

List of works cited

Periodical Materials in English

- Anonymous, *Docetaxel: Alcoholic intoxication due to alcohol excipient: case report*, Reactions Weekly 13, Issue 1375 (Oct. 9, 2011).
- Anonymous, *Latanoprost SPC ends in top EU markets*, Generics bulletin, Jan. 13, 2012.
- Anonymous, *News & highlights from week 40*, 12 Curr. Pat. Gaz. 1, (2009).
- Anonymous, *Patent expiries to hit glaucoma drug market growth until 2018*, The Pharma Letter, Sept. 18, 2011.
- Christophe Baudouin, Luisa Riancho, Jean-Michel Warnet, Françoise Brignole, *In vitro Studies of Antiglaucomatous Prostaglandin Analogues: Travoprost with and without Benzalkonium Chloride and Preserved Latanoprost*, 48 Invest. Ophthalmol. Vis. Sci. 4123, (2007).
- Josef Drexl, *Astra Zeneca and the EU Sector Inquiry: when do patent filings violate competition law?*, Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 12-02, (2012).
- Ernst R. Berndt, Iain M. Cockburn, Karen A. Grepin, *The impact of Incremental Innovation in Biopharmaceutical*, 24 Pharmacoeconomics 69, (2006).
- Steven C. Carlson, Willy Chang, *"Obviously" a challenge: Patent survival statistics*, 5 Ind. Biotechnol. 172, (2009).
- Curtis R Chong, David J. Sullivan Jr., *New Uses for old Drugs*, 448 Nature 645, 645 (2007).
- Ami J. Claxton, Joyce Cramer, Courtney Pierce, *A systematic review of the associations between dose regimens and medication compliance*, 23 Clin. Ther. 1296, (2001).
- Patrick J. Crowley, Luigi G. Martini, *Formulation design: new drugs from old*, 1 Drug Discovery Today: Therapeutic Strategies 537, (2004).
- John Crown, Michael O'Leary, Wei-Song Ooi, *Docetaxel and Paclitaxel in the Treatment of Breast Cancer: A Review of Clinical Experience*, 9 (suppl. 2) The Oncologist 24, (2004)
- Philippe Daull, Ronald Buggage, Grégory Lambert, Marie O. Faure, Janet Serle, Rong F. Wang, Jean S. Garrigue, *A Comparative Study of a Preservative-Free Latanoprost Cationic Emulsion (Catioprost®) and a BAK-Preserved Latanoprost Solution in Animal Models*, J. Ocul. Pharm. Ther., (online ahead of print: June 6, 2012).
- M. Diestelhorst, Brigitta Almegård, *Comparison of two fixed combinations of latanoprost and timolol in open-angle glaucoma*, 236 Graefe's Archive for Clinical and Experimental Ophthalmology 577, (1998).
- Joseph A. DiMasi, Cherie Paquette, *The Economics of Follow-on Drug Research and Development*, 22 Pharmacoeconomics 1, (2004).

- Gaurav Dwivedi, Sharanabasava Hallihosur, Latha Rangan, *Evergreening: A deceptive device in patent rights*, 32 *Technology in Society* 324, (2010).
- G. Emilien, M. Ponchon, C. Caldas, O. Isacson and J.-M. Maloteaux, *Impact of genomics on drug discovery and clinical medicine*, 93 *Q. J. Med* 391, (2000).
- O. Esposito, M. Bonfill, E. Moyano, M. Onrubia, M.H. Mirjalili, R.M. Cusidó, J. Palazón, *Biotechnological Production of Taxol and Related Taxoids: Current State and Prospects*, 9 *Anti-Cancer Agents in Medicinal Chemistry* 109, (2009).
- Ronald D. Fitzmartin, *The challenge of global electronic submission standards in the biopharmaceutical industry*, 32 *Drug Inf. J.* 745 (1998).
- Edd Fleming, Philip Ma, *Drug life-cycle technologies*, 1 *Nat. Rev. Drug Disc.* 751, (2002).
- John Fraher, *Life-Cycle Management: The Link to Drug Delivery*, 2 *Drug Deliv. Tech.* 158, (2002).
- George Frisvold, Kelly Day-Rubenstein, *Bioprospecting and Biodiversity Conservation: What happens when discoveries are made?*, 50 *Ariz. L. Rev.* (2007).
- Ulrich M. Gassner, *Supplementary protection certificates for combination products: new combinatorics?*, 7 *J. Intell. Prop. L. & Pract.* 52, (2012).
- Kate S. Gaudry, *Evergreening: a common practice to protect new drugs*, 29 *Nat. Biotechnol.* 876, (2011).
- Michele Giannino, *Patents: Beware of competition law! Relying on patents to extend protection for medicines may be anticompetitive*, 7 *J. Intell. Prop. L. & Pract.* 391, (2012).
- C. Scott Hemphill, Bhaven N. Sampat, *Evergreening, patent challenges, and effective market life in pharmaceuticals*, 31 *J. Health Econ.* 327, (2012).
- Leighton Howard, *Use of patents in drug lifecycle management*, 4 *J. generic medicines* 230, (2007).
- W. Kruse, W. Eggert-Kruse, J. Rampmaier, B. Runnebaum, E. Weber, *Dosage frequency and drug-compliance behaviour – a comparative study on compliance with a medication to be taken twice or four times daily*, 41 *Eur. J. Clin. Pharm.* 589, (1991).
- Dahlia Ismail, Mourad Amrane, Jean S. Garrigue, Ronald Buggage, *A phase II, randomized study evaluating the safety and efficacy of Catioprost® compared to Travatan Z® in subjects with glaucoma and ocular surface disease*, 89 *Acta Ophthalmol.* 188, (2011).
- M.A. Johnstone, *Hypertrichosis and increased pigmentation of eyelashes and adjacent hair in the region of the ipsilateral eyelids of patients treated with unilateral topical latanoprost*, 124 *Am. J. Ophthalmol.* 544, (1997).
- N.R. Labiris, M.B. Dolovich, *Pulmonary drug delivery. Part II: The role of inhalant delivery devices and drug formulations in therapeutic effectiveness of aerosolized medications*, 56 *Br. J. Clin. Pharm.* 600, (2003).
- Kevin Mack, *Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands*, 21 *Berkeley Tech. L. J.* 147, (2006).
- Terry Mahn, *Protecting New Investments in Old Drugs*, Issue 2 *FDLI Update Magazine* 38 (2009), available at <http://www.fr.com>.

- Michael McCoy, *Generic Drugs*, 80 Chem. Eng. News 23, (2002).
- Dan-Feng Mei, Josephine Liu, Michael A. Davitz, *Formulation Patents and Dermatology and Obviousness*, 3 Pharmaceutics 914, (2011).
- Jessica Merrill, *2010 Drug Launches: A Year of Firsts Offers Hope for a Rebound*, 11 The Pink Sheet, Jan. 3, 2011, at 3.
- Stéphanie Michiels, Béatrice Holtz, *Patent exemption for clinical trials: current status of the Bolar-type provisions in Europe*, Life Sci. IP Rev. 68, (2008).
- Tudor I. Oprea, *Current trends in lead discovery: Are we looking for the appropriate properties?* 16 J. Comp. Mol. Des. 325, (2002).
- B. M. Padhy, Y. K. Gupta, *Drug repositioning: Re-investigating existing drugs for new therapeutic indications*, 57 J. Postgrad. Med. 153, (2011).
- Vanessa Peden, Imti Choonara, Brian Gennery, Hilary Done, *Recruiting Children to a Clinical Trial*, 4 Paed. Perinat. Drug Ther. 75, (2000).
- Jack W. Scannell, Alex Blanckley, Helen Boldon, Brian Warrington, *Diagnosing the decline in pharmaceutical R&D efficiency*, 11 Nat. Rev. Drug Discov. 191, (2012).
- Ravi Srinivasan & Chris Milton, *EPO second medical use claims: The skinny SmPC loophole*, Managing IP Magazine Supplement Life Science IP Focus (9th ed. 2011), available at <http://www.managingip.com/IssueArticle/2918674/Supplements/EPO-second-medical-use-claims-The-skinny-SmPC-loophole.html?supplementListId=83781>.
- Christian Sternitzke, *Knowledge sources, patent protection, and commercialization of pharmaceutical innovations*, 39 Research Policy 810, (2010).
- Christopher Stothers, Marco Ramondino, *Aftermath of AstraZeneca and the Pharmaceutical Sector Inquiry: The Big Chill?*, 12 Eur. Comp. L. Rev. 591, (2011).
- A. Sulkes, J. Smyth, C. Sessa, L.Y. Dirix, J. B Vermorken, S. Kaye, J. Wanders, H. Franklin, N. LeBail, J. Verweij, *Docetaxel (Taxotere), in advance gastric cancer: results of a phase II clinical trial*, 70 British Journal of Cancer 380, (1994).
- Eddy D. Ventose, *Federal Circuit clarifies patent unenforceable for inequitable conduct*, 7 J. Intell. Prop. L. & Pract. 551, (2012).
- Jeff Viksjo, *Pharmaceutical Treatments in Ophthalmology*, 1 Healthcare Observer 2, (2009).
- Brian Whitehead, Stuart Jackson, Richard Kempner, *Managing generic competition and patent strategies in the pharmaceutical industry*, 3 J. Intell. Prop. L. & Pract. 226, (2008).
- Manfred E. Wolff, *Drug Discovery Market Exclusivity After KSR: The Challenge to Pharmaceutical Scientists and the US Congress*, 100 J. Pharm. Sci. 3044, (2011).
- L. Zaske, M. A. Perrin, C. Daiguebonne, O. Guillou, *Docetaxel (Taxotere® Trihydrate) Forms: Crystal Structure Determination from XRPD & XRSCD data*, 443-444 Mat. Sci. Forum 411, (2004).

Periodical Material in German

- Simon Klopschinski, *Arzneimittelrechtliche Genehmigungsverfahren, staatliche Preisfestsetzung und Kostenerstattung für Arzneimittel im Lichte des Patentschutzes – Rechtsprechungsübersicht Belgien, Deutschland, Frankreich und Österreich*, GRURInt. 993, (2011).
- Johanna Müller-Graff, Filipe Fischmann, *Der Fall AstraZeneca: “Tool boxes“ im Arzneimittelsektor – wer hat die besseren Werkzeuge und welche sind erlaubt? Zum Urteil des Gerichts der Europäischen Union vom 1. Juli 2010, Rs. T-321/05*, 792 GRUR Int 1, (2010).

Non Periodical Material

- John E. Calfee, White Paper on Pharmaceutical Market Competition Issues, June 2, 2008, available at <http://62.102.106.100/content/default.asp?PageID=559&DocID=4894>.
- R. Thomas, *Patent “Evergreening”: Issues in Innovation and Competition*, Congressional Research Service, (Nov. 13, 2009).
- OECD Policy Roundtables, “Roundtable on Generic Pharmaceuticals 2009” DAF/COMP(2009) 39, Oct. 5, 2010 at 148.
- William C. Stewart, *Combination Therapy: Is the Whole Greater?*, Rev. Ophthalmol., Jun. 15, 2005.

Table of books

- V. N. Bhat, *The Challenges of the new EU Pharmaceutical legislation Pharmaceuticals Policy and Law*, (1st ed. 2005).
- Kim B. Clark, Steven C. Wheelwright, *Managing New Product and Process Development: Text and Cases*, (1st ed. 1993).
- Bengt Domeij, *Pharmaceutical Patents in Europe*, (1st ed. 2000).
- Jan I. Drayer, James P. Burns, *From Discovery to Market: The Development of Pharmaceuticals*, in BURGER’S MEDICINAL CHEMISTRY AND DRUG DISCOVERY, (1995).
- Philip W. Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology* (5th ed. 2010).
- Sajiv K. Nair, Kevin E. Henegar, *Modern Drug Synthesis*, (1st ed. 2010).
- Kristof Roox, Julia Pike, Andrew Brown, Stefan Becker, *Patent-related Barriers to Market Entry for Generic Medicines in the European Union*, (2008).
- Ulrich Storz, *Biopatent Law: Patent Strategies and Patent Management*, (1st ed. 2012).
- Derk Visser, *The annotated European patent convention*, (17th ed., 2009).