

List of works cited

Novartis v. Mylan, Tribunale Ordinario di Roma Sezione Nona, R.G. 68881/2011, Nov. 25, 2011 found at <http://www.eupatent.com/spc-protection-for-combination-products-future-scenarios/>.

Pfizer vs AGCM, Tribunale Amministrativo Regionale [Regional Administrative Court] per il Lazio Sezione Prima, 07467/2012 REG.PROV.COLL., Sept. 4, 2012 available at http://www.giustizia-amministrativa.it/DocumentiGA/Roma/Sezione%201/2011/201109968/Provvedimenti/201207467_01.XML.

United Kingdom

KCI Licensing v. Smith & Nephew, (2010) England and Wales High Court (EWHC) 1487 (Pat).

United States

Aventis Pharma SA v. Hospira Inc. and Apotex Inc., 743 F. Supp. 2d 305, 2010 U.S. Dist. LEXIS 101442 (D. C. Delaware Sept. 27, 2010).

Aventis Pharma v Hospira Inc., 2011 F.3d 1018 (Fed. Cir. Apr. 2012).

McNeil-PPC v Perrigo Company, 485 F.3d 1157 (Fed. Cir. Apr. 2008).

Statutes

Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), 1994.

Council Regulation (EEC) 1768/92, 1992.

Council Regulation (EEC) 2309/93, 1993 and Annex.

Council Regulation (EC) 726/2004, 2004 and Annex.

Council Regulation 1901/2006, 2006.

Directive (EC) 2004/27, 2004.

Regulation (EC) No 1901/2006, 2006.

Regulation (EC) 764/2008, 2008.

Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009.

The U.S. Patent Act, 35 U.S.C.

The U.S. Patent Act, 21 U.S.C.

European Patent Convention (14th ed. amended 2010).

Guidelines for Examination in the European Patent Office (June 2012).

Patentgesetz [German Patent Act] (1936, revised 1980, amended 2009) (Ger.); translated in World Intellectual Property Organization, Patent Law, http://www.wipo.int/wipolex/en/text.jsp?file_id=238776.

Speeches and Reports

European Commission, *Communication from the Commission – Executive Summary of the Pharmaceutical Sector Inquiry Report*, (July 8, 2011) available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

Institute for Quality and Efficiency in Health Care, IQWiG Reports – Commission No. A11-24 Cabazitaxel – Benefit assessment according to § 35a Social Code Book V, (Jan. 12, 2012), available at https://www.iqwig.de/download/A11-24_Extract_Cabazitaxel_Benefit_assessment_35a_Social_Code_Book_V.pdf.

Sir R. Jacob, *Patents and Pharmaceuticals – a speech given on 28th November 2008 at the presentation of the Directorate-General of Competition’s Preliminary Report of the Pharma-sector inquiry*, available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/jacob.pdf>.

Press release

Press release, AGCM, Drugs: Pfizer sanctioned with 10.6 million Euro fine for abuse of a dominant position (Jan. 17, 2012).

Press release Novagali Pharma, Catioprost Phase II positive results (Sept. 8, 2011).

Press release, QLT inc., (Aug. 29, 2011).

Press release, Sanofi, 2011 Results Benefit from Genzyme Acquisition Net Sales and Business EPS1 up 9.2%2 in Q4 (Feb. 8, 2012).

Others

M. Dickson, J.P. Gagnon, The Cost of New Drug Discovery and Development, available at: <http://www.discoverymedicine.com/Michael-Dickson/2009/06/20/the-cost-of-new-drug-discovery-and-development/>.

Angelo DePalma, *Patent expiration: Innovate or die*, Eyeforpharma, Feb. 3, 2011, available at <http://social.eyeforpharma.com/>.

European Federation of Pharmaceutical Industries and Associations: The Pharmaceutical Industry in Figures, 2012 Edition, available at: http://www.efpia.eu/sites/www.efpia.eu/files/EFPIA_Figures_2012_Final-20120622-003-EN-v 1.pdf.