PharmaBulletin

WILMERHALE

REGULATORY

UNITED STATES

FDA New Nanotechnology Task Force to Hold a Public Meeting on FDA-Regulated Products that Use Nanotechnology

The Food and Drug Administration (FDA) recently announced the formation of an internal Nanotechnology Task Force. This new task force will determine regulatory approaches that encourage the continued development of FDA-regulated products that use nanotechnology and will identify and recommend ways to address any knowledge or policy gaps so that the agency can better evaluate possible adverse health effects from such products.

The FDA has not established a formal definition of "nanotechnology." However, the National Nanotechnology Initiative definition, which the FDA helped to develop, describes nanotechnology as the understanding and control of matter that falls roughly within the 1–100 nanometer range. Currently, the FDA regulates nanotechnology-related products under the existing regulatory framework for the different product areas (e.g., drugs, devices, etc.).

The FDA Nanotechnology Task Force chaired a public meeting on October 10, 2006, to help the FDA further its understanding of developments and any new or emerging scientific issues in nanotechnology relating to FDA-regulated products. Attendees at the meeting emphasized the need to manage risk without stifling innovation. The FDA is aware of the potential benefits of nanotechnology, but also recognizes that nanotechnology materials have unique properties that may pose different safety issues than their larger counterparts.

Transcripts of the meeting are available for review at the Division of Dockets Management. Interested parties may submit written or electronic comments to the public docket. Comments must be submitted by November 10, 2006. For more information, visit www.fda.gov/nanotechnology

EUROPE

Foreign Internet Pharmacy Permitted to Sell Prescription Drugs in Germany by Mail Order

The District Court of Frankfurt/Main, Germany, ruled on July 21, 2006, that medicinal drugs allowed to be sold exclusively in pharmacies, may be traded lawfully via an Internet-based mail order service. This non-final ruling is one of many recent decisions putting traditional German drug distribution laws to the test.

The defendant, 0800DocMorris N.V., has been operating a mail order service via its website, selling medicinal drugs to German end users. In addition to selling prescription and non-prescription drugs licensed in Germany, the defendant offered drugs that had not been licensed in Germany.

The court held that while the marketing and distribution of drugs that are not licensed, registered or exempt from licensing in Germany violated competition laws invoked by the German Drugs Act (*Arzneimittelgesetz,* AMG), the sale of drugs by mail order did—in principle—conform to the recently amended AMG. It is particularly noteworthy that the court applied this principle expressly to prescription drugs.

On August 28, 2006, the plaintiff, Deutscher Apothekerverband e.V., filed an appeal against the judgment with the Higher Regional Court of Frankfurt/Main.

CHINA

Poor Manufacturing Practices and Fraud Plague Pharma in China

Several recent cases have exposed manufacturing shortcomings and outright fraud in China's pharmaceutical industry, resulting in calls for more stringent regulation.

During June and July 2006, more than 80 illnesses, and at least six deaths were attributed to "Xinfu," a clindamycin phosphate glucose injection manufactured in Anhui by Huayuan Worldbest Biology Pharmacy

The Food and Drug Administration recently announced the formation of an internal Nanotechnology Task Force

Several recent cases have exposed manufacturing shortcomings and outright fraud in China's pharmaceutical industry

Co., a subsidiary of Shanghai Worldbest Pharmaceuticals Co. Ltd., one of China's largest pharmaceutical groups. Investigators found that the drug was manufactured with improper sterilization. Disinfection should have been conducted for thirty minutes at 105 degrees Celsius as prescribed, but the process was shortened to four minutes or less at 100-104 degrees. Disinfection cabinets had also been overloaded.

Efforts to recall the defective product have been hampered by the failure to mark the batch on product labels and inadequate distribution records, a common problem in China.

This is not the first such problem in China this year. Two months earlier, an injectable drug manufactured by Qiqihar No. 2 Pharmaceutical Co. Ltd., a privately owned business in Heilongjiang, using a less expensive chemical unsuitable for human consumption, caused at least 11 deaths.

Both manufacturers were licensed pharmaceutical companies. The drugs produced by each were marketed through legal channels and each company held Good Managing Practice (GMP) certificates. These facts have intensified public concern about drug safety. Industry insiders say loose management and inadequate inspection are key difficulties. In addition, even though pharmaceutical companies may have invested millions of dollars to meet the criteria for the GMP certificates, some have then disregarded the requirements.

On August 15, 2006 at a national work conference, Shao Mingli, Director-General of the State Food and Drug Administration (SFDA), said that the Anhui incident exposed chaos in the drug market and loopholes in industry regulation. The SFDA, along with other relevant government authorities, is planning to launch a year-long nationwide campaign to regulate the drug market. The SFDA intends to target malpractice in drug research, production, distribution and application, in addition to slack supervision. The accomplishments of such campaigns are, however, often only evanescent.

Foreign-invested pharmaceutical companies have not been held responsible for these manufacturing problems, but they too can expect more intensive scrutiny under the heightened regulatory regime. At the same time, they can enhance their market reputation by emphasizing their worldwide commitment to quality and safety. In the meantime, they can assist those domestic manufacturers who are their business partners to comply better with international best practices.

INTELLECTUAL PROPERTY

UNITED STATES

In *eBay Inc. v. MercExchange, L.L.C.,* the US Supreme Court made it clear that district courts may not automatically grant permanent injunctions after a patent's claims have been held to be valid and infringed. Instead, the courts should exercise case-by-case equitable discretion in deciding whether to issue injunctions.

To obtain a permanent injunction, a patent owner "must demonstrate" that (i) denial of the injunction will result in "irreparable injury"; (ii) legal remedies, "such as monetary damages," will be "inadequate to compensate for that injury"; (iii) "the balance of hardships" between the patent owner and the infringer justifies equitable relief; and (iv) an injunction will not be against the public interest.

By emphasizing a patent owner's need to justify injunctions on a case-by-case basis, has the Supreme Court's decision caused district courts to be less willing to grant permanent injunctions? The reported district court cases since *eBay Inc. v. MercExchange, L.L.C.* indicate that permanent injunctions were not issued in nearly half of the decisions.

The key factors that district courts have applied in not issuing a permanent injunction fall into three broad categories: (i) the patentee did not practice the invention; (ii) the patentee demonstrated a willingness to license the patent-in-suit; and (iii) there would be significant harm or disruption to third-party consumers.

The decisions of courts that issued a permanent injunction focused on the following determinations: (i) loss of market share; (ii) uncollectible monetary damages; (iii) loss of reputation and product standards; and (iv) public interest in enforceable patents.

eBay Inc. v. MercExchange L.L.C.

EUROPE

ECJ Rules End to Cross-Border Jurisdiction in European Patent Infringement Actions

Previously, it has been possible in certain circumstances, to bring multiple patent infringement actions in a single jurisdiction and to obtain a pan-European decision and injunctions. The justification for this, was based on an interpretation of the Article 6(1)

of the European Jurisdiction and Judgments Convention (re-enacted as the "Brussels Regulation"), whereby several defendants could be sued in the state of domicile of one of the defendants, provided the cases were so closely connected that it would be expedient to hear them together to avoid the risk of irreconcilable judgments. The Dutch courts in particular had taken the view that such a connection existed where related companies were infringing a European patent by selling infringing products in a number of states, provided the controlling entity was based in the Netherlands. However, following two recent decisions of the European Court of Justice, it is clear that there is now no jurisdiction for a court in Europe to hear pan-European patent infringement cases.

In July 2006, the European Court of Justice (ECJ) gave judgment in two references arising from national European patent (EP) proceedings.

In the first reference, *GAT v. LuK*, issued on appeal in 2002 by the Düsseldorf Higher Regional Court, the parties were competitors in the motor vehicle market, both established in Germany, LuK alleged that GAT had infringed two of its French national EPs relating to mechanical damper springs. GAT then launched preemptive proceedings seeking a declaration of non-infringement and challenging validity of the French patent in the Düsseldorf Regional Court. According to the Brussels Regulation, proceedings may generally be brought in the state where the defendant is domiciled. However, proceedings relating to the validity of patents, must be heard in the courts of the Contracting State where the patent is registered. In this case, the Claimant argued that it was not attacking the validity of the patent as such, but raising invalidity in support of its arguments of non-infringement. The ECJ ruled that the court of the state of registration of an EP has exclusive jurisdiction over its validity, regardless of whether it is raised as an action or a plea in objection to infringement.

In the second reference, *Roche v. Primus*, issued on appeal in 2003 by the Dutch Supreme Court, the defendants were the co-owners of an EP relating to a method of immunometric analysis used to determine the presence of carcinoembryonic antigens (CEA) in serum and to an immuno-assay kit used to treat such antigens. The defendants claimed, commencing summary proceedings in the Dutch court against Roche and nine other "foreign" Roche companies, that by marketing a CEA immuno-assay kit within various EU jurisdictions—including the Netherlands—Roche (and the Roche companies) had infringed its various national EPs.

The ECJ ruled that there was no jurisdiction for the Dutch court to determine issues of multi-jurisdiction infringement, since there was no risk of irreconcilable judgments in such cases. In particular, European patents are governed by the national law of each of the Contracting States for which it has been granted and so any divergences between the decisions given by the courts concerned would not arise in the context of the same legal situation. Furthermore, to hold otherwise would lead to at least a partial fragmentation of the patent issues since, on the basis of *GAT v. LuK*, validity issues could not be raised or determined other than in the courts of the states where the various patents were registered.

By firmly upholding the sovereignty of the national courts as regards validity and confirming that Article 6(1) does not provide jurisdiction in cross-border infringement cases, the ECJ has quashed the attempts by some national courts to offer themselves as "one-stop-shops" for pan-European litigation.

Case C-4/03 — *GAT Gesellschaft für Antriebstechnik mBH & Co. KG v. Lamellen und Kupplungsbau Beteiligungs KG* [2006]

Case C-539/03 — *Roche Nederland BV & Others v. (1) Dr Primus; (2) Dr. Goldenberg* [2006]

There is now no jurisdiction for a court in Europe to hear pan-European patent infringement cases

Stay of UK Patent Action Refused Pending EPO Opposition

The UK High Court has recently refused a stay of European patent (EP) proceedings, pending the outcome of European Patent Office (EPO) Opposition proceedings and a Belgian infringement action, where the issue was "essentially one of costs."

In March 2006, Opposition proceedings relating to Baxter's EP for intravenously injectable immunoglobulin (IVIG) were rejected. The reasoned decision was awaited and an appeal to the Technical Board of Appeal was expected. Baxter then brought proceedings for a declaration of non-infringement in the Belgian court. A further declaration and revocation was then sought in the United Kingdom and a trial was listed for March 2007.

Baxter manufactured IVIG in Belgium and had obtained a European Union marketing authorization from the European Medicines Agency (EMEA). According to the court, sales were presently "about £1 million per annum," but were expected "to increase." Evidence suggested that an unfavourable Belgian decision might result in "at least the relevant part" of the production process being moved to the United Kingdom.

Favouring the start point of "whether, on balance, a stay is in the interests of justice," Pumfrey J commented that "the exercise of [this] power" is "normally" considered where there is the potential for "the same" conclusion to be "reached in two different jurisdictions." Where there are simultaneous Opposition proceedings, there is a "presumption in favour of a stay but not where to do so would cause injustice." In this case, "the ultimate balance [was] between an earlier certainty" of a March 2007 trial "against a potential waste" of "substantial...costs in respect of a comparative modest trade." Pumfrey J further considered that where "both sides are able to pay," particularly "in the face of an Opposition which has failed and which may fail again on appeal," the "mere question" of costs cannot "justify a stay unless the potential waste is so disproportionate to the interest to be protected that the refusal of a stay amounts to an injustice."

Finally, turning his attention to the Belgian proceedings, Pumfrey J considered that there is doubt that a stay should be granted pending "the outcome of other parallel proceedings [with] no direct legal impact in this country"—although he conceded that this consideration may have been different if "those proceedings had determined Baxter's ability to manufacture in Europe."

Baxter Healthcare SA v. Bayer Corp. [2006] EWHC 1890

Dutch Competition Authority made it clear that it intends to actively monitor the generic medicine market

ANTITRUST / COMPETITION

EUROPE

Dutch Competition Authority Terminates Investigation into Generic Medicine Producers

On August 8, 2006, the Dutch Competition Authority (NMa) announced that it was terminating its investigation into alleged anti-competitive behaviour by producers of generic medicines, on the basis that there was insufficient evidence of an infringement. Despite this termination, the NMa made it clear that it intends to actively monitor the generic medicine market.

Dutch Competition Authority Report

Fines Imposed on Pharmaceutical Wholesalers in Germany

On September 1, 2006, the Bundeskartellamt imposed fines totalling €2.6 million, finding evidence of a market sharing agreement between pharmaceutical wholesalers Anzag, Phoenix, Gehe and SanaCorp, reached in order to put an end to a "discount battle." Anzag, Phoenix and Gehe have announced that they intend to appeal the decision.

Bundeskartellamt Report

A very warm welcome to James N. Czaban who has joined the firm as a partner in the FDA group in Washington DC. Mr. Czaban advises life science clients in all aspects of FDA regulation,and has been named a "Top Lawyer" in Food and Drug Law by Washingtonian magazine. He is a frequent author and speaker on topics of FDA regulation of therapeutic products. Mr. Czaban can be contacted at james.czaban@wilmerhale.com

IF YOU HAVE ANY QUESTIONS OR NEED ADDITIONAL INFORMATION, PLEASE CONTACT:

Regulatory: Mark Heller +1 202 663 6005 mark.heller@wilmerhale.com

IP–United States: Hollie Baker +1 617 526 6110 hollie.baker@wilmerhale.com

IP–Europe: Robert Barry +44 20 7645 2501 robert.barry@wilmerhale.com

US Antitrust: James Burling +1 617 526 6416 james.burling@wilmerhale.com

European Competition: Suyong Kim +44 20 7645 2579 suyong.kim@wilmerhale.com

WILMER CUTLER PICKERING HALE AND DORR LLP

wilmerhale.com • Baltimore • Beijing • Berlin • Boston • Brussels • London • Munich • New York • Northern Virginia • Oxford • Palo Alto • Waltham • Washington