APOTEX
ADVANCING GENERICS

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Subcommittee on Commerce, Trade, and Consumer Protection
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Introduction

Chairman Rush, Ranking Member Whitfield, Members of the Subcommittee, thank you very much for the opportunity to testify before you on anti-competitive patent settlements between brand and generic pharmaceutical companies. My name is Bernard Sherman. I am the CEO and Chairman of Apotex Inc. Apotex is the largest Canadian pharmaceutical manufacturer. We are also one of the largest generic drug manufacturers in the world. In the United States, we are the 5th largest generic drug manufacturer measured by sales. Our U.S headquarters is located in Weston, Florida. We also have a distribution center in Indianapolis, Indiana.

At Apotex, we believe generic companies should endeavor to bring generics to market at the earliest possible time, and that the legislative and regulatory framework should facilitate, not obstruct, early generic entry. Our record in advocating for such a public policy framework, from our opposition to patent settlements, our efforts in the courts to vacate anti-competitive settlements, our support for a district court trigger for exclusivity rather than an appellate trigger, our pursuit of declaratory judgment actions, and our pursuit of infringement verdicts even where there is no guaranteed benefit to us, is unique and unmatched among generic manufacturers.

Fixing Flaws in Hatch-Waxman Critical To Effectively Addressing the Problem

I testified before this Subcommittee in May 2007 in opposition to collusive agreements between generic and brand drug companies. I supported your legislation to end such anti-consumer practices due to its inclusion of a provision that addressed the ability of brand companies to delay generic competition by refusing to sue non first filers – the so called "declaratory judgment (DJ) problem." At that hearing I also testified that in order for any legislation aimed at ending the settlement problem to be effective, it is *absolutely vital* that it address the fundamental flaws in the Hatch-Waxman Act that are the root cause of the settlement problem: (1) the ability of the first to file generic company who is eligible for 180 day marketing exclusivity to keep that exclusivity despite the fact that it has settled with its brand counterpart and given up the fight to

knock out weak patents that unduly block consumer access to generics, and; (2) the lack of any incentive for a generic who is not the first to file to fight to open a market blocked by a "parked" exclusivity because winning only causes the first to file to launch its product while the generic that won, and thereby opened the market early for consumers, gets nothing.

As my testimony today details, *these flaws can be corrected by making the first generic company to win a patent challenge at the district court level eligible to share the 180-day marketing exclusivity period along with the first company to submit an application with a patent challenge to the FDA.*

The Hatch-Waxman Incentive Problem

In my 2007 testimony, I stated that "Apotex very much wants to continue to fight for the interests of consumers, as intended by the Hatch-Waxman provisions. However, it should be clear, that we will be unable to continue to do what is right, unless Congress addresses the essential problems." The vital importance of addressing the flaws was particularly evident to us at that time. Just two months prior, Apotex invalidated a patent on a blockbuster Pfizer drug, Norvasc®, but, despite being the first to win the patent case, and thereby responsible for opening the market early for consumers, we were not the first to file an application with a patent challenge (known as paragraph iv certification after the appropriate section of the Hatch-Waxman Act) and therefore were not able to launch the product. The first filer, Mylan, who had lost a district court decision just a month prior to Apotex's victory, was able to launch and reap the benefits from our success. Though Mylan had not entered into a settlement in that case, our victory and inability to launch shone a spotlight on the flaw in the Hatch-Waxman system that we identified as the root of the settlement problem: the lack of incentive for subsequent filers to prosecute the patent fight in the face of a settlement in which the generic company eligible for the Hatch-Waxman 180 day marketing exclusivity period blocks other generics from entering the market by "parking" its exclusivity in a collusive arrangement with its brand partner.

Just four months after I testified, the dynamic repeated itself in a case that did indeed involve a subsequent filer who invalidated a patent but was prevented from launching by a first filer who had settled and blocked the market by parking its exclusivity. In September of 2007, Lupin pharmaceuticals invalidated a patent covering King Pharmaceutical's product Altace®, a treatment for high blood pressure with nearly $1 billion in annual sales. King, however, had previously settled with the first generic company to file its application with the FDA, Cobalt, who was entitled to the 180 day exclusivity period by virtue of being the first to submit is application with the Agency. Cobalt's agreement with King in the settlement to delay its launch of generic Altace® thus bottlenecked the market. Because of Cobalt's entitlement to the 180 day exclusivity period, no other generic company could enter the market until 6 months after Cobalt first entered with its product. The agreement included what is *a standard part of all settlements with first filers today*, an acceleration clause, or "poison pill," which enabled

Cobalt to immediately enter the market at a date earlier than the delayed entry date agreed to in the settlement, in the event another generic challenger knocked out the patent.

Upon Lupin's victory, Cobalt immediately entered the market. Lupin was left with nothing despite being the party responsible for opening the market early for consumers. Cobalt, on the other hand, who had agreed to delay consumer access to the generic by abandoning its effort to knock out what proved to be a patent that never should have been issued in the first place, was able to "double dip". They were able to keep the money they got paid by the brand company to abandon the patent fight and then benefit from being the only generic on the market during the exclusivity period even though it was Lupin that opened the market early for consumers.

At first blush, the acceleration of Cobalt's entry into the market resulting from Lupin's victory may sound like a good outcome for consumers because it expedited access to the generic. However, no subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. ***Consumers are the biggest losers under this system***. If subsequent filers do not have the incentive to take on the cost of multimillion patent challenges these challenges will not occur. Weak patents that should be knocked out will remain in place, unduly blocking consumer access to generics. The challenges to brand patents by generic companies that Hatch-Waxman was designed to generate will decrease. And settlements that delay consumer access to the generic will, in turn, increase. With it being futile for subsequent filers to invest in a patent challenge that is guaranteed to produce no return, Congress' objective of providing a means for subsequent filers to break through parked exclusivities will never be realized.

If Hatch-Waxman is to facilitate the early access to generics that it was originally intended to facilitate, further reform is necessary to provide the incentive for a subsequent filer to carry on the patent fight. Accordingly, Mr. Chairman, Apotex implores you to take advantage of the opportunity your legislation provides to address this fundamental flaw in the Hatch-Waxman Act. *We urge you to include in your legislation a provision that would enable the first generic to win the patent litigation to enter the market upon a district court victory, with shared exclusivity.*

Another Case in Point: The Anticompetitive Provigil® Settlements

While there are any number of cases that could be cited to illustrate how the systemic gaming of Hatch-Waxman is carried out and defended by generic and brand drug settlers, the Provigil® case epitomizes how the game is played. The "early" access to generic drugs settlements are purported to provide consumers by those defending these anti-consumer arrangements is in reality just the opposite: delayed entry. The benefits such settlements are alleged to provide consumers and taxpayers are a smokescreen. The costs these settlements impose on consumers are in actuality very substantial. Consider the following.

In the Provigil® case, Cephalon settled patent challenges with Barr, Teva, Mylan, and Ranbaxy. The four generic companies all filed applications challenging the disputed brand patent on the same day, December 24, 2002. Under the law they are therefore all eligible for 180-day exclusivity, a situation referred to as "shared exclusivity". They were all sued by Cephalon on or about March 28, 2003. The disputed patent expires on October 6, 2014 but the product is protected for an additional 6 months by pediatric exclusivity, which runs to April 6, 2015. The settlements were reached in late 2005/early 2006. They allow for generic competition in 2012. Because the settlements allow for generic entry three years prior to the April 2015 expiration of pediatric exclusivity, this settlement is purported by the generic pharmaceutical industry to be "pro consumer" because it contains an "early" entry date.

The disputed patent in this case, however, is extremely weak. It is highly unlikely that Cephalon would have prevailed against all four generic challengers. Indeed, upon reaching the settlements with the four generics, Cephalon's CEO Frank Baldino, Jr. crowed that "A lot of [Wall Street's enthusiasm for Cepahlon's stock] is a result of the patent litigation getting resolved for Provigil®. We were able to get six more years of patent protection. That's $4 billion in sales that no one expected."[1] The FTC chose this suit to prosecute in 2008 as a follow up to previous loses in the courts against settlers precisely because this purported "pro consumer" settlement left a weak patent in place to prevent other generics from entering the market.

An appeals court decision in favor of any one generic company would have trigged exclusivity for all of them. All four of them would have launched upon such a decision in any one of their cases. It typically takes four years to get to an appeals court decision. Thus if the patent challenges had been successfully pursued, generic competition with 5 companies (including an expected authorized generic) would likely have begun in 2007 or 2008 if not sooner. *That is 4 to 5 years earlier than the 2012 date allowed for in the "pro-consumer" settlements with the four first filers.* ***The delay in access to generic Provigil® until 2012 resulting from these purportedly "pro consumer" settlements will cost consumers $2.2 billion in unrealized savings.***[2]

The incentive for subsequent generic filers to have continued to fight to open this market when it should have been opened is non-existent. Just as in the Lupin case, any successful outcome by a subsequent filer will leave it with a loss on the investment because if they win, they will not be able to enter the market. All the settlements include the aforementioned "poison pill" acceleration clause.

Enabled by the market blockage created by these anti-consumer settlements, Cephalon has sharply increased the price of Provigil® in a strategy designed to switch consumers to its next generation drug, Nuvigil®, before generic competition begins in 2012. On November 17, 2008, *The Wall Street Journal* reported that Provigil was "28%

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[1] *See* http://philadelphia.bizjournals.com/philadelphia/stories/2006/03/20/story1.html

[2] According to IMS Health, 2008 sales of Provigil were approximately $944 million. The figure for lost savings was determined by with the following assumptions: the generic price would be 50% of the brand price for the first year and 30% for subsequent years, and the generic penetration rate would be 90%.

more expensive than it was in March and 74% more expensive than four years ago…" The strategy, continued *The Wall Street Journal*:

> …works like this: Knowing that Provigil will face generic competition in 2012 as its patent nears expiration, Cephalon is planning to launch a longer-acting version of the drug called Nuvigil next year. To convert patients from Provigil to Nuvigil, Cephalon has suggested in investor presentation it will price Nuvigil lower than the sharply increased price of Provigil.
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> By the time copycat versions of Provigil hit the market the company is banking that most Provigil user will have switched to the less-expensive Nuvigil, which is patent-protected until 2023. In the meantime, Cephalon will have maximized its Provigil revenue with repeated price hikes.[3]

FTC Commissioner Jon Leibowitz hit the nail on the head upon the filing of the FTC's suit against these settlements in 2008 when he asked, "Why would companies that make 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." [4]

A settlement that allows the generic to enter the market early when that early date is calculated against the expiration of a weak patent is not pro consumer. It is critical, Mr. Chairman, that any legislation addressing the patent settlement issue correct the incentive problem to ensure subsequent filers have an opportunity to achieve a return on their investment if they fight on and win. *Consumers and taxpayers will be the biggest beneficiaries of such a system as this system will make it more attractive for generics to fight to knock out weak patents rather than settle their challenges of them.* Were it not for this systemic Hatch-Waxman flaw, Apotex would likely already be on the market with a generic version of Provigil®. We have a tentative approval for the product but are blocked by the settlements.

In the meantime, as *The Wall Street Journal* detailed, consumers and taxpayers who are paying for this drug, which is used frequently by senior citizens and the military, are being gouged by sharp price increases. The Provigil® settlement – and the many others like it which allow for an "early" entry date of the generic – is anything but "pro-consumer."[5] I was so steamed by it that Apotex filed a suit against it on principle in

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[3] "How a Drug Maker Tries to Outwit Generics," *The Wall Street Journal*, November 17, 2008.

[4] *See http://www.ftc.gov/os/caselist/0610182/080213comment.pdf*

[5] Generic companies have settled and agreed to delayed entry even in cases they have ***won*** in the district court. One example of this occurred just last year when Barr Labs settled a case and agreed to delay its entry into the market place after it invalidated a patent covering Boehringer Ingelheim's Mirapex®, a treatment for Parkinson's disease and Restless Leg Syndrome. A second example is Barr's 1993 settlement with AstraZeneca, which it entered into after it won a district court decision invalidating a patent covering tamoxifen, a treatment of breast cancer. Barr and the Generic Pharmaceutical Association often cite the tamoxifen case as an example of a "pro consumer" settlement, because under the terms of the settlement, Barr was granted a license by Astra to sell tamoxifen in 1993. Barr did so at a price reported to

2006. That suit is regretfully languishing in the courts, Mr. Chairman, on the slow track to nowhere.[6] It is essential that Congress intervene to end the ability of generic and brand companies to game the system through arrangements like the Provigil® settlement that block the market for years on end.

Settlement Problem Has Worsened Since 2007

The settlement problem, Mr. Chairman, has only worsened since the 2007 hearing this Subcommittee held on the issue. Settlements are becoming the norm in Hatch-Waxman patent challenges. According to a report released in February of this year by the Stanford Financial Group, the number of settlements doubled from 21 in 2007 to 42 in 2008. Settlements, moreover, are only going to continue to grow in the wake of the Lupin case, which drove home the futility of continuing the patent fight in the face of first filer settlements that include acceleration clauses. It is inevitable that there will be an increase in settlements by subsequent filers. FTC Chairman Jon Leibowitz again got it

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be about 15% lower than the brand price. In support of their argument that the tamoxifen settlement was "pro consumer," Barr and the Generic Pharmaceutical Association often point out that after Barr settled the case, other generic companies lost their attempts to invalidate the patent. Because of the settlement, they argue, Barr was able to provide a lower cost alternative to consumers earlier than the 2002 patent expiry. The settlement was pro consumer, they add, because the failure of the subsequent challengers to win their patent challenges shows Barr's decision was the best one for consumers. What they don't explain is that none of the other companies who attempted to knock the patent out after Barr settled the case could take advantage of what Barr had discovered that enabled them to knock out the tamoxifen patent. Barr and AstraZeneca sealed the case when they settled. There was a smoking gun in this case that others challengers were blocked from seeing. I know this because I was Chairman of Barr's Board of Directors at the time. It is absurd to suggest the settlement was pro consumer. Generic prices drop to as much as 10% of the brand price or lower when full competition ensues following the expiration of the 180 day exclusivity period. Patients should have benefited from the lower prices full generic competition in the tamoxifen market would have generated at the end of 1993 had Barr launched after winning. Instead, full generic competition did not begin until the patent Barr had invalidated expired in 2002. The cost to patients and taxpayers was hundreds of millions if not billions of dollars.

[6] The pace of both Apotex's and the FTC's suits against the Provigil® settlements underscore the inadequacy of the provision Congress added to Hatch Waxman in 2003 under which a generic company can be stripped of the 180 day exclusivity reward upon a finding by an appeals court that it entered into a settlement that violates anti-trust laws. It takes a tremendously long time before an appeals court decision in an antitrust case can be attained. In the Cipro® case in which Barr and Bayer settled, it took nearly 12 years from the time of the settlement was reached in January 1997 before the appeals court ruled in 2008. In the tamoxifen case in which Barr and AstraZeneca settled, it took nearly 13 years from the time of the settlement before an appeals court ruled ('93 settlement, '06 decision). In the K-Dur® case in which Schering Plough and Upsher Smith settled it took nearly 8 years ('97 settlement,'05 decision). In the Cardizem® case in which Andrx and Hoechst settled, it took nearly 6 years ('97 settlement, '03 decision). In a class action case brought by several plaintiffs against Cephalon and the four generic settlers in the Provigil® case, a motion to dismiss was filed over two years ago and the judge has yet to rule on the motion. In the FTC's case against Cephalon, a motion to dismiss was filed in June 2008 and the judge has not yet ruled. In the meantime, as *The Wall Street Journal* article detailed, Cephalon is working to switch patients from Provigil® to the next generation product Nuvigil®. Thus, as these examples show, by the time the required appeals court finding is reached, changes in the market place, such as the conversion by the brand company of the patient population to the next generation product, will have significantly reduced if not eliminated the opportunity for any savings from full generic competition.

exactly right when he stated upon the filing of a case by the Commission in January of this year against Watson, Par, Paddock and Solvay concerning their settlement of litigation over the drug AndroGel® that "Generic entry prior to patent expiration, which had been a common occurrence until the past few years, is at the risk of becoming the rare exception. Congress enacted the landmark 1984 Hatch-Waxman Act to encourage early generic entry and save consumers money, but these anticompetitive deals threaten to destroy that benefit and make crucial portions of the Hatch-Waxman Act extinct and all but name."[7]

Solely Amending the Antitrust Laws is Not a Sufficient Solution to the Problem

Since the Subcommittee's hearing on this matter in 2007, Mr. Chairman, there have also been developments in the litigation of "reverse payment" cases and antitrust cases in other regulated industries that strongly suggest that antitrust legislative reform alone is an insufficient means to address the patent settlement problem. The proposed legislation would enact a change to antitrust laws to declare reverse payments *per se* illegal. Solely enacting a change to the antitrust laws declaring reverse payments *per se* illegal will not be sufficient to stop anticompetitive settlements.

While we do not oppose this change, we urge Congress to appreciate that "reverse payments" are not the fundamental problem, but only a symptom of the problem. Eliminating reverse payments will not solve the problem of a first filer settling for late entry and blocking market entry by a subsequent filer who would otherwise fight for a much earlier entry date and win.

Thus the inclusion in your legislation of a provision granting shared exclusivity to a subsequent filer who is first to win would remain crucial to solving the problem.

Fixing Hatch-Waxman Essential: Problem Can Be Fixed ONLY By Giving Shared Exclusivity to the First to Win

As previously stated, Congress can correct the flaw in the Hatch-Waxman act that lies at the root of the settlement problem *by making the first generic to win eligible to share the exclusivity along with the first generic to simply file its application with the FDA.*

This proposal, Mr. Chairman, is anything but radical. It is how Hatch-Waxman was intended to work by Congress and the FDA when it was originally enacted. When it implemented the law after its passage in 1984, FDA awarded the exclusivity to the first generic to win the patent case, not the first to file. Subsequent court challenges, however, struck the first to win interpretation down, leaving in place a system which awards the exclusivity period to the first generic company to submit an application with a patent challenge to the FDA even if it is not the first generic company to win the litigation.

[7] *See* http://ftc.gov/speeches/leibowitz/090202watsonpharm.pdf

Senator Hatch confirmed that the first to win interpretation was the correct interpretation in 2003 when Congress amended the Hatch-Waxman Act but failed to restore it to its original intent. Said Senator Hatch:

> The intent of this section of the 1984 law was to award the 180-day head start to the first successful challenger of the innovator 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 applicant to file an application with the FDA that challenges the patents…The mismatch between the rights accorded to the first applicants and the first successful challenger contributed to an atmosphere in which anti-competitive agreements were entered into between certain generic and pioneer firms.[8]

It should also be noted that the concept of expanding exclusivity to enable the first to win to share the exclusivity with the first to file is consistent with current law. Current law allows for shared exclusivity already in instances when multiple generic companies are first to file applications with patent challenges on the same day, as occurred in the Provigil® case.

District Court Victory Must Be the Trigger in First to Win Fix

For this proposal to be effective it is essential that *a victory at the district court level be sufficient* to make the generic company eligible to share the 180 day exclusivity reward. If the threshold is set at the appeals court level, the same lack of incentive subsequent filers currently have to continue the patent fight will persist unabated. The first filer will simply accelerate its entry into the market as soon as a subsequent filer wins at the district court level, leaving the successful subsequent filer in the same position as it is today – guaranteed to get nothing if it wins.

It is essential not to confuse the concepts of triggering the exclusivity of the first to file with granting shared exclusivity to the first to win. Even if the triggering of the first to file remains set at the appellate court level, it is crucial that the granting of shared exclusivity to the first to win occur upon a district court victory by the first to win, without awaiting affirmation on appeal.

There is no doubt whatsoever that implementing shared exclusivity for the first to win with a district court trigger will generate enormous savings for consumers as a result of generic drugs entering the market earlier than is possible under the existing Hatch-Waxman system. To the benefit of consumers, a subsequent generic filers who is first to win would almost certainly enter the market upon a favorable district court decision even though such a decision could be reversed on appeal. The odds of the case being reversed against the generic are extremely low. The aforementioned Stanford Financial Group Report on generic litigation success rates found that only 2 of 92 cases in which the

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[8] *See Congressional Record*, December 9, 2003, p 16105

generic company prevailed were reversed against the generic. FTC data reinforce the Stanford report's findings. In its 2002 study "Generic Drug Entry Prior to Patent Expiry," which analyzed the outcome of generic challenges between 1992 and 2002, the FTC found that district court decisions favorable to the generic company were upheld 92% of the time (13 out of 14).[9]

Generic companies are very well aware that a large number of brand patents are weak and would be knocked out if they fully prosecuted the patent fight. For instance, in April 2008, the general patent counsel for Teva Pharmaceuticals stated "A large portion of these patents should never have been registered in the first place."[10] In fact, first to file generic companies are using the threat of at risk launches to cajole brand companies into entering into anticompetitive settlements. Brand companies have taken note of generic companies' increased willingness to launch at risk. They know the threat is more real than it has ever been. The willingness of generic companies to launch at risk, particularly on a blockbuster drug, sends an unmistakable message: the patents generics are challenging are weak. If a generic company is willing to launch at risk before even a district court decision, it most certainly follows that it will be willing to launch after a district court victory. Yet the generic industry is fighting tooth and nail to preserve its ability to enter into settlements that will permit generic companies to preserve weak patents in settlements that block consumer access to generics for years longer than is necessary or right.

The Stanford Financial Group report found that generics won their cases about 50 percent of the time. Other data, including the 2002 FTC study which found generic companies prevailed in 73% of the cases ultimately resolved by a court decision, show even higher generic success rates. [11] Thus if generics win at least half their challenges, it stands to follow that in half the cases that are settled, consumers would have had access to generics much earlier than the purported "early" or "pro consumer" dates the generic industry asserts can only be attained with certainty by settling. With generic companies being well aware of the weakness of brand patents, the public should be benefiting from more generic victories in the courts and earlier consumer access to generics, not more settlements and later generic access. Yet, the data shows that settlements are on the rise. And they are on the rise because by settling, the generic company can eliminate all the risk of losing the litigation without giving up the 180 day exclusivity reward that was supposed to be earned by knocking out the same weak patents they are leaving in place in collusive agreements with their brand partners to delay full and fair generic competition. Elimination of the risk of losing by the generic company is not just a payment in and of itself, but *the primary* form of payment in Hatch-Waxman settlements. *Banning reverse payments without addressing the incentive problem will therefore not effectively prevent*

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[9] "Generic Drug Entry Prior to Patent Expiration: An FTC Study," July 2002, p 21. http://www.ftc.gov/2002/07/genericdrugstudy.pdf

[10] *See* "Teva's patent marathon runner," Globes [on line], April 24, 2008.www.globes.co.il/serveEN/globes/docView.asp?did=1000336068&fid=1724.

[11] July 2002 FTC Study, p. 20. A 2006 study also documented this trend, finding that patent holders in the pharmaceutical industry were successful on the merits in only 30% of Federal Circuit decisions from 2002 through 2004. *See* Paul Janicke & Lilan Ren, "Who Wins Patent Infringement Cases?" 34 AIPLA Quart. J.1.20 (2006).

market blockages. Generic companies will still settle cases that leave weak patents in place. Congress must create a viable mechanism – allowing the first generic to win in the district court to gain shared exclusivity – for subsequent filers to break through parked exclusivities even if reverse payments are banned.

Apotex's example, Mr. Chairman, shows that if the system is changed in the manner we are suggesting, consumers will benefit from the incentives the new statutory framework would create for generic companies to pursue patent challenges instead of settling them. The data published in the Stanford Financial Group report demonstrates the point.

The report analyzed the results of nearly 280 challenges by generics from 2000 to 2008. The report considered the outcome for the generic company successful if the generic company won the case, settled the case, or the case was dropped (I do not agree that a settlement should be counted as a success, but that is how the report measured success). According to this measurement system, Apotex is the least successful generic challenger. The implication is that Wall Street thinks Apotex would be a bad investment because Apotex settles very few cases.

The report, however, also includes data on the number of times generic companies were successful in overturning district court cases that had gone against the generic. Of the 10 such cases identified in the report, Apotex led all companies with four victories on appeal. In reality, we were responsible for 5. Apotex was also involved with one of the victories (Prozac®) attributed to the company with the next highest total (Barr Labs: 2)[12]. I was Chairman of Barr's Board of Directors at the time and developed the Prozac® case. Profits from the victory were split 50/50 between Apotex and Barr. In short, the data clearly reflects our commitment to fighting for consumers as was originally intended by the Hatch-Waxman Act.

I want to be clear that I am not suggesting that generics should be forced to fully prosecute every patent challenge. We are not opposed to generics settling cases and believe the right to settle should be preserved. But the original intent of Hatch-Waxman is unambiguous: to get generic drugs into the market as fast as possible. If a generic company believes the best it can do is to reach a settlement that allows it to enter the market a few months prior to the expiration of a patent it should take that deal. But that deal must not be allowed to block another generic that is willing to continue the patent fight in the face of that settlement, does so, and wins.

What Apotex's litigation record shows, Mr. Chairman, is that a generic company that is willing to vigorously pursue the patent case can both profit and produce much greater savings for consumers than a system in which every case is settled. Consistent

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[12] Barr won the Prozac case only after Eli Lilly rejected the offer of Barr's CEO to settle the case for $200 million. *See* "Trial is Getting Underway Today in Prozac Patent Lawsuit," *New York Times*, 1/25/99. Had Barr had its way, the case would have been settled and the billions of dollars in savings for consumers that were realized as a result of the full prosecution of the patent case would never have been realized.

with Hatch-Waxman's original intent, generics should be rewarded for knocking out weak patents and opening markets earlier, not for letting weak patents stand and delaying consumer access to generics, as is the case today. A system that gives shared exclusivity to the first to win *with a district court trigger* will correct this perversion of Hatch-Waxman by providing subsequent filers with the needed incentive to carry on the patent fight in the face of a settlement – incentive that is non-existent under today's statutory framework. In so doing, this change will end the settlement problem by making it possible for generics to reach consumers even earlier than the purported "early" dates the generic drug industry says it is providing in settlements that allow for generic entry a few months earlier than the expiration of a patent that would have been knocked out years prior had the patent fight been fully prosecuted.

As I testified to in 2007 and reiterated again today, we urge Congress to make it possible for Apotex and other generic companies to operate in a manner consistent with the original intent of the Hatch-Waxman Act. Implementing a first to win system with a district court trigger will accomplish this goal.

Also Essential to Neutralize "Poison Pill" Provisions in Settlements

As explained earlier in this testimony, the use of "poison pill" provisions which allow a first filer who has settled to accelerate its entry into the market upon a victory by a subsequent filer is a standard component of every settlement today. These "poison pills" undermine the incentive of subsequent filers to carry on the patent fight and empower first filers to accept later entry dates. Acceptance of later entry dates in settlements is possible because the "poison pill" guarantees the first filer's ability to retain exclusivity no matter how long the period of delay it agrees to is.

To be effective, legislation addressing the settlement problem must not only give shared exclusivity to the first to win but must also ban these "poison pills". Banning "poison pills" will accomplish two essential goals. Firstly, it will ensure the subsequent filer has adequate incentive to carry on the patent fight in the face of a settlement. Secondly, it will shorten the period of delay first filers are willing to accept in settlements. For if they agree to a lengthy delay in a settlement and a subsequent filer wins and is permitted to enter the market, the first filer will then find itself far behind its competitors instead of ahead of them. This will serve the public's interest by ensuring that when generic companies negotiate settlements of patent challenges with brand companies, they are incentivized to negotiate for market entry at the earliest possible time.

This correction can be implemented by providing that FDA cannot grant final approval or must suspend final approval for the first filer until the date to which the first filer has agreed to accept delayed market entry, without acceleration by a "poison pill" provision.

Declaratory Judgment (DJ) Problem

Before closing, Mr. Chairman, I also want to urge you to retain in your legislation the provision that corrects the DJ problem by making both the dismissal of a DJ action for lack of subject matter jurisdiction and the execution of a covenant not to sue triggering events for the first filer's exclusivity. However, it is essential to supplement this provision by granting shared exclusivity to the subsequent filer who has obtained dismissal of the DJ action and/or the covenant not to sue.

In the 2003 amendments to Hatch-Waxman, Congress included a provision intended to redress the inability of generic companies to bring declaratory judgment actions in instances where the brand company declined to sue the generic company for patent infringement, a common and effective tactic used by brand companies to delay generic competition.[13] The provision proved to be less than effective until a 2007 holding by the Supreme Court in MedImmune v. Genentech that enhanced the ability of generics to get DJs under the 2003 provision added to Hatch-Waxman by Congress for this purpose. *See* 549 U.S. 118 (2007) In that case the Supreme Court held that the Federal Circuit was being too restrictive in deciding when a declaratory judgment can be maintained thereby improving the ability of generic drug companies to bring DJ actions under the 2003 amendments to Hatch-Waxman. The DJ problem, however, is by no means resolved. The provision is not functioning as Congress intended.

While the Federal Circuit did indeed rule in Caraco v. Forest that a subsequent generic company can bring a declaratory judgment action even if the brand company promises not to assert its patents against that applicant, the Federal Circuit reached the opposite conclusion in Janssen v. Apotex despite the two cases containing an extremely similar set of circumstances. *See Caraco Pharm. Labs. v. Forest Labs.*, No. 2007-1404 (Fed. Cir. 2008); *Janssen Pharmaceuticals, N.V. v. Apotex, Inc.*, No. 2008-1062 (Fed. Cir. 2008) Apotex was also denied a DJ in another post MedImmune case in which the

[13] 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. 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. As the body of this section of the testimony discusses as well, even if the DJ issue is resolved definitively through a legislative solution, there is no less of a need to correct the systemic flaws in the Hatch-Waxman Act identified in this testimony in order to resolve the settlement problem.

brand company provided a covenant not to sue. *See Merck v, Apotex*, 488 F. Supp. 2d 418 (D. Del 2007) So although the ability of generic companies to bring DJ actions has improved in the wake of the MedImmune decision[14], the question of just when generic manufacturers can and can not get DJs has not been resolved definitively. Legislation is needed to resolve the matter once and for all. The provision in your legislation that makes both dismissal of a DJ action for lack of subject matter jurisdiction and execution of a covenant not to sue triggering events for the first filer's exclusivity would effectively address this issue.

I would emphasize, however, that as important as it is for the DJ provision to function as Congress intended, the status of that provision is irrelevant to resolving the patent settlement problem if its resolution is not coupled with the correction of the fundamental flaw in the Hatch-Waxman statute that is the cause of the problem: the failure of the statute to provide any incentive for non first filers to continue the patent fight when blocked by a first filer's exclusivity.

Even if a subsequent generic filer can get a DJ and thereby attain a court decision on a disputed patent's validity or infringement status, a victory by the subsequent filer guarantees that the first filer who delayed its entry date in a settlement will immediately launch upon the victory of the subsequent filer in order to protect its exclusivity. A fully functioning DJ provision would do absolutely nothing to correct this problem.

Conclusion

As detailed in this testimony, in Apotex's view, it is critical to recognize that the primary anticompetitive aspects of settlements are those that eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry in the face of a settlement in which the first filer has blocked the market by parking its exclusivity.

We thus urge the Subcommittee to work for legislation that includes all of the following features:

1. An amendment that gives shared exclusivity to a generic challenger who, although not first to file an application with a patent challenge with the FDA, is first to succeed in addressing the listed patents at the district court level.

2. An amendment that overrides the "poison pill" provision in any settlement whereby the generic who settles for a delayed entry date can accelerate that date on the basis of a victory of a subsequent filer who was first to win, which as aforesaid can be affected by providing that FDA cannot

[14] After the MedImmune decision, the Federal Circuit, in Teva v. Novartis, 482 F .3d 1330 (2007), reversed a District Court decision denying Teva a DJ in case where Novartis sued Teva on only one of 5 patents listed in the FDA's Orange Book. As a result of the reversal, Teva was able to bring a DJ against the four patents Novartis had filed suit against.

grant final approval for the first filer until the delayed entry date to which the first filer has agreed.

3. A provision that makes both dismissal of a DJ action for lack of subject matter jurisdiction and execution of a covenant not to sue triggering events for the first filer's exclusivity, as proposed in your legislation.

Including these proposals in your legislation will achieve our shared goal of ending the ability of generic and brand drug companies to unduly delay timely consumer access to generic drugs through anti-consumer and anti-competitive agreements that bottleneck the market. The savings for consumers and taxpayers will be massive – untold billions of dollars in lower drug costs. Apotex, as always, stands ready to assist you in bringing these savings to fruition.

Thank you, Mr. Chairman, for the opportunity to once again testify on this important consumer issue. I look forward to any questions the Members of the Subcommittee may have.