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EC Official and U.S. Senator Raise Concerns About IEEE’s Proposed IPR Policy Changes

U.S. Senator Christopher Coons (D-DE) and European Commission Director for Electronic Communications Policy Gerard de Graaf have expressed concerns about the IEEE’s plans to amend its intellectual property rights policy. The proposed changes, which would prohibit the seeking of injunctive relief except under limited circumstances and require standard-essential patent holders to calculate royalties based on the “smallest salable unit,” are currently before the Department of Justice’s (DOJ’s) Antitrust Division under its Business Review Letter (BRL) process.

Senator Coons, a member of the Senate Judiciary Committee with oversight of the DOJ, sent a letter on January 14, 2015 to Attorney General Eric Holder and Assistant Attorney General for Antitrust Bill Baer expressing “serious concerns about the[] proposed [IEEE] policy changes,” stating that they “represent an unprecedented move by an international standards body to weaken the value and enforceability of patented technology.” (Ltr. from Senator Coons at 1.) Senator Coons further stated that “[t]he proposed policy changes would impose new conditions on American patent owners, suppressing returns on R&D investments and restricting a patent owner’s right to exclude even when an infringing party is entirely unwilling to engage in any
negotiation of ‘reasonable and non-discriminatory’ (RAND) licensing terms.” (Id.) Senator Coons urge[d] the DOJ to consider carefully the impact of any BRL,” stating that “[a] favorable BRL could pave the way for policy changes that will weaken incentives for both large companies and small investors to invest in the research that will lead to tomorrow’s most innovative technologies.” (Id.)

Director de Graaf reportedly sent a letter on January 5, 2015, stating that IEEE’s pending proposal to use the “smallest salable” unit to calculate reasonable royalty rates “would constitute a change in the IEEE policy and . . . such a policy may risk having a significant impact.” According to reports, the letter further states that “[w]e would expect that such a change, and its potential consequences for the standardization ecosystem, would be carefully examined before a decision would be taken to implement it,” and that standard-setting organizations should follow principles of “transparency, openness, impartiality, consensus, efficiency, relevance, and consistency.”

Sources:


EC Releases Non-Confidential Version of Lundbeck Pay-for-Delay Decision

On January 19, 2015, the European Commission (EC) published a 464-page non-confidential version of its June 2013 decision to fine brand-pharmaceutical company Lundbeck and four generic manufacturers for entering into agreements to delay market entry of cheaper generic versions of Lundbeck’s branded citalopram. The EC imposed a fine of € 93,8 million on Lundbeck and fines totaling € 52,2 million on the generic drug manufacturers.

In its decision, the EC concluded that the agreements at issue contained transfers of value from Lundbeck that induced the generic undertakings not to pursue their independent efforts to enter the market, and that such agreements violate EU antitrust law, which prohibits anticompetitive agreements (Article 101 of the Treaty on the Functioning of the European Union). The EC held that the agreements constituted an “infringement by object” (as opposed to an “infringement by effect”) because they “were by their very nature injurious to the proper functioning of normal competition.” (Decision ¶¶ 821, 1084.) With respect to each of the agreements at issue, the EC
concluded that “the provisions of the agreement considered together in their context make it clear that it was an objective aim, a necessary consequence of the agreement to make it impossible, for the term of the agreement,” for the generic undertakings to sell any citalopram in the EEA markets covered by the agreement, in exchange for the transfer of “significant value” from Lundbeck.  (*Id.* ¶¶ 871, 874, 1087, 1171.)

The EC found that:

- Each of the agreements “prohibited entry by a potential competitor” and “contained a transfer of value from Lundbeck to a potential or actual generic competitor, which was related to the latter’s agreement not to market generic citalopram.”
- The value that Lundbeck transferred “took into consideration the turnover or the profit the generic undertaking expected if it had successfully entered the market.”
- The agreements “did not resolve any patent dispute; rather they postponed the issue raised by potential generic market entry.”
- The agreements contained no commitment from Lundbeck to refrain from infringement proceedings if the generic undertaking entered the markets after expiry of the agreement.
- The agreements “obtained results for Lundbeck that Lundbeck could not have achieved by enforcing its process patents before the national courts.”

(Decision ¶ 6.)

The EC also found that Lundbeck had engaged in an “overall strategy against generic entry,” relying extensively on Lundbeck’s internal documents to conclude that Lundbeck believed that generic entry represented the greatest threat to its future profitability, and that, as early as 1997, Lundbeck had started planning for possible generic entry. According to the Commission, Lundbeck’s “overall strategy” included creating a window of opportunity for Lundbeck to switch a maximum of new patients to escitalopram, patenting processes to manufacture citalopram, intervening in market authorization procedures for generic citalopram, eliminating the competitive threat of upcoming citalopram active pharmaceutical ingredient procedures, and persuading generic suppliers to stop their efforts to enter the citalopram market.

Lastly, the EC emphasized that the agreements at issue must be distinguished from patent settlements, which “may in many cases be procompetitive enabling the generic company to enter the market prior to the lapse of the patent.” (*Id.* § 79.) In contrast, in the agreements at issue, “the parties did not resolve or terminate any patent disputes and did not agree on any entry date for the generic company but rather agreed on a period in which the generic company would be excluded from the generic market, without any guarantee of unrestricted market entry thereafter, in exchange for a considerable sum of money from the originator [brand] company.” (*Id.* ¶ 80.) The agreements “effectively extend[ed], at least in respect of the generic companies concerned, the period of exclusivity for Lundbeck well beyond the expiry of the original compound and original process patents.” (*Id.*)

Source:

Pennsylvania Federal Court Denies Defendants’ Motions for Summary Judgment in FTC’s Pay-for-Delay Suit

On January 28, 2015, U.S. District Court Judge Mitchell Goldberg denied the defendants’ motions for summary judgment in the Federal Trade Commission’s (FTC’s) pay-for-delay suit over Cephalon’s Provigil narcolepsy drug. (The motions were brought under the consolidated antitrust lawsuits referred to as the In re Modafinil Litig., which centers around four reverse-payment settlement agreements between Cephalon and several generic drug manufacturers. The plaintiffs in these actions are the FTC, direct purchasers, end payors, and Apotex.) The court rejected the defendants’ contention that, under the Supreme Court’s decision in Actavis, plaintiffs must establish that the reverse payment is both large and unjustified as a threshold matter, and failure to meet this burden prohibits analysis under the rule of reason. The court held that Actavis requires no such “threshold burden” but instead “primarily instructs that the familiar antitrust rule of reason analysis be applied to cases challenging reverse payment settlements.” (Opinion at 2.) “Rather, Plaintiffs must present evidence of a large reverse payment as part of their initial burden of demonstrating anticompetitive effects under the rule of reason.” (Id. 2-3.) In determining what constitutes a “large payment,” the court stated that, while Actavis did not identify any specific formula for determining what constitutes a large payment, the court finds that Actavis “supports” the plaintiffs’ approach, i.e., that “a reverse payment is sufficiently large if it exceeds saved litigation costs and a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its patent claim.” (Id. at 22.) The court found that the plaintiffs satisfied their burden by presenting evidence “that the amounts paid to these Generic Defendants have come close to, or in some instances, greatly exceeded the profits they could have expected to earn through an at-risk launch.” (Id. at 24.)

Source:

EC Approves Deal Between GlaxoSmithKline and Novartis With Conditions

On January 28, 2015, the European Commission (EC) required divestitures and behavioral remedies in clearing a complex deal between GlaxoSmithKline and Novartis. The deal included both the acquisition of Novartis’s vaccine business by GSK and the creation of a new entity combining the consumer health business of GSK and Novartis. The vaccine portion of the deal raised concerns with the EC that the transaction would have led to a monopoly in vaccines for bacterial meningitis and likely price increases in bivalent vaccines for diphtheria and tetanus in Germany and Italy. To address the EC’s concerns, GSK committed to grant a worldwide, exclusive, perpetual license for one vaccine for bacterial meningitis; divest another bacterial meningitis vaccine; and “enter into an exclusive distribution agreement for Germany and Italy, a 10 year supply agreement, and transfer marketing authorisations in the relevant countries for Novartis’[s] TD-Pur and Dif-Tet-All vaccines for diphtheria and tetanus.” GSK also agreed to divest several consumer health assets for the supply of smoking cessation aids, cold sore management products, cold and flu products, and pain management products.
Source:


UPCOMING PROGRAMS

The ASCAP and BMI Consent Decrees—Do They Protect Competition?
February 11, 2015 Noon-1p.m. EST
Details and registration available at http://www.americanbar.org/content/dam/aba/marketing/antitrust/20150211_at150211.authcheckdam.pdf.