

## Will The E.U. Report on Alleged Competitive Abuses in the Pharmaceutical Industry Prompt Enforcement Action by the Federal Trade Commission in the U.S.?

On November 28, 2008, the European Commission issued a preliminary report prepared by the DG Competition Staff on the results of its ongoing Pharmaceutical Sector Inquiry (the "Report").<sup>1</sup> The Report runs 426 pages, including annexes, and is based upon responses to questionnaires submitted to some 43 brand name and 27 generic drug manufacturers, and documents obtained through "dawn raids" on selected manufacturers. It must be read in conjunction with a draft guidance document issued a few days later, on December 3, describing the Commission's priorities on bringing cases to enforce Article 82 EC against alleged abuses of a dominant position (the "Guidance").<sup>2</sup>

The Report focuses on practices of brand name drug manufacturers in obtaining and enforcing patents, and is based upon a review of 219 molecules that collectively account for 47% of E.U. pharmaceutical sales. It purports to document that these practices have both delayed the entry of competitive generic drugs as well as competitive innovative drugs by other manufacturers. The Report purports to take no view on the lawfulness of the conduct of any manufacturer, or of the practices discussed. E.U. Competition Commissioner Neelie Kroes was not so circumspect, however, stating in her opening remarks at the conference presenting the Report that "competition in this industry **does not** work as well as it should" (emphasis in original), and characterizing as "damaging practices which delayed or blocked market entry of competitors" pretty much the universe of tactics and approaches by brand name manufacturers that the Report considered.<sup>3</sup> The Pharmaceutical Sector study was launched with unprecedented dawn raids, and enforcement actions may well be initiated even before some version of the Report is finalized, most likely next year.

The Guidance, in turn, lays out a useful, if by no means self-effectuating, identification of the types of situations that are most likely to generate an enforcement action by E.U. Competition authorities. It is clear that exclusionary conduct is high on the list, and the suggestion is made that actions by dominant firms to make payments to delay the introduction of competitive products (how the FTC views certain patent settlements) should receive almost *per se* condemnation.<sup>4</sup>

A reader might be inclined to think of the Report's (and the Guidance's) significance as being essentially limited to Europe, as is the case with many European competition enforcement actions. Indeed, the Report is a survey of many of the points of difference between U.S. and European pharmaceutical antitrust law, most notably differences in the regulatory structures governing drug pricing, generic drug entry and the absence in the E.U. of a counterpart to American First Amendment protections, which inform the *Noerr-Pennington* doctrine and protect much advocacy in administrative and judicial processes.<sup>5</sup> More broadly, the Report reflects the European sense of greater limitations on the ability of dominant firms to compete, referring disparagingly to evidence of an intent by unnamed brand name manufacturers to take advantage of the legal system in order to gain a competitive advantage.<sup>6</sup> But this time may be different, and there is some reason for antitrust counsel to be aware of the possible significance of the Report to U.S. operations of pharmaceutical companies, and the U.S. enforcement actions it may be likely to support. Consider these points:

- The E.U. inquiry, relating to alleged efforts by brand name drug manufacturers to deter generic drug entry, was begun in January 2008 following announcement of a similar study by

the U.S. Federal Trade Commission. The Commission expressly acknowledged its ongoing communications with “competition authorities outside the community,” and it is clear that these include the FTC.<sup>7</sup>

- The Report does what it can to minimize perceived differences between the E.U. and U.S. systems. It catalogues many significant differences between U.S. and E.U. settlements of patent infringement cases, but observes (at Section 2.4.1.5, ¶ 661) that “Overall, however, it seems legitimate to conclude that there are more similarities than differences between the two systems.” Moreover, the Report gives a place of honor to the FTC’s enforcement position on patent settlements, while inadequately describing the growing body of U.S. case law (and the contrary position of the U.S. Department of Justice) rejecting the FTC’s categorical legal analysis.<sup>8</sup>
- The FTC has maintained an aggressive enforcement position with respect to alleged efforts by brand name drug companies to deter generic entry, specifically including alleged IP-based efforts, and notably has pursued cases even after adverse court decisions had rejected prior efforts.<sup>9</sup>
- The FTC has recently and pointedly staked out a more aggressive enforcement stance than the U.S. Department of Justice in response to DOJ’s encyclopedic report on monopolization and the reach of Section 2 of the Sherman Act.<sup>10</sup> The Report could provide the kind of intellectual backup that would encourage the FTC to pursue what, for this country, would be cutting-edge theories.
- The incoming Obama administration is expected generally to pursue antitrust enforcement more vigorously than regulators in the Bush Administration, and the reduction of healthcare costs has been one of its political goals.

Still, it would be wrong simply to presume that most or even much of the legal theories reflected in the Report will be imported to these shores. In the United States, far more so than in Europe, control over legal theories as a practical matter rests with the courts. And in this case there is a lot of case law and accumulated learning that would have to be cast aside to give the theories advanced by the European regulators a congenial home — especially with a U.S. Supreme Court that appears, for the foreseeable future, to be actively pursuing more defense-oriented changes in antitrust law.

- 
1. The text of the Report, and its Executive Summary, are available at: [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary\\_report.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf).
  2. Guidance on the Commission’s Enforcement Priorities in Applying Article 82 EC Treaty to Abusive Exclusionary Conduct by Dominant Undertakings, (COM) (2008) (Dec. 3, 2008), available at: <http://ec.europa.eu/competition/antitrust/art82/guidance.pdf>.
  3. The text of Commissioner Kroes’ remarks is available at: [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/speech\\_nk\\_hearing.pdf?reference=SPEEC/08/659&format=HTML&aged=0&language=EN&guiLanguage=en](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/speech_nk_hearing.pdf?reference=SPEEC/08/659&format=HTML&aged=0&language=EN&guiLanguage=en).
  4. “There may be circumstances where it may not be necessary for the Commission to carry out a detailed assessment before concluding that the conduct in question is likely to result in consumer harm. If it appears that the conduct can only raise obstacles to competition and that it creates no efficiencies, its anti-competitive effect may be inferred. This could be the case, for instance, if the dominant undertaking prevents its customers from testing the products of competitors or provides financial incentives to its customers on condition that they do not test such products, or pays a distributor or a customer to delay the introduction of a rival’s product.” Guidance at ¶ 21.
  5. See, e.g., *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993) (“PRE”).
  6. A revealing example is the Report’s conclusion that generic manufacturers won 60% of the patent infringement cases between 2000 and 2007 that were studied. (Report, Section 2.2.2.6 at ¶ 505.) In the United States, a track record of that sort would hardly be evidence that patent infringement litigation was “objectively baseless,” as required for there to be liability under the PRE standard.
  7. Report at Section A, Paragraph (18).
  8. The Report (Section C.2.4.1.1, at ¶ 579) states:

“However, as shown by the enforcement action of the USA competition authorities, in particular the Federal Trade Commission, it might also be argued that settlements contain arrangements that could fall within the scope of competition rules. A patent settlement agreement might, for example, lead to a delay in a generic product’s entry in a specific market in return for a payment by the originator company to the generic company. Ultimately, it is the

consumer who pays the price for such a delay in market entry.”

The Report makes it appear as if the Eleventh Circuit, through its decision in *FTC v. Schering-Plough Corp.*, 402 F.3d 1056 (11th Cir. 2005), stands alone against the FTC’s position, not so much as referring to the subsequent decisions in *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), and *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, No. 08-1097 (Fed. Cir. Oct. 15, 2008), was decided more than six weeks before the Report was released. Indeed, the United States, acting through the Solicitor General, itself disagreed with the FTC’s analysis in *opposing* the FTC’s effort to obtain Supreme Court review of the *Schering-Plough* decision. See *Federal Trade Commission v. Schering-Plough Corp.*, No. 05-273 (U.S. petition for certiorari filed May 17, 2006).

9. See, e.g., the complaint filed in February 2008 in *United States v. Cephalon, Inc.*, which one FTC Commissioner expressly described as having been filed in part in order to provoke further appellate review of issues that had been decided adversely to the Commission. We have written about this matter previously. See James B. Kobak, Jr., “2008 FTC Actions in the Drug Industry” (“2008 FTC Actions Advisory”) available at: <http://www.hugheshubbard.com/pen/pubdetail.aspx?pub=1498>.
10. This issue is also discussed more fully in our 2008 FTC Actions advisory cited in n.8 above.

---

James B. Kobak  
(212) 837-6757  
[kobak@hugheshubbard.com](mailto:kobak@hugheshubbard.com)

Antitrust Group and the  
Pharmaceutical and Healthcare Industry Group  
December 2008



Hughes Hubbard & Reed LLP  
One Battery Park Plaza | New York, New York 10004-1482 | 212-837-6000

Attorney advertising — prior results do not guarantee a similar outcome.

This e-ALERT is for informational purposes only and is not intended to be and should not be relied on for legal advice. If you wish to discontinue receiving e-ALERTS, please send an email to [opt-out@HughesHubbard.com](mailto:opt-out@HughesHubbard.com).

© 2008 Hughes Hubbard & Reed LLP