

List of Works Cited

Journal Articles

- Stanley P. Kowalski, *Freedom to Operate: The Preparations, IPHANDBOOK OF BEST PRACTICES* (last visited September 5, 2016), <http://www.iphandbook.org/handbook/ch14/p02/>.
- European Federation of Pharmaceutical Industries and Associations, *The Pharmaceutical Industry in Figures, 2016 Edition* (last visited September 5, 2016), <http://www.efpia.eu/uploads/Modules/Documents/the-pharmaceutical-industry-in-figures-2016.pdf>.
- M. Dickson, J.P. Gagnon, *The Cost of New Drug Discovery and Development* (June 20, 2009), <http://www.discoverymedicine.com/Michael-Dickson/2009/06/20/the-cost-of-new-drug-discovery-and-development/>.
- Tudor I. Oprea, Current trends in lead discovery: *Are we looking for the appropriate properties?* 16 J. COMP.MOL.DES. 325, (2002).
- Ryoko Iseki, *Patent term extension in Japan: an academic and comparative perspective*, in PHARMACEUTICAL INNOVATION, COMPETITION AND PATENT LAW (Josef Drexl & Nari Lee eds., Edward Elgar Pub 2013)
- Matsui, S. and T. Aoki, “*Tokkyoseido no kokusaiteki seigouka to iyakuhinbunya no tokkyoken kikan enchouseido ni mirareru hiseigou* (International Harmonization of the Patent System and Disconformities in the Patent Right Term Extension System in the Drug Field)”, AIPPI, 2008, 53(6), 2 and 14
- Anatole Krattiger, *Freedom to Operate, Public Sector Research, and Product-Development Partnerships: Strategies and Risk-Management Options*, IPHANDBOOK OF BEST PRACTICES (last visited September 6, 2016), <http://www.iphandbook.org/handbook/ch14/p01/>
- Philip Mendes, *Licensing and Technology Transfer in the Pharmaceutical Industry* (last visited September 7, 2016), http://www.wipo.int/export/sites/www/sme/en/documents/pdf/pharma_licensing.pdf
- John LaMattina, *What Is The Rationale For The Pricing Of New Drugs?* (Sep. 10, 2012, 11:55AM), <http://www.forbes.com/sites/johnlamattina/2012/09/10/on-the-pricing-of-new-drugs/#500d64ed4b8e>
- Takatori et al., *Seiyakukigyō to baiobentyā to no araisan: nichibeiou seiyakukigyō no hikaku bunseki* (An alliance between a pharmaceutical company and bio venture company: Comparison and analysis of pharmaceutical companies in Japan, US and EU) (Nov., 2009), http://www.jpma.or.jp/opir/research/rs_048/paper-48.pdf.
- Kenji Tomita, *Seiyakusangyō ni okeru raisensu-in/auto no muzukashisa* (Difficulties in licensing-in/out in the pharmaceutical industry) DousishaShogaku, Dai-66-kan, Dai-1-gou (Jul., 2014), <https://doors.doshisha.ac.jp/duar/repository/ir/16560/017066010015.pdf>.

List of Works Cited

Kenzo Takada, *Seiyakugaisya tonō raisensu keiken kara mita koutaiiyakuhin kaihatsu* (The development of antibody pharmaceuticals in the sense of licensing-out the technology to a larger pharmaceutical company), *Yakugaku Zasshi*, 133(1), 61-66.

Books

- ROBIN JACOB, *IP AND OTHER THINGS: A COLLECTION OF ESSAYS AND SPEECHES* (2015).
- H. JACKSON KNIGHT, *PATENT STRATEGY* (3rd ed. Wiley 2013)
- JANICE M. MUELLER, *PATENT LAW* (4th ed. Wolters Kluwer 2013)
- PHILIP W. GRUBB, PETER R. THOMSEN, *PATENTS FOR CHEMICALS, PHARMACEUTICALS AND BIOTECHNOLOGY: FUNDAMENTALS OF GLOBAL LAW, PRACTICE AND STRATEGY* (Oxford University 5th ed. 2010)
- GIICHI MARUYAMA, CHITEKIZAISAN SENRYAKU, GIJYUTU DE JIGYOU WO TSUYOKUSU-RUTAME NI (THE IP STRATEGY: STRENGTHENING THE BUSINESS BY MEANS OF THE TECHNOLOGY) (Diamond sya 2012)
- JONATHAN D.C. TURNER, *INTELLECTUAL PROPERTY AND EU COMPETITION LAW* (2nd ed. Oxford 2015).
- ARIEL EZRACHI, *EU COMPETITION LAW: AN ANALYTICAL GUIDE TO THE LEADING CASES* (4th ed., 2014).
- PATRICIA M. DANZON, ANDREW J. EPSTEIN, *WORKING PAPER SERIES: EFFECTS OF REGULATION ON DRUG LAUNCH AND PRICING IN INTERDEPENDENT MARKETS* (Working paper 14041, National Bureau of Economic Research 2008).

Reports & Database

- European Commission, *EU R&D Scoreboard (The 2015 EU Industrial R&D Investment Scoreboard)*, <http://iri.jrc.ec.europa.eu/scoreboard15.html>.
- Biotechnology Innovation Organization, *Clinical Development Success Rates 2006-2015* (June 2016), <https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf>.
- Orange Book, *Approved Drug Products with Therapeutic Equivalence Evaluations* (last visited September 6, 2016), <http://www.accessdata.fda.gov/scripts/cder/ob/>.
- The Merck Index Online (last visited September 6, 2016), <https://www.rsc.org/merck-index?c=1>.
- Japan Patent Office (last visited September 6, 2016), <https://www.jpo.go.jp/>
- European Commission press release, *Antitrust: Commission adopts revised competition regime for technology transfer agreements* (Mar. 21, 2014), http://europa.eu/rapid/press-release_IP-14-299_en.htm
- Pharmaphorum, *Alexion must 'explain' high cost of Soliris, says NICE* (Mar. 4, 2014), <http://pharmaphorum.com/news/alexion-must-explain-high-cost-of-soliris-says-nice/>.

Case

Case C-193/83 Windsurfing International v Commission of the European Communities.

Statutes and Regulations

TRIPS Art. 31

TFEU Art. 101

TTBER Art. 2

TTBER Art. 4(1)(a), (d)

The Guidelines (2014/C 89/03) § 101, 116, 183(e), 184, and 185.

EPC Art. 69

EPC Art. 93(1)(a)

EPC Art. 94(1)(2)

EPC Art. 123(2)(3)

JPA Art. 17bis(3)

JPA Art. 35

JPA Art. 48ter(4)

JPA Art. 64

JPA Art. 68bis

JPA Art. 70(1)(2)

JPA Art. 126(6)

GPA Art. 6

Council Regulation (EEC) No. 1768/92 Art. 13,1

35 U.S.C. §101

35 U.S.C. § 122(b)(2)(A)(ii), (iv)

35 U.S.C. § 156(c).

UK Patent Act Art. 39(1)

French Intellectual Property Act Art. 611.7(1)

SPC § 4

