Contact Information: (Please use emails below rather than GMU email)

Professor Shubin  
shubin@mwzb.com  703-812-5306

Professor Heaney  
Heaney@mwzb.com  703-812-5308

Office Hours: By appointment upon mutual agreement with students.

Class Prerequisites: Students are to have completed Patent Law I and II. The course is a survey course of legal concepts learned in basic patent law classes, but with particular focus on areas that are unique to, or especially problematic in, the chemical/biotech arts, with the majority of readings and examples drawn from legal decisions in those arts. While a background in chemistry, biochemistry or biology is desirable, many prior students have not had a scientific background, and the professors will explain to the extent practical any necessary concepts during class.

Course Readings: There is no text for this course, but instead students are assigned on a weekly basis readings selected from relevant case law and materials published by the United States Patent and Trademark Office, as set forth on the following pages. Students are expected to have completed the readings prior to each class.

Grading: Grading is based upon a final exam at the conclusion of the course. The exam will be a take home, open book, open notes exam (consultation with other persons is prohibited). The exam will be available in the records office at the beginning of the exam period, and due not later than the end of the exam period. Students will be restricted as to the number of days the exam can be retained.

Class Participation: Class attendance is critically important, as the majority of instruction is based on discussion and lecture during the class period. Class participation in discussions may, at the discretion of the professors, be used as an increment adjustment of the final grade.
Reading Assignments:

January 7  Introduction/Inventorship


January 14  Inventorship

*Hitzmann v. Rutter*, 58 U.S.P.Q. 2d 1161 (Fed. Cir. 2001)

January 21  Restriction/Double-Patenting

*In re Basell Poliolefine Italia S.P.A.*, 547 F.3d 1371, 89 USPQ2d 1030 (Fed. Cir. 2009)
*Boehringer Ingelheim GmbH v. Barr Laboratories, Inc.*, 592 F.3d 1340, 93 U.S.P.Q.2d 1417 (Fed. Cir. 2010)
Markush Claims

In re Harnisch, 206 U.S.P.Q. 300 (C.C.P.A. 1980)
Ex parte Hozumi, 3 U.S.P.Q. 2d 1059 (Bd App 1984)

January 28 Utility (101)

In re Brana, 34 U.S.P.Q. 2d 1436 (Fed. Cir. 1995)
Cross v. Iizuka, 224 U.S.P.Q. 739 (CCPA 1985)
In re Fisher, 76 U.S.P.Q. 2d 1225 (Fed. Cir. 2005)
PTO “Revised Interim Utility Guidelines” 66 FR 1092-1099 (available on the PTO website)
In re Bilski, 545 F.3d 943 ,88 U.S.P.Q. 2d 1385 (Fed. Cir. 2008)
Prometheus Labs. v. Mayo Collaborative Services, 581 F.3d 1336, 92 U.S.P.Q. 2d 1075 (Fed. Cir. 2009)
Classen Immunotherapies v. Biogen Idec, Case no. 2006-1634 (Fed. Cir. August 31, 2011)

PTO Examiner Training Materials: “Personalized Medicine”(Given out in class)

February 4 Product-by-Process Claims


Process Claims


Jepson Claims

In re Ehrreich and Avery, 200 U.S.P.Q. 504 (C.C.P.A. 1979)
Preambles


Transition Phrases

*Ex parte Davis and Tuukkanen*, 80 U.S.P.Q. 448 (P.O.B.A. 1949)

February 11 112, Second Paragraph, Indefiniteness

*Eiselstein v. Frank*, 34 U.S.P.Q. 2d 1467 (Fed. Cir. 1995)

Sixth Paragraph


February 18 112, First Paragraph, Enablement

*In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988)
*In re Vaeck*, 20 U.S.P.Q. 1438 (Fed. Cir. 1991)

February 25 112, First Paragraph, Written Description

In re Grasselli, 138 F. 2d 453 (unpublished) (Fed. Cir. 1984)
In re Driscoll, 195 U.S.P.Q. 434 (C.C.P.A. 1977)
Purdue Pharma v. Faulding, 56 U.S.P.Q. 2d 1481 (Fed. Cir. 2000)
Chiron v. Genentech, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004)

PTO “Written Description Training Materials” (Revision 1: 3/25/08)
(available on the PTO website)

**Written Description:** incorporation by reference


**March 4**

**Written Description (or not?)**

*In re Alonso,* 545 F.3d 1015, 88 U.S.P.Q.2d 1849 (Fed. Cir. 2008)
*Ariad v. Lilly,* 560 F.3d 1366, 90 U.S.P.Q.2d 1549 (Fed. Cir. 2009)

**March 11**

**NO CLASS**

**March 18**

**112, First Paragraph, Best Mode**

*Bayer v. Schein Pharmaceuticals,* 64 U.S.P.Q. 2d 1001 (Fed. Cir. 2002)
*Chemcast Corp. v. Arco Industries Corp.,* 16 U.S.P.Q. 2d 1033 (Fed. Cir. 1990)
*Dana Corp. v. IPC Ltd. Partnership,* 8 U.S.P.Q. 2d 1692 (Fed. Cir. 1988)

The “America Invents Act” – Wither 35 USC §102?


March 25  Anticipation

In re Donohue, 226 U.S.P.Q. 619 (Fed. Cir. 1985)
In re Schoenwald, 22 U.S.P.Q. 2d 1671 (Fed. Cir. 1992)
In re Petering, 133 U.S.P.Q. 275 (C.C.P.A. 1962)
In re Ruschig, 145 U.S.P.Q. 274 (C.C.P.A. 1965)
In re Cruciferous Sprout Litigation, 64 U.S.P.Q. 2d 1202 (Fed. Cir. 2002)

April 1  Obviousness

(Although not specifically assigned, this topic assumes familiarity with the Supreme Court’s decision in KSR Int’l Co., v. Teleflex, Inc., 82 U.S.P.Q. 2d (US 2007)
In re Grabiak, 226 U.S.P.Q. 870 (Fed. Cir. 1985)
In re Jones, 21 U.S.P.Q. 2d 1941 (Fed. Cir. 1992)
In re Lalu, 223 U.S.P.Q. 1257 (Fed. Cir. 1984)
In re Baird, 29 U.S.P.Q. 2d 1550 (Fed. Cir. 1994)
Daiichi Sankyo Co., Ltd. V. Apotex, Inc., 84 U.S.P.Q. 2d 1285 (Fed. Cir. 2007)
Takeda Chemical Ind., Ltd. V. Alphapharm Pty., Ltd., 84 U.S.P.Q. 2d 1197 (Fed. Cir. 2007)
Aventis Pharma Deutschland GmbH v. Lupin, Ltd., 82 U.S.P.Q. 2d 1852 (Fed. Cir. 2007)
In re Kubin, 561 F.3d 1351, 90 USPQ2d 1417 (Fed. Cir. 2009)
Examination Guidelines Update: Developments in the Obviousness Inquiry After KSR v.Teleflex: Federal Register /Vol. 75, No. 169 /Wednesday, September 1, 2010 (Also available on the PTO website.)

April 8  Obviousness

*Rule 132 Declarations
In re Soni, 34 U.S.P.Q. 2d 1684 (Fed. Cir. 1995)
In re Chupp, 2 U.S.P.Q. 2d 1437 (Fed. Cir. 1987)
In re Zenitz, 142 U.S.P.Q. 158 (C.C.P.A. 1964)
In re Davies, 177 U.S.P.Q. 381 (C.C.P.A. 1973)
*”Analogous” Process
In re Ochiai, 37 U.S.P.Q. 2d 1127 (Fed. Cir. 1995)
Sanofi-Synthelabo v. Apotex Inc., (Fed. Cir. 12/12/08)
Genetics Institute v. Novartis Vaccines, 655 F.3d 1291, (Fed. Cir. 2011)

April 17  Overview of Biotech Issues: What’s left after Myriad?
(Guest Lecture)
Association for Molecular Pathology v. Myriad Genetics, 569 US - , -
USPQ – (2013)

Questions
Review