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Cases Update

An overview of key recently filed cases and noteworthy rulings of relevance of the pharmaceutical and biotechnology industries

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Pfizer v. The Italian Competition & Markets Authority

The Regional Administrative Court for
Lazio (First Division), September 3

The Italian Administrative Tribunal for Lazio annulled an earlier decision of the Italian Competition Authority, which had fined pharmaceutical group, Pfizer, €10.6 million for abuse of dominance in the market for medicines based on the active substance latanoprost for the treatment of glaucoma. The Authority's initial decision ruled that Pfizer had engaged in anti-competitive practices by artificially extending the patent protection of its Xalatan[®] product and simultaneously threatening to sue various generic medicine producers likely to enter the market. According to the Authority, Pfizer's Xalatan Italian patent expired in September 2009, but the company effectively extended its protection to July 2011 and later to January 2012. The judgment accepted Pfizer's complaints and criticized the Italian authority's decision for lack of sufficient investigation, reasoning and logic.

Source: www.giustizia-amministrativa.it/DocumentiGA/Roma/Sezione%201/2011/201109968/Provvedimenti/201207467_01.XML

Medtronic Inc. v. Boston Scientific Corp.

US Court of Appeals for the Federal
Circuit, September 18

In this decision, the Federal Circuit explained that the district court erred in allocating the burden-of-proof to the patent owner, Medtronic, for its patents relating to implantable defibrillators and incorrectly read limitations into claim terms. The judge also improperly placed the burden on Boston Scientific to prove infringement when it was Medtronic that filed the suit, the appeals court said. The patentee entered an agreement with the accused infringer that allowed Boston Scientific to have a license while seeking a declaratory judgment of noninfringement. As the accused infringer had a license, the patentee could not assert a counterclaim for infringement. At trial, the district court held that the patentee had the burden to prove infringement, that it failed to meet that burden, and that the accused infringer was entitled to its judgment. The patentee appealed, and the Federal Circuit vacated and remanded.

Source: www.cafc.uscourts.gov/images/stories/opinions-orders/11-1313-1372.pdf

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**Actavis Group PTC EHF &
another v. Sanofi Pharma &
Bristol-Myers Squibb SNC**

Patents Court of England & Wales,
September 20

The Patents Court of England and Wales refers to two questions on supplementary protection certificates (SPCs) to the CJEU in relation to a combination drug. In this action, Sanofi was firstly granted a first SPC on the single product directed to an antihypertensive drug (also known as irbesartan) and then granted a second SPC for a combination of irbesartan and hydrochlorothiazide (sold under the trademark 'CoAprovel') on in respect of European Patent (UK) No. 0454511, which is directed to "*N*-substituted heterocycle derivatives, their preparation, compositions containing them." The first SPC for the single product was expired on 14 August 2012. The expiry date of the second SPC falls on 14 October 2013. Actavis challenged this grant by arguing that: "*that the Combination SPC is invalid because the combination of irbesartan and HCT was not 'protected by' the Patent within the meaning of Article 3(a) of the Regulation since it was not specified or identified in the wording of any of the claims of the Patent*" [59]. The judge's first question to the CJEU is in response to this Actavis' question and is stated in [74] "*What are the criteria for deciding whether 'the product is protected by a basic patent in force' in Article 3(a) of the Regulation?*" Second and lastly, Actavis argued that "[T]he Combination SPC is invalid either because the product had already been the subject of an SPC (namely the Irbesartan SPC) contrary to Article 3(c) of the Regulation or because the product had already been the subject of a marketing authorisation (namely the authorisations for Aprovel) contrary to Article 3(d) of the Regulation before the application for the Combination SPC was filed. Sanofi contend that both the Irbesartan SPC and the Aprovel marketing authorisations relate to irbesartan whereas the Combination SPC and the CoAprovel marketing authorisations relate to the combination of irbesartan and HCT, which is a different product, and thus there is no contravention of either Article 3(c) or 3(d)." In relation thereto, the judge posed a question by stating "[It] appears . that the Dutch Patent Office has adopted the opposite interpretation of (the CJEU's ruling in Case C-322) *Medeva* to that adopted by the UK IPO, namely that it prohibits the grant of more than one SPC per patent regardless of the number of products claimed in the basic patent. In Case AWB 10/4769 *Georgetown University v. Octrooiencentrum Nederland* (11 July 2012), which is a parallel case to the *Georgetown* case in this country, the Rechtbank S-Gravenhage (Judge van Walderveen) held that the correct interpretation of Article 3(c) was unclear and decided to refer a question to the CJEU provisionally worded as follows: "*Does [the Regulation], more specifically Article 3(c), in the situation in which multiple products are protected by (the claims) of a basic patent, preclude the proprietor of the basic patent being issued a certificate for each of the products protected?*"

Source: www.bailii.org/ew/cases/EWHC/Patents/2012/2545.html

**Takeda Pharmaceutical Inc. v.
Sawai Pharmaceutical et al.**

Osaka District Court of Japan,
September 27

Osaka District Court of Japan held a decision regarding the combination drug, and further commented patentability of patents directed to administration/dosage features. In Japan, under the current practice based on the Examination Guidelines published by the Japan Patent Office, a combination drug may be patentable as long as such a combination has attained a 'significant' effect. In the subject case, the patentee sought enforcement of the patent directed to a combination drug by arguing that the manufacture and sales of one of the combination constitutes an indirect infringement under Article 101(2) of the Japanese Patent Act, if a medical doctor, pharmacist or patient prescribes or uses the drug simultaneously with the other drug of the combination such that the patented combination should be made. However, the Court did not accept the patentee's arguments because the drug is just sold and used in its original form without essential change, and does not fall within the "manufacture" of the combination drug. The Court further stated that an invention

of the combination 'use' of a plurality of drugs are interpreted to be a method invention rather than a product invention, which is not a statutory subject matter due to industrial inapplicability by stating that: "[As] such, if the technical scope of each of the subject patented inventions were to encompass combination use of 'pioglitazone or a pharmacologically acceptable salt thereof and the pharmaceutical product to be combined of the subject patented invention (i.e. combination therapy), then it would mean that medical act per se be the subject of a patent, which inevitably means that the technical scope of a patent encompasses the subject matter which cannot be patented under Art. 69(3) and 29(1), the main paragraph of the Japanese Patent Act." In this respect, the subject Court's decision appears contradictory to the Japan Patent Office's Examination Guidelines, which defines that a medicinal invention encompasses a pharmaceutical composition wherein only use such as administration/dosage has a patentable feature.

Source: www.courts.go.jp/hanrei/pdf/20121005161748.pdf

Appeal from the USPTO, Board of Patent Appeals & Interferences In re Abbott Diabetes Care Inc.

US Court of Appeals for the Federal Circuit, September 28

Abbott requested the US Court of Appeals for the Federal Circuit to review an adverse decision at the USPTO's Board of Patent Appeals and Interferences in two *ex parte* re-examination proceedings. During these, the Board rejected several claims of the 752 and 509 patents, which share a specification relating to methods and devices for the *in vivo* monitoring of an analyte (e.g., blood glucose) by means of an implanted electrochemical sensor.

Key to the case was the construction of the electrochemical sensor, as claimed in both patents. The examiner stated that the broadest possible interpretation of 'electrochemical sensor' included wires and cables, a decision upheld by the Board during the USPTO appeal. According to Federal Circuit precedent: "[a]lthough the PTO emphasizes that it [is] required to give all claims their broadest reasonable construction... this court has instructed that any such construction be consistent with the specification." As such, the Federal Circuit held that, in this instance, where the only discussion of a sensor with external cables or wires was one statement addressing deficiencies in the prior art, this limitation could not be read into the claim.

Source: www.cafc.uscourts.gov/images/stories/opinions-orders/11-1516-1517.pdf

Federal Trade Commission v. Watson Pharmaceuticals Inc.

The Supreme Court of the USA,
October 4

On the request of the Federal Trade Commission (FTC), the US Solicitor General requested that the Supreme Court review a federal appeals court ruling in respect of the FTC's case against a so-called pay-for-delay agreement, which postponed generic competition for the drug AndroGel. A vote by FTC staff over whether to permit the request that the Solicitor General file the petition for certiorari was won 5–0.

In 2003, Solvay, which produces the testosterone-replacement drug, filed a lawsuit accusing Watson Pharmaceuticals Inc, Paddock Laboratories Inc and Par Pharmaceutical Co Inc of infringing its patents for the drug. In 2006 the three companies settled. Solvay subsequently made an agreement to share part of its AndroGel profits with the generic companies until 2015; in return, the latter agreed to keep its own versions of AndroGel off the market. In 2009, citing violation of antitrust law, the FTC sued both the brand-name and generic companies. However, the FTC lost in the district court as well as on appeal.

Source: www.ftc.gov/opa/2012/10/androgel.shtm

**Federal Trade Commission
amicus curiae in re: K-Dur
anti-trust litigation**

US District Court for the District of
New Jersey, October 5

The FTC filed an *amicus curiae* brief before the federal district court in New Jersey requesting the application of the 2012 Third Circuit ruling in *K-Dur* (In re K-Dur antitrust litigation, 686 F.3d 197, 218) to an agreement in which Teva Pharmaceutical Industries Ltd promised to delay the launch of an authorized generic version of the drug Lamictal® (lamotrigine), while GSK granted Teva a license to market a generic product exclusively. The Third Circuit ruling in *K-Dur* had stated that a payment from a patent holder to a generic drug company to delay the generic from entering the market is “*prima facie* evidence of an unreasonable restraint on trade.” In its amicus brief the FTC argued that: “*This empirical evidence confirms what the pharmaceutical industry has long understood: that a [no-authorized generic] commitment provides a convenient method for branded drug firms to pay generic patent challengers for agreeing to delay entry*”.

Source: www.ftc.gov/os/2012/10/121005lamictalamicusbrief.pdf

**AstraZeneca AB v. Comptroller-
General of Patents, Designs
& Trade Marks**

Patents Court for England and Wales,
October 19

The latest decision of the Patents Court for England and Wales refers to another series of questions on SPCs to the CJEU. AstraZeneca applied for a SPC on 11 December 2009 for the product gefitinib, this is the active ingredient in a medicinal product marketed by AstraZeneca as Iressa, which is used to treat non-small-cell lung cancer. The SPC was granted with an expiry date of 1 March 2019, being calculated by reference to a marketing authorisation granted by the Swiss regulatory authority on 2 March 2004 (‘the Swiss Marketing Authorisation’). AstraZeneca appealed this, contending that the correct expiry date is 22 April 2021 because the duration of the SPC should be calculated by reference to a marketing authorisation granted by the European Medicines Agency on 24 June 2009. Stating that the resolution of the appeal depends on two issues of interpretation of Regulation 469/2009/EC of 6 May 2009 (‘the SPC Regulation’) Mr Justice Arnold has referred the following questions to the CJEU: “[I]s a Swiss marketing authorisation not granted pursuant to the administrative authorisation procedure laid down in Directive 2001/83/EC, but automatically recognised by Liechtenstein, capable of constituting the ‘first authorisation to place the product on the market’ for the purposes of Article 13(1) of Regulation 469/2009/EC?” And: “Does it make a difference to the answer to the first question if: (a) the set of clinical data upon which the Swiss authority granted the marketing authorisation was considered by the European Medicines Agency as not satisfying the conditions for the grant of a marketing authorisation pursuant to Regulation 726/2004/EC; and/or (b) the Swiss marketing authorisation was suspended after grant and was only reinstated following the submission of additional data?” In addition, in Section 68, the following question has been referred: “if Article 13(1) of Regulation 469/2009 refers solely to marketing authorisations granted pursuant to the administrative authorisation procedure laid down in Directive 2001/83/EC, does the fact that a medicinal product was first placed on the market within the EEA pursuant to a Swiss marketing authorisation automatically recognised in Liechtenstein which was not granted pursuant to Directive 2001/83/EC render that product ineligible for the grant of a supplementary protection certificate pursuant to Article 2 of Regulation 469/2009?”

Source: www.bailii.org/ew/cases/EWHC/Patents/2012/2840.html

F. Hoffmann-La Roche AG v. The Assistant Controller of Patents & Designs

IP Appellate Board of India, November 2

A patent covering Pegasys®, Roche's hepatitis C drug (PEG-interferon α -2b formulation) has been revoked by Indian IP Appellate Board. Indian Patent 198952 is the patent in issue, which is directed to "[A] physiologically active branched PEG-IFN alpha conjugate," and is the first patent to receive patent protection from the Indian Patent Office covering a drug, since 1970, under revised legislation introduced in 2005. The Sankalp Rehabilitation Trust, a civil society group based in Mumbai, appealed to the IP Appellate Board and argued that the Roche's Peg-IFN is anticipated and/or obvious. Arguments regarding anticipation have been dismissed. With respect to the obviousness, Roche tried to argue that the Roche's Peg-IFN would not have been obvious since: "*specifications show experiments only with the unconjugated IFN, though this invention is said to be superior to the other conjugates and linear conjugates.*" However, the Court held that: "[F]or this we have no contemporaneous intrinsic or extrinsic evidence. The examples in the Complete Specification show improvement over unconjugated interferon, but the inventor claims surprising activity when compared with other conjugated interferon which is not shown. Hence the evidence for the 'surprising activity' is not adequate. Annexures A and C are without the supporting affidavits of the authors. The authors must present themselves as witnesses either in person or through proof affidavits for only then the evidence can be admitted. They are also documents published after the priority date. We have already held against the respondent on obviousness." As such, Roche's patent covering Pegasys has been revoked.

Source: www.ipab.tn.nic.in/250-2012.htm

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