University of Washington School of Law

Biotechnology and the Law
LAW E570 A

Spring 2002 (3 Credits)

Monday/Wednesday 1:30-2:45 p.m.

GENERAL INFORMATION AND COURSE SYLLABUS

Anna Mastroianni JD, MPH
Assistant Professor
Condon Hall 608; Health Sciences F363D
Tel.: 206/616-3482 (CH);
206/616-1257 (HS)
E-mail: amastroi@u.washington.edu
Office Hours: By Appointment

Jennifer Johnson, MS (Microbiology), JD
Patent Attorney
Associate Director, Intellectual Property
ZymoGenetics, Inc.
Tel: 206/ 442-6676
E-mail: johnsonj@zgi.com
Office Hours: By Appointment

Summary of Course

This seminar course will address the dynamic biotechnology industry and the law affecting it. The course will begin with an overview of the history and trends within the industry, considering biotechnologic products and methods in the production of food, in pesticides and in the drugs and biologics used in medicine. Part II of the course will consider protection of and property rights in new biotechnology products including ownership and patentability. Part III will turn to the regulatory framework applicable to these new products and how it has been modified to address the special issues presented by use of biotechnologic methods, focusing on FDA, EPA and USDA regulations. In Part IV, the course will conclude with examination of the risks and liability faced by the biotechnology industry, especially in the context of product liability and toxic torts. During the course, students will research and write a four-part case study on a biotechnologic product assigned by the professors (see attached list).

Required Texts

There is no textbook for this course. The Course Materials include several cases, articles, excerpts from books and other texts, and legislative/regulatory materials. They are available for purchase in two parts from RAMS Copy Center, 4144 University Way N.E., 206/632-6630. Since RAMS conservatively estimates the number of copies it makes, anticipating course drops, you may wish to call ahead to ensure that a copy is immediately available. RAMS assured us that they would turn a copy request around within a day.

In addition to the assigned reading materials, the syllabus identifies supplemental, optional readings that may prove useful for researching the case studies. You can locate these references via Lexis/Nexis, WestLaw or through the Law Library.


**Class Participation**

The course will be conducted in lecture/discussion format. Active participation by students is strongly encouraged.

**Course Grade**

The course grade will be based upon a four-part case study researching the development and use of a biotechnology product. The class sessions will serve to provide students with a general overview of the law to serve as the underpinnings for the more detailed and product-oriented research necessary for the case study. You are welcome and encouraged to contact the manufacturer or developer early in the course for background information.

**Part I** of the case study (5-10 pages) will describe the biotechnologic and scientific advances leading up to the development of the product, the uses for the product, and public policy and ethical concerns (if any) raised during or after development.

**Part II** of the study (12-15 pages) will focus on the intellectual property protections available to and chosen by the manufacturer and/or developer of the product. The paper should include: an evaluation or critique of the IP protection available for the product; an assessment of the strength/weakness of that IP under current law; how a manufacturer may protect follow-on inventions (what are those inventions), as well as how a competitor may draft applications on related products around the protections a manufacturer currently has in place, as well as additional ways, aside from patent protection, that a manufacturer may protect the product, or gain value from the product.

**Part III** of the study (12-15 pages) will trace the product’s journey through the regulatory maze and identify the specific regulations that had to be complied with to bring the product to market. In addition, the paper should include an analysis under current law, as discussed in class, if the law differs from the time of product approval.

**Part IV** of the study (8-10 pages) will consider the potential liability associated with the product and means by which the manufacturer might protect against that liability.

Papers should be *double spaced, one-inch margins, 12-point font.* In fairness to other students, *papers handed in late will receive 1 point off for every day late.*

Due dates and grading weights/points for each part of the case study are presented below. Early submissions are always welcome, but graded papers will be handed back to the class as a group.

<table>
<thead>
<tr>
<th>Part</th>
<th>Topic</th>
<th>Due Date</th>
<th>Grade Weight (%/points)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Product, Policy, Ethics</td>
<td>Monday, April 15, 2002 (beginning of class)</td>
<td>20</td>
</tr>
<tr>
<td>II</td>
<td>Intellectual Property Protections</td>
<td>Monday, May 6, 2002 (beginning of class)</td>
<td>30</td>
</tr>
<tr>
<td>III</td>
<td>Regulatory Approaches</td>
<td>Wednesday, May 29, 2002 (beginning of class)</td>
<td>30</td>
</tr>
<tr>
<td>IV</td>
<td>Potential Liability</td>
<td>June 7, 2002, 4:00 p.m., to Prof. Mastroianni’s mailbox, 3rd Floor</td>
<td>20</td>
</tr>
</tbody>
</table>
**COURSE SYLLABUS**

Below is the syllabus for the first half of the course. The syllabus for the remainder of the course will be provided to students by the third week of classes and will cover regulation (FDA/EPA/USDA and international) and liability (products liability and toxic torts).

The syllabus is presented to you in two formats: (1) a Condensed Syllabus, which references topics and pages in the Course Materials, and (2) a Detailed Syllabus, which provides more detailed topic descriptions, specific citations to required readings in the Course Materials, and, various research materials which you can access on your own to aid in product research, including additional legal resources, readings, and on-line resources.

**CONDENSED SYLLABUS**

<table>
<thead>
<tr>
<th>Class #</th>
<th>Date</th>
<th>Assignment Due</th>
<th>Subject Matter (See Detailed Syllabus for specific topics)</th>
<th>Reading (See Detailed Syllabus for specific citations)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>April 1</td>
<td></td>
<td>1. Introduction to Course 2. Library Research Training 3. Product Assignments</td>
<td>None</td>
</tr>
<tr>
<td>2</td>
<td>April 3</td>
<td></td>
<td>Part I: Biotechnology: History and Market Trends</td>
<td>Course Materials pp. 1-70</td>
</tr>
<tr>
<td>3</td>
<td>April 8</td>
<td></td>
<td>Part I: Biotechnology: Ethics and Public Policy</td>
<td>Course Materials pp. 71-161</td>
</tr>
<tr>
<td>4</td>
<td>April 10</td>
<td></td>
<td>Part II: Intro. to Biotech. IP Intro. to Patent Law</td>
<td>Course Materials pp. 162-247</td>
</tr>
<tr>
<td>5</td>
<td>April 15</td>
<td>Part I (beginning of class)</td>
<td>Part II: 1. 35 USC 101 Utility 2. 35 USC 102 Novelty</td>
<td>Course Materials pp. 248-286</td>
</tr>
<tr>
<td>6</td>
<td>April 17</td>
<td></td>
<td>Part II: 1. 35 USC 103 Non-Obviousness 2. 35 USC 112, ¶1 - Written description</td>
<td>Course Materials pp. 287-383</td>
</tr>
<tr>
<td>7</td>
<td>April 22</td>
<td></td>
<td>Part II: 1. 35 USC 112, ¶1 - Enablement 2. 35 USC 112, ¶1 - Best Mode 3. 35 USC 112, ¶2 - SM regarded/clarity</td>
<td>Course Materials pp. 384-440</td>
</tr>
<tr>
<td>8</td>
<td>April 24</td>
<td></td>
<td>Part II: Patent Law - Other Aspects</td>
<td>Course Materials pp. 441-512</td>
</tr>
<tr>
<td>9</td>
<td>April 29</td>
<td></td>
<td>Part II: Intro. To Licensing</td>
<td>Course Materials pp. 513-552</td>
</tr>
</tbody>
</table>
DETAILED SYLLABUS

April 1, 2002

Introduction to Course
Library Research Training
Product Assignments

Reading: None

April 3, 2002

I. Biotechnology: History, Market Trends, Public Policy and Ethics
   A. History and Market Trends

Reading:


April 8, 2002

I. Biotechnology: History, Market Trends, Public Policy and Ethics (cont.)
   B. Ethics and Public Policy

Reading:


April 10, 2002:

II. Introduction to Biotechnology Intellectual Property
   (a) Where one might protect a biotech invention as the product is developed
   (b) Types of protection (focus: Patents): Patent; TM; TS; licensing
   (c) What types of concerns to consider (e.g., freedom to operate and competition)
   (d) What to do with it once it is yours - realizing value of a product
(1) co-development/manufacturing
(2) licensing
(3) trademark

Resources online:

Legal Resources:
37 CFR - Patents, Trademarks, and Copyrights
Title 35 - United States Code - Patents; particularly CHAPTERS 10-14, and 26-29

Reading:
Select sections of Title 35 - United States Code - Patents: §101-103 and §112
Rebecca Eisenberg, Proprietary Rights and Norms of Science in Biotechnology Research, 97 YALE L.J. 177 (1987)

(1) Introduction to Patent Law for Biotechnology Inventions
(a) Purpose of obtaining Patent - associated rights
(b) Structure of a patent application
(c) What needed to obtain patent: Novelty, Non-Obvious, Useful
(d) Patent Law: Subject matter of an Invention

Reading:
Ex Parte Hibberd, 1985 Pat. App. LEXIS 11; 227 USPQ.2d 443 (1985)

Additional Reading:
Funk Bros. V. Kalo, 333 US 127 (S. CT 1948)
Parke-Davis & Co. v. HK Mulford 189 F 95 (1911)

April 15, 2002:
(1) Introduction to Patent Law for Biotechnology Inventions (cont.)
(e) Patent Law: 35 USC 101 - Utility
   (i) Utility Guidelines
   (ii) Specific, Substantial, Credible

Reading:
Utility Examination Guidelines, 66 FR 1092 (January 5, 2001)


**Additional Reading:**
*Raytheon v. Roper*, 724 F.2d 951 (Fed. Cir 1983)
*In re Gottlieb*, 328 F.2d 1016 (CCPA 1964)
*In re Brana*, 51 F.3d 1560 (Fed. Cir 1995)
*In re Jolles*, 628 F.2d 1322 (CCPA 1980)
*Cross v. Iiziuka*, 453 F.2d 1040 (Fed. Cir 1985)
*In re Langer*, 503 F.2d 1380 (CCPA 1974)
*In re Oetiker*, 977 F.2d 1443 (Fed. Cir 1992)

(f) **Patent Law: 35 USC 102/103 - Novelty/Non-Obviousness**

(i) 35 USC §102 - Novelty
   a. What is Prior Art?
   b. Test for Anticipation §102(a)(b)(e)

**Reading:**
*In re Hall*, 781 F.2d 897 (Fed. Cir. 1986)
*Verdegaal Bros. v. Union Oil*, 814 F.2d 628 (Fed. Cir. 1987)
*In re Gosteli*, 872 F.2d 1008 (Fed. Cir. 1989)
*In re Spada*, 911 F.2d 705 (Fed. Cir. 1990)

**Additional Reading:**
*In re Moreton*, 288 F.2d 708 (CCPA 1961)
*In re Nomiya*, 509 F.2d 566 (CCPA 1975)
*In re Slayter*, 276 F.2d 408 (CCPA 1960)
*In re Hack*, 245 F.2d 246 (CCPA. 1957)
*Structural Rubber Products Co. v. Park Rubber Co.*, 749 F.2d 707(Fed. Cir. 1984)

April 17, 2002:

(1) **Introduction to Patent Law for Biotechnology Inventions (cont.)**

(f) **Patent Law: 35 USC 102/103 - Novelty/Non-Obviousness (cont.)**

(ii)35 USC §103 - Obviousness - different Sections
   a. References must be prior art under 102
   b. Test for Obviousness

**Reading:**
*In re Geiger*, 815 F.2d 686 (Fed. Cir. 1987)
*In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995)
*In re Bell*, 991 F.2d 781 (Fed. Cir. 1993)
*Hybritech, Inc. v. Monoclonal Antibodies, Inc*, 802 F.2d 1367 (Fed. Cir. 1986)

**Additional Reading:**
*Panduit Corp. v. Dennison Mfg.*, 810 F.2d 1561 (Fed. Cir. 1987)
*Stratoflex v. Aeroquip*, 713 F.2d 1530 (Fed. Cir. 1983)
*In re Mills*, 916 F.2d 680 (Fed. Cir. 1990)
*In re Brouwer*, 77 F.3d 422 (Fed. Cir. 1996)
In re Papesch, 315 F.2d 381 (CCPA 1963)
In re O’Farrell, 853 F.2d 894 (Fed. Cir. 1988)

(g) Patent Law: 35 USC §112 - Written Description, Enablement, Best Mode, Clarity

(i) 35 USC §112, First paragraph - Written Description
(a) Written Description Guidelines
(b) Tests for Written Description
(c) MPEP

Reading:
    Requirement, 66 FR 1099 (January 5, 2001)
University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997)
Fiers v. Revel v. Sugano, 984 F.2d 1164 (Fed. Cir. 1993)
In re Grimme, 274 F.2d 949 (CCPA 1960)
In re Angstadt, 537 F.2d 498 (CCPA 1976)
Lockwood v. American Airlines, 107 F.3d 1565 (Fed. Cir. 1997)
Purdue Pharma v. Faulding, 230 F.3d 1320 (Fed. Cir. 1994)

Additional Reading:
Margaret Sampson, The Evolution of the Enablement and Written Description Requirements Under 35
In re Deuel, 51 F.3d 1552 (Fed. Cir. 1995)
In re Bell, 991 F.2d 781 (Fed. Cir. 1993)
Vas-Cath Inc. v. Marhurkar, 935 F.2d 1555 (Fed. Cir. 1991)
In re Ruschig, 54 CCPA 1551 (CCPA, 1967)
Hughes Aircraft Co. v. United States, 140 F.3d 1470 (Fed. Cir. 1998)
In re Newton, 414 F.2d 1400 (CCPA 1969)
Hybritech, Inc. v. Monoclonal Antibodies, Inc, 802 F.2d 1367 (Fed. Cir. 1986)
In re Gosteli, 872 F.2d 1008 (Fed. Cir. 1989)
Burroughs Welcome v. Barr Laboratories, 40 F.3d 1223 (Fed. Cir. 1994)
In re Marzocchi, 439 F.2d 220 (CCPA 1971)
April 22, 2002

(1) Introduction to Patent Law for Biotechnology Inventions (cont.)
   (g) Patent Law: 35 USC §112 - Written Description, Enablement, Best Mode, Clarity (cont.)
   (ii) 35 USC §112, First paragraph - Enablement
         (a) Tests for Enablement
         (b) MPEP

Reading:
Amgen. v. Chugai, 927 F.2d 1200 (Fed. Cir. 1991)
In re Fischer, 427 F.2d 833 (CCPA 1970)
In re Wands, 858 F.2d 731 (Fed. Cir. 1998)
In re Angstadt, 537 F.2d 498 (CCPA 1976) - See 35 USC §112, First paragraph - Written Description

Additional Reading:
Gould v. Quigg, 822 F.2d 1074 (Fed. Cir. 1987)
Vas-Cath Inc. v. Marhurkar, 935 F.2d 1555 (Fed. Cir. 1991)
Hybritech, Inc. v. Monoclonal Antibodies, Inc, 802 F.2d 1367 (Fed. Cir. 1986)
In re Marzocchi, 439 F.2d 220 (CCPA 1971)
In re Brana, 51 F.3d 1560 (Fed. Cir 1995)
Cross v. Iizuka, 453 F.2d 1040 (Fed. Cir 1985)
In re Wright 999 F.2d 1557 (Fed. Cir 1993)

(iii) 35 USC §112, First paragraph - Best Mode
      (a) Definition -brief

Reading:
Chemcast Corp. v. Arco, 913 F.2d 923 (Fed. Cir. 1990)
Eli Lilly v. Barr Laboratories, 251 F.3d 955 (Fed. Cir 2001)

Additional Reading:
In re Newton, 414 F.2d 1400 (CCPA 1969)
In re Nelson, 280 F.2d 172 (CCPA 1960)
Irnsthausen v. Nakayama, 1 USPQ2d 1539 (B. Pat. App. & Int. 1985)

(iv) 35 USC §112, Second paragraph - SM regards +Point out and distinctly claim
      (a) Definition -brief/Notice function
      (b) 2-part test

Reading:
In re Moore, 439 F.2d 1232 (CCPA 1971)

Additional Reading:
In re Hill, 161F.2d 367 (CCPA 1947)
Hormone Research Foundation v. Genentech, 904 F.2d 1558 (Fed. Cir 1990)
Ex Parte Porter, 25 USPQ2d 1144 (B. Pat. App. & Int. 1992)
April 24, 2002:
(1) Introduction to Patent Law for Biotechnology Inventions
   (h) Patent Law: Other Aspects -
   (1) Ownership
   (i) Moore v. Regents of the University of California
   (2) Conception and Reduction to Practice
   (3) Inventorship
   (4) Infringement/Defense (35 USC 271/273)
   (5) Orphan Drug Act
   (6) Others - Inventorship

Reading:
Moore v. Regents of the University of California, 793 P.2d 479 (CA S.Ct. 1990)
Fiers v. Revel v. Sugano, 984 F.2d 1164 (Fed. Cir. 1993) - See 35 USC §112, First paragraph - Written Description
Select sections of Title 35 - United States Code - Patents: §271 and §273
Burroughs Welcome v. Barr Laboratories, 40 F.3d 1223 (Fed. Cir. 1994)

Additional Reading:
Gould v. Quigg, 822 F.2d 1074 (Fed. Cir. 1987)
Festo Corp. v. Shoketsu 234 F.3d 558 (Fed. Cir. 2000) - pet'n for certiorari granted

April 24, 2002:
(2) Introduction to Licensing - Technology Transfer; MTA; CDA
   (a) Issues in licensing/Parts of a License for Patented Inventions
   (b) Sections of K's MTA/CDA/RA/License
   (c) Bayh-Dole Act (35 USC §200-212) and Limitations

Reading:
Select sections of Title 35 - United States Code - Patents: Chapter 18 §200 to §212
Dan L. Burk, Misappropriation Of Trade Secrets In Biotechnology Licensing, 4 Alb. L.J. Sci. & Tech. 121 (1994)

Additional Reading:
PRODUCTS

Avonex
Bollgard Insect-Protected Cotton
Cerezyme
CIBA Maximizer Hybrid Corn
Epogen
Herceptin
Humatrope
Leukocell 2
LibertyLink Corn
LYMErix
Neupogen
NewLeaf Potato
Remicade
Synagis
Zanaflex