COURSE SYLLABUS

BIOTECHNOLOGY LAW
Fall 2023, Biotechnology GU4160

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Course Objective

This course introduces students to the interrelated fields of patent law, regulatory law, and contract law that are vital to the biotech and biopharmaceutical sectors. It presents core concepts in a way that permits students to use them throughout their careers.

Overview

"Biotechnology law" is used here to mean the interrelated areas of patent law, regulatory law, and contract law.

Patents and related agreements have become critical resources for universities and research institutes. Similarly, patents, regulatory filings, and patent-related agreements are indispensible to biotech and pharmaceutical companies. There are, of course, many other legal disciplines having at least some nexus with the biotech and pharmaceutical industries. They include such diverse specialties as corporate law, securities law, real estate law, employment law, tax law, and healthcare law. However, the patent, regulatory, and contract law concepts that this course presents are not only central to these industries, but also uniquely intertwined with each other and the underlying science.

This course arms students with an understanding of these fields so that, during their biotech careers, they can productively work with counsel to manage their organizations' patent portfolios and litigations, negotiate and draft development and license agreements, and oversee regulatory affairs germane to patent protection, licensing, innovator small molecule and biologic drugs, generic drugs, and biosimilars.

The biotech, pharmaceutical, and molecular diagnostic sectors are the course's industrial focus. Students are presumed to have a solid understanding of the underlying science (e.g., the structure and function of proteins, nucleic acids, antibodies, enzymes, and receptors, and the basics of organic chemistry and metabolic pathways). Graduate

students and upper level undergraduate students in biotechnology, biomedical engineering, and the like are more than qualified to take this course.

Lectures

The lecture schedule is provided below. Within reason, the material to be covered is subject to change, particularly to accommodate changes in the law and the addition of relevant topics based on student demand.

Class 1 – September 5, 2023

Course overview.

The concept of intellectual property law. Introduction to patents, trademarks, copyrights and trade secrets, and the differences between these forms of protection.

The patent as a negative right, and as a quid pro quo for disclosing an invention to the public. Components of a patent, particularly the specification and claims. Technical content versus legal content.

The claim as the business end of a patent. Claim types, language, and structure. The notions of claim element and claim scope, including a Venn diagram approach to understanding a claim's scope and resulting function.

Class 2 – September 12, 2023

Claim construction by courts. Intrinsic and extrinsic evidence considered in determining the meaning of individual claim elements.

The requirements for patentability. Patent-eligible subject matter and the shifting and controversial patent-eligibility threshold in the United States. Utility, and the need to understand an invention's purpose. Novelty, and anticipation by inherency. Non-obviousness, and related factors. The requirements for the patent document – enablement, written description, and definiteness, and related challenges in patenting biotech and pharmaceutical inventions.

Class 3 – September 19, 2023

Patent prosecution, and the steps and strategies for obtaining patents. Identifying the invention rather than the science. Preparing and filing a patent application. Substantive examination by a patent office, and strategic considerations (e.g., business objectives, patentability considerations, timing, and cost).

Patent term, term extensions, term adjustments, and their importance in the biopharmaceutical industry. Continuing patent application practice as a means for broadly protecting multifaceted inventions.

Class 4 – September 26, 2023

The importance of inventorship under U.S. patent law. Distinguishing inventorship from authorship. The consequences of incorrectly determining inventorship.

How patents operate. Preclusion of third party activity, ideally without adversarial action by the patentee. Patent licensing and assignment, and related tactical considerations (covered in more detail in Class 11).

Patent infringement and enforcement. Types of infringement, namely, direct infringement, induced infringement, contributory infringement, literal infringement, and infringement under the doctrine of equivalents. Infringement determination by a court.

Defenses to a patent infringement suit, namely, the non-infringement defense, the invalidity defense, the unenforceability defense, and others. The differences between invalidity, non-patentability, and unenforceability. The duty of candor and patent unenforceability under U.S. law.

Class 5 – October 3, 2023

The role of legal opinions regarding patent infringement, patent invalidity, and freedom-to-operate. Standards for a proper legal opinion, and degrees of risk. Consequences of obtaining and relying on patent-related legal opinions.

Understanding and managing patent portfolios. Portfolio valuation, relevance to companies and universities, potential for licensing, and cost management.

Trademark and trade secret protection for biotech and pharmaceutical inventions. Seeking trade secret protection versus patent protection. Using multiple forms of intellectual property protection for a single drug product.

Class 6 – October 10, 2023

Patent law and public policy, i.e., patent-related ethics. The U.S. Supreme Court and its controversial rulings on patenting genes and diagnostic and personalized medical methods. "Breaking" drug patents to combat health crises; the case of AIDS drug patents in South Africa. A patentee's right to control the post-sale use of its invention; the case of Monsanto's Roundup Ready® seed patents.

Class 7 – October 17, 2023

Exam 1 during the first hour.

Obtaining FDA approval for an innovator small molecule drug. The key stages in drug development, including (i) research and development; (ii) pre-clinical testing; (iii) IND filing; (iv) clinical trials (e.g., Phases I-III); (v) NDA filing and approval; and (vi) post-approval studies.

FDA data and market exclusivities (e.g., NCE, CI, pediatric, and orphan drug exclusivities); the differences and interplay between FDA exclusivity and patent protection.

Class 8 – October 24, 2023

The Hatch-Waxman Act and generic drugs. Historical problems with the pre-1984 drug approval regime and patent system. The ANDA and its advantages. Orange Book patent listings, paragraph IV certifications, and related litigation.

Pricing and consumer benefits of generic drugs. Ethically fraught tactics such as reverse payment agreements, evergreening, and product hopping.

Class 9 – October 31, 2023

The BLA and requirements for obtaining FDA approval for a biologic drug. The biologic drug industry generally; development costs and pricing; length of monopoly; and the need for a biosimilars pathway.

The Biosimilars Act (i.e., the BPCI Act) as part of the 2010 Affordable Care Act. Obtaining FDA approval for biosimilar products as opposed to interchangeable products. The 12-year exclusivity period for innovator biologics, and related public policy issues.

Comparison between the biosimilar and generic drug industries (e.g., different molecules and manufacturing problems; different industry players; different exclusivities; different economics; different legal proceedings; and the different roles of the Orange Book and Purple Book).

Class 10 – November 9, 2023 [Thursday, Election Week]

Contracts generally. Required elements of a contract, namely lawful purpose, competent parties, offer and acceptance, and mutual consideration.

Key factors to consider, such as the basic nature of the transaction or underlying activity, and future events to be ensured or avoided.

Material Transfer Agreements. Key factors, such as the material being transferred and the reason for its transfer.

Confidentiality Agreements. Key factors, such as length of the confidentiality obligation, and the need for the obligation in the first place.

Class 11 – November 14, 2023

License Agreements. Key factors, such as the subject matter being licensed; mode of licensing (e.g., know-how versus patent rights); the bundle of rights being licensed; license territory; and license exclusivity.

As applicable, other key provisions such as parties; definitions; grant of rights (for licenses); payments; intellectual property ownership and costs; termination; and assumption of risk.

Collaboration Agreements – Part I. Key factors, such as the goal of the agreement; likely inventions; ownership of, and control over, the resulting intellectual property; marketing and manufacturing obligations; assumption of risk; and other factors also germane to license agreements.

Class 12 – November 21, 2023

Collaboration Agreements – Part II (See Above).

Additional Topics – Part I. *Medimmune v. Genentech* and the right of a patent licensee in good standing to challenge the validity of the licensor's patent. State government regulation of biosimilar drug sales. The inability of a consumer to obtain monetary damages from a generic drug manufacturer for bodily harm caused by the manufacturer's product. The pros and cons of compassionate use for investigational new drugs. New and pending U.S. legislation regarding regulatory and patent matters.

Class 13 – November 28, 2023

Additional Topics – Part II (See Above).

Class 14 – December 5, 2023

Exam 2 during the first hour.

Reading Materials

The textbook BIOTECHNOLOGY LAW: A PRIMER FOR SCIENTISTS (Columbia University Press, 2020) is required for this course.

In addition, I'll provide written comments before each lecture. The comments will include (i) the required textbook reading and (ii) a robust list (with links) of supplemental reading materials and resources such as relevant statutes, regulations, case law, scholarly articles, websites, news reports, and other helpful sources of information. The supplemental reading materials and resources are entirely optional, and are intended solely to enhance students' understanding and enjoyment of the material presented in class. For a few of the lectures, the comments will also include brief explanations of subjects to be covered during class that are not addressed in the textbook.

The texts and treatises listed below are written for attorneys specializing in patent and regulatory law. As such, they may be useful as library resources for the research paper assigned in this course. However, I do not recommend that you purchase any of them.

Burchfiel, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT, BNA Books

Iver Cooper, BIOTECHNOLOGY AND THE LAW

Donald S. Chisum, CHISUM ON PATENTS

Brunsvold and O'Reilly, DRAFTING PATENT LICENSE AGREEMENTS, 4th Ed., BNA Books

Beers and Karst, GENERIC AND INNOVATOR DRUGS: A GUIDE TO FDA APPROVAL REQUIREMENTS, Wolters Kluwer

PHARMACEUTICAL AND BIOTECH PATENT LAW, Practising Law Institute (Arnold Porter Kaye Scholer LLP)

Thomas, PHARMACEUTICAL PATENT LAW, BNA Books

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