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I. INTRODUCTION

The year is 2025. For the past two decades, brand-name drug companies have settled infringement lawsuits with generic firms by paying them to drop their patent challenges. Early in the 21st century, courts had explained that this was the natural state of affairs. By 2025, this is true many times over.

This outcome traces back to 2005, when the *Schering* and *Tamoxifen* appellate courts upheld reverse-payment agreements. In the five years before that, drug firms had been more careful. In 2000, the FTC announced that it would challenge such settlements. And the first appellate case to address the issue, *Cardizem*, found one such agreement to be *per se* illegal. As a result, parties settled cases, but without payments from brands to generics, and with licenses allowing early generic entry.

After 2006, the pendulum swung quickly in the other direction. To be sure, there were baby steps towards vigorous scrutiny. Between 2006 and 2010, Congress had considered legislation that would have made reverse payments illegal. The Federal Trade Commission had brought several high-profile challenges. And the Second Circuit, recognizing concerns with its *Tamoxifen* ruling, even requested that plaintiffs file for en banc review in the *Cipro* case.

None of these developments, however, slowed the careening snowball of *per se* legality. In this short article, I will offer three predictions for drug patent settlements in the next 15 years:

1. The Eastern District of Pennsylvania court will deny summary judgment in the *Cephalon* case.
2. The Supreme Court will grant certiorari, and affirm, in the 2nd Circuit *Cipro* case.
3. Congress will pass reverse-payments legislation.

Going even further out on a limb, the first two predictions will occur in 2011 and the third will happen in 2017.

II. PREDICTION 1: THE COURT WILL DENY SUMMARY JUDGMENT IN THE *CEPHALON* CASE

First, the Eastern District of Pennsylvania court will deny summary judgment in the *Cephalon* case. In a nutshell, Cephalon paid four generics $200 million to delay entering the market from 2006 to 2012 with generic versions of sleep-disorder drug Provigil. In March 2010, the court denied Cephalon's motion to dismiss, finding that an array of activity alleged by the plaintiffs could have exceeded the patent's scope. Such conduct included "fraud and misrepresentations to the PTO, non-infringement, patent invalidity, 'sham litigation,' the

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creation of a bottleneck, antitrust conspiracy, and agreements . . . regarding products not protected by Cephalon's patent."[2]

My prediction is that the court, after reviewing a more developed record, will deny summary judgment. It will hold that the "scope of the patent" test is more complex than typically recognized. And it will find that such a test should consider not just the temporal duration of the patent, but also generalized inquiries concerning validity and infringement.

Part of the reason for the misunderstanding of an appropriate scope test can be traced to *Cardizem*. In that case, the brand paid the generic to stop competing on *not only* the patented hypertension drug at the center of the litigation *but also* products not covered by the patent. Such a scenario led to the unremarkable conclusion that a party violates the antitrust laws by blocking competition on products outside the scope of the patent.

This finding, however, tells us nothing about the inverse scenario. In other words, just because an agreement concerning a product outside the scope of a patent is illegal does not mean that a settlement on a patented product necessarily is legal.

The *Cephalon* court will engage in a context-specific analysis of the patent. It will find that the patent at issue is weak, covering not the active ingredient of modafinil (whose patent expired in 2001) but only a formulation consisting of a specified distribution of small particles. The industry widely recognized that generics could easily invent around this patent. Cephalon, the four first-filing generics, and Wall Street analysts all predicted generic entry in 2006, with the settlement delaying entry until 2012 providing (according to Cephalon's CEO) "$4 billion in sales that no one expected."[3] The *Cephalon* court will emphasize this weak patent and the $200 million payment to the generics in concluding that there is, at a minimum, substantial evidence that the patent is not valid and the agreement violates the antitrust laws.

While this would appear to be a positive development for challenges to concerning settlements, it will matter less than many will anticipate. One reason is that the case involves a combination of settlement and product hopping that forestalled competition. Through settlement, Cephalon received 6 years of guaranteed exclusivity. During this period, it switched the market from Provigil to its similar successor, Nuvigil. It did this by raising the price of Provigil 74 percent and exclusively promoting Nuvigil. So by the time generics could enter the market in 2012, consumers would not be interested in generic versions of Provigil. Another reason it matters less deals with my second prediction.

III. PREDICTION 2: THE SUPREME COURT WILL AFFIRM THE SECOND CIRCUIT IN THE *CIPRO* CASE

I predict that the Supreme Court will grant certiorari in the *Cipro* case. Although it denied certiorari in *Schering-Plough* and *Tamoxifen*, the Department of Justice now will join the FTC in recommending that the Court hear the case. The Court will be swayed by this, as well as the opportunity to review the last clear case in which (before the agreements became more complicated) the brand firm makes a naked cash payment to a generic.

The Court will affirm *Cipro*. It will follow the reasoning of the Second Circuit, which had relied on *Tamoxifen*. It will find that public policy favors settlements, that patents are presumed

[2] King Drug Co. of Florence, Inc. v. Cephalon, Inc., 2010 WL 1221793, at *17 (E.D. Pa., Mar. 29, 2010).
[3] Complaint for Injunctive Relief, FTC v. Cephalon, Inc., ¶ 4, No. 08-cv-00244(JDB) (D.D.C. 2008).

valid, that the payment at issue fell within the scope of the patent, and that reverse payments are natural by-products of the Hatch Waxman Act.

And then it will be over in the courts. The *Cephalon* court will dismiss the case, and the FTC will not bring additional cases. The Supreme Court will have put the final nail in the judicial coffin of critical review of settlements.

It did not have to be this way. Such a ruling merely perpetuated the line of reasoning that took hold with *Schering*, *Tamoxifen*, and *Cipro* in the appellate courts. But it ignored a fundamental purpose of the Hatch-Waxman Act: to promote patent *challenges*, not agreements *not to challenge* patents.

This neglect flies in the face of the Court's teachings on the intersection of antitrust and regulation. In *Trinko*, the Court explained that courts must take "careful account" of "the pervasive federal and state regulation characteristic of the industry."[4] Hatch Waxman is a complicated regulatory regime. It involves a nuanced equilibrium between fostering innovation (patent term extension, non-patent market exclusivity, 30-month stay of FDA approval) and promoting competition (experimental use defense, expedited Abbreviated New Drug Application ("ANDA") process, 180-day marketing exclusivity for first Paragraph IV challenger certifying invalidity or claiming non-infringement).[5]

This complex balance has been upset by these agreements. In other words, the regulatory regime is not effective. To be sure, the number of generics on the market has increased. But the central policy of promoting patent challenges has failed. For that reason, the Court should have looked at the role that antitrust could play. This is especially the case given the severe anticompetitive harms of paying a competitor not to compete. Nonetheless, the Supreme Court's upholding of the *Cipro* settlement will eventually pave the way for legislative action.

IV. PREDICTION 3: CONGRESS WILL ENACT REVERSE-PAYMENTS LEGISLATION

My third prediction is that Congress will enact reverse-payments legislation. When the Democrats regain control of both houses in 2017 (after the elections of 2016), they will pass legislation that would make clear that, regardless of any rulings to the contrary in the *Cipro* case, it is presumptively anticompetitive for a generic to receive anything of value in exchange for delaying entry into the market. Passage of this legislation will be followed by a round of back-slapping and an elaborate signing ceremony. But its effect will be more limited than its drafters envision.

For starters, a test for presumptive illegality is weaker than one of *per se* illegality. The settling parties can rebut the presumption if they can demonstrate by clear and convincing evidence that the agreement's pro-competitive effects outweigh its anticompetitive effects. The parties likely would claim that their side deals—by which brands pay generics for, e.g., IP licenses, the supply of raw materials or finished products, and assistance in product promotion—are independent transactions not related to settlement.

As a result, each case threatens to devolve into a side-show on the independence of the parties' ancillary deals. And even though many of these deals would not appear reasonable (such

[4] Verizon v. Trinko, 540 U.S. 398, 412 (2004).

[5] Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37 (2009).

as those relying on a generic's marketing capacities or other assets in which it had no expertise), courts would be reluctant to reach such a conclusion. In *Schering-Plough*, for example, the Eleventh Circuit upheld a $60 million payment from the brand to the generic even though there were safety concerns with the drug and the generic ignored the brand's requests and ultimately (without protest) suspended its work.[6]

The one piece of legislation that would have made a difference, Senate Bill 1315, wound up gathering dust in the Health, Education, Labor, and Pensions Committee. This legislation would have redefined the category of "first Paragraph IV filers" receiving 180 days of marketing exclusivity. It would have included not only (1) the first generic to file a Paragraph IV certification but also (2) the first generic to obtain a court decision that the patent is invalid or not infringed and (3) a generic not sued for infringement. The bill thus would have shifted the focus from the first to challenge a patent (even if it then settles and delays entering the market) to the first to enter the market.

Back in the future of 2025, we have not seen activity on the settlements front in nearly a decade. Brand and generic drug firms continue settling cases with payments for delay. Two decades ago, in the early 21st century, not all settlements were characterized by delayed entry. In 2025, that period seems long ago indeed.

[6] *In re* Schering-Plough Corp., 2003 WL 22989651, §§ IV.C, IV.D, *vacated*, Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1069-72 (11th Cir. 2005).