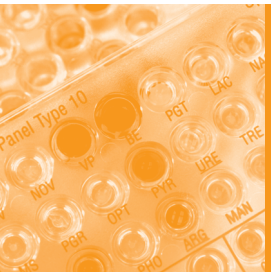

PharmaBulletin

WILMERHALE

Regulatory

United States

Congress Negotiates Drug User Fee Amendments

As this issue of *PharmaBulletin* goes to press, the US Congress is actively negotiating the terms of the Prescription Drug User Fee Amendments of 2007, S. 1082 (PDUFA-IV). The bill, as passed by the Senate HELP Committee on April 18, 2007, would authorize nearly $400 million in industry-paid fees over the next five years to support the FDA's review of new drug applications, as well as the review of direct-to-consumer (DTC) drug advertisements. The bill would also reauthorize the medical device user fee law, with the aim of collecting $287 million in user fees. Several other high-profile pharma-related bills are also under negotiation, some of which may ultimately be added, in whole or in part, to PDUFA-IV. In particular, proposed changes to the FDA's system of drug safety oversight (including some currently present in the HELP Committee version)—as well as proposals to establish an approval pathway for "follow-on biologics" and to ban "reverse payments" to generic drug companies in settlement of patent litigation—may be candidates for inclusion in PDUFA-IV. The user fee bill is considered "must pass" legislation, as the current user fee law expires in September and the FDA's heavy reliance on user fees to fund drug and device review activities means that FDA layoffs would occur if the law is not reauthorized in time, causing severe delays in drug and device review and approvals. Negotiations over the bill are still very fluid, and the House has yet to pass a companion version. Any differences between the Senate and House versions would have to be further negotiated and harmonized before being sent to the President for signature.

Future issues of *PharmaBulletin* will include detailed analyses of the final bill.

HELP Committee – PDUFA-IV

Europe

EMEA Releases Draft "First-in-Man" Clinical Trial Guideline

On March 26, 2007, the European Medicines Agency (EMEA) published a draft guideline on the requirements for first-in-man clinical trials for potential high-risk medicinal products. The guideline, produced in conjunction with national competent authorities and the European Commission, follows an extensive review of the serious adverse reactions that occurred during the TGN1412 clinical trials. Aiming to provide a common approach to the design and conduct of such trials across all EU Member States, the guideline is available for public consultation until May 23, 2007.

EMEA Press Release
EMEA Draft Guidelines

EMEA 2006 Annual Report Published

On March 14, 2007, the EMEA published its 2006 annual report, detailing the first full year in which the Agency operated under the revised EU pharmaceutical legislation. The report highlights a record volume receipt of initial marketing-authorization and post-authorization–variation applications, together with substantially reduced assessment times for initial evaluation and orphan designations.

EMEA Press Release
EMEA Annual Reports

The US Congress is actively negotiating the terms of the Prescription Drug User Fee Amendments of 2007

Intellectual Property

United States

Patent Reform Act of 2007

The Senate and the House introduce the Patent Reform Act of 2007

On April 18, 2007, both the Senate and the House introduced the Patent Reform Act of 2007 (S. 1145, or H.R. 1908). In their press releases, the Senate and House sponsors touted the proposal as bipartisan, bicameral patent reform legislation. These proposals follow various pieces of proposed legislation introduced in 2005 and 2006. The Patent Act of 2007 addresses many of the same topics as the earlier Senate and House proposals, adopting certain earlier provisions and changing or eliminating others.

The major substantive provisions of the Patent Reform Act of 2007 are as follows:

- ***First-Inventor-to-File.*** The bill would change the United States to a "first-inventor-to-file" system, the system followed by the majority of countries.
- ***Post-Grant Review Proceeding.*** A new post-grant review proceeding would be created to provide an administrative forum for challenging the validity of patents. The Patent Act of 2007 includes both a "first window" to file a petition for cancellation challenging a patent's validity (within the first 12 months from issue of the patent) and a "second window" (which may be filed at any time by anyone who is likely to suffer "significant economic harm" based upon the existence of the patent or anyone who had received a notice alleging infringement). The bill adds significant estoppels should a party use this procedure.
- ***Apportionment.*** The bill includes provisions aimed at reforming how damage awards are calculated after a finding of infringement. It directs the court to ensure that a "reasonable royalty" is "applied only to that economic value properly attributable to the patentee's specific improvement over the prior art." The bill forbids damages to be based on the "entire market value" of the infringing product or process unless the patent's specific improvement over the prior art is the "predominant basis for market demand" for the infringing product or process.
- ***Willful Infringement.*** The Patent Act of 2007 would modify the basis on which "willful" infringement is determined in a district court, thereby limiting findings of "willful infringement" and the award of treble damages that follows such a finding.
- ***PTO Rulemaking Authority.*** The bill would give the Director of the Patent and Trademark Office (PTO) broad new rulemaking authority.

Patent Reform Act of 2007

PTO Publishes Proposed Rule Packages

In 2006, the US Patent and Trademark Office published three proposed rule packages: the first governing continuation applications, dramatically limiting the number of allowed continuation applications (including continuations, continuations-in-part and requests for continued examination); the second relating to the examination of patent claims, limiting the number of claims examined in an application; and the third regarding Information Disclosure Statements, limiting how and when prior art could be submitted to the Patent Office. These proposals attempted to address a rising backlog of applications awaiting examination and to increase efficiency of examination. The public was invited to comment on the proposals. Approximately 600 comments were received, the majority not being in favor. These proposals have drawn ire from the patent bar for being ill-conceived and having the potential to weaken the patent system.

After almost a year of silence, the PTO has begun the process of finalizing these proposed rule packages. PTO Commissioner for Patents John Doll announced on April 11 at a DC Bar meeting that the final rules on continuation and designated claims practices have been sent to the Office of Management and Budget (OMB) for approval. The final rules were logged in on April 10, and OMB is expected to complete its review by July 10. The agency, however, frequently grants itself an extension of time. The final Information Disclosure Statement (IDS) rules were said to be on the desk of Director Dudas for approval, and will follow the other two packages to OMB in due course. Each of the rule packages is said to include modified versions of the rules published in the Federal Register's Notice of Proposed Rulemaking;

however, the specific rules were not disclosed. Presently, late summer would be an approximation for publication of the final rules, with 30 days (based on previous PTO statements) to implementation.

PTO Rule Packages

Europe

EPO Publishes Draft Examination Guidelines under EPC 2000

In March 2007, the European Patent Office (EPO) published draft Guidelines for Examination under the European Patent Convention 2000. The amended Convention is due to enter into force in all Contracting States by December 13, 2007. Further amendments are expected to the Guidelines before the final draft is published in all three official languages in September 2007.

To date, 22 Member States have acceded to or ratified the amended Convention. Those failing to do so before it enters into force shall cease to be a party to the EPC.

EPC 2000 Text
Contracting State Status
Draft Examination Guidelines

China

China's Pending Amendments to the Patent Law

China's Patent Law, first enacted barely 20 years ago in 1984, is now pending amendment for the third time. Having been submitted in December 2006 to the State Council, China's cabinet, legislative action this year (with effect beginning next year) is likely.

While most of the amendments are of a technical nature or otherwise provide welcome clarification, several will be of concern to the pharmaceutical industry.

The items of greatest concern involve greater latitude to grant compulsory licenses. The State Intellectual Property Office (SIPO) has existing authority to grant compulsory licenses, which has naturally been a concern to patentees given China's poor record with respect to IP enforcement, even though Chinese authorities no longer have the authority to approve ordinary licenses and influence royalties.

Of critical importance, however, is the fact that the Chinese government has never exercised its compulsory licensing authority. Given that history and China's vast foreign exchange reserves, the attention to compulsory licensing in the pending amendments is puzzling and a cause of concern. Pending Article 48(2) would newly authorize the grant of a compulsory license if it is determined that exercise of the patent right constitutes an act that is intended to eliminate or restrict competition. Article 49 would newly do so with respect to the prevention, treatment and control of epidemic diseases, which could conceivably cover any product, not just vaccines or therapies. Article 50 would newly authorize such grant for export to developing or least-developed counties without sufficient domestic capability to manufacture the drug.

China's Patent Law is pending amendment for the third time

One provision, which unfortunately is not slated for change, is the prohibition on the patenting of substances obtained by means of nuclear transformation in Article 25(5). This provision is to be made more problematic by amendments requiring declaration of the source of genetic resources used in an invention-creation, which injects a nationalistic element into the patent review process. These and other provisions will impede biomedical research.

Other amendments of concern are low ceilings on monetary penalties, a chronic problem with respect to IP enforcement in China.

Finally, another provision, which the amendments do not address, is the length of the patent term under Article 42. The 20-year term would still not provide for an extended term for products such as drugs, which must undergo an extensive government registration process before they can be launched on the market.

In sum, while the pending amendments to the Patent Law constitute an improvement in some respects, they still fall short of the changes needed by the pharmaceutical industry, and to some extent by patentees generally, to achieve the "innovation society" goal set by China's leaders.

Antitrust/Competition

United States

DoJ and FTC Release Joint Report on Antitrust and IP

The FTC and Department of Justice issue a joint report on "Antitrust Enforcement and Intellectual Property Rights"

On April 17, 2007, the Federal Trade Commission and Department of Justice issued a joint report, "Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition." The report emanates from an extensive series of hearings concerning antitrust and intellectual property and reflects testimony from participants in a wide range of IP-focused industries (including pharmaceuticals) and academics, as well as practicing lawyers.

On a broad level, the report emphasizes the agencies' continuing view that standard methods of antitrust analysis are appropriate for conduct involving intellectual property. The agencies also emphasize that they will continue to rely on their 1995 Antitrust Guidelines for the Licensing of Intellectual Property and evaluate the great majority of conduct relating to intellectual property under the rule of reason, balancing any potential anticompetitive effects against the pro-competitive aspects of the conduct. The report makes clear that the agencies are highly attuned to potential pro-competitive benefits from agreements among intellectual property holders, and that their analysis will focus on whether a particular restraint produces demonstrable anticompetitive effects.

The report is of interest to the pharmaceutical sector in many respects and focuses on several important areas, including:

- ***Settlements of Patent Disputes.*** Notably, the report does not discuss this controversial issue, which was discussed in depth at the hearings. The omission is likely the result of the agencies' apparently diverging views, at least in the context of settlements involving name brand and generic drug manufacturers. (In *FTC v. Schering*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S.Ct. 2929 (2006), DoJ opposed the FTC's efforts to obtain Supreme Court review of an Eleventh Circuit decision vacating an FTC decision that held a "reverse payment" settlement illegal.)
- ***Unilateral Refusals to License Patents.*** After considerable discussion about the teachings of *Verizon Communications Inc. v. Trinko*, 540 U.S. 398 (2004), and several other considerations, the agencies "conclude that liability for mere unconditional, unilateral refusals to license will not play a meaningful part in the interface between patent rights and antitrust protections." (Report at 29-31.)
- ***Standard-Setting Activities.*** The agencies devote particular attention to "*ex ante*" license discussions, whereby owners of patented technology that a standard setting organization (SSO) is considering incorporating in a standard negotiate with SSO participants, or unilaterally announce licensing terms before the standard is set. (*Id.* at 49-56.) The agencies emphasize that they will evaluate under the rule of reason bona fide joint activities to establish licensing terms before a standard is set, recognizing that such activities "have strong potential for pro-competitive benefits." (*Id.* at 53-56.)
- ***Patent Pools.*** Patent pooling arrangements typically involve two or more patent holders contributing patents to a pool and offering multi-patent licenses. The Report emphasizes the substantial pro-competitive benefits patent pools provide. In particular, while DoJ has in the past suggested that including patents for competing technology (rather than just patents for complementary technology) in a pool may raise concerns, the report arguably takes a more permissive approach to pools that include competing patents. The agencies suggest that in analyzing such pools their rule-of-reason analysis will focus on the overall competitive impact of the pooling arrangement, rather than on the narrow competitive impact of including each particular patent in the pool (*e.g.*, patents that are potential substitutes for other patents in the pool). (*Id.* at 78.)
- ***Tying and Bundling.*** A tying arrangement arises when a seller conditions the sale of one product (the "tying" product) on the purchase of another product (the "tied" product). US courts have generally held that if the seller has market power in the market for the tying product the tie violates the antitrust laws, even absent

proof of actual anticompetitive effects in the market for the tied product. However, the report makes clear that, as a matter of enforcement policy, the agencies will not simply presume competitive harm in the market for the tied product based on market power in the tying market. Instead, they will make an intensive, fact-specific inquiry to determine "whether the [tying arrangement] is likely to be anticompetitive on balance." (Report at 111.)

An email alert further discussing the topic above will be published shortly.

FTC Report – Antitrust Enforcement and IPRs

Europe

OFT Publishes Report into PPRS

On February 20, 2007, the UK Office of Fair Trading published a market study report into the Pharmaceutical Price Regulation Scheme (PPRS), which seeks to control branded medicine prices. The OFT identified wide price disparities between drugs with similar benefits, concluding that the UK National Health Service does not get value for money when purchasing branded drugs. The OFT recommended that the PPRS should be replaced with an approach based on the cost effectiveness of drugs.

OFT Press Release

OFT Launches Study into UK Medicines Distribution

On April 4, 2007, the OFT launched a market study into the distribution of medicines in the United Kingdom. The decision follows a move by Pfizer in March 2007 to begin selling prescription drugs solely through one wholesaler, Unichem. It is understood that other suppliers are also considering introducing significant changes to their own distribution arrangements. The OFT has stated that its study will consider the impact of these changes on competition, the UK National Health Service and patients, and that its report will be issued by the end of the year.

OFT Press Release
OFT Report – April 4, 2007

Czech Competition Authority Fines Drug Distributors

On December 20, 2006, the Czech Republic competition authority fined four drug distributors (Alliance Unichem CZ, GEHE Pharma Praha, Pharmos and Phoenix Lekarensky Velkoobcop) a total of €3.6 million for agreeing to suspend supplies to three hospitals in financial difficulties. The decision is the subject of an appeal.

European Commission Announces Boehringer Proceedings

On March 30, 2007, the European Commission announced that it had initiated proceedings against German drug maker Boehringer AG and its subsidiaries for allegedly misusing the patent system to eliminate competition in the market for lung disease drugs.

Commission Announcement

The UK Office of Fair Trading launches a market study into the distribution of medicines in the United Kingdom

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

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