Separate Statement of Commissioners Maureen K. Ohlhausen and Joshua D. Wright Federal Trade Commission v. Cephalon, Inc. May 28, 2015

We voted to accept the proposed consent in this matter. We write separately to explain why disgorgement is appropriate in this case, but also to convey our continuing concerns about the lack of guidance the Commission has provided on the pursuit of this extraordinary remedy in competition cases.

Based on the evidence we have seen in this case, it appears that the use of disgorgement here would meet the factors set forth in the since-withdrawn Commission policy statement on pursuing disgorgement in competition cases (the Policy Statement or Statement). Given that the vast majority of the alleged harm at issue took place while the Statement was in effect, it ought to guide the Commission's use of disgorgement in this case. The Statement identified three determinative factors: (1) whether "the underlying violation is clear;" (2) whether there is "a reasonable basis for calculating the amount of a remedial payment;" and (3) "the value of seeking monetary relief in light of any other remedies available in the matter, including private actions and criminal proceedings."

The "clear violation" factor is, in our view, the most important of the three considerations. A violation is "clear" if, measured at the time the conduct is undertaken, and "based on existing precedent, a reasonable party should expect that the conduct at issue would likely be found to be illegal." Here, although the so-called scope of the patent test was the prevailing standard for assessing pay-for-delay agreements when Cephalon entered into the agreements with the four generic firms, that test included an exception for settlements involving fraudulently procured patents. Court decisions have held that Cephalon engaged in inequitable conduct before the U.S. Patent & Trademark Office in obtaining the relevant patent. Given this

⁴ See, e.g., In re Tamoxifen Citrate Antitrust Litig., 429 F.3d 370, 398 (2d Cir. 2005) ("Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.") (quoting *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005)); accord Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1306-07 & n.19 (11th Cir. 2003) (holding that "the mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis" and noting that "appellees have neither alleged nor asserted that the patent was procured by fraud, that appellants knew the patent was invalid, that there was no objective basis to believe that the patent was valid, or any such similar allegations").

¹ See Fed. Trade Comm'n, Policy Statement on Monetary Equitable Remedies in Competition Cases, 68 Fed. Reg. 45820 (Aug. 4, 2003).

² *Id.* at 45821.

³ *Id*.

⁵ See Apotex Inc. v. Cephalon, Inc., Civ. Action No. 06-cv-2768, 2011 WL 6090676, at *28 (E.D. Pa. 2011) ("[G]iven the unmistakable importance of the Lafon information, the inexplicable concealment of that information from the PTO, even after the examiner's obviousness challenge unequivocally alerted Cephalon to its importance, as well as the direct misrepresentations made by Cephalon to the PTO, the

fraudulent behavior, there is reason to believe that Cephalon should have known that it was violating the antitrust laws when it entered into the pay-for-delay agreements at issue. Under this set of facts, we are satisfied that the clear violation factor is met.

There also appears to be a reasonable basis for calculating the disgorgement amount sought in this case. With respect to the third factor in the Policy Statement, the framework of the proposed settlement fund would appear to prevent any duplicative recovery by the private plaintiffs that have settled with, or continue to litigate against, Cephalon. To the extent that there remains some question about the additional value of the FTC's disgorgement remedy given the existing private lawsuits, the Policy Statement explained that a strong showing on one factor "may tip the decision whether to seek monetary remedies." Here, a strong showing on the most important factor (clear violation) assuages some of our concerns that we are seeking disgorgement at the same time that settlements of private litigation are being reached.

Notwithstanding our support for obtaining disgorgement in this case, we continue to have significant concerns about the Commission's use of this powerful remedial tool without Commission guidance about when it will seek this remedy. As we explained in our dissents in the recent *Cardinal Health* matter, following the withdrawal of the Policy Statement in 2012, firms subject to our jurisdiction have no meaningful guidance on when they will be forced to disgorge their profits for an antitrust violation. In fact, the *Cardinal Health* case exemplifies just how unpredictable our pursuit of disgorgement is and how far from the Policy Statement the

only reasonable inference to be drawn is that Cephalon made a deliberate choice to deceive the PTO about the origin of its claimed invention."), *aff'd per curiam*, 500 F. App'x 959 (Fed. Cir. 2013).

⁶ Policy Statement, *supra* note 1, at 45821; *see also id*. ("For example, a particularly egregious violation may justify pursuit of these remedies even if there appears to be some likelihood of private actions.").

⁷ See Dissenting Statement of Commissioner Maureen K. Ohlhausen, *In re* Cardinal Health, Inc., FTC File No. 101-0006 (Apr. 17, 2015), *available at* https://www.ftc.gov/public-statement-cardinal-health-inc; Dissenting Statement of Commissioner Joshua D. Wright, *In re* Cardinal Health, Inc., FTC File No. 101-0006 (Apr. 17, 2015), *available at* https://www.ftc.gov/public-statements/2015/04/dissenting-statement-commissioner-joshua-d-wright-cardinal-health-inc.

⁸ See Fed. Trade Comm'n, Withdrawal of the Commission's Policy Statement on Monetary Equitable Remedies in Competition Cases (July 31, 2012), available at https://www.ftc.gov/public-statement. Commissioner Ohlhausen dissented from the withdrawal of the Statement. See Statement of Commissioner Maureen K. Ohlhausen Dissenting from the Commission's Decision to Withdraw its Policy Statement on Monetary Equitable Remedies in Competition Cases, at 2 (July 31, 2012), available at https://www.ftc.gov/public-statements/2012/07/statement-commissioner-maureen-k-ohlhausen-dissenting-commissions-decision ("In essence, we are moving from clear guidance on disgorgement to virtually no guidance on this important policy issue."). Commissioner Wright, while not at the Commission at the time of the Statement's withdrawal, agrees that "the business community is now without any guidance whatsoever regarding the conditions under which the Commission will pursue disgorgement or other monetary remedies in antitrust cases." Joshua D. Wright, The Federal Trade Commission and Monetary Remedies, Remarks at the European University Institute Department of Law Annual Workshop, at 31 (July 19, 2013), available at https://www.ftc.gov/public-statements/2013/07/federal-trade-commission-and-monetary-remedies.

Commission may veer in seeking this remedy. This uncertainty and lack of predictability faced by firms is unacceptable. We therefore urge the Commission to reinstate the Policy Statement or provide some additional guidance on when it plans to seek the extraordinary remedy of disgorgement in antitrust cases. Simply saying that the agency will be guided by the case law is insufficient.⁹

Commissioner Ohlhausen also reiterates the concerns she raised in *Cardinal Health* that using disgorgement with increasing frequency will cause the Commission to stray from its special mission to develop the antitrust laws. ¹⁰ Disgorgement is a tool that affects the behavior of those against whom it may be wielded. ¹¹ It also, however, affects the behavior of the entity that wields this "immensely powerful antitrust weapon." ¹² Although justified in the present case, Commissioner Ohlhausen is concerned that the incentive to pursue monetary remedies more frequently, particularly in other cases without a clear violation, may cause the Commission to neglect its special mission to develop the antitrust laws through Part III litigation and other unique tools. That concern is only heightened now that we are counting disgorgement in the billions of dollars.

Commissioner Wright also reiterates his view, that the economic analysis of penalties and optimal deterrence should guide the Commission decisions as to whether to seek monetary relief. The Policy Statement embraces the notion that the Commission's use of monetary remedies should further "society's interest in optimal deterrence." A foundational principle of optimal deterrence is that penalties should be set at a level to induce offenders to internalize the full social cost of their violation. This basic economic principle implies the Commission should seek monetary relief in cases where there is both a significant probability that a violation escapes detection and punishment and where other remedies are insufficient to make the unlawful activity unprofitable. Commissioner Wright's view, informed by this approach, is that conduct associated with a high probability of punishment or with plausible efficiency justifications are not appropriate for disgorgement. However, disgorgement may facilitate optimal deterrence

⁹ See Fed. Trade Comm'n, Withdrawal of the Commission's Policy Statement on Monetary Equitable Remedies in Competition Cases, at 1 (July 31, 2012), available at https://www.ftc.gov/public-statements/2012/07/statement-commission-regarding-withdrawal-commissions-policy-statement ("Existing case law suffices to guide our use of disgorgement and restitution remedies").

¹⁰ See Ohlhausen Cardinal Health dissent, supra note 7, at 5-6.

¹¹ See Policy Statement, *supra* note 1, at 45821 ("One key purpose of the disgorgement remedy is to remove the incentive to commit violations by demonstrating to the potential violator that unlawful conduct will not be profitable.").

¹² Mylan Labs., Inc., FTC File No. X990015, Statement of Commissioner Thomas B. Leary, Dissenting in Part and Concurring in Part, at 5 (Nov. 29, 2000), *available at* https://www.ftc.gov/sites/default/files/documents/cases/2000/11/mylanlearystatment.htm.

¹³ See Wright Cardinal Health dissent, supra note 7, at 1-3.

¹⁴ Policy Statement, *supra* note 1, at 45823.

¹⁵ Thus, Commissioner Wright believes the Commission should not seek monetary relief in cases involving single-firm conduct unless there are no plausible efficiency justifications because such conduct is generally open, transparent to the market, and usually involves at least some procompetitive virtues, thus creating significant risk of over-deterrence. *See* Wright *Cardinal Health* dissent, *supra* note 7, at 3.

for business conduct with a low probability of detection and punishment or that lacks any plausible efficiency justification – such as naked price-fixing conspiracies, fraud, or deception. While the probability of detecting a blatantly anticompetitive pay-for-delay agreement is likely relatively high because reverse payment settlements must be filed with the FTC and the Department of Justice, the fact that Cephalon engaged in fraudulent behavior materially reduces the probability of detection and strengthens the case for disgorgement relative to a typical reverse payment settlement. ¹⁶

In sum, although we believe disgorgement is appropriate in this case, the Commission's increased interest in seeking this extraordinary remedy renders it critically important that we provide guidance to the firms under our jurisdiction about when the Commission will seek disgorgement in antitrust cases. We call upon our colleagues to reinstate the Policy Statement or provide alternative guidance on this important issue of competition policy. Absent such guidance, and short of particularly egregious conduct or extraordinary circumstances, we would be hard-pressed to support disgorgement cases involving conduct initiated after the withdrawal of the Policy Statement.

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¹⁶ The Commission's Order prohibits Teva and Celphalon from entering into settlements with generic entrants above \$7 million in saved future litigation expenses without "prior approval of the Commission." *See* Proposed Stipulated Order for Permanent Injunction and Equitable Monetary Relief at 4, 9. To the extent that settlement amounts greater than the \$7 million threshold are essentially deemed "large and unjustified" and for that reason prohibited on the grounds that they are likely anticompetitive, Commissioner Wright does not believe this injunctive provision is effective. Commissioner Wright does not believe that payments in excess of saved litigation costs are an economically robust and reliable predictor of anticompetitive effects. *See* Bruce H. Kobayashi, Joshua D. Wright, Douglas H. Ginsburg, & Joanna Tsai, Actavis *and Multiple ANDA Entrants: Beyond the Temporary Duopoly*, ANTITRUST, Spring 2015, at 90 ("[U]sing litigation cost as an indicator of an anticompetitive settlement would neither induce litigation that would invalidate 'bad' patents nor encourage settlements that would increase consumer welfare.").