PharmaBulletin

WILMERHALE

REGULATORY

UNITED STATES

FDA Announces New Rules on Exporting Unapproved New Drug Products from the United States

The FDA recently amended its regulations for exporting investigational new drugs, including biologics, from the United States. Such drugs can be exported under four mechanisms:

The first mechanism applies to drugs for which an Investigational New Drug (IND) application is in effect in the United States. In order to be exported, the drug must comply with the laws of the country to which it is being exported and each person who receives the drug must be an investigator in a study under the IND.

The second mechanism applies to investigational drugs that have valid marketing authorization in countries listed by the FDA (Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, or in any country in the EU or the European Economic Area). Again, the drug must comply with the laws of the country to which it is being exported and, among other things, be manufactured according to Good Manufacturing Practices (GMPs) or must meet international standards; and not be sold or offered in US commerce. Prior FDA authorization is not required for such exports.

The third mechanism applies to investigational drugs being exported to one of the above "listed countries" for investigational use. This mechanism requires satisfaction of the same requirements as the second mechanism. Prior FDA authorization also is not required. Importantly, the FDA does not interpret this third mechanism as allowing transshipment (the practice of shipping a product to a listed country from which it will later be shipped to another country).

The fourth mechanism applies to unapproved new drugs exported to any country for investigational use without an IND. The FDA has now eliminated the requirement of prior FDA authorization for these exports. However, the exporter must submit a certificate to the FDA at the time of exportation that affirms various conditions or criteria, including that the clinical investigation will be conducted in accordance with the FDA regulation on foreign clinical studies not conducted under an IND, and that the drugs are "intended for export." The amended regulations also permit, under the fourth mechanism, the export of investigational drugs to a foreign country in the case of a national emergency (whether for stockpiling in anticipation of, or for use in, a sudden and immediate national emergency).

November 23, 2005, Federal Register

INTELLECTUAL PROPERTY

UNITED STATES

Major US Patent Overhaul Planned for 2006

Last year, a committee of the House of Representatives began drafting legislation that if enacted, would be the most significant overhaul of US patent laws since 1952. Although the legislation stalled amidst intense lobbying efforts by representatives of industries with disparate interests, the chairmen of both the House and Senate subcommittees with oversight of intellectual property have indicated that they are determined to introduce patent "reform" legislation in 2006. The proposed legislation is intended to respond to concerns over subjective standards in patent examination and patent litigation, and the enormous cost of patent litigation, among other issues.

One of the most significant proposals is conversion of the US patent system from a "first-to-invent" to a "first-inventor-to-file" system. Under the latter system, the first inventor to file an application in either the US Patent

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Office or abroad would be entitled to the patent, assuming the application satisfies the other conditions for patentability. The current "patent interference" procedure, which attempts to determine who was the first to "conceive" an invention, would no longer be necessary to determine rights of priority.

Another far-reaching proposal is the creation of a post-grant opposition proceeding, whereby third parties could challenge the validity of issued patents at the Patent Office. The proposed legislation attempts to provide a proceeding for eliminating invalid patents that is both less expensive than litigation and less restrictive than current reexamination proceedings.

Both the first-to-invent and post-grant opposition proposals would bring the US laws closer to European laws, thereby furthering the long-term goal of international "harmonization" of patent laws.

Other proposed changes would reduce the uncertainty and cost associated with patent procurement and litigation. These include revisions of the "prior art" standards, elimination of the "best mode" disclosure requirement, the creation of new procedures for allegations of "inequitable conduct," and the tightening of the requirements for permanent injunctions and the imposition of increased damages for willful infringement.

For more information on the progress and significance of the proposed patent legislation, visit http://www.wilmerhale.com/patent_act_2005/

EUROPE

New Patent Infringement Exemption Assists Generic Competition

As of October 30, 2005, the infringement provision of the UK 1977 Patents Act has been amended, so that an act committed while "conducting a study, test or trial which is necessary for" and "conducted with a view to" applying for marketing authorization for a generic version of a drug will not infringe a patent covering that drug. This amendment grants generic drug manufacturers a safe harbor, allowing pre-patent-expiration testing in the UK.

For more information on the 2005 Medicines Amendment Regulations, visit http://www.wilmerhale.com/uk_meds_1205

House of Lords Clarifies Law of Novelty

Continuing a spell of unusual activity in patent matters, the House of Lords has recently provided guidance on the issues of "disclosure" and "enablement", clarifying the test for "novelty".

In an action relating to the question of which company — Synthon or Smithkline Beecham — was first to disclose a particular crystalline form of paroxetine mesylate, a key ingredient in a widely prescribed antidepressant, the House has reversed the judgment of the Court of Appeal, upholding that of Jacob J at first instance, thereby invalidating Smithkline's UK patent.

In summary, Synthon had filed an international patent application claiming a broad class of compounds, including paroxetine mesylate; the specification describing how to make this compound in crystalline form. Prior to its publication, Smithkline filed a priority document for a UK patent application, claiming the particular crystalline form. The Court was asked to decide, first, whether the Synthon application disclosed the claimed invention (the "disclosure" issue); and second, whether the ordinary skilled addressee would be able to perform this invention, if he attempted to do so, using the disclosed matter and his common general knowledge (the "enablement" issue). The House held that, on the facts, both requirements had been satisfied.

Importantly, Lord Hoffman further clarified that disclosure and enablement were distinct concepts: each had its own rules and each had to be separately satisfied. In order to satisfy disclosure, the matter relied upon as prior art must disclose subject matter that if performed, would necessarily result in patent infringement. In order to satisfy enablement, this disclosure must then provide sufficient information (in conjunction with common general knowledge), for the ordinary skilled reader to be able to perform the claimed invention.

Synthon v. Smithkline Beecham (2005)

CHINA

New Compulsory Licensing Regulations in China

On November 29, 2005, China's State Intellectual Property Office (SIPO) promulgated new regulations providing for compul-

sory licensing of patented pharmaceutical products. The Measures on Implementing the Compulsory Licensing of Patents Concerning Public Health Problems, apply the WTO's Doha Declaration on the TRIPs Agreement and public health to China's pharmaceutical industry.

Pharmaceutical products, including their active ingredients and the diagnostic reagents required for their use, related to the prevention and control of the emergence or spread of communicable diseases are made subject to compulsory licensing. Three specific communicable diseases — AIDS, pulmonary tuberculosis and malaria — are listed. However, other communicable diseases resulting in public health problems are also subject to compulsory licensing under the Communicable Diseases Prevention and Control Law.

Procedurally, the competent government authority, presumably the Ministry of Health, would request SIPO to issue a compulsory license to exploit the relevant patent upon a finding of insufficient Chinese production capacity. Royalties would then be set at a reasonable level. A product for which a compulsory license is granted may not, however, be exported, except to a WTO member or less developed non-WTO-member, in accordance with the Doha Declaration.

The Measures entered into effect on January 1, 2006. They constitute the first instance in which China has promulgated product-specific compulsory license regulations, although the government has had the authority for some time to do so.

Although the Measures address a public health contingency and appear WTO-compliant, there is a risk of discouraging innovation in the underinvested pharmaceutical and life sciences industries. Some 69% of invention patents in China in the pharmaceuticals industry (as opposed to Traditional Chinese Medicine) are currently granted to foreigners, not Chinese. On the other hand, the Measures may induce foreign manufacturers of relevant products to invest in production facilities in China so that they can better meet demand in a national public health emergency and be in a better political position to defend their royalty rates.

ANTITRUST/COMPETITION

UNITED STATES

Supreme Court Requests Views of Solicitor General and Second Circuit Court of Appeals Rule on Hatch-Waxman Patent Settlements

China issues new regulations providing for compulsory licensing of patented pharmaceutical products

In the last issue, we reported that the FTC's constraints on Hatch-Waxman patent settlements between pioneer and generic drug companies had been rejected by the Eleventh Circuit Court of Appeals. The court concluded that any settlement involving generic exclusion that was less than or equal to the scope of the patent was presumptively valid. The FTC thereafter sought review by the US Supreme Court, and its application remains pending. Ironically, the Supreme Court has now asked for the views of the Solicitor General, who normally represents agencies of the federal government before the Supreme Court. The Solicitor General had declined to advance the FTC's position in the initial review petition, after which the FTC elected to pursue review on its own. The request for the views of the Solicitor General may delay for many months the Court's decision on whether to accept the review, pending the Court's receipt of the SG's brief.

Meanwhile, another Court of Appeals — the Second Circuit — has also rejected the FTC position that any settlement including compensation from the pioneer drug patent holder to a generic drug challenger, coupled with "delayed" generic entry, is almost always illegal. In Re: Tamoxifen, a private civil litigation brought by a variety of third party payers and tamoxifen consumers, the Second Circuit affirmed the District Court's dismissal of the claim, endorsing the analysis employed by the Eleventh Circuit in the Schering-Plough case: "[S]imply because a brand-name pharmaceutical company holidng a patent paid its generic competitor money [in the settlement of patent litigation] cannot be the sole basis for a violation of the antitrust law unless the exclusionary effects of the agreement exceed the scope of the patent's protection." The plaintiffs have sought rehearing and the FTC has filed an amicus brief in support of that motion.

Schering-Plough Corp. v. FTC

Re: Tamoxifen Citrate Antitrust Litigation

EUROPE

European Commission Receives a Complaint against Pfizer from European Lobby Group

On October 17, 2005, the European Association of Euro-Pharmaceutical Companies (EAEPC) filed a complaint with the European Commission, alleging that Pfizer is infringing EU competition law by implementing a deliberate strategy of preventing the export of medicines from Spain to other EU countries.

The EAEPC alleges that Pfizer's actions amount to a dual-pricing system and an export ban, and that Pfizer's agreements with wholesalers prevent, restrict or distort competition in breach of Article 81 EC Treaty, and that its conduct constitutes an abuse of a dominant position in breach of Article 82 EC Treaty.

The European Commission has not yet commented, but is understood to be considering the complaint.

EAEPC Press Release

UK Competition Appeal Tribunal Imposes Directions on Genzyme

On September 29, 2005, the UK Competition Appeal Tribunal (CAT) gave judgment on the remedy to be imposed on Genzyme Limited, following the CAT's decision of 2004 that Genzyme had infringed UK competition law by pricing Cerezyme (a drug used for the treatment for Gaucher's disease) and associated homecare services at levels that precluded third party competitors from making a profit.

The CAT's directions, which are to be monitored by the UK Office of Fair Trading, requires Genzyme inter alia to: (1) set the price of Cerezyme to providers of homecare services at a level that enables third party providers to make a profit on the homecare services; (2) supply Cerezyme to all bona fide providers of homecare services at a drug-only price and at a discount from the prevailing NHS list price; and (3) ensure that sales of Cerezyme to Genzyme's former homecare business are made on an arm's length basis.

This is the first occasion on which the CAT has given directions on a remedy to be imposed.

Genzyme Ltd v. OFT

We would like to give special thanks for this issue to Corinne Atton, Robert Barry, James Burling, Christopher Hutton, Lars Klein, Stephanie Philbin, Lester Ross and Michael Twomey.

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