004).

3. See Somers, *supra* note 1.

4. See Rebecca S. Eisenberg, *The Problem of New Uses*, 5 *YALE J. HEALTH POL’Y L. & ETHICS* 717, 731 (2005).

by the licensor's patent that the party was not given the right to develop.

The U.S. Supreme Court has held that activity outside of the licensed field can constitute patent infringement because the patent owner has not transferred the rights for use or product development in that field.⁵ However, in 2008, the Supreme Court, in *Quanta Computer, Inc. v. LG Electronics, Inc.*,⁶ implied that the patent holder in this situation may have exhausted its rights by licensing the technology and, therefore, cannot sue a third party for infringement even if the use being promoted is covered by the patent.⁷

This Note discusses how *Quanta* should be interpreted and applied in the context of field-of-use restrictions in biotech license agreements and how a biotech licensor may sue for patent infringement as a remedy for downstream off-label use promotion when it licenses technology to be developed within a restricted field. Section I provides an overview of the biotech industry and how patent licensing plays an essential role in the growth and continuation of the industry. Section II highlights the problem of off-label use promotion and how the FDA appears to fall short of adequate regulation in this area. Section III outlines how the doctrine of exhaustion affects patent license agreements, specifically in the wake of *Quanta*. Section IV discusses the post-*Quanta* application of the doctrine of exhaustion to biotech licenses that incorporate field-of-use restrictions and how licensors should respond to *Quanta* when drafting license agreements to prevent off-label use.

5. See *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 126 (1938).

6. 553 U.S. 617 (2008).

7. See *id.* at 638.

II. BACKGROUND OF PATENT LICENSING IN THE BIOTECHNOLOGY INDUSTRY

A. *Brief Overview of the Biotechnology Industry*

Biotechnology itself goes back as far as the development of fermentation techniques in ancient Egypt,⁸ but the biotechnology industry that we know today has its origins in the 1970s and 1980s when a new industry began exploiting biological processes instead of traditional chemical methods in order to solve problems and invent products.⁹ One of the first biotechnology drugs to emerge was human insulin in genetically-modified bacteria in 1982.¹⁰ Since then, the biotech industry has produced more than four hundred approved drugs and vaccines for a variety of diseases including cancer, heart disease, diabetes, AIDS, and multiple sclerosis.¹¹ Since its emergence, the industry has grown dramatically¹² and continues to make significant contributions to health care, medicine, and scientific research.¹³

8. DuPont Biotechnology, History of Biotechnology, http://www2.dupont.com/Biotechnology/en_US/intro/history.html (last visited Oct. 27, 2010).

9. CLAUDE BARFIELD & JOHN E. CALFEE, BIOTECHNOLOGY AND THE PATENT SYSTEM: BALANCING INNOVATION AND PROPERTY RIGHTS 3 (2007).

10. *Id.*

11. *Id.* at 3–4.

12. An annual review of the biotech industry revealed “1,456 firms, of which 336 are publicly traded, . . . a total U.S. market capitalization of about \$400 billion[,] . . . U.S. revenues [that] grew from \$8 billion in 1992 to \$51 billion in 2005,” and private financing amounting to almost \$100 billion from the years 2000–2005 combined and \$20.3 billion in 2006. *See id.* at 4 (citing ERNST & YOUNG, RESILIENCE: AMERICA’S BIOTECHNOLOGY REPORT 7 (2007)).

13. For example, research from the biotech industry has made it possible to sequence the complete human genome, which has led to diagnostic testing for genetic disorders and forensic DNA testing. Brief of the Biotechnology Industry Organization as Amicus Curiae in Support of Neither Party at 2, *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008) (No. 06-937), 2007 WL 3353099, at *3 [hereinafter BIO Amicus Brief]. It has also enhanced agricultural production through seed technology to make crops more resistant to insects and herbicides, increasing the U.S. farm income by \$10.7 billion. *Id.* at 3.

B. *Biotech License Agreements*

In the biotech industry, bringing a product or drug to market can often involve a lengthy and extensive collaboration between research universities and small and large biotechnology or biopharmaceutical companies.¹⁴ To illustrate, a university might patent technology derived from a university researcher's discovery of a protein linked to a certain disease, such as cancer, and then license the technology to a small biotech company, which will invest the necessary capital and time to develop the technology to produce real-world applications, such as diagnostic methods or therapeutic treatments.¹⁵ This mutually beneficial arrangement will provide the university with the revenue to support more academic research and will provide the small biotech company the exclusive patent rights that will attract investments for research and development (R&D), which, over time, will increase the value of the patented technology.¹⁶

Additionally, as the value of the patented technology grows and becomes more widely used and scientifically validated, more specialized biotechnology companies may enter into the R&D process to develop the technology toward specific indications or "fields of use."¹⁷ Eventually, larger companies with more resources may become involved in order to help with the cost and burden of developing a useful application or therapeutic product from the patented technology.¹⁸ The interplay between universities, small biotech companies, and larger biopharmaceutical entities is a crucial aspect

14. *Id.* at 4.

15. For every successful product from biotechnology innovation, approximately 10,000 other attempts will fail to yield any success. *Id.* at 5. The time required to bring a drug from clinical development, through regulatory approval, and into the marketplace averages about eight years. *Id.*

16. *Id.* at 6.

17. *Id.*

18. BIO Amicus Brief, *supra* note 13, at 6. For example, a patented drug, which was used to treat an aggressive form of breast cancer, and was based on the identification of a specific gene, cost more than \$200 million, took almost twenty years to develop, and involved collaborative research efforts between companies and a university. See ROBERT BAZELL, HER-2: THE MAKING OF HERCEPTIN, A REVOLUTIONARY TREATMENT FOR BREAST CANCER 33, 37-38, 45, 48, 53-54 (1998).

of the biotech industry. It ensures the viability of the small and publicly-funded biotech companies that otherwise may not be able to afford licensing fees or R&D costs and also makes it possible for researchers and inventors to successfully navigate the complicated and expensive road to commercial use of their innovations.¹⁹

An important tool in this interplay is the patent license, which allows patent owners to license their patent rights to others. The primary function of licensing patent rights is to allow inventions to be put to “their most valuable uses by the people best able to use them.”²⁰ In most situations, other entities can manufacture, market, or sell an invention better than the patent owner, and the ability to license the invention increases both the value of the specific invention and the general value of inventive efforts because it provides an incentive for people to make inventions regardless of their ability to successfully bring a product to market.²¹

An essential component to the patent license is the patent owner’s right to control the scope and the terms of the patent license.²² A patent owner may employ the following limitations when granting a patent license: a licensee may only have the right to sell 1) a certain type of the product; 2) to certain customers; 3) in certain geographic areas; 4) for a limited amount of time; and/or 5) in limited amounts.²³

A frequently employed clause in biotech licensing is the field-of-use restriction through which a patent owner grants a licensee the right to use a patented invention, but only in a specific, well-defined way.²⁴ The field-of-use restriction divides the license rights among various applications or fields and is a useful tool, especially for allowing the patent owner to generate license revenue without creating

19. BIO Amicus Brief, *supra* note 13, at 6.

20. John W. Schlicher, *The New Patent Exhaustion Doctrine of Quanta v. LG: What It Means for Patent Owners, Licensees, and Product Customers*, 90 J. PAT & TRADEMARK OFF. SOC’Y 758, 767 (2008).

21. *See id.*

22. *See id.*

23. *Id.* at 773.

24. *See* Mark R. Patterson, *Contractual Expansion of the Scope of Patent Infringement Through Field-of-Use Licensing*, 49 WM. & MARY L. REV 157, 159 (2007).

competition in its own market.²⁵ To illustrate, a compound developed by a biotech company might have many potential uses (preventive, diagnostic, or therapeutic) for several different diseases, perhaps in both humans and animals.²⁶ In drafting a license agreement, the patent owner will want a narrow field of use that will reserve the opportunity to exploit other potential uses of the compound for the owner/licensor.²⁷ For example, there may be indications that the compound may treat two different diseases, such as diabetes and leukemia.²⁸ A hypothetical biotech company may be interested in licensing the compound because the company focuses on developing cancer treatments, but it is unlikely that the company would want to invest in the development of the compound for diabetes treatments.²⁹ The biotech company may, however, want a broad field of use or no field-of-use restriction because it is investing early in the development stage and does not want to lock itself into a specific use and then miss out later on a more successful use that is not included in the licensed field.³⁰ In this situation, if the patent owner licenses its rights to the company to develop the compound without a field-of-use restriction to leukemia, the patent owner will risk depriving itself of the ability to develop or further license the compound in the field of diabetes or for any other potential use.³¹

III. OFF-LABEL USE PROMOTION IN THE BIOTECHNOLOGY INDUSTRY

While field-of-use restrictions are, for the most part, successful in affording patent owners some control over their intellectual property, the off-label use market creates potential problems for patent owners in the biotech industry. The “off-label” use of a drug occurs

25. BRUNSVOLD & O'REILLY, *supra* note 2, at 39.

26. *See* Somers, *supra* note 1.

27. *Id.*

28. *See id.* (discussing similar patent research).

29. *See id.*

30. *See id.* (“From your client’s perspective, it would like . . . a world-wide exclusive license of and under all of the patents related to the engineered peptide. Having paid for the discovery of the multi-purpose compound, its position is that it is entitled to all of the potential value of the discovery.”).

31. *See id.*

when a drug is used or prescribed “for a purpose other than that for which the FDA has approved the drug as safe and effective.”³² For example, a drug may be approved by the FDA as safe and effective for use in the treatment of diabetes but has an indication (another use) as a potentially effective treatment of leukemia. If a doctor were to prescribe the approved diabetes drug to treat a patient suffering from leukemia, this would constitute an “off-label” use.

The off-label use problem within the biotech industry occurs more often between generic drug manufacturers and brand-name drug manufacturers.³³ However, off-label use may also become an issue between biotech companies and universities involved in licensing arrangements. For example, a licensee or a downstream third party could develop a drug from licensed technology within the licensed field, gain FDA approval for that drug for a specific treatment within that licensed field, and bring the drug to market. It may then discover that the drug has indications for an unapproved use to treat a different disease and promote the drug for that unapproved use, which is outside the scope of the licensed field, in order to capitalize on a different and potentially more profitable treatment market. Additionally, under current FDA guidelines, the company could disseminate information from scientific research for the yet unapproved use of that drug to doctors, who could begin prescribing the drug to patients.³⁴ In this scenario, the patent owner/licensor may lose the market for the patented, but unapproved use, because it licensed its rights and will not be able to control the downstream implementations of other uses of its technology.

A. FDA Regulation of the Off-Label Use Market

Once the FDA approves a drug for one use in a particular set of patients, doctors are free to prescribe that drug for any use in any

32. Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 359 n.57 (2007).

33. See Carrie Stewart Martin, *Proving Inducement of Infringement of Method-of-Use Patents in Hatch-Waxman Act Litigation: Are the Standards Realistic for the Pharmaceutical Industry?*, 32 AIPLA Q.J. 163, 167 (2004).

34. See FDA Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices, 21 C.F.R. § 99.101 (2010); see also Eisenberg, *supra* note 32, at 369.

patient, even without clinical trial data to support the safety and efficacy of the drug outside of its approved use.³⁵ To elaborate, as soon as a new drug is approved and reaches the market, the FDA will not prevent its prescription for an off-label use that was not tested; the FDA does not regulate the practice of medicine or interfere with a doctor's best judgment on what treatment to prescribe for its patients.³⁶ Prescribing drugs for off-label uses is a significant part of medical practice in certain specialties, such as oncology,³⁷ and it is common for off-label sales to account for a significant portion of the sales of a lucrative drug.³⁸ The off-label use market has emerged in the biotech industry because clinical trials to test new uses for already approved drugs are not only expensive, but can also be risky for a company if the testing of a lucrative drug yields a negative or harmful result.³⁹

Even though the FDA does not have authority to prevent doctors from prescribing approved drugs for off-label uses, the agency has some authority to regulate the marketing claims made by drug manufacturers regarding off-label uses of drug products.⁴⁰ The FDA has authority under the Food, Drug, and Cosmetic Act (FDCA)⁴¹ to regulate the promotional materials of pharmaceutical companies, which include: print, broadcast, and Internet advertisements; visual aids, handouts, and other materials produced for dissemination to healthcare professionals; and brochures, letters, flyers, and other materials produced for dissemination to patients.⁴² The FDA supports

35. Eisenberg, *supra* note 32, at 369.

36. Eisenberg, *supra* note 4, at 731.

37. Eisenberg, *supra* note 32, at 369–70.

38. Eisenberg, *supra* note 4, at 731.

39. *See id.* at 732 n.65 (citing, as an example, the reduced sales of the drug Prempro, after the National Institute of Health found increased risk of heart disease after the hormone replacement drug was being prescribed to prevent heart disease in women).

40. *Id.* at 733. The FDA has had some difficulty enforcing this authority because companies have asserted that regulating their marketing efforts is a violation of their First Amendment rights to disseminate information about their drugs to doctors. *See, e.g.,* Thompson v. W. States Med. Ctr., 535 U.S. 357, 375–77 (2002).

41. 21 U.S.C. § 331 (2006).

42. *See* Michelle M. Mello et al., *Shifting Terrain in the Regulation of Off-Label Promotion of Pharmaceuticals*, 360 NEW ENG. J. MED. 1557, 1558 (2009).

its authority to regulate this area by stating that it ensures that promotional communications are “truthful, balanced, not misleading in their representations or omissions, and supported by substantial evidence from clinical trials or clinical experience”⁴³ in order to: 1) make certain that doctors receive accurate and unbiased information in order to make informed decisions on prescriptions; and 2) provide manufacturers with incentives to test previously unapproved uses and submit them for FDA approval.⁴⁴

Over the years, however, changes in FDA policy toward off-label use promotion have created uncertainty and have eroded confidence that the FDA has any real regulatory power over the off-label use promotion activities of biopharmaceutical companies.⁴⁵ First, the FDA Modernization Act of 1997 (FDAMA)⁴⁶ permitted manufacturers of drugs and biologics to disseminate peer-reviewed scientific journal articles, but the manufacturers were permitted to do so only if the off-label use described in the articles was included, or would be included, in a supplemental new drug application and if the manufacturers provided the FDA with advance copies of any materials they planned to disseminate.⁴⁷ However, Congress allowed the FDAMA provisions to expire in 2006,⁴⁸ which left some confusion as to where the FDA stood on regulation of off-label use promotion.⁴⁹

43. *Id.*

44. Eisenberg, *supra* note 32, at 372. The FDCA does not directly preclude off-label use promotion, but two provisions effectively give the FDA the regulatory authority over this activity: 1) pharmaceutical manufacturers are prohibited from introducing a drug into interstate commerce unless the drug and its label have FDA approval (marketing drugs for off-label use would violate this provision); and 2) manufacturers are prohibited from introducing misbranded drugs into interstate commerce (including information about unapproved uses qualifies as misbranding). 21 U.S.C. §§ 331(a)–(c), 355(a) (2006); *see also* FDA New Drugs, 21 C.F.R. § 310.3(h) (2010); FDA Prescription Drug Advertising, 21 C.F.R. § 202.1(e)(4) (2010).

45. *See* Mello et al., *supra* note 42, at 1558–59.

46. 21 U.S.C. § 301 (2006).

47. FDA Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices, 21 C.F.R. § 99.101 (2010).

48. *See* Mello et al., *supra* note 42, at 1559.

49. Perhaps Congress was responding to challenges that regulation of activities in this area violated constitutional rights, specifically the First Amendment right of

Second, changes made in draft FDA guidelines in January 2009 will allow companies to distribute reprints of peer-reviewed journal articles relating to doctors describing off-label uses.⁵⁰ These guidelines have been characterized as a clarification of existing policy rather than a change in policy direction, but have been criticized as more permissive than the FDAMA or previous FDA policy for three reasons: 1) dissemination of peer-reviewed articles is explicitly allowed; 2) companies are not restricted to promoting off-label uses for which the company will file a supplemental new drug application; and 3) companies do not have to submit their promotional materials to the FDA in advance.⁵¹ Although drug companies may welcome these FDA guidelines because the guidelines are less restrictive on marketing activities, there are concerns that these guidelines will result in publication bias in scientific literature, misleading representations or interpretations of data in peer-reviewed journals, dissemination of low-quality studies merely because they support a pharmaceutical agenda, suppression of data on safety risks, and increasing conflicts of interest resulting from journal articles written by researchers who are sponsored by pharmaceutical companies.⁵² To illustrate these concerns, a 2006 study of the prescription of off-label uses of common drugs found that while off-label use made up 21% of all prescriptions, 73% of these off-label uses had little or no scientific support.⁵³ Figure 1 provides an illustration that breaks down these common drugs.

drug manufacturers to engage in commercial speech. Mello et al., *supra* note 42, at 1559 (citing Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998), *vacated in part by* Wash. Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000)).

50. Eisenberg, *supra* note 4, at 733–34; *see also* Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices, 21 C.F.R. § 99.1 (2010).

51. Mello et al., *supra* note 42, at 1560.

52. *Id.* at 1563.

53. Randall S. Stafford, *Regulating Off-Label Use—Rethinking the Role of the FDA*, 358 NEW ENG. J. MED. 1427, 1428 (2008).

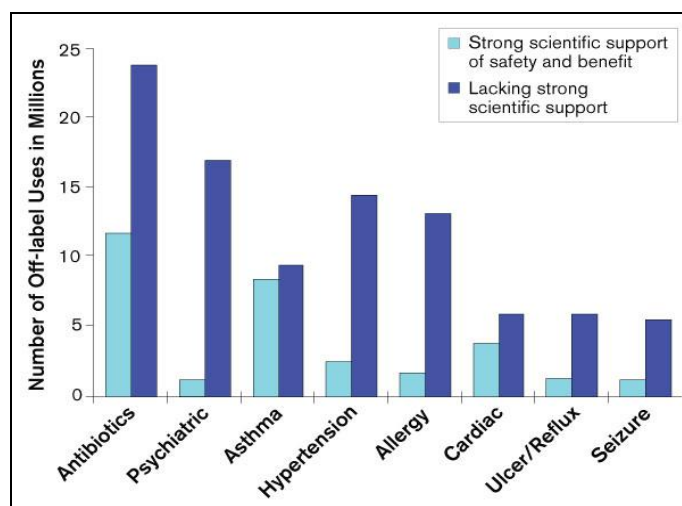


Figure 1.⁵⁴

In addition, there are broader concerns that individuals, universities, or biotech companies may not be able to rely on the FDA's regulatory authority to provide them with a remedy in situations where unsafe drugs may harm patients as a result of off-label use promotion, or in situations where a company is promoting its drug for an off-label use protected by another's patent.

B. *Patents, the Off-Label Use Market, and the Role of Field-of-Use Restrictions*

To circumvent the problem of off-label use promotion in the absence of more restrictive FDA regulation, the biotech industry relies on the protection of patent law. The biotech industry depends heavily on patent protection to support the costs of researching and developing pharmaceutical products and consistently seeks stronger patent rights.⁵⁵ Patent law allows a patent owner to sue any party that "without authority makes, uses, offers to sell, or sells any patented invention, within the United States"⁵⁶ Additionally, patents on

54. *Id.*

55. Eisenberg, *supra* note 4, at 721.

56. 35 U.S.C. § 271(a) (2006).

pharmaceutical products and processes, such as drugs and methods of treatment, “motivate firms to invest in data production in order to develop markets for their inventions.”⁵⁷ Data from clinical trials regarding new uses of these pharmaceutical inventions can expand the market for a drug product, and patents on these uses can be employed to “exclude free riders from competing for these sales during the patent term.”⁵⁸

One problem with patent protection in this area—and the main reason that off-label use promotion is increasingly prevalent—is that, even for a successful clinical trial, the patent term may not be well timed to allow patent owners to capitalize on the value of the data, especially for clinical trials on new uses of the drug.⁵⁹ For example, the timeline of drug development often places the discovery of new compounds before the therapeutic value can be determined or established by clinical trials.⁶⁰ Because patent law promotes early filing in order to avoid the risk of losing protection due to statutory bars and standards of novelty, inventors file patent applications on new compounds as soon as reasonably possible—even if it may be years before a drug is commercially viable or a treatment is well understood.⁶¹ New data on uses of an existing compound can sometimes permit the developer to obtain a process patent (as opposed to patenting the compound itself), such as when clinical trials show the drug works for a new indication or new method of treatment.⁶² The new method of treatment can be patent eligible even though the same drug has previously been used for another purpose.⁶³ However, process patent claims limited to a particular use of a compound are considered less valuable in the industry than product patent claims covering the drug itself because a narrower process patent cannot stop a competitor from selling the drug for other uses not covered by the patent.⁶⁴

57. Eisenberg, *supra* note 4, at 721.

58. *Id.*

59. *Id.* at 722.

60. *Id.*

61. *Id.*

62. *Id.* at 724.

63. Eisenberg, *supra* note 4, at 724.

64. *Id.*

In the context of off-label use, patent owners may enforce the process patent against consumers who take the drug for the patented use, the doctors who prescribe the drug for the patented use, the pharmacists who fill prescriptions, or competitors who encourage use of their generic version of the drug.⁶⁵ But the enforcement option is not often employed because: 1) remedies for this course of action are generally unsatisfactory; 2) detection of infringing uses is difficult; and 3) suing numerous patients and doctors is not efficient.⁶⁶ Additionally, it is generally not in a company's best interests from a marketing perspective to sue its customers—patients and doctors—for patent infringement.⁶⁷

C. Contributory Infringement in Off-Label Use Scenarios

Under 35 U.S.C. § 271(b), “[w]hoever actively induces infringement of a patent shall be liable as an infringer.”⁶⁸ In the context of off-label use promotion, a drug manufacturer promoting a drug for an unapproved use—a use covered by another's patent—could be liable as an infringer if the promotion activity amounts to actively encouraging purchasers of the drug to use it in a way that is patented and unlicensed.⁶⁹ For patent owners faced with a downstream party promoting the off-label use of a drug, it might be a better course of action to pursue a remedy against the downstream party under a theory of contributory infringement instead of suing doctors or patients.

However, a theory of contributory infringement is not without difficulty; courts have required “specific intent and action to induce infringement” in situations involving off-label use promotion.⁷⁰ To illustrate, in *Warner-Lambert Co. v. Apotex Corp.*, the U.S. Court of Appeals for the Federal Circuit stated that “[e]specially where a

65. *Id.*

66. *Id.*

67. *Id.* at 724–25.

68. 35 U.S.C. § 271(b) (2006).

69. *See generally* *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 621 (2008); *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 126–27 (1938); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 702–03 (Fed. Cir. 1992).

70. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003).

product has substantial noninfringing uses, intent to induce infringement cannot be inferred even when the defendant has actual knowledge that some users of its product may be infringing the patent.”⁷¹ Further, the court also rejected liability for infringing off-label use of the drug⁷² and ruled that a company does not commit infringement by submitting an abbreviated new drug application (“ANDA”) for approval to market a drug for a use when both the patent on the drug and the patent on the approved use were expired, even if a patent still existed covering a non-approved use of the drug.⁷³ Simply stated, as it relates to generic drug applications, patent infringement does not apply to off-label uses because an ANDA cannot be obtained for a non-FDA approved use.⁷⁴

While *Warner-Lambert* is important for understanding the limitations surrounding infringement in off-label use scenarios (the “specific intent and action to induce infringement” requirement), in order to avoid confusion, it is important to narrowly apply its criteria for establishing contributory infringement. For example, while *Warner-Lambert* precludes liability for infringement where there is promotion of a patented but non-approved use for a generic drug,⁷⁵ it is not analogous to the situation of a patent owner enforcing rights against a downstream party to a license agreement. In contrast, in a licensing scenario, there is already an approved drug developed for a specific use, not a competing generic drug. Further, in a licensing arrangement, at issue is whether promotion of the approved drug for an

71. *Id.* at 1365.

72. *Id.*

73. *Id.* at 1356. Under the Hatch-Waxman Act, ANDAs can be filed for a generic drug that is the same as the approved drug in terms of active ingredient, dosage form strength, route of administration, labeling, or is “bioequivalent” to the approved drug. 21 U.S.C. § 355(j)(2)(A)(ii)–(v). The Act provides protection for the patent owner of the approved drug by requiring that the ANDA applicant certify the status of patents, which claim the drug or method of using the drug, and provides a thirty-month stay of FDA approval of the generic drug once litigation is initiated on certified patents even if the ANDA meets the criteria for approval. *See id.* § 355(j).

74. The prohibited “use” as defined in 35 U.S.C. § 271(e)(2)(A) does not apply to off-label uses because an ANDA cannot be obtained for a non-FDA approved use. Martin, *supra* note 33, at 167.

75. *See Warner-Lambert Co.*, 316 F.3d at 1365.

unapproved but patented use qualifies as inducing infringement as a result of some breach of the license agreement with respect to the field restriction. In this scenario, the analysis of whether patent infringement has occurred is not whether *Warner-Lambert* precludes liability for off-label use promotion, but whether the downstream party to the license agreement had specific intent and action to induce infringement through the promotion of its drug for the off-label use in violation of the license agreement. Key to this patent infringement analysis will be whether the patent owner/licensor has adequately defined the scope of the license grant and whether the doctrine of exhaustion has been triggered.

IV. THE DOCTRINE OF EXHAUSTION AND BIOTECH LICENSE AGREEMENTS

According to the doctrine of exhaustion, which is also known as the “first-sale doctrine,” the sale of a patented product by or with the permission of the patent owner will exhaust the patent rights to that product.⁷⁶ If exhaustion has been triggered, the patent owner cannot control what the buyer or user of the patented good does with that good, nor sue the buyer or user for patent infringement.⁷⁷ In the context of license agreements, patent owners should be concerned with when exhaustion may be triggered, specifically if they seek to restrict certain uses of their patented technology through the license agreement. To illustrate, biotech companies often utilize field-of-use restrictions in their license agreements to define the scope of the license, which is the area in which the patent owner agrees not to sue the licensee for patent infringement.⁷⁸ Field-of-use restrictions in biotech licensing agreements should afford the patent owner protections going forward into R&D collaborations and provide remedies if a party breaches the agreement.⁷⁹ Unfortunately, the legal support

76. Eisenberg, *supra* note 32, at 362; *see also* John. W. Osborne, *A Coherent View of Patent Exhaustion: A Standard Based on Patentable Distinctiveness*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 643, 646 (2004).

77. *See* Osborne, *supra* note 76, at 647.

78. *See* BIO Amicus Brief, *supra* note 13, at 17–18.

79. *See id.* at 18–19.

for field-of-use restrictions is currently in a confused state.⁸⁰ Simply stated, recent U.S. Supreme Court case law suggests that there are strict limitations on licensing practices, such as field-of-use restrictions, which appears to be at odds with Federal Circuit case law as well as previous U.S. Supreme Court precedent.⁸¹

A. *U.S. Supreme Court and Federal Circuit Field-of-Use Restrictions Precedent*

Field-of-use restrictions in licensing agreements were legitimized by the U.S. Supreme Court in *General Talking Pictures Corp. v. Western Electric Co.*, in which the Court stated that a patent owner “may grant a license ‘upon any condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure.’”⁸² *General Talking Pictures* involved a field restriction in a license agreement that allowed American Transformer Company to manufacture vacuum tubes from AT&T’s patented technology for non-commercial use, but not for commercial use.⁸³ The Court held that American Transformer Company and its purchaser, General Talking Pictures, were liable for patent infringement for manufacturing vacuum tubes for commercial theater use in violation of the license agreement.⁸⁴

Additionally, the Federal Circuit Court of Appeals has held that an express restriction precludes the doctrine of exhaustion unless there is some antitrust violation or patent misuse; the field restriction must be within the scope of the patent.⁸⁵ For example, in *Mallinckrodt, Inc. v. Medipart, Inc.*, the Federal Circuit confirmed that a purchaser of a patented product will infringe the patent when it uses the product in violation of a lawful restriction or condition as specified

80. See Patterson, *supra* note 24, at 164.

81. See *id.*

82. *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 127 (1938) (quoting *United States v. Gen. Elec. Co.*, 272 U.S. 476, 489 (1926)).

83. See *id.* at 125–26.

84. See *id.* at 127.

85. See *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) (“Unless the condition violates some other law or policy (in the patent field, notably the misuse or antitrust law), private parties retain the freedom to contract concerning conditions of sale.” (citation omitted)).

by the seller or patent owner at the time of the sale.⁸⁶ In *Mallinckrodt*, Mallinckrodt, Inc. owned patents on a device for delivering chemicals in aerosol form to a patient's lungs.⁸⁷ The devices were sold to hospitals as kits, and, although some parts were marked "Single Use Only" and included instructions that the entire kit should be disposed of after use, some of the hospitals did not dispose of the devices and, instead, shipped parts to Medipart, Inc., which sterilized them, reassembled them with new parts, and shipped the kits back to the hospitals.⁸⁸ The court ruled that such use, in violation of a valid restriction, might be remedied under patent law because the restriction related to subject matter within the scope of the patent claims.⁸⁹

B. *Quanta and the Doctrine of Exhaustion Revisited*

While *General Talking Pictures* and *Mallinckrodt* upheld license restrictions and limited the application of the doctrine of exhaustion, in 2008, the U.S. Supreme Court revisited the doctrine of exhaustion in *Quanta* in a way that has created significant confusion across many industries that rely on patent licensing.⁹⁰ The Court's opinion in *Quanta* reinforces the idea that "the exclusive right in a patent claim is exhausted when an article embodying the 'essential features' of the claim is transferred in an authorized and unrestricted manner."⁹¹ Specifically at issue was 1) whether the doctrine of exhaustion applied to the sale of components of a patented system, where the components could be combined with unpatented components in order to practice the patented method; and 2) whether the licensor's attempt to restrict downstream manufacturers from combining these components was valid.⁹² For the biotech industry, however, this decision has created confusion over the Court's opaque interpretation of the term "post-sale restriction," whether or when

86. *See id.* at 701.

87. *See id.* at 701–02.

88. *Id.* at 702.

89. *See id.* at 708–09.

90. *See Osborne, supra* note 76, at 657.

91. *Id.* at 646; *see also Schlicher, supra* note 20, at 827.

92. *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 621 (2008).

post-sale restrictions are invalid, and how to respond to what appears to be a stricter interpretation of the doctrine of exhaustion compared to Federal Circuit precedent and *General Talking Pictures*.⁹³

In *Quanta*, LG Electronics (“LGE”) and Intel entered into a cross-licensing agreement in which LGE authorized Intel to “make use, sell (directly or indirectly), offer to sell, import or otherwise dispose of” Intel products, but provided that no license would be “granted by either party hereto . . . to any third party for the combination by a third party . . . or for the use, import, offer for sale or sale of such combination.”⁹⁴ This license arrangement between LGE and Intel involved two separate agreements: a License Agreement and a Master Agreement.⁹⁵ The License Agreement provided Intel the broad set of patent rights and also ensured that any Intel product purchased by a third party would be licensed by LGE.⁹⁶ However, the License Agreement included a provision that stated that the license would not extend to third-party products made by combining Intel products with any non-Intel product, which was an attempt to exert some control over the third-party licenses.⁹⁷

Furthermore, the Master Agreement required Intel to provide its customers with written notice of this provision but stated that a breach of the Master Agreement would not be grounds for termination of the License Agreement.⁹⁸ Intel sold microprocessors and chip sets under the license to manufacturers, including Quanta, and Quanta used the microprocessors and chip sets to assemble computers that were sold for resale to computer users.⁹⁹ The Court held that the components sold by Intel substantially embodied the inventions of LGE’s patents, that Intel’s sale to Quanta constituted an autho-

93. See Schlicher, *supra* note 20, at 828.

94. *Quanta Computer, Inc.*, 553 U.S. at 623 (quoting Brief for Petitioners at 8, *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008) (No. 06-9307), 2007 WL 3276505, at *7 [hereinafter Brief for Petitioners]).

95. See *id.*

96. See *id.* (citing Brief for Petitioners at 8).

97. See *id.* at 624 (citing Brief for Respondent in Opposition at 7, *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008) (No. 06-9307, 2007 WL 760215, at *7 [hereinafter Brief for Respondent])).

98. See *id.* at 623–24 (citing Brief for Respondent at 7, 26).

99. See *id.* at 624.

rized sale, and that Intel's authorized sale exhausted LGE's patent rights.¹⁰⁰

Quanta has three significant consequences for the patent licensing community.¹⁰¹ First, before *Quanta*, the Court applied the doctrine of exhaustion to prohibit an infringement claim against a purchaser only when the patent owner (or licensee) sold a patented product that embodied all the features claimed by the patent.¹⁰² Following *Quanta*, in order to determine if exhaustion will apply, the patent owner needs to "understand the novel features of each invention of each patent . . . and must make judgments about whether all those novel features are found in the product to be sold and whether there are alternative uses for the product at the time of the sale."¹⁰³ Second, in *Quanta*, the Court stated that "post-sale" restrictions are invalid, which could mean that when exhaustion applies, patent owners may not sell a patented invention and then license the patent rights separately in a way that would reserve any patent rights.¹⁰⁴ Third, *Quanta* determined that exhaustion only applies to sales that the license agreement authorized a licensee to make, which, depending on the scope of the license agreement, means that a licensee could sell unpatented products to a purchaser who subsequently makes its own product or carries out a process covered by the original patent.¹⁰⁵

What *Quanta* leaves unclear is whether field-of-use restrictions in biotech license agreements qualify as the type of "post-sale" restriction that the Court found invalid and whether patent owners will be precluded by the doctrine of exhaustion from enforcing patent rights against downstream uses of their patented technology even if they employ field-of-use restrictions.

100. See *Quanta Computer, Inc.*, 553 U.S. at 621 ("Because the exhaustion doctrine applies to method patents, and because the license authorizes the sale of components that substantially embody the patents in suit, the sale exhausted the patents.").

101. See Schlicher, *supra* note 20, at 764. ("The language of the *Quanta* decision has three and perhaps four important consequences.").

102. *Id.*

103. *Id.*

104. *Quanta Computer, Inc.*, 553 U.S. at 638; see Schlicher, *supra* note 20, at 764.

105. See Schlicher, *supra* note 20, at 764.

V. POST-*QUANTA* APPLICATION OF THE DOCTRINE OF EXHAUSTION
TO THE BIOTECH INDUSTRY

A. *Narrow Construction of Quanta and the Doctrine of Exhaustion*

In his article, *The New Patent Exhaustion Doctrine of Quanta v. LG: What It Means for Patent Owners, Licensees, and Product Customers*, John Schlicher states that “*Quanta* is understandable. However, it is also unfortunate. In this situation, an oddly written agreement may have resulted in fundamental and sensible doctrines of patent law being swept away for no good reasons.”¹⁰⁶

According to Schlicher, *Quanta* held that a patent owner could enter a license agreement with a purchaser who agrees to limit its use of the patented technology or product.¹⁰⁷ However, the Court implied that this kind of agreement may not be used by the patent owner to reserve any of its patent rights related to the purchaser’s use of the product; the patent owner’s only remedy in regard to the agreement would be for breach of contract, not patent infringement.¹⁰⁸ Further, the Court stated that the initial authorized sale of a patented product terminated all the patent rights to that product, and that the initial authorized sale of an unpatented product that “substantially embodies” a patented invention also terminates all the patent rights to invention.¹⁰⁹

In deciding this issue, the Court neither discussed the Federal Circuit’s decision in *Mallinckrodt* regarding conditioned sales, nor analyzed the reasoning of *General Talking Pictures* regarding field-of-use restrictions. However, a careful reading of *Quanta* can find that neither *Mallinckrodt* nor *General Talking Pictures* has been expressly overruled.¹¹⁰ Instead, *Quanta* only affirmed that an authorized sale by a licensee will trigger exhaustion.¹¹¹ To illustrate, the Court interpreted the language of the Intel-LGE license agreement as

106. *Id.* at 849.

107. *Id.* at 836.

108. *See Quanta Computer, Inc.*, 553 U.S. at 637 n.7; Schlicher, *supra* note 20, at 846.

109. *Quanta Computer, Inc.*, 553 U.S. at 637; *see* Schlicher, *supra* note 20, at 793.

110. *See generally Quanta Computer, Inc.*, 553 U.S. at 621.

111. *See id.* at 638.

imposing no express limitations on Intel's right to sell products to purchasers who would combine Intel's products with others to make computers.¹¹² Specifically, the Court ruled that the Intel-LGE agreement "broadly permits Intel to 'make, use, [or] sell' products free of LGE's patent claims."¹¹³ Further, the Court held that Intel's authority to sell products containing LGE's patented technology was not conditioned on a notice appearing in the separate Master Agreement, requiring Intel to give notice to customers that LGE did not license Intel customers to practice its patents.¹¹⁴ The Court held that this notice did not constitute an express limitation, and, because there was no express limitation in the license agreement, Intel's sale to Quanta was authorized, thereby triggering exhaustion and precluding LGE from suing Quanta for patent infringement.¹¹⁵ Additionally, while not analyzing *General Talking Pictures* with any depth, *Quanta* appeared to interpret *General Talking Pictures* as holding that the licensee, American Transformer Company, did not breach the license agreement with AT&T but, instead, made a sale outside the scope of its license, therefore rendering the downstream manufacturer, General Talking Pictures, a patent infringer.¹¹⁶

The Court in *Quanta* was narrowly applying the doctrine of exhaustion to a poorly written license agreement and was not attempting to broaden exhaustion to preclude field-of-use restrictions in any license agreement. *Quanta* merely holds that a provision that required notification to the licensee's customers that they were not licensed to practice the licensor's patents was not a clear or express restriction on the licensee's rights.¹¹⁷ As a result, even though the Court did not provide guidance on how a clear or express restriction should be written, *Quanta* still supports the argument that selling

112. See *Quanta Computer, Inc.*, 553 U.S. at 635–37; Schlicher, *supra* note 20, at 848.

113. *Quanta Computer, Inc.*, 553 U.S. at 636.

114. See *id.*

115. See *id.* at 637.

116. See Schlicher, *supra* note 20, at 848 (citing *Quanta Computer, Inc.*, 553 U.S. at 635–36); see also *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 126 (1938).

117. See Schlicher, *supra* note 20, at 848.

outside of the scope of a license agreement—an unauthorized sale—can constitute patent infringement.¹¹⁸

B. *Biotech License Agreements Should Be Structured to Prohibit the Doctrine of Exhaustion*

Under a narrow reading of *Quanta*, there are three scenarios that can prevent the doctrine of exhaustion from being triggered: 1) a sale was not authorized; 2) a purchaser lacked the authority to buy a patented product; or 3) the purchaser violated a reasonable restriction on alternative uses of the product that are within the scope of the patent rights.¹¹⁹ Underlying all of these scenarios is the premise, derived from *General Talking Pictures*, that a sale made without authority cannot confer rights on the purchaser because the seller cannot transfer rights that it does not have.¹²⁰

Additionally, even though the U.S. Supreme Court in *Quanta* confined its analysis to the specific LGE-Intel license agreement terms and did not attempt to address broader issues (such as how its holding might impact biotech or software industries), biotech licensors should still be wary of triggering the doctrine of exhaustion. Obviously, in the biotech industry, the purpose of licensing patent rights through collaborative license agreements is to maintain the patent owner's rights, not to exhaust them.¹²¹ Further, the kinds of arrangements in the biotech industry—between patent owner and licensee, between patent owner and multiple licensees for the same product, or between patent owner, licensee, and sublicensee or third party—are not the kind of “arms-length” sales with purchasers that the doctrine of exhaustion evolved to address.¹²² However, *Quanta* demonstrates that the Court will view a poorly written license restriction as an invalid attempt to exert control beyond the scope of the patent rights. Therefore, despite a narrow interpretation of

118. *Id.* at 848–49.

119. BIO Amicus Brief, *supra* note 13, at 16.

120. *Gen. Talking Pictures Corp.*, 305 U.S. at 127; *see also* *Mitchell v. Hawley*, 83 U.S. 544, 550 (1873) (“[N]o one can convey in such a case better title than he owns . . .”).

121. BIO Amicus Brief, *supra* note 13, at 21.

122. *Id.* at 21.

Quanta, field-of-use restrictions in biotech license agreements, while still valid provisions, will not always prevent exhaustion of one's patent rights unless the restrictions are clearly and expressly stated.¹²³

VI. CONCLUSION

As successful as the biotech industry has become in the last few decades, off-label use promotion is still a significant issue due to increased competition within the industry and a lack of strong FDA regulation. Biotech companies often seek to combat off-label use promotion or other abuses of patent rights by including field-of-use restrictions in their license agreements. While the *Quanta* and *Warner-Lambert* decisions create some uncertainty regarding whether field-of-use restrictions can be effective in combating off-label use promotion, *Warner-Lambert* should not be construed as prohibiting patent infringement remedies against all forms of off-label use promotion, and *Quanta* should be narrowly interpreted as holding that only authorized sales by a licensee will trigger patent exhaustion.

In summary, patent owners in the biotech industry should be able to prevent off-label use promotion with carefully drafted field-of-use restrictions within license agreements. However, such field-of-use restrictions must reasonably define the scope of the license, so that the doctrine of exhaustion will not be triggered when a licensee or downstream third party promotes a drug for an unlicensed and unapproved off-label use. Otherwise, the licensee or third party could be held liable for patent infringement.

123. *See id.* at 20.