

Chapter 2. Intellectual Property Management

Exercises

Exercise 2.1. Choose your standing among IP protection system proponents or critics. Identify 10 arguments supporting your side, as well as specific arguments negating your opponents' views. Present them in a debate.

IP PROTECTION PROPONENTS

Intellectual Property and Innovation Policy - Executive Summary
James A. Lewis, CSIS
December 2007
http://csis.org/files/media/csis/pubs/071210_ipexecsummary.pdf

Caslon Analytics
Intellectual Property
<http://www.caslon.com.au/ipguide1.htm>

Intellectual Property
Pharmaceutical Research and Manufacturers of America (PhRMA)
http://www.phrma.org/issues/intellectual_property

IP PROTECTION CRITICS

Intellectual property
From Wikipedia, the free encyclopedia
http://en.wikipedia.org/wiki/Intellectual_property

Wiki: Criticism of intellectual property (1/2)
Wapedia
http://wapedia.mobi/en/Criticism_of_intellectual_property

A CRITIQUE OF INTELLECTUAL PROPERTY RIGHTS
A THESIS SUBMITTED TO DR. STEVEN SNYDER
IN CANDIDACY FOR THE DEGREE OF BACHELOR OF ARTS, DEPARTMENT OF PHILOSOPHY
BY DANE JOSEPH WEBER
FRONT ROYAL, VIRGINIA
DECEMBER, 2002
<http://dane.weber.org/concept/thesis.html>

Who Owns Ideas? The War Over Global Intellectual Property
War Over Global Intellectual Property David S. Evans
FOREIGN AFFAIRS, November/December 2002
<http://www.foreignaffairs.com/articles/58450/david-s-evans/who-owns-ideas-the-war-over-global-intellectual-property?page=show>

Exercise 2.2. Identify one of the top selling biopharmaceuticals in 2009. Then, using publicly available databases identify some of the patents protecting it, challenges they may have faced along their lifecycle, as well as their expiration dates.

Signals Magazine and RecapRx present: 20 Compounds That Defined Biotech
<http://www.recaprx.com/882571150067ddaa/Top20>

PHARMAFOCUS ASIA: Global Biogenerics Market – Opportunities and Challenges
http://www.pharmafocusasia.com/research_development/global-biogenerics-market.htm

Exercise 2.3. Identify three of the top selling biopharmaceuticals in 2009. Then, by using free, international patent office resources, describe their respective trademarks and what these cover.

United States Patent and Trademark Office - Trademark Electronic Search System (TESS)
<http://tess2.uspto.gov/bin/gate.exe?f=searchss&state=4002:gepf89.1.1>

Search for: Aranesp, Enbrel, Eprex, Remicade, neulasta, Mabthera, Epogen, etc.

Exercise 2.4. By using publicly available web resources, identify a biopharmaceutical-related trade secret and describe its nature, its potential use by the legal holders, as well as legal challenges that it may have faced over the years. What was the legal outcome of any disputes?

See:

UNITED STATES ATTORNEYS' BULLETIN: Economic Espionage and Trade Secrets
http://www.justice.gov/usao/eousa/foia_reading_room/usab5705.pdf

Criminal Penalties for Theft of Biological Materials, by Liz Howard. BioPharm JUNE 2002.

Exercise 2.5. Name five examples of start-up biopharmaceutical companies owning or vying to acquire freedom-to-operate on a significant biotechnological invention. What did it take to finally secure such a right?

See:

Kowalski SP. 2007. Freedom to Operate: The Preparations. In Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.
http://www.iphandbook.org/handbook/ch14/p02/index_print.html

Asklepios Biopharmaceutical Inc.
<http://www.askbio.com/ip.html>

Invitrogen enters into worldwide co-marketing agreement with genOway focused on RNAi services
Deal positions companies to address in vivo target validation market
Carlsbad, California USA and Lyon, France, December 15th, 2005
<http://www.genoway.com/news2005.htm>

Antyra has 6 issued patents based on its Peptimetics libraries and their use in drug discovery. In addition, there are several pending patents covering the Company's technology platform, individual targets, Peptimetics and lead products. The Company believes that it has Freedom-to-Operate in its areas of focus. In addition, the Company is committed to pursuing worldwide composition of matter patent coverage for all its internal lead Peptimetics and collaboration programs.
<http://www.antyra.com/research.html>

SR Pharma Granted Core RNAi Patent by the European Patent Office
European Patent EP1527176 B1 – Reinforces Company's Leading Position in RNAi Therapeutics
http://www.silence-therapeutics.com/content/newsandevents/news/srp_sirna_patent_grant.pdf

Scil Proteins' Affilin® Drug Discovery Platform Validated in Animals
23/06/2010 13:15:00
<http://www.euroinvestor.co.uk/news/story.aspx?id=11141762&bw=20100623005754>

Exercise 2.6. What role have the so-called Chakrabarty bacteria and the Harvard onco-mouse played in modern healthcare biotechnology? Describe a brief history of both cases and their eventual consequences on the field.

Patenting Life: The Harvard Mouse that Has Not Roared
The Scientist, Volume 14, Issue 23, Page 6, Date: 27/11/2000
<http://www.the-scientist.com/article/display/12161>

Patenting Life, executiveview.com, 19 March 2010, DM Kisch Incorporated
By At van Rooy and Simon Thanyani
http://www.executiveview.com/knowledge_centre.php?id=11448

Patenting Life: Issues and Controversies
Susan J. Friedman, Ph.D., J.D.
(Prepared for the Washington State Bar Association Animal Law Section Newsletter, Vol. 1, No. 3, Fall 2003)
<http://www.speckmanlaw.com/SLG%20Materials/IP%20Materials/Patenting%20Life.pdf>

Exercise 2.7. A biopharmaceutical start-up is asking for your help in guiding them through the maze of international patenting processes. Visit the web pages of the US, European, and Japanese Patent offices, and identify the major steps, fees, and timelines involved for the start-up's research project to be patented.

US:

Process for Obtaining a Utility Patent
<http://www.uspto.gov/patents/process/index.jsp>

Search for Patents
<http://www.uspto.gov/patents/process/search/index.jsp>

FEE SCHEDULE - Effective October 2, 2008
<http://www.uspto.gov/web/offices/ac/qs/ope/fee2009september15.htm#patapp>

Forms, USPTO
<http://www.uspto.gov/forms/index.jsp>

File Online
<http://www.uspto.gov/patents/process/file/index.jsp>

Check the Filing Status of Your Patent Application
<http://www.uspto.gov/patents/process/status/index.jsp>

EUROPE:

European applications
<http://www.epo.org/patents/Grant-procedure/Filing-an-application/European-applications.html>

Guide for applicants. Part 1
<http://www.epo.org/patents/Grant-procedure/Filing-an-application/European-applications/Guide-for-applicants.html>

Filing options
<http://www.epo.org/patents/Grant-procedure/Filing-an-application/European-applications/Filing-options.html>

EPC proceedings – forms
<http://www.epo.org/patents/Grant-procedure/Filing-an-application/European-applications/forms.html>

Online Filing
<http://www.epoline.org/portal/portal/default/default/MyEpolineWebSitePortletNavigation?mode=view&action=e&windowstate=normal>

Fees, expenses and prices
<http://www.epo.org/patents/Grant-procedure/Filing-an-application/costs-and-fees.html>

JAPAN:

Procedures for Obtaining a Patent Right
http://www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/t_gaiyo_e/pa_right.htm

Schedule of fees (on or after April 1, 2009)
http://www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/ryoukin_e/ryokine.htm

Frequently Asked Questions (FAQs)
http://www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/faqs.htm

Exercise 2.8. Name some examples of patentable organisms in the U.S.A., Europe, and Australia, and identify some prominent differences between these jurisdictions.

Industry, Technology and the Global Marketplace
International Patenting Trends in Two New Technology Areas
International Patenting of Human DNA Sequences
International Patenting of Internet-Related Business Methods
National Science Foundation, Division of Science Resources Statistics
Science and Engineering Indicators–2002, Arlington, VA (NSB 02-01) [April 2002]
<http://www.nsf.gov/statistics/seind02/c6/c6s5.htm>

Concept Foundation, PIPRA, FIOCRUZ and bioDevelopments-Int. Institute.

CHAPTER NO. 4.2

Nottenburg C. 2007. How to Read a Biotech Patent. In Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.
<http://www.iphandbook.org/handbook/ch04/p02/>

Exercise 2.9. Why is it better to patent a biopharmaceutical molecule before entering clinical trials? What are the potential rewards and risks in speeding-up or postponing its patent application until a later stage?

If the effective patent date is practically limited to ten years, then why should a biopharma not file for a patent following the drug's FDA approval and enjoy the maximum patent protection of twenty years? There are multiple reasons for inhibiting this option.

First, it is practically easier to get a patent than a marketing approval. While both organizations require the satisfaction of safety standards, those set by the PTO are only "sufficient probability of safety" based on preclinical information, while FDA requires extensive clinical studies spanning several phases, multiple years, dozens of research centers and thousands of treated patients. Second, it is practically impossible to conduct the clinical testing phase of the magnitude just mentioned while keeping a biopharmaceutical invention secret or even a competitor from rushing to file a patent before the inventing biopharma manages to do so. Third, a prerequisite for filing a patent application is that the invention has been kept secret or has been disclosed only within the prior year before filing, otherwise the invention enters the public domain forever. Fourth, FDA approval is accelerated for patented biopharmaceutical compounds.

Fifth, conducting clinical trials requires significant amounts of money, the majority of which is usually provided by external investors. These investors will obviously demand the patent protection, before they commit significant amounts in any investigation of the drug. Sixth, before clinical trials can be conducted, the biopharma needs to submit to the FDA an Investigational New Drug (IND) application (see Chapter 6), containing the following parts: 1) animal pharmacology and toxicology studies, 2) manufacturing information, and 3) clinical protocols and investigator information. Obviously, by doing so it jeopardizes the product's secrecy and also the one-year patent filing deadline. Seventh, instead of going for a marketing approval first and then a patent for an effective patent life of twenty years, a biopharma avoids risking it all (e.g. losing the patent right all together) and opts for a shorter effective life, but the opportunity to prolong the product's commercial life cycle (see Chapter 12) past the patent expiration date through intensive product branding and marketing, that can theoretically prolong the product's revenue stream for even beyond one hundred

years – think of reference medicines such as aspirin (since 1897) and penicillin (since 1945).

Exercise 2.10. Choose two major global biopharmaceutical enterprises. Then, using publicly available web resources compare them as far as their strategic IP management processes are concerned. How do they align or differ? Defend either side in a debate.

Managing IP in light of changing U.S. patent law

Ian Liu, Finnegan, Henderson, Farabow, garrett & Dunner, LLP

<http://www.slideshare.net/ianliu/managing-ip-in-light-of-changing-us-patent-law>

Intellectual Property Strategy - From Patent Portfolio to Profit

MIT IAP 2003

Joe Hadzima, IPVision Co-Founder

Joost Bensen, MIT \$50K Lead Organizer Emeritus, MIT Committee on IP Rep.

Karl Ruping, IP Lawyer, IncTANK Co-Founder

<http://www.web.media.mit.edu/%2F~jpbensen/%2FIPStrategy-2003IAP-Final.ppt>

UNIVERSITÄT HAMBURG - HOCHSCHULE FÜR ANGEWANDTE WISSENSCHAFTEN HAMBURG -
TECHNISCHE UNIVERSITÄT HAMBURG-HARBURG

Hochschulübergreifender Studiengang Wirtschaftsingenieurwesen

DIPLOMARBEIT - Gem. § 20 der Prüfungsordnung vom 04.10.2000

Development of Intellectual Property Management - Cases from German and Swedish Biotechnology Companies

Verfasser: Cand. Ing.-Oec. Frank Tietze

Matrikel - Nr. 1537170

Betreuer: Prof. Dr. C. Herstatt

2. Gutachter: Prof. Dr. W. Kersten

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http://doku.b.tu-harburg.de/volltexte/2007/333/pdf/Diplomarbeit_Frank_Tietze_final.pdf