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Provigil and *Nexium*: Conflicting Conclusions About Accelerated Entry Provisions in Hatch-Waxman Settlements



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Introduction

A generic drug company decides to settle a Hatch-Waxman patent infringement claim brought against it by a branded drug company, and as part of that settlement agrees to defer entry of its generic product until a date pressed by the brand during negotiations. The settling generic, however, insists that its licensed entry date accelerate if another generic product enters the market first. That ''accelerated entry'' clause would, in effect, ensure that the settling generic would be among the first generics on the market. Importantly, the settling generic does not know if any other generic company will settle with the brand at all, let alone on similar terms. Sometime later, a second generic company does settle with the same brand over the same product and patent. The brand presses for the same entry date, and once again, the generic seeks and obtains the same condition that accelerates its licensed entry date if another generic enters earlier. Thereafter, a third generic company enters into a similar settlement agreement with the brand.

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While *Actavis*[1] provides the legal framework for assessing whether each settlement agreement independently is an unlawful restraint of trade, the question addressed in this article is whether agreements containing these accelerated entry clauses (sometimes referred to as ''contingent launch'' clauses) are sufficient to infer a different kind of antitrust violation—an overarching hub-and-spoke conspiracy among the brand and all set-

[1] *F.T.C. v. Actavis*, 133 S. Ct. 2223 (2013).

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tling generics. In the last several months, two district courts have reached opposite conclusions.[2] This article explores both decisions and explains why the type of accelerated entry clause described above is not sufficient to infer a hub-and-spoke conspiracy among the brand and settling generics.

In the recent *Nexium* decision, the district court found that accelerated entry provisions were sufficient to overcome a summary judgment motion against a conspiracy claim. In doing so, it misconstrued the agreements, misapplied recent antitrust conspiracy law, and misinterpreted dicta in an outdated and seldom-cited Supreme Court decision. Following *Nexium*'s lead could have significant implications for the pharmaceutical industry and beyond. Independently-negotiated Hatch-Waxman settlements that pass muster even under *Actavis* could expose settling parties to substantial antitrust liability if they include accelerated entry clauses. In fact, the logical extension of the *Nexium* decision is that other provisions, including most favored nation (''MFN'') clauses, could be sufficient to infer a hub-and-spoke conspiracy if competitors obtain similar MFNs. This article offers an analysis of accelerated entry clauses and the *Nexium* opinion to steer courts clear of that slippery slope.

Background

Accelerated entry provisions, and the business rationale behind them, can be fully understood only against the unique backdrop of the Hatch-Waxman Act, which Congress enacted in 1984. The Act features an intricate web of provisions designed both to encourage development of new, innovative drug treatments and to speed subsequent entry of low-cost generic versions of those drugs.[3] The Act's centerpiece is the Abbreviated New Drug Application (''ANDA''), which is intended to reduce the cost and burden of generic drug approval. Most significantly, the ANDA provisions reduce the level of scientific evidence required for approval. In particular, unlike an innovator's New Drug Application (''NDA''), an ANDA need not include expensive, time-consuming studies proving that the proposed drug is safe and effective for its intended uses.[4] Instead, ANDAs need only demonstrate that the generic drug is ''bioequivalent'' to the ''reference listed drug'' (i.e., the branded counterpart).[5]

In addition to streamlining the generic's application requirements, the Act incentivizes generics to challenge patents covering branded drugs by lowering the risk associated with those challenges. Under the Act, a generic drug company may challenge the innovator's patent rights before the generic even launches its product (and thus before it incurs potential damages liability). A brand must submit for listing in the FDA's ''Orange Book'' all patents that cover the approved drug.[6] If the Orange Book identifies an unexpired patent as covering the reference listed drug, the ANDA filer must certify either that the FDA should defer approval of the ANDA until the patent expires (a ''paragraph III certification''), or that the patent is invalid or will not be infringed by the generic drug (a ''paragraph IV certification'').[7] The Hatch-Waxman Act deems a paragraph IV certification an act of infringement that triggers the patent-holder's right to sue.[8]

Finally, the Act creates incentives for prospective generics to challenge patents early by awarding the first paragraph IV challenger 180 days of generic market exclusivity once it brings its drug to market (subject to certain exceptions and forfeiture provisions not relevant here). During this generic exclusivity period, the FDA will withhold final approval of all other pending ANDAs for the same reference listed drug. This exclusivity period can prove extremely valuable and often represents most of a generic drug's potential profits because prices typically decline rapidly once other generics enter the market.[9]

The end result of these incentives is that generic drug manufacturers often race to file paragraph IV ANDAs for particular brand drugs as soon as the FDA permits such filings. This in turn triggers a series of developments that often ultimately result in accelerated entry provisions in settlements between branded suppliers and generics. The brand files patent infringement suits against all ANDA filers, and the cases typically proceed simultaneously. When settlement is possible, the brand—cognizant of the antitrust implications of a multi-party settlement—seeks to negotiate separate settlements with the ANDA filers, often by negotiating a licensed, generic entry date. Finally, the generics seek to maintain their relative entry position vis-à-vis other generics by ensuring that their licenses can accelerate in the event another generic enters earlier, whether as a result of settlement, entering at risk of infringement damages, or prevailing in litigation.[10] The generic thus

[2] *In re Modafinil Litig.*, Civil Action Nos.: 2:06-cv-1797, 2:06-cv-1833, 2:06-cv-2768, 2014 WL 2813312 (E.D. Pa. June 23, 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, Civ. No. 12–md—02409-WGY F. Supp. 2d —-, 2014 WL 4370333 (D. Mass. Sept. 4, 2014).

[3] *See Mead Johnson Pharm. Grp. v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988).

[4] 21 U.S.C. §§ 355(b)(1).

[5] *Id.* at §§ 355(d), (j)(2)(A)(ii) & (iv). ''Bioequivalence'' is defined as: ''the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.'' 21 C.F.R. § 320.1(e).

[6] *See Approved Drug Products with Therapeutic Equivalence Evaluations*, 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e).

[7] 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

[8] *See* 35 U.S.C. § 271(e)(2). The Hatch-Waxman Act also provides that the FDA will not approve the ANDA for thirty months if the patentee files an infringement suit within forty-five days of the paragraph IV certification. At the end of this period, and if the litigation is resolved, the FDA will take action consistent with the final judgment. If the litigation is ongoing, the FDA will review the ANDA, and, if approved, the generic drug manufacturer can chose to enter the market at the risk of incurring damages for patent infringement (i.e., enter ''at risk'').

[9] *See Actavis*, 133 S. Ct. at 2229 (citing Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)); Generic Pharmaceutical Association letter to F.T.C., June 27, 2006, at 2 (available at: http://tinyurl.com/qg96x7q); Coughlin & Dede, *Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective: From Ticlid® to Pravachol®, Apotex Has Difficulty Telling Who's on First*, 25 Biotechnology L. Rep. 525, 525-26 (2006).

[10] *See* Brief of the Petitioner at 52, *Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416). When the settling generic party is a first-filer, it understandably seeks to preserve its right to be at least

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negotiates to obtain an accelerated entry provision that will permit it to enter the market as soon as any other generic enters the market with a competing product. This is what happened in *Provigil* and *Nexium*.

The *Provigil* Settlement Agreements

In *In re Modafinil* (''*Provigil*''), the branded drug manufacturer and patentee, Cephalon, marketed its drug Provigil as ''a wakefulness-promoting agent'' to treat narcolepsy and other sleep disorders. The FDA approved Provigil in 1999. Four generic drug manufacturers filed ANDAs with paragraph IV certifications in 2002 on the first day the FDA accepted such filings. According to then-current FDA policy, each of those four filers shared first-filer exclusivity.[11] Cephalon sued all four ANDA-filers in early 2003 and settled with each between December 2005 and February 2006. Among other terms, each settlement contained an accelerated entry provision under which (1) Cephalon agreed to grant the generic drug manufacturer a non-exclusive license to make and sell generic Provigil on the earlier of April 2012 or the date any other company brought a generic version of Provigil to market; and (2) the generic drug manufacturer agreed not to make, use, or sell a generic version of Provigil until the generic's license became effective.

Subsequent antitrust lawsuits challenging these settlements were coordinated in the Eastern District of Pennsylvania. The plaintiffs included direct purchasers (wholesale drug distributors), end payors (those that allegedly paid or reimbursed some or all of the final purchase price), another generic drug manufacturer (Apotex, Inc.), and the Federal Trade Commission. All plaintiffs asserted that each of the four Provigil settlements was an unlawful restraint of trade under *Actavis*. Each of the private plaintiffs also alleged that there was a broader conspiracy among Cephalon and each of the four generics to defer entry until 2012. In June 2014, the district court granted the defendants' motions for summary judgment on this ''overall conspiracy'' claim, finding that ''the circumstantial evidence does not support an inference of concerted, as opposed to independent, action.''[12]

The *Nexium* Settlement Agreements

In *In re Nexium (Esomeprazole) Antitrust Litig.* (''*Nexium*''), the relevant facts regarding the acceleration clauses were similar. The branded drug manufacturer and patentee, AstraZeneca, marketed its drug Nexium to treat symptoms of acid reflux disease, including persistent heartburn. The FDA approved Nexium in 2001. In 2005, generic drug manufacturer Ranbaxy filed the first ANDA with a paragraph IV certification to market a generic form of Nexium, and was followed in subsequent months by two other generic drug manufacturers. AstraZeneca sued all three generics and eventually settled with each during the period between April 2008 and January 2011, although more than a year passed between each settlement and the next. Each settlement agreement contained an accelerated entry provision whereby the settling generic was licensed to enter on the earlier of May 27, 2014 or the date another generic entered the market.

The subsequent antitrust litigation challenging these settlements was consolidated in the District of Massachusetts and included allegations that AstraZeneca and each of the settling generics entered a single conspiracy to delay entry of generic Nexium. In September 2014, the court denied the defendants' motions for summary judgment on these ''overarching conspiracy'' claims. As discussed further below, the court disagreed with the reasoning in *Provigil*, and held that ''a reasonable factfinder could draw an inference of conspiracy.''[13]

Governing Law on Conspiracy

Because, as Judge Posner put it, Sherman Act Section 1''does not require sellers to compete; it just forbids their agreeing or conspiring not to compete,''[14] the threshold showing for any Section 1 claim is the existence of an agreement, i.e. ''some form of concerted action.''[15] Even conscious parallelism—when firms allegedly observe and match each other's conduct (for example, by setting their prices at a profit-maximizing, supracompetitive level)—does not violate Section 1 without more.[16] Inferring an agreement on the basis of parallel conduct alone runs the risk of sanctioning independent competition.[17] Therefore, evidence must be of-

among the first, if not the first, generic to enter the market. Accordingly, the generic may negotiate an accelerated entry provision that allows it to launch earlier if another generic enters or if its exclusivity period is triggered by a court judgment against the patent or patents-at-issue. Even when the settling generic is not a first-filer, and would need to wait until the first-filer's exclusivity period expires, it still is interested in preserving its position vis-à-vis that first-filer by negotiating an accelerated entry provision that accelerates its license and allows it to launch as soon as the FDA is otherwise able to grant its product final approval.

[11] After the settlements were entered into, one generic was determined to have sole exclusivity by virtue of its filing a paragraph IV certification with respect to a different patent not at issue in *Provigil*.

[12] *See generally Provigil*, at *1-3, *14.

[13] *See generally Nexium*, at *7-8, *10, *18.

[14] *In re Text Messaging Antitrust Litig.*, 630 F.3d 622, 627 (7th Cir. 2010) (Posner, J.).

[15] *InterVest, Inc. v. Bloomberg, L.P.*, 340 F.3d 144, 159 (3d Cir. 2003); *see also Nexium*, at *10 (''Independent decisions by individual firms, even if they constitute parallel business behavior and 'lead to the same anticompetitive results as an actual agreement among market actors' are not prohibited by the federal antitrust laws.'' (quoting *White v. R.M. Packer Co.*, 635 F.3d 571, 575 (1st. Cir. 2011))).

[16] *See Brooke Grp., Ltd v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 227 (1993); *White*, 635 F.3d at 576; *Golden Bridge Tech., Inc. v. Motorola, Inc.*, 547 F.3d 266, 271 (5th Cir. 2008); *In re Travel Agent Comm'n Antitrust Litig.* 583 F.3d 896, 903 (6th Cir. 2009).

[17] *See Theatre Enter. v. Paramount Film Distrib. Corp.*, 346 U.S. 537 (1954); *Bell Atl. Corp. v. Twombly, Inc.*, 550 U.S. 544, 561 n.7 (2007); *see also White*, 635 F.3d at 580 (''evidence [that] does not tend to exclude the possibility that the alleged conspirators acted independently . . . is not enough to permit a reasonable inference that defendants' behavior was more than mere conscious parallelism.''); *In re Baby Food Antitrust Litig.*, 166 F.3d 112, 122 (3d Cir. 1999) (''Because the evidence of conscious parallelism is circumstantial in nature, courts are concerned that they do not punish unilateral, independent conduct of competitors . . . . They therefore require that evidence of a defendant's parallel pricing be supplemented with 'plus factors.' ''); *Blomkest Fertilizer, Inc. v. Potash Corp. of Saskatchewan*, 203 F.3d 1028, 1033 (8th Cir. 2000) (en banc) (''An

fered that ''tends to exclude the possibility that the [alleged conspirators] were acting independently'' and ''reasonably tends to prove that the [alleged conspirators] had a conscious commitment to a common scheme designed to achieve an unlawful objective.''[18] Accordingly, the plaintiff must prove ''plus factors'' to infer a conspiracy from consciously parallel conduct, including that the accused conspirators (1) took actions that would be contrary to their individual economic interests in the absence of conspiracy, and (2) had a motivation to enter into such an agreement.[19]

Analysis of *Provigil* and *Nexium*

Provigil and *Nexium* are examples of an antitrust conspiracy claim based on parallel conduct and circumstantial evidence. In both cases, there was no allegation that any settling generic drug manufacturer had discussed the settlement agreements or their terms with any other generic.[20] Neither court found any direct evidence of an agreement among the generics.[21] Rather, both decisions were based on an analysis of the accelerated entry provisions themselves, the fact that similar provisions were included in each settlement agreement, and the fact that as each settlement agreement was reached, its broad terms were publicly disclosed in security filings or press releases.[22] The different results arise from what the *Nexium* decision refers to as a different ''understanding of the nature of these settlements.''[23]

The *Provigil* Decision

In *Provigil*, the court first concluded that because each settling generic had a plausible independent reason to agree to the entry date in conjunction with the accelerated entry provision, the fact that each agreed to a substantially similar term was as consistent with ''independent responses to common stimuli'' as with a conspiracy.[24] The plaintiffs had argued that the accelerated entry provision gave each settling generic the '' 'comfort' of knowing that they would not lose the opportunity to launch should another Generic Defendant negotiate or otherwise obtain an earlier entry date.''[25] But the court reasoned that while true, this only ''highlight[s] the independent reasons each Generic Defendant had for accepting Cephalon's terms,'' which actually ''undermines the Plaintiffs' overall conspiracy theory.''[26] The court distinguished other cases involving ''willing acceptance of an agreement that *contravenes* each defendant's self-interest in the absence of similar behavior by rivals.''[27] That evidence, according to the court, ''might well suggest that the defendant has received assurances that all its rivals will act similarly.''[28] The court discussed two cases reflecting that principle: *United States v. Apple*[29] and *Toys ''R'' Us, Inc. v. F.T.C.*[30]

Apple involved book publishers that had historically sold books under a ''wholesale'' model that allowed retailers to set their own prices.[31] According to the court, the book publishers came to fear that one retailer's (Amazon) practice of selling electronic books (''e-books'') for $9.99 regardless of the wholesale price would threaten the profitability of hardcover books and the viability of physical booksellers. Before Apple's launch of the iPad and its iBookstore, the book publishers each entered into substantially similar agreements with Apple to sell e-books under an ''agency'' model, where the publisher set the retail price and Apple sold the e-book as its agent and received a 30% commission. Each agreement with Apple also included an MFN clause which required the publisher to set the retail price for e-books offered through the iBookstore at a level no higher than that offered by any other retailer. This provision, according to the court, would have been untenable to the publishers if Amazon continued to sell e-books at the $9.99 price point. In particular, the court found that the MFN clause ''imposed a severe financial penalty'' on any publisher that agreed to its terms with Apple, unless every publisher (1) entered into the same agreement with Apple, (2) collectively forced Amazon to change to an agency model, and (3) collectively raised e-book retail prices.[32] The court found that Apple assured each publisher that it was receiving terms identical to those received by others, and kept each apprised of how many others agreed to Apple's terms.[33]

In *Toys ''R'' Us*, each of several toy manufacturers entered agreements with a single toy retailer agreeing not to sell certain toys to the retailer's competitors, in particular to warehouse clubs.[34] The court observed that ''each manufacturer was afraid to curb its sales to the warehouse clubs alone, because it was afraid its rivals would cheat and gain a special advantage in that popu-

agreement is properly inferred from conscious parallelism only when certain 'plus factors' exist.'').

[18] *Monsanto Co. v. Spray-Rite Srvc. Corp.*, 465 U.S. 752, 764 (1984) (internal quotation marks omitted); *see also Twombly*, 550 U.S. at 556-57 (Section 1 claims ''must be placed in a context that raises a suggestion of a precedent agreement, not merely parallel conduct that could just as well be independent action''); *Cosmetic Gallery, Inc. v. Schoeneman Corp.*, 495 F.3d 46, 53 (3d Cir. 2007) (''Evidence that does not exclude the possibility of independent action . . . is insufficient to withstand summary judgment.'').

[19] *InterVest*, 340 F.3d at 165; *N. Penn Oil & Tire Co. v. Phillips Petroleum Co.*, 358 F. Supp. 908, 923 (E.D. Pa. 1973) (''Parallel conduct is clearly not sufficient to make out a conspiracy without some showing that the actions taken appear to be contradictory to the self-interest of the parties or that actions of one party are rational only if the other parties to the alleged conspiracy act in a similar manner.'').

[20] *Provigil*, at *3; *Nexium*, at *10.

[21] *Provigil*, at *7; *Nexium*, at *12.

[22] *Provigil*, at *8; *Nexium*, at *10.

[23] *Nexium*, at *18.

[24] *Provigil*, at *10; *see also In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 325 (3d Cir. 2010); *Twombly*, 550 U.S. at 556 n.4.

[25] *Provigil*, at *10.

[26] *Id.*

[27] *Id.* at *11 (emphasis added) (internal quotations omitted).

[28] *Id.* (citing *Starr v. Sony BMG Music Entm't*, 592 F.3d 314, 327 (2d Cir. 2010)).

[29] 952 F. Supp. 2d 638 (S.D.N.Y. 2013).

[30] 221 F.3d 928 (7th Cir. 2000).

[31] As of the publication date, the *Apple* decision is on appeal to the Second Circuit Court of Appeals, and Apple disputes many of the district court's legal and factual conclusions. For purposes of this article, we recite the facts as found by the district court in *Apple* and as applied by the district courts in *Provigil* and *Nexium*.

[32] *See generally Apple*, 952 F. Supp. 2d at 647-48 (summarizing findings, including that (1)-(3) all occurred).

[33] *Id.* at 692.

[34] *Toys ''R'' Us*, 221 F.3d at 931-32.

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lar new market niche.''[35] Because ''the only condition on which each toy manufacturer would agree to [the retailer's] demands was if it could be sure its competitors were doing the same thing,'' the retailer ''assure[d] individual manufacturers that no one would be singled out'' and then ''served as the central clearinghouse for complaints about breaches in the agreement.''[36]

After summarizing these two cases, *Provigil* concluded:

> Here, the situation facing the Generic Defendants stands in stark contrast to those in *Apple* and *Toys ''R'' Us*. While the evidence in those cases indicated that the individual agreements were economically disadvantageous for the alleged conspirators, here, the settlement agreements with the Generics were economically beneficial. Moreover, there is no comparable evidence that the Generic Defendants were dependent on the universal agreement to make the settlements economically attractive. Indeed, the settlements seemed to offer the best of both worlds: an end to costly litigation, combined with lucrative business deals and an assurance that each Generic Defendant would not be disadvantaged regarding the entry of generic Provigil.[37]

Further, *Provigil* found that the accelerated entry provisions eliminated any motive to conspire regarding the entry date, because in fact each settling Generic Defendant ''could obtain the best deal by agreeing to Cephalon's terms and hoping that the independent actions of the other Generic Defendants would produce a still better deal.''[38]

The court also rejected the plaintiffs' argument that the accelerated entry clauses were sufficient to infer a conspiracy under the Supreme Court's 1942 decision in *United States v. Masonite Corp.*[39] In *Masonite*, a building material manufacturer with a patented form of hardboard entered into bilateral ''del credere'' agency agreements with its competitors to sell the patented hardboard at a minimum price established by Masonite.[40] The Court held that there was sufficient evidence of a price-fixing conspiracy among Masonite and the agents despite the district court's finding that each of the agents first contracted with Masonite independently and without regard to what the other agents decided. The court in *Provigil* observed that *Masonite*, which we address in more detail below, ''[was] largely inapposite . . . because it involved a conspiracy proven by *direct* evidence.''[41] As a result, the court continued, the ''economic self-interest inquiry'' that limits inferences drawn from circumstantial evidence is not informed by *Masonite*, because the Supreme Court was not seeking to infer a conspiracy from purely circumstantial evidence.[42]

[35] *Id.* at 936.
[36] *Id.* at 933, 936.
[37] *Provigil*, at *12.
[38] *Id.* at *14.
[39] 316 U.S. 265 (1942).
[40] *Id.* at 270-71.
[41] *Provigil*, at *13 (emphasis added).
[42] *Id.* (acknowledging that, for example, ''[i]t is obviously not a defense to price-fixing that the agreement was in the conspirators' economic self-interest.'').

The *Nexium* Decision

The court in *Nexium* described the settlement agreements and the key issues quite differently. Critically, the court stated that ''[d]elayed entry, not contingent launch, is the substance of this part of each settlement agreement, and the actual concession for which AstraZeneca allegedly paid valuable consideration.''[43] Accordingly, the court framed the issue as ''whether it was rational for each generic manufacturer to agree to delay entering the generic market until May 27, 2014.''[44]

In answering that question, the court viewed the very existence of the accelerated entry provisions as evidence that agreeing to delay entry until May 2014 was against the settling generics' economic self-interest:

> The unattractiveness of being ''stuck on the sidelines'' until May 27, 2014 meant that to each Generic Defendant, delayed entry on its own was not a viable proposition unless it could be assured of its position vis-à-vis its competitors. This dilemma set up a clear incentive for the Defendants to cooperate with each other, and they did so by providing for contingent launch clauses that would coordinate the Generic Defendants' entries into the market.[45]

The court found these facts to be ''no different than the situation faced by the parties in *Toys ''R'' Us*,'' and concluded that ''[f]rom the fact that the Nexium settlement agreements were not in the Generic Defendants' self-interest unless their agreements contained provisions aligning their behavior, a reasonable fact-finder could draw an inference of conspiracy. This is enough.''[46]

The court was ''not dissuaded by evidence that each agreement was independently negotiated and apparently settled without consultation between any other Generic Defendant.''[47] Instead, the court viewed the Supreme Court's decision in *Masonite* as ''establishing'' that a hub-and-spoke conspiracy can exist even when each spoke in the rim ''acted independently of the others, negotiated only with [the hub], desired the agreement [with the hub] regardless of the action that might be taken by any of the others, and did not require as a condition of its acceptance that [the hub] make such an agreement with any of the others, and had no discussion with any of the others.''[48] The court criticized the *Provigil* decision for not following the ''controlling nature of this principle.''[49]

Deconstructing *Nexium*

At bottom, the plaintiffs in both *Nexium* and *Provigil* asserted the same theory: that the brand orchestrated a ''hub-and-spoke'' conspiracy, similar to those alleged in

[43] *Nexium*, at *18; *see also id.* at *7-8 (''First, on April 14, 2008 . . . Ranbaxy [agreed] to delay launching a generic version of Nexium until May 27, 2014.'' . . . ''On January 7, 2010 Teva agreed . . . to delay its entry into the generic Nexium market until May 27, 2014.'' . . . ''The following year, on January 28, 2011, . . . DRL [agreed] to defer entering the generic Nexium market until May 27, 2014.'').
[44] *Id.* at *18.
[45] *Id.*
[46] *Id.*
[47] *Id.* at *15.
[48] *Id.* (quoting *Masonite*, 316 U.S. at 275).
[49] *Id.* at n.4.

Toys ''R'' Us and *Apple*, by orchestrating an agreement among the generics to fix the generic entry date. In both cases, the court considered the same fundamental question: whether it would have been economically rational for each generic to have entered into the bilateral agreement with the brand *without some additional agreement among generics*. In deciding this key question, however, the court in *Nexium* became derailed.

There are at least three fundamental flaws with *Nexium*'s analysis. First, the court initially characterized the agreements in isolation from the accelerated entry provisions, focusing only on the entry dates, and leading to a flawed assessment as to whether the agreement was in each settling generic's independent interests. Second, in applying *Toys ''R'' Us*, the court misconstrued the type of ''assurances'' that were deemed sufficient to infer a broader conspiracy. Finally, in applying the Supreme Court's opinion in *Masonite*, the court mistakenly construed a portion of that opinion to be describing a conspiracy when, in fact, that portion references a period of independent, lawful conduct arising before the conspiracy.

1. Mischaracterizing the Agreements

Provigil saw the brand-generic agreements for what they actually were: agreements that set a default entry date but also granted the generic an accelerated entry provision that would become operational if other generics were able to negotiate or otherwise attain earlier entry. *On those terms*, agreement with the brand was independently rational for each settling generic, because regardless of whether any other generic settled with the brand, or on what terms, the settling generic's interest in not finding itself behind the generic entry line was protected. Therefore, it was reasonable to conclude that any individual settling generic accepted those terms without any separate agreement with the other generics. Put another way, acceptance of terms that are indisputably consistent with an alleged conspirator's independent interest does not ''tend[] to exclude the possibility of independent action,'' as required for circumstantial evidence to infer a conspiracy.[50]

Nexium, however, took an artificially narrow view of the brand-generic agreement as simply an agreement on a specific entry date, and effectively jettisoned the accelerated entry provision as if it were not a feature of each a bilateral agreement (though it clearly was). From that flawed premise, the court observed that no generic would rationally agree on a specific date without a *separate* assurance that the other generics would make the same agreement.

Nexium's conclusion that ''[d]elayed entry, not contingent launch, is the substance of this part of each settlement agreement'' thus allowed it to disregard the reasons leading to *Provigil*'s determination that ''with the presence of the contingent launch provisions, there was nothing to gain from conspiring with the other Generic Defendants to fix [the] entry date.''[51] For instance, *Nexium* finds that ''[t]he Defendants possessed strong motives to coordinate the actions they took,'' because ''each Generic Defendant would be reluctant to agree to delay its entry unless AstraZeneca could secure the same guarantee of delay from all its generic competitors, lest a competitor capture the market before May 27, 2014.''[52] But AstraZeneca could not and did not ''secure the same guarantee of delay,'' which is why the accelerated entry provisions were necessary in the first place.[53]

To this point, *Nexium* responds:

> This argument seems to assume that the Plaintiffs imagine the existence of a secret, back room deal to delay market entry, which was then memorialized in three separate settlement agreements. While the Defendants are correct that such an arrangement cannot be reasonably inferred from the evidence, this is not the inference the Plaintiffs ask the Court to draw. Rather, the Court infers—as commanded by Fed. R. Civ. P. 56—that the contingent launch clauses themselves were the mechanisms of a single agreement, the means by which individual market delay concessions knit together into a network of related agreements.[54]

The court claims it is not inferring a ''secret, back room deal to delay market entry,'' but nevertheless describes the ''Defendants' unity of purpose'' as an agreement to delay market entry until May 2014.[55] This ignores *Provigil*'s correct reasoning that the accelerated entry provisions *eliminated* the need for ''unity of purpose'' among the generics, by making the settlement agreements economically beneficial for each generic regardless of any other generic's actions. If the decision to settle with AstraZeneca was reached individually by each generic (as *Nexium* arguably concedes),[56] there can be no conspiracy even if the ''mechanisms'' of the settlement agreement are contingent on actions taken by other generics. ''Unilateral activity by a defendant, no matter the motivation, cannot give rise to a section 1 violation.''[57]

2. Misinterpreting Assurances

To the court in *Nexium*, the accelerated entry provisions are simply the mechanism the brand used to ''assure'' the settling generics that other generics would agree to the same terms.[58] In framing the provisions

[50] *Monsanto*, 465 U.S. at 768.

[51] *Nexium,* at *17; *Provigil*, at *13.

[52] *Nexium*, at *16.

[53] Stated another way, agreeing to delay entry *because* every other generic also agrees to delay entry is different than agreeing to delay entry *only if* every other generic agrees to delay entry. The first agreement means that (1) the generic agreed to delay entry, *and* (2) every other generic agreed to delay entry. The second agreement by itself does not mean that every other generic agreed to delay entry, and so does not mean that the agreeing generic actually agreed to delay entry at all.

[54] *Nexium*, at *15.

[55] *Id.* at *20.

[56] *Id.* at *15 (''Each Generic Defendant may have made an *independent* decision to sign its agreement with AstraZeneca, but it did not enter into an arrangement independent of its generic competitors.'') (emphasis added); *see also id*. (''the contingent launch clauses [were] the means by which *individual* market delay concessions knit together'') (emphasis added).

[57] *InterVest* 340 F.3d at 159; *White*, 635 F.3d at 575 (Sherman Act section 1''does not reach independent decisions, even if they lead to the same anticompetitive result as an actual agreement'').

[58] *See, e.g.*, *Nexium* , at *18 (''The Defendants themselves have conceded that the Generic Defendants 'needed' protec-

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that way, the court sought to compare the facts of *Toys ''R'' Us* in which ''[e]ach manufacturer's calculus changed . . . when it received assurance that it would only have to restrict its business if its competitors did the same.''[59] The ''assurance'' that Toys ''R'' Us provided to each manufacturer, however, differs significantly from the ''comfort'' the accelerated entry provisions provided each generic.

In *Toys ''R'' Us*, each toy manufacturer agreed to boycott the warehouse clubs because Toys ''R'' Us assured them that their competitors *would do the same*, and then Toys ''R'' Us supervised and enforced that overall agreement.[60] The toy manufacturers ''were unwilling to limit sales to the clubs without assurances that their competitors would do likewise,''[61] and so Toys ''R'' Us ''assure[d] [the] individual manufacturers that no one would be singled out.''[62] This assurance—*that all competitors were agreeing to the same terms*—provided the ''rim'' necessary for a hub-and-spoke conspiracy.

The accelerated entry provision in *Nexium*, however, did not assure that every generic would also agree to delay entry until May 2014, or that any other generic would agree to settle at all. Importantly, *Nexium* does not, and could not, claim that the provision gave any assurance that each alleged conspirator was agreeing to the same thing (and thus, that all were agreeing with each other). Instead, *Nexium* describes the effect of the accelerated entry provision as:

- ''assur[ing] [each Generic Defendant] of its position vis-à-vis its competitors,''
- ''coordinat[ing] each Generic Defendants' entries into the market,''
- ''aligning [the Generic Defendants'] behavior,'' and
- ''assur[ing] that market delay would not unduly disadvantage any one Generic Defendant.''[63]

Agreeing to this provision does assure the settling generic of ''its position vis-à-vis its competitors,'' but it does not suggest or require any further agreement by its competitors. To the contrary, it protects the settling generic's priority *irrespective* of whether other generics settle on the same terms, or different terms, or continue to litigate, or enter at risk. To the extent agreeing to this provision ''coordinates'' or ''aligns'' generic entry, it does so without any consent or even awareness by any other generic drug manufacturer. And this provision does not ''assur[e] that market delay would not unduly disadvantage any one Generic Defendant'' because it does not assure that ''market delay'' will even happen; it assures that agreeing to the *settlement agreement* will not unduly disadvantage the settling generic, because the generic is not committed to market delay if it would be a disadvantage. By contrast, the first toy manufacturer in *Toys ''R'' Us* to enter the agreements challenged in those cases would be at a great disadvantage if none of its competitors later agreed to the same terms.

The court in *Nexium* acknowledges that accelerated entry provisions ''prevent a settling generic manufacturer from being locked out of the market while its competitors take over,''[64] but then inexplicably infers a conspiracy from ''the fact that the Nexium settlement agreements were not in the Generic Defendants' self-interest unless the agreements contained provisions aligning their behavior.''[65] But this fact only confirms that *because* each Nexium settlement agreement *did* contain an accelerated entry provision, the settlement agreements were in the settling generics' self-interest.

3. Misinterpreting *Masonite*

Finally, *Nexium* relied on dicta in *Masonite* to soften the fact that each settlement was independently negotiated without any direct or indirect coordination among the generics.[66] But the court in *Nexium* fundamentally misinterpreted that portion of *Masonite*. When read in proper context, the language cited from *Masonite* actually highlights why no broader hub-and-spoke conspiracy can be inferred from the facts in *Nexium*, and exposes the flaw in *Nexium*'s analysis of the settlement agreements.

As stated above, in *Masonite* a building material manufacturer entered into bilateral agency agreements with its competitors in an alleged effort to fix prices.[67] A first round of agreements was executed in 1933 and 1934, followed by a second round in 1936 and 1937.[68] With respect to the first set of agreements, the Court observed that each agent was conscious that Masonite was negotiating similar agreements with competitors, but nevertheless was independently motivated to enter the agreement with Masonite regardless of what the other competitors did.[69] During the second round of agreements, however, ''[e]ach agreement when executed . . . was placed in escrow. The escrow agreement was signed by each of the companies and included the name of each of the other as 'agents.' . . . The escrow agreement provided that it should become effective only when all the 'agents' had agreed to it.' ''[70]

Nexium cites *Masonite* as ''establish[ing] that an illegal conspiracy can exist under'' the conditions surrounding the first round of agreements when, according to the Court in *Masonite*, each agent ''acted independently of the others, negotiated only with Masonite, desired the agreement regardless of the action that might be taken by any of the others, did not require as a condition of its acceptance that Masonite make such an agreement with any of the others, and had no discussions with any of the others.''[71] This reading of *Masonite*—that an illegal conspiracy can be inferred

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tion from the actions of their competitors to justify agreeing to delayed entry. This is sufficient, for the purposes of summary judgment, to give rise to a reasonable inference that delayed entry on its own was not an economically beneficial proposition for any of the Generic Defendants.'' (citations omitted)).

[59] *Id.*

[60] *Toys ''R'' Us*, 221 F.3d at 932.

[61] *Id.*

[62] *Id.* at 932-33 (''[a] Mattel executive said that it would not sell the clubs the same items it was selling to Toys ''R'' Us, and that this decision was 'based on the fact that competition would do the same.' '').

[63] *Nexium*, at *16, *18.

[64] *Id.* at *18.

[65] *See generally id.* at *7-8, *10, *18.

[66] *Nexium*, at *15, *15 n.4.

[67] 316 U.S. at 270-71.

[68] *Id.* at 270.

[69] *Id.* at 275.

[70] *Id.* at 270.

[71] *Nexium*, at *15 n.4.

even when each alleged conspirator makes entirely independent decisions—cannot be reconciled with more recent Supreme Court authority such as *Monsanto v. Spray-Rite*,[72] *Matsushita v. Zenith Radio Corp.*,[73] and *Bell Atlantic v. Twombly*,[74]—all of which require evidence tending to *exclude* the possibility of independent action.[75]

Masonite itself, however, is not inconsistent with those subsequent decisions. *Masonite* held that *even though* the circumstances surrounding the first round of agreements demonstrated an *absence* of conspiracy, there was sufficient evidence for the district court to conclude that a conspiracy *later developed*. Immediately after describing the circumstances surrounding the first agreements (quoted in the preceding paragraph), the Court explained that ''[i]t is not clear at what precise point of time each appellee became aware of the fact that its contract was not an isolated transaction but part of a larger arrangement. But it is clear that *as the arrangement continued* each became familiar with its purpose and scope.''[76] The existence of a conspiracy became indisputably clear, according to the Court, by 1936, when the ''circumstances surrounding'' the *second round* of agreements (where each amendment was held in escrow and would become effective only when all the so-called ''agents'' had agreed to the same terms) left ''no room for doubt that all [of the agents] had an awareness of the general scope and purpose of the undertaking.''[77] Thus, *Masonite* did not find an illegal conspiracy existing under the conditions quoted in *Nexium*; the Court grounded its conclusion that the separate contracts were not isolated transactions ''but part of a larger arrangement'' on additional and different conditions not present in *Nexium*.[78]

Conclusions

Perhaps the most important thing that the court in *Provigil* implicitly understands is that these accelerated entry clauses are not at all unusual or exotic. These provisions are most easily understood as concessions extracted from the brand by each generic in their bilateral agreements. Although each accelerated entry provision made the ultimate effect of a bilateral agreement dependent on the actions of third-party competitors, that effect was in no way dependent on an *agreement with* third-party competitors. As the First Circuit explained in *White*, evidence of parallel conduct merely begs the question ''whether the parallel [conduct] was achieved by agreement or mere interdependent decisions,'' only the former of which is illegal.[79] Thus, in a true hub-and-spoke conspiracy, plaintiffs must show more than a series of similar, bilateral agreements; they must show evidence from which an *agreement* among the ''spokes'' can be inferred.[80]

Nexium relies on the ''intrinsic interdependence of the contingent launch clauses as sufficient evidence of connection between the Generic Defendant 'spokes,' ''[81] but courts have long held that interdependence is not the same as agreement, and it is not sufficient evidence of a Section 1 violation without further evidence that the parties were acting pursuant to ''some level of commitment to a common cause.''[82] In stark contrast, the court in *Provigil* correctly focused on the fundamental element of any Section 1 claim: the existence of an agreement among the alleged conspirators.

Following *Nexium*'s lead is bound to chill settlements in many Hatch-Waxman cases. At a minimum, first-filers may feel compelled to litigate if they want to preserve their valuable first-filer exclusivity rights. *Nexium* itself acknowledges that the effect of its ruling is that ''if any one of the Defendants is subject to antitrust liability, all of the Defendants may be liable as co-conspirators.''[83] That is to say, if any one of the settlement agreements fails under the rule of reason test prescribed by *Actavis*, all of the settling generics could be subject to potential liability even if their particular settlement agreement is deemed *procompetitive* under the same test. In fact, *Nexium* may be underestimating the potential consequences of its holding because the plaintiffs' bar may very well apply *Nexium* to a series of settlements involving no payment whatsoever to the generic drug manufacturer.[84]

Beyond the Hatch-Waxman context, *Nexium* might also be applied to other bilateral agreements that depend in some respect on the actions of third parties, including MFN clauses that protect parties in common areas, such as pricing.[85] After all, such provisions ''align[] [competitors'] behavior'' in the same way as the accelerated entry provisions in *Nexium*, and provide a ''mechanism'' by which each party agreeing to an MFN can be ''assured of its position vis-à-vis its competi-

[72] 465 U.S. 752 (1984).
[73] 475 U.S. 574 (1986).
[74] 550 U.S. 544 (2007).
[75] In the seventy years since Masonite was decided, the case has rarely been cited, and was not cited in *Monsanto, Matsushita* or *Twombly*. The Court did cite *Masonite* in *Brown v. Pro Football, Inc.*, but did so for the proposition that ''[a]ntitrust law also sometimes permits judges or juries to premise antitrust liability upon little more than uniform behavior among competitors . . . *accompanied by other conduct that in context suggests that each competitor failed to make an independent decision*.'' *See* 518 U.S. 231, 241 (1996) (emphasis added).
[76] 316 U.S. at 275 (emphasis added).
[77] *Id.*
[78] *See Provigil*, at *13 (citing the escrow agreements in *Masonite* as direct evidence of a conspiracy and distinguishing the case on these grounds).
[79] *White*, 635 F.3d at 580.
[80] *United States v. Kemp*, 500 F.3d 257, 291 (3d Cir. 2007).
[81] *Nexium*, at *16.
[82] *See* 6 Areeda & Hovenkamp, ANTITRUST LAW ¶ 1410 (3d edition 2010) (''Areeda'') (''[C]ourts are unanimous in saying that mere interdependent parallelism is not a Sherman Act § 1 agreement.''); *Baby Food*, 166 F.3d at 135 (evidence of conspiracy must ''go beyond mere interdependence.''). Interdependence is a necessary but not sufficient condition for inferring a conspiracy from parallel conduct. Areeda ¶ 1411.
[83] *Nexium*, at *21.
[84] *See* Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions (January 2010), 3 (available at: http://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff) (''[P]arties may agree that the generic can enter at some time before the patent's expiration date, but not as soon as the generic seeks through its litigation. Absent compensation to the generic for the delay in its entry, *such settlement agreements are unlikely to raise antitrust issues*.'' (emphasis added)).
[85] In *Blue Cross & Blue Shield United v. Marshfield Clinic*, Judge Posner rejected a similar argument that a ''most favored nations'' clause ''put a floor underneath'' the prices charged by agreeing physicians. *See* 65 F.3d 1406, 1415 (7th Cir. 1995) (''This is an ingenuous but perverse argument.'').

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tors.''[86] This would mark a drastic change in the law. MFNs, standing alone, do not make a contract unlawful.[87]

Fortunately, *Nexium* likely will not be the last word on this important issue and *Provigil* provides a more appropriate roadmap for addressing ''overall conspiracy'' claims arising from accelerated entry provisions[88]. Nevertheless, the *Nexium* decision has interjected more uncertainty into the world of Hatch-Waxman settlements at a time when businesses and the courts are already struggling to find clarity in the wake of *Actavis*.

[86] *See Nexium*, at *18.

[87] *See City of Pontiac v. Blue Cross Blue Shield of Mich.*, No. 11-cv-10276, 2012 WL 1531960, at *7 (E.D. Mich. Mar. 30, 2012) (dismissing antitrust conspiracy claim where ''[t]he Complaint merely alleges that each Hospital Defendant 'joined Blue Cross's conspiracy' by signing and enforcing one or more MFN-plus contract with Blue Cross that fix and inflate the price of hospital services in Michigan'' because ''[n]othing in the Complaint asserts that the Hospital Defendants, between them, agreed to fix and inflate the price of hospital services in Michigan''); *E.I. du Pont de Nemours & Co. v. F.T.C.*, 729 F.2d 128, 140 (2d Cir. 1984) (noting concession by FTC that agreements to most favored nations provision were not collusive even when FTC challenged same agreements as ''unfair'' under § 5 of the FTC Act).

[88] On November 21, 2014, the *Nexium* court ruled during trial and from the bench that plaintiffs had presented insufficient evidence on the conspiracy claim. As of publication of this article, the court had not issued any written order or opinion summarizing the grounds for its decision.