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Patent Settlements Between Brand and Generic Pharmaceutical Companies:

Parked Exclusivity & Lack of Incentive for Subsequent Generic Filers to Fight On Are the Problems, Not "Reverse Payments"

The Root of the Settlement Problem

To their credit, key leaders in Congress and the Federal Trade Commission have vowed to address the anti-consumer and anti-competitive effects of patent settlements between brand and generic pharmaceutical companies. These settlements have turned the intent of the Hatch-Waxman Act – expedited consumer access to quality, affordable generic drugs – on its head. Apotex applauds the spotlight Congress and the FTC have shone on these anti-consumer agreements and shares the goal of correcting a system that permits collusive agreements between brand and generic drug companies to deprive the public of timely access to generic medicines, *and at a great cost.* In our view, however, it is utterly critical that Congress address the systemic problems with the Hatch-Waxman framework that are the root cause of the settlement problem.

Reverse payments are not the cause of the settlement problem. The causes of the settlement problem are: (1) the ability of the first-to-file generic company to retain exclusivity even if it abandons its patent fight and settles its litigation with the brand company, and (2) the lack of any incentive for a generic company that is not first-to-file to fight to win because winning only causes the first-to-file to launch while the generic that won gets nothing.

Legislation is needed to correct these systemic problems. Settlements by first-filers should result in the forfeiture of 180-day exclusivity. In addition, the first generic company to win patent litigation should be eligible at a minimum to share the 180-day exclusivity reward.

Though the FDA originally interpreted the Hatch-Waxman Act in a manner that awarded exclusivity to the first generic to successfully defend the patent infringement lawsuit over a given product, the courts struck down that interpretation. The court's ruling, combined with changes to Hatch-Waxman in the 2003 Medicare Modernization Act (MMA) that made the settlement problem worse, have unintentionally created an illogical and unjust system in which generic companies who are the first to prevail in court are given no reward for removing the patent barrier and opening the market to competition early – the very accomplishment 180-day exclusivity was conceived to incentivize. This system

fuels market blockages, depriving consumers of the savings Hatch-Waxman is supposed to facilitate.

This backwards outcome has occurred recently on two occasions. In March of 2007, Apotex won an appeals court decision invalidating a patent covering Pfizer's blockbuster drug Norvasc®, opening the market to generic competition six months early. Exclusivity, however, was awarded to Mylan, who one month prior to the Apotex decision had lost its case in the district court. The result of Apotex's investment, work, and victory was that Mylan, and not Apotex, was able to immediately launch a generic amlodipine product. As a consequence, consumers saved hundreds of millions of dollars, Mylan garnered hundreds of millions of dollars in profits that should have gone to Apotex, and Apotex received no benefit whatsoever and was left with a large loss on the investment.

The second example actually included a settlement that prevented the victorious subsequent filer from entering the market place. In September of 2007 Lupin Pharmaceuticals won an appeals court decision invalidating a patent covering King Pharmaceutical's Altace®, whose generic name is ramipril. Lupin, however, was prevented from entering the market despite its victory because of a settlement the first-to-file generic company, Cobalt, had entered into with King. The FDA subsequently opened a docket asking for comments on whether the circumstances warranted the forfeiture of Cobalt's exclusivity. The FDA's decision was that events required by the statute to force a forfeiture of a first-filer's exclusivity were not met in the Lupin case and therefore did not permit the Agency to rule that Cobalt's exclusivity could be forfeited. "In this case," the Agency concluded, "there is no unappealable order finding that the King/Cobalt agreement violates antitrust law. Consequently, despite the fact that the settlement agreement, and the circumstances around it, may be objectionable to Lupin and others, there is no legal basis for the Agency to find that Cobalt has forfeited its exclusivity."

Both the Apotex and Lupin cases involved ANDAs that were filed prior to the forfeiture structure adopted by the amendments to Hatch-Waxman in the Medicare Modernization Act (MMA) of 2003[1]. Under the pre-MMA framework, a parked exclusivity can be triggered by an appeals court decision in any company's litigation concerning the product in question. In the Lupin case, this meant that Cobalt's exclusivity was triggered upon issuance of the mandate from the appeals court certifying Lupin's invalidation of the Altace® patent. Accordingly, Cobalt promptly launched the product in order to preserve its 180 days of exclusivity, just as any first-to-file generic company ever confronting that

[1] The FDA's conclusion that Cobalt was entitled to keep its exclusivity because there was "no unappealable order finding that the King/Cobalt agreement violates antirust law" refers to a forfeiture provision added to the Hatch-Waxman Act by the MMA. This provision, however, is fatally flawed. As the FDA noted, it requires a determination to be made by an appeals court before forfeiture can occur – a process that takes years to effectuate, by which time any benefit for consumers from the nullification of the settlement will likely have long passed. Apotex' suit against Cephalon, Barr, Teva, Mylan, and Ranbaxy concerning Provigil® is a case in point. The suit was filed in 2006. As of 2008, by which time the FTC had filed its own suit against Cephalon, the court had taken no action whatsoever on Apotex' case.

situation will. Lupin, like Apotex in the amlodipine case, was left with nothing to show for its success in opening the market early for consumers.

It is this very flaw that prompted Senator Orrin Hatch, co-author of the Hatch-Waxman Act, to cast the one vote in opposition to the amendments to the Hatch-Waxman Act when the full Senate approved the changes by a vote of 94-1 in the summer of 2003, prior to the ultimate inclusion of the amendments in the Medicare Modernization Act later in the year.

On December 9, 2003, the day after President Bush signed the Medicare Modernization Act of 2003 into law, Senator Hatch detailed his concerns about the changes to the Hatch-Waxman Act enacted by the MMA:

> The 180-day marketing exclusivity rules were first enacted as part of the Hatch-Waxman Act. The policy behind these provisions is to benefit the public by creating an atmosphere that ensures vigorous challenges of the patents held by innovator drug firms.
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> The intent of this section of the 1984 law was to award the 180-day head start to the first successful challenger of a pioneer firm's patents. Unfortunately, we drafters of the statute employed language that has been interpreted by the courts to grant the 180-days of exclusivity to the first generic drug applicant to file an application with the FDA that challenges the patents.
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> I must say that in most cases the first filer and first successful applicant was the same applicant. But I believe that the line of court decisions that include the Mova and Granutec cases has resulted in the establishment of a first filer regime that is not without unintended consequences and perverse incentives. The mismatch between the rights accorded to the first applicants and first successful challenger contributed to an atmosphere in which anti-competitive agreements were entered into between certain pioneer and generic drug firms.

After praising the bill's inclusion of the requirement that all settlements of brand-generic patent litigation be reported to the FTC, Senator Hatch continued:

> ...I must also unfortunately report to my colleagues in the Senate and the American public that we have not accomplished as much as possible with respect to the 180-day provisions.
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> First off, I continue to believe that it is both unfair and ill-advised to retain the bill language that does not reward a non-first filer to gain the 180-days marketing exclusivity in the case, which will admittedly be rare, in which the subsequent filer prevails on a patent invalidity challenge. I am told that conferee staff first

thought that the provision as drafted would result in a subsequent filer's successful invalidity challenge forfeiting the first filer's 180 days of marketing exclusivity. Although the successful challenger does not get the 180 day head start, at least under this reading, the subsequent filer is not penalized with respect to market entry. Upon further scrutiny of the statutory language, it is my understanding that in such circumstances the language may actually work to grant the 180-days of marketing exclusivity to the first filer, so that the successful subsequent challenger not only does not get the 180-day benefit, but actually receives a 180-day penalty for invalidating the patent.

If this is the correct way to read the statute, the law should be changed.

I am told that the staff of any conferee nor the FDA strongly defended this policy. Unfortunately, nor was there agreement to change the language to at least clarify that the subsequent challenger's success was at least a forfeiture event or, preferable from my perspective, would result in the granting of the 180-days to the successful challenger in a patent invalidity challenge rather than benefiting the first paper shuffler.

This is bad policy. **(emphasis added)**

MMA Changes to Hatch-Waxman Exacerbated Settlement Problem

Senator Hatch was correct. As the Apotex and Lupin cases clearly demonstrate, this is bad policy. Subsequent filers who are the first to win are not only guaranteed to get no reward for opening up the market early to generic competition, but are penalized for doing so. Consequently, the MMA's attempt to provide a route for a subsequent filer to open a market blocked by a parked exclusivity is fatally flawed. The system provides no incentive whatsoever for a subsequent filer to continue the patent fight when a first filer has blocked the market through a settlement with the brand company. In fact, despite the well-intentioned effort by Congress in the MMA to provide a mechanism in which subsequent filers could unblock markets obstructed by a parked exclusivity, the MMA framework made the problem worse, not better.[2]

[2] Prior to the changes made to the Hatch-Waxman regime by the MMA, a first filer's exclusivity could be triggered by a district court decision in any litigant's case concerning the given product. Under the MMA framework, an appeals court decision is required before a first filer is put in a position wherein its exclusivity is forfeited if it fails to launch within 75 days of a ruling in its favor. Moving the threshold from the district court to the appeals court exacerbated the settlement problem by lengthening the period of time it takes for a subsequent filer to reach the point where it places the first filer in a position of having to launch or forfeit its exclusivity. The FTC and Senator Hatch opposed moving the threshold to an appeals court decision. Explaining his position in 2003, Senator Hatch said "Finally I must unfortunately report to my colleagues that the new statute retains the Gregg-Schumer-Kennedy provision that may cost the Federal government, according to the Congressional Budget Office, $700 million over the next 10 years. Moreover, it is my understanding that the total cost of these provisions to consumers over the next 10 years could exceed $3 billion. At issue are the sections of the bill that essentially give the first filer an exclusive right to the potential 180-day marketing exclusivity until its case is decided at the appellate court level. The

If the Lupin case had been governed by the post-MMA framework, Cobalt would have had 75 days to launch its product or it would have forfeited exclusivity. That is because the MMA framework gives the first-filer 75 days to launch its product if a subsequent filer wins an appeals court decision before the first-filer. Under this scenario, the same outcome would have again occurred. Cobalt would have launched its product, as will any first-filer who is ever in the position of having to launch or lose its exclusivity.

While at first blush this may sound like a good outcome for consumers, it is not. No subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. The first-filer will always accelerate its launch to preserve its exclusivity. Indeed, settlements today invariably include "poison pills" which stipulate the first-to-file generic(s) can accelerate its entry into the market place if its exclusivity is in jeopardy due to a litigation victory by a subsequent filer (the Cephalon settlements which the FTC filed suit against in February 2008 include such provisions). The bottom line is that under the post-MMA framework, first-filers will forever be able to block the market knowing they need not worry that a subsequent filer will be able to force the forfeiture of their exclusivity even if the subsequent filer wins an appeals decision before the first-filer.

Importantly, the dire need to change the statute to fix this problem was underscored by the FDA in a post-MMA exclusivity forfeiture question for which the Agency opened a docket concerning the drug granisetron in the fall of 2007. In that case, even though it did not involve a settlement, the FDA went out of its way to observe in its letter deciding the issue at hand that it lacked the statutory authority to break market blockages caused by settlements:

> Inherent in the structure of the 'failure to market forfeiture' provisions is the possibility that the first filer would be able to enter into a settlement agreement with the NDA holder or patent owner in which the court does not enter a final judgment of invalidity or non-infringement (i.e. with a forfeiture event under subpart (bb) occurring) and that subsequent applicants would be unable to initiate a forfeiture with a declaratory judgment action. ***This inability to force a forfeiture of 180 day exclusivity could result in delays in the approval of otherwise approvable ANDAs owned by applicants that would market their generic drugs***

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question arises of what happens if a subsequent filer is not sued by the pioneer firm and is ready, willing and able to go to market but for waiting for the disposition of the first filer's challenge in the appellate court. If the first filer prevails, it will receive the 180-days of exclusive marketing even though one or more subsequent filers were ready, willing, and able to go to the market long before the first filer's challenge was resolved."

It is imperative that the changes to the Hatch-Waxman framework that are needed to end the settlement problem use a district court decision as the basis to open a blocked market. Setting the threshold at the district court level will ensure the public benefits from generic competition at the earliest possible time.

if they could but obtain approval. This potential scenario is not one for which the statute currently provides a remedy. (emphasis added)

An absolutely critical point to add to the FDA's observation is that even if generic companies can now get declaratory judgments (DJ) when brand companies decline to sue subsequent filers[3], the settlement problem will continue unabated if the systemic flaws in Hatch-Waxman are not corrected. Though obtaining a DJ would enable a subsequent filer to litigate, any victory that follows is guaranteed to produce no benefit for the subsequent filer.

The Apotex and Lupin cases as much as any stand out as poster children for the root cause of the settlement problem. Subsequent filers interested in carrying on their patent fights in the face of a parked exclusivity need only look at these cases to see the hard proof that there is no chance that fighting on will yield a return on the investment even if they win. Conspiring brand and generic companies will continue to divvy up the profits that parked exclusivities bring them at the public's expense.

FTC Commissioner Leibowitz Weighs In on Exclusivity, Incentive Problems

The need to address both the exclusivity and incentive problems was underscored by FTC Commissioner Jon Leibowitz in his partial dissent to the FTC's February 2008 suit against Cephalon regarding its settlement with Barr, Teva, Mylan and Ranbaxy over the drug Provigil® – a settlement which Apotex filed suit against in 2006. Rightly dissenting on the grounds that the FTC filed suit only against Cephalon and not the four

[3]The January 2007 Supreme Court ruling in the MedImmune v. Genentech case appears to have resolved the inability of generic companies to obtain declaratory judgments when brand companies decline to sue generics for patent infringement – a dynamic commonly referred to as the "DJ problem." Two appeals court decisions on the DJ question since MedImmune was decided bode well for the resolution of the problem. Prior to the MedImmune decision, brand companies have for many years been able to exploit generic companies' inability to obtain DJs to forestall generic competition. The inability to get DJs when not sued for infringement prevents generic companies from resolving patent liability issues prior to launching products, which in turn stifles competition; generic companies are confronted with the choice of launching products at risk and potentially being held liable for treble damages if they do so, are subsequently sued, and lose, or not launching at all until all liability issues are resolved – the safer option. Generic companies' inability to get DJs also has made it exceedingly easy for brand companies to game the Hatch-Waxman Act's forfeiture provisions as added by the MMA. In order for a subsequent filer to put a first-filer in a "use it or lose it" position regarding 180-day exclusivity under the MMA amendments, the subsequent filer is required to win an appeals court decision before the first-filer does. If the subsequent filer achieves an appeals court victory on the same set of patents the first-filer has certified to qualifying the first-filer for exclusivity, the first-filer has 75 days to launch its product or it forfeits its exclusivity. Brand companies seeking to preserve a market blocked by a parked exclusivity simply refrain from suing subsequent generic applicants, thus denying them the ability to litigate the patents they are required to litigate in order to have any chance to put the first-filer in a "use it or lose it" position regarding its 180 exclusivity reward. Even if the DJ issue is resolved as the trend in the courts strongly suggests is the case, there is no less of a need to correct the systemic flaws in the Hatch-Waxman Act identified in this paper in order to resolve the settlement problem.

generic companies, Commissioner Leibowitz noted:

> Here, the 180-day exclusivity, which Congress created to reward generics for entering early, does precisely the opposite: it extends the brand's monopoly, forcing consumers to pay excessive prices for Provigil throughout the span of these illegal deals...
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> Apotex and Caraco have already received tentative approval from the Food and Drug Administration, and Cephalon has not sued either one. At this point, the 180-day exclusivity prevents these companies from receiving final FDA approval and going to market. Ironically, if either Apotex or Caraco were to enter, the four settling generics could also immediately enter the market with their own competing products under the very terms of the settlement with Cephalon. So why would a generic company refuse to relinquish its exclusivity when that exclusivity arguably has little value to the generic but creates near iron-clad protection for Cephalon's Provigil monopoly? Why would companies that have made the hallmark of their business delivering low-cost drugs actually prevent that result from happening here? The answer is as troubling as the settlements themselves. Here, the non-relinquishing generics appear to be sending a clear signal to PhRMA Companies: you can do business with us in the future; we will protect your monopolies.
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> Although I am confident the Commission will win its case against Cephalon, it will likely take years, as most antitrust cases do. In the mean time, Congress should pass the bipartisan legislation – now moving through both Houses – that would ban these pay for delay deals completely (while allowing legitimate settlements)....***Finally, in exercising its general oversight responsibility over the pharmaceutical industry, Congress should consider asking these generics whether they are willing to waive this right (shared exclusivity) that arguably has very little financial value to them when the benefits of waivers to American consumers seem so substantial – and, if not, why not.*** (emphasis added)

Apotex commends commissioner Liebowitz for addressing these critical issues. As noted in the opening paragraphs of this paper, we do, however, disagree with the Commission's and Congress' central and continued focus on prohibiting reverse payments as a solution to this problem.

Why Reverse Payments Are Not the Problem

Outlawing reverse payments, if not coupled with other amendments, will have no significant impact on the number of settlements or their anticompetitive impact, but will simply reduce the cost of such agreements for patentees. This can be understood from the following analysis.

A settlement typically includes a provision that the first generic applicant will be licensed to enter the market during the last year or less prior to patent expiration. The significant value for the first generic applicant is the 180 day exclusivity. Litigation is almost always uncertain as to outcome. If the generic litigates, there is always a risk of losing and ending up with nothing. Hence, it is inevitable that it will ***always*** make more sense for a generic to settle for exclusivity during the last months of patent life than to litigate in the hope of winning and getting earlier entry. The reason that generics have been able to negotiate for "reverse payments" in addition to market entry during the last months is that the agreement is enormously valuable to the patentee. The patentee keeps the monopoly for all but the last months, so the benefit to the patentee is generally enormously greater than to the generic. The generic thus takes the position that it is not willing to settle for only a generic monopoly during the last months and the patentee is always willing to provide a further benefit to the generic through a "reverse payment". It may appear that, if such reverse payments are made illegal, the generic company will simply demand that the patentee allow it to enter the market even earlier than the last months of patent life as a substitute for the branded payment. However, that fails to take into account that earlier entry for the generic has very little additional value, because the exclusivity will terminate and other generics will enter the market 180 days after the first sale by the first generic. It follows that making reverse payments illegal is unlikely to have any substantive effect on settlements, that generics will still settle for guaranteed market entry during the last months of patent life, and the only effect, if any, will be that the cost of settling will be reduced for the patentee, with no benefit for consumers.

We further urge policymakers to take a much more thorough examination of the notion that settlements are pro-consumer so long as they allow for market entry prior to patent expiry and do not include reverse payments. This may be true when compared to no alternative, but the contention does not stand up to daylight when compared to the notion of allowing patent litigation to takes its course. Allowing first-filers to retain exclusivity when they settle for market entry only months before patent expiry (as the House and Senate bills banning reverse payments would) will result in a system in which every early generic entry will forever be capped at only months before patent expiry. There is no doubt that if permitted to get away with it, the first-filer and brand company will ALWAYS settle for generic entry only slightly before patent expiry, maintaining almost all the life of every monopoly, even when patents are invalid or not infringed. Consumers are much better off with a system that allows for the possibility of generic entry years rather than just months earlier. Indeed, as previously noted, Congress' intent in passing Hatch-Waxman was to create a framework under which generics were incentivized – for the benefit of consumers – to break, not preserve patents that are invalid or not infringed. The concept of allowing generic companies to retain the 180-day exclusivity reward when they opt to settle and allow obviously weak patents to stand as barriers to generic competition simply cannot be reconciled with the intent of the Hatch-Waxman Act.