Computing Legal Damages in High-Profile Patent Infringement

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ABSTRACT

When estimating patent damages, the fundamental task is to construct a "but-for" model that simulates, as closely as possible, the marketplace absent infringement. ¹ Calculation of damages is premised upon four principles. These are: 1) A patent's economic and commercial value derives largely from the market power it confers to the patent owner; therefore, in estimating damages from patent infringement, the market power conferred by the patent must be taken into account; 2) When the price of a good increases, consumption of the good declines, and vice versa (law of demand); 3) Only costs caused by extra sales should be charged against extra sales revenues; therefore, incremental costing is the proper approach. Both the technology and the size of the output increment determine which costs are relevant; 4) Royalties are determined in hypothetical negotiations in which both the market power flowing from the patent and the relative bargaining power of the negotiators influence the outcome. In response, this essay's system dynamics model simulates the BuSpar® market as close as possible, absent infringement. The modeling process illustrated in this essay accounts for:

The market power that the BuSpar® patent confers to Bristol-Myers Squibb Co. (BMS).

The demand and price relation in the $BuSpar \ensuremath{\mathbb{R}}$ market.

The cost of regaining lost sales by using incremental costing.

The difference between royalty and lost profit damages.

EXECUTIVE SUMMARY

Case History

On November 21, 2000 the Bristol-Myers Squibb's ("BMS") patent for BuSpar® expired On November 21, 2000, BMS lists new patent in FDA's Orange Book, triggering an artificial extension of the original patent

On November 22, 2000, Mylan Pharmaceuticals, a generics drug manufacturer, was ready to start selling the generic version of Buspar pursuant to a tentative final approval by the FDA

On November 22, 2000, upon receiving BMS's new patent, FDA suspends final approval of Mylan's generic version

Mylan and other generic manufacturers challenge FDA's listing of BMS's patent because it did not a claim a method of use

On November 30, 2000 in response, FDA requests clarification from BMS whether the new patent claimed only a metabolite of buspirone, which is the active ingredient of BuSpar.

FDA satisfied with BMS's response deemed the new patent listed as of 11/21/2000 On November 30, 2000, instead of following the FDA's procedural rules, Mylan files law suit against BMS and the FDA in the District Court for the District of Columbia On March 13, 2001, United States District Judge Ricardo M. Urbina orders BMS to request the FDA to de-list its patent extension from the Orange Book On March 28, 2001, the FDA gives Mylan approval to sell its 35 mg generic version of BuSpar

Subsequently, BMS files an appeal with the US Court of Appeal.

On June 29, 2001, Mylan is granted final approval to sell its 15 mg generic version of BuSpar

On October 12, 2001 Chief Judge Mayer reverses District Judge Urbina's judgment against BMS

From March 28, 2001 until present, Mylan continues to sell its generic version despite the Federal Circuit's reversal.

Proposed Actions

Option 1: Stop generic and regain full market power, losing goodwill

Option 2: Stop generic and sue for infringement damages, including goodwill

Option 3: Let generic sell and sue for infringement damages

Option 4: Let generic sell and write off BuSpar®

<u>Actual Economic Damages</u>

Allowing the generic drug to enter the market causes a major revenue loss for BMS. In fact, from March 2001 until October 2001, BMS lost an estimated total of \$289MM.

BuSpar® sales have dropped off by 85% in just under six months. The net dollar amount of sales revenue lost is \$307MM in first six months alone.

	Option 1	Option 2	Option 3	Option 4
Advantage	Damages estimated at \$1.5 billion	Right to sue for both past and future loss of revenue	Goodwill is not damaged; can sue for past and future losses estimated at \$177MM plus any gains from licensing agreement	Absolutely no loss of goodwill; no battle in court
Disadvantage	Incremental Cost of \$95MM; Loss of goodwill	Could severely tarnish credibility	Still lose market share to the generic drug	Loss of a very profitable product line

Expected Economic Damages

Recommendation

Allow generics to remain on the market and sue for patent infringement.

Objective of this Paper

The objective of this paper is to present a system dynamics model that simulates the BuSpar® market as close as possible, absent infringement.

The modeling process illustrated in this paper will account for:

The market power that the BuSpar® patent confers to Bristol-Myers Squibb Co. (BMS). The demand and price relation in the BuSpar® market.

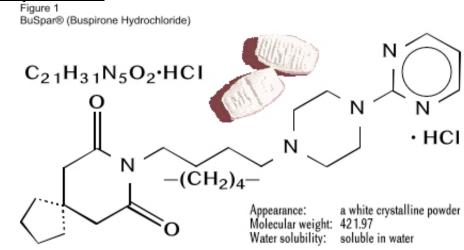
The cost of regaining lost sales by using incremental costing. The difference between royalty and lost profit damages.

System Dynamics

We used system dynamics in this case because it offers a unique approach to answering several questions that are driving this situation. System Dynamics aids us in deriving the answer we need because it allows us to interpret multiple variables and known factors through a system of equations and graphs. This case involves a combination of ongoing events that must be combined to derive at an answer. You will see the applicability of System Dynamics in the following sections regarding damages suffered by BMS, and more importantly the quantification of those damages using System Dynamics.

BuSpar®: A Brief Definition

BuSpar® (buspirone hydrochloride) is a widely prescribed anti-anxiety medication manufactured by Bristol-Myers Squibb Co. (BMS). More precisely, it is a nonhabit-forming medication, for the treatment of generalized anxiety disorder. BuSpar® is usually safe and effective in relieving both the emotional and physical symptoms of generalized anxiety disorder. Its *chemical representation* is as follows:



A few words on Generalized Anxiety Disorder

Generalized anxiety disorder is a mental illness that causes a person to suffer from persistent, nagging feelings of worry or anxiety (apprehension or uneasiness triggered by a threatening situation). These feelings are either unusually intense, or definitely out of proportion to the real troubles and dangers of the sufferer's everyday life.

There is no clear dividing line between normal worry and a diagnosis of generalized anxiety disorder. People with the disorder typically experience excessive, persistent worry every day, or almost every day, for periods of six months or more. In some cases, a person with generalized anxiety disorder finds it hard to remember a time when he or she was not "always worrying."

In addition to suffering from nagging worries and anxieties, people with generalized anxiety disorder also have a variety of physical and psychological symptoms that are related to their anxious feelings. In fact, anxiety-related physical symptoms are so prominent in people with generalized anxiety disorder that most of these individuals initially seek treatment with a primary care doctor, cardiologist, pulmonary specialist or gastroenterologist. Stress can also intensify the anxiety or lead to a situation-specific phobia. Affected individuals may have low self-esteem or may feel insecure, because they interpret people's intentions or the meaning of events in negative, intimidating or critical ways.

Although the exact origin of generalized anxiety disorder remains a mystery, several studies involving close relatives of persons with the illness show that there is some evidence for a genetic (inherited) tendency toward it. Physiologically, doctors believe that generalized anxiety disorder involves a disturbance in levels of certain neurotransmitters (chemicals that carry signals between brain cells), particularly the neurotransmitters gamma aminobutyric acid and serotonin.

Currently in the U.S., an estimated 3 percent to 8 percent of all Americans suffer from generalized anxiety disorder, with women affected twice as often as men. Although the illness can be found in people of all age groups, the average adult patient first seeks medical attention (usually for physical symptoms) between the ages of 20 and 30. Generalized anxiety disorder has also been diagnosed in young children, teenagers and elderly individuals, especially in those who come to a primary care doctor complaining of an unusually large number of physical symptoms. The illness is the most common anxiety disorder affecting persons age 65 and older.

Of all the psychiatric illnesses, generalized anxiety disorder is the least likely to occur alone. From 50 percent to 90 percent of persons with the disorder also suffer from at least one other mental illness, particularly panic disorder, a phobia, depression, dysthymia (a less severe form of depression), alcoholism or some other form of substance abuse.

<u>Symptoms</u>

According to the definition established by the American Psychiatric Association, generalized anxiety disorder causes persistent worry or anxiety that lasts for at least six months. This worry or anxiety is excessive, troubling and hard to control, and it often interferes with a person's ability to function at home, at work or in social situations.

In addition to causing worry and anxiety, generalized anxiety disorder also produces at least three of the following groups of symptoms:

Feeling restless, "keyed up" or "edgy"

Becoming tired very easily

Having difficulty concentrating or remembering (your mind "goes blank")

Feeling irritable, "crabby" or "grouchy"

Having tense muscles

Having trouble falling asleep or staying asleep, or not feeling rested after sleep

People with generalized anxiety disorder may also suffer from a wide range of anxietyrelated physical symptoms that may mimic those of heart disease, respiratory illness, digestive diseases and other medical illnesses.

Regulatory Background

An understanding of the statutory and regulatory framework governing the approval of generic drugs is critical in understanding the facts and circumstances surrounding the BMS/Mylan dispute, and the effects of their respective market share.

The Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, authorizes the FDA to regulate the production, distribution, and sale of drugs in the United States. See <u>21 U.S.C. § 321-397</u>. An applicant seeking to market a new brand-name drug ("a pioneer maker") must prepare a rigorous New Drug Application ("NDA") for FDA consideration. See <u>21 U.S.C. § 355</u>. The NDA contains reports of the drug's safety and effectiveness, a list of the articles used as components in

the drug, a statement of the composition of the drug, a description of the methods, facilities and controls used in the manufacture, processing and packaging of the drug, samples of the drug or components, if necessary, and samples of the proposed labeling. See <u>21 U.S.C. § 355(b)(1)</u>. In addition, the NDA must contain information on any patents that claim the drug or a method of using the drug and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. See <u>21 U.S.C. § § 355(b)(1), (c)(2)</u>. Upon approval of the NDA, the FDA publishes any claimed patents for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book." See <u>21 U.S.C. § 355(j)(7)(A)(iii)</u>.

Generic drugs are versions of brand-name prescription drugs that typically contain the same active ingredients but not necessarily the same inactive ingredients as the brand-name original. See <u>United States v. Generix Drug Corp.</u>, 460 U.S. 453, 454-55, 103 S.Ct. 1298, 75 <u>L.Ed.2d 198 (1983)</u>; <u>Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1062 (D.C.Cir.1998)</u>.</u> Before 1984, a company that wished to make a generic version of an FDA-approved brand-name drug ("a generic maker") had to file another NDA. Preparation of the second NDA was as time-consuming and costly as the original, because the applicant had to include new studies showing the drug's safety and effectiveness. See <u>Mova, 140 F.3d at 1063</u>. In 1984, however, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the **Hatch-Waxman Act**, which simplified the procedure for obtaining approval of generic drugs. See <u>Pub.L. No. 98-417</u>, 98 Stat. 1585 (1984), codified at <u>21 U.S.C. § 355</u> and <u>25 U.S.C. § § 156</u> and <u>271(e)</u>.

The Hatch-Waxman Act represented Congress's efforts to strike a compromise between the competing interests of pioneer pharmaceutical companies and generic manufacturers. The Hatch-Waxman Act "emerged from Congress' efforts to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." <u>Abbott Labs. v. Young, 920 F.2d 984, 991</u> (D.C.Cir.1990) (Edwards, J., dissenting on other grounds) (citations omitted), cert. denied, <u>502</u> U.S. 819, 112 S.Ct. 76, 116 L.Ed.2d 49 (1991).

Under the Hatch-Waxman Act, Congress continues to require the pioneer maker to file an NDA, complete with safety and effectiveness data. Subsequent applicants who wish to manufacture generic versions of the original drug, however, are required to file only an Abbreviated New Drug Application ("ANDA"). See <u>21 U.S.C. § 355(j)</u>. Unlike the stringent requirements for an NDA, an ANDA applicant need not show independent evidence of the safety and efficacy of its generic drug, but instead can rely on the FDA's previous determination that the drug is safe and effective. See <u>21 U.S.C. § 355(j)</u>; <u>21 C.F.R. § 314.94(a)(3)</u>; <u>Mead</u> <u>Johnson Pharm. Group v. Bowen, 838 F.2d 1332, 1333 (D.C.Cir.1988)</u>. The ANDA innovation thus allows manufacturers to market generic copies of pioneer drugs without repeating the expensive and lengthy clinical trials otherwise required by federal law. For this reason, among others, generic drugs are generally much cheaper to the consumer than brand-name drugs. See <u>Ben Venue Labs., Inc. v. Novartis Pharm. Corp., 10 F.Supp.2d 446, 449 (D.N.J.1998)</u>; see also <u>Generix Drug Corp., 460 U.S. at 455 n. 1, 103 S.Ct. 1298</u>.

To receive approval of its ANDA, an applicant must show that its generic drug is "bioequivalent" to the listed reference drug. See <u>21 U.S.C. § 355(j)(4)(F)</u>. Bioequivalence refers to the rate at which, and the extent to which, the body absorbs the active ingredient(s) in the drug. See id. § 355(j)(8)(A); <u>21 C.F.R. § 320.1(e)</u>. In this case, the reference drug is

BuSpar®, the brand of buspirone marketed by Bristol. The applicant must also show that the generic drug has the same route of administration, strength, and dosage form as the reference drug. See <u>21 U.S.C. § § 355(j)(2)(A)(iii), (j)(4)(D)(i)-(ii)</u>; see also <u>21 C.F.R. § 314.92(a)(1)</u> (1999) (indicating the categories of drug products for which an ANDA may be filed).

In addition, when a generic maker files an ANDA seeking approval of a generic version of a drug that is listed in the Orange Book, the applicant must certify that any patent information listed in the Orange Book does not bar FDA approval of a generic version of the drug. See <u>21</u> <u>U.S.C. § 355(j)(2)(A)(vii)</u>; <u>21 C.F.R. § 314.94(a)(12)</u>. The Hatch-Waxman Act provides ANDA applicants with four certification options: (I) that no patent information on the drug product that is the subject of the ANDA has been submitted to the FDA; (II) that the patent has expired; (III) that the patent will expire on a stated date; or (IV) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the ANDA applicant seeks approval. See <u>21 U.S.C. § § 355(j)(2)(A)(vii)(I) to (IV)</u>. These are referred to as Paragraph I, II, III and IV certifications, respectively. In the case of a patent that has not yet expired (such as Bristol's '763 patent and '365 patent) the ANDA applicant's only certification options are Paragraph III or IV certifications.

The timing of FDA approval of the ANDA depends in part on the type of certification. If the ANDA contains a Paragraph I or II certification, the FDA may approve the ANDA as soon as it is satisfied that the product is safe and effective. See <u>21 U.S.C. § 355(j)(5)(B)(i)</u>. If the ANDA contains a Paragraph III certification, the FDA cannot make the approval effective until the patent expires. See <u>21 U.S.C. § 355(j)(5)(B)(i)</u>. If the ANDA contains a Paragraph-IV certification, the date of approval is determined by a complicated statutory scheme under which the ANDA applicant must provide notice to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA refers. See <u>21 U.S.C. §</u> <u>355(j)(2)(B)(i)</u>. This notice must include a detailed statement of the factual and legal basis for the ANDA applicant's assertion that the patent is not valid or will not be infringed by its generic product.

A **Paragraph IV** certification has significant legal effects. See <u>Ben Venue Labs., 10</u> <u>F.Supp.2d at 449</u>. The patent law provides that submitting an application for an infringing product is itself an act of infringement. See <u>id.</u> (citing <u>35 U.S.C. § 271(e)(2)(A)</u>). Thus, a Paragraph IV certification automatically creates a cause of action for patent infringement. See <u>id.</u> Upon receiving notice of a Paragraph IV certification, the patent holder has **45 days** in which to file suit against the generic manufacturer. See <u>21 U.S.C. § 355(j)(5)(B)(iii)</u>. If the patent-holder brings such an action, the FDA is prohibited from approving the generic maker's ANDA for a period of **30 months.** See <u>id.</u> This **30-month stay** allows the parties to litigate the patent would be infringed by the product proposed in the ANDA, the FDA will not approve the ANDA until the patent expires. If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid or not infringed, the FDA must approve the ANDA effective on the date of the court's decision. See <u>id.</u>

Factual Background

Since the mid 80's, BMS has held a patent for BuSpar® (Patent # 4,182,763) directed to the treatment of anxiety through the administration of buspirone hyddrochlorite. Bristol's '763 patent was due to expire on November 21, 2000. In anticipation of its expiration, Mylan, a generic manufacturer, had filed and received tentative approval of an ANDA for its buspirone

product under a Paragraph III certification, certifying that Bristol's patent '763 was set to expire on November 21, 2000.

On November 21, 2000, 11 hours prior to the expiration of patent '763, BMS announced a scientific discovery that shed new light on the optimal use of an anxiety medication to treat patients suffering from generalized anxiety disorder (GAD). As a result of this medical advance, which could provide patients with significant relief of their symptoms and enhance patient compliance, the company was issued a patent from the U.S. Patent and Trademark Office (PTO). The new patent (Pat. # 6,150,365) was issued on that same day, November 21, 2000 covered a method of use of a metabolite* produced by the administration of the medication *BuSpar*® (buspirone HCl, USP) tablets.

This discovery pertained specifically to the systemic use of a metabolite, known as 6hydroxy-buspirone, which is produced by the body after administration of non-addictive anxiolytic agents known as azapirones, of which *BuSpar*® is the most widely prescribed. Company scientists found that the metabolite, previously not known to be active is, in fact, largely responsible for the onset of therapeutic relief and may offer improvements in patient response rates, thereby allowing a greater number of patients to achieve optimal relief from their anxiety.

Upon receiving the '365 patent from Bristol, the FDA suspended approval of Mylan's ANDA. Mylan challenged the FDA's listing of the '365 patent on the grounds that it only covered a metabolite of buspirone and therefore should not be listed in the Orange Book because it did not claim the drug, Buspar. Mylan also filed a Section viii Statement that the '365 patent did not claim a use for which it was seeking approval.

On November 30, 2000, the FDA asked Bristol to clarify whether the '365 patent claimed only a metabolite of buspirone. Bristol responded that the '365 patent did not simply claim a method of using the metabolite, but also a method of using buspirone itself. Taking Bristol's clarification at face value, the FDA found Bristol's response adequate and listed the '365 patent in the Orange Book. On the same day, instead of filing a paragraph IV certification which essentially requires Mylan to certify that its ANDA will not be infringing upon Bristol's '365 patent, Mylan sued Bristol and the FDA in the US District Court, for the District of Columbia. Mylan sought a declaratory judgment that Bristol improperly listed the '365 patent, and a preliminary injuction requiring Bristol to de-list the '365 patent and directing the FDA to approve Mylan's ANDA.

Mylan's reasoning for suing Bristol and not filing a Paragraph IV certification was to avoid being sued by Bristol for patent infringement. Under 35 U.S.C. § 271(e)(2), an applicant, such as Mylan, infringes a patent if it submits an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent . . . before the expiration of such patent." Therefore, Mylan argued that had it filed an ANDA with a Paragraph IV certification, it would have been charged with infringing the '365 patent. Mylan further argued that it should not have been required to file a Paragraph IV certification in the first instance because the '365 patent did not claim BuSpar or an approved method of using BuSpar, and accordingly, Bristol improperly submitted the '365 patent for listing in the Orange Book.

On March 13, 2001, United States District Court Judge Ricardo M. Urbina found in favor of Mylan and ordered BMS to request the FDA to de-list its patent extension. Judge Urbina also ordered the FDA to approve Mylan's application to market a generic version of BuSpar®. On March 28, 2001, the FDA gave Mylan approval to sell its generic version of 15mg. On June 29, 2001, the FDA also approved Mylan's generic version of 35 mg.

Bristol appealed the District Court's order. On October 12, the US Court of Appeals reversed the District Court's decision, holding that Mylan's claim – that is, that the '365 patent was imporperly listed – does not constitute a recognized defense under the patent infringement laws or the Hatch-Waxman Amendements to the FFDCA.

It is crucial to note that the filing of Paragraph IV certification would have stayed the listing of Bristol's '365 patent for 30 months until it was determined whether Mylan did or did not infringe upon Bristol's patent. If the court determined that Mylar did infringe prior to the 30-month stay, then Mylan's ANDA would have be rejected effective on the court's ruling. Mylan, however, did not follow the procedure of filing a Paragraph IV certification, as promulgated in the Hatch-Waxman Amendments, and therefore Bristol is denied its 30-month stay under the law.

At present, Mylan's approval to sell its generic version has not been stayed nor has it been forced out of the market by Bristol. Bristol's patent remains de-listed. Meanwhile, Bristol's infringement law suit in the Southern Disctirct of New York is on-going. If Bristol successfully proves the validity and applicability of its new patent, then its damages would be the lost profit on every pill Mylan has ever sold. Bristol also has an extremely good chance to collect treble damages if it is deemed that Mylan's infringement was willful. There is a high likelihood that it was since Mylan tried cleverly to circumvent the law.

This essay calculates the economic damages suffered by Bristol as a result of Mylan's approval by the FDA to sell its generic version of BuSpar since March 28, 2001. The economic damages calculated here are based on the assumption that the resolution of Bristol's patent infringement case against Mylan will last at least 2.5 years, the estimated length of time it takes to litigate a patent case, absent legal complications requiring further extension. Assuming December 1, 2000, Bristol filed its law suit against Mylan, as indicated in Judge Mayer's decision, then the cutting point for the sake of calculating total damages will be July 15, 2003. Moreover, the actual damages began accruing on March 28, 2001, the day the FDA gave Mylan final approval to start selling the drug.

Patent Infringement Damages

When estimating patent damages, the fundamental task is to construct a "but-for" model that simulates, as closely as possible, the marketplace absent infringement. ¹ Calculation of damages is premised upon four principles. These are: 1) A patent's economic and commercial value derives largely from the market power it confers to the patent owner; therefore, in estimating damages from patent infringement, the market power conferred by the patent must be taken into account; 2) When the price of a good increases, consumption of the good declines, and vice versa (law of demand); 3) Only costs caused by extra sales should be charged against extra sales revenues; therefore, incremental costing is the proper approach. Both the technology and the size of the output increment determine which costs are relevant; 4) Royalties are determined in hypothetical negotiations in which both the market power flowing from the patent and the relative bargaining power of the negotiators influence the outcome.

BuSpar's History

- * Original patent issued Feb 20, 1973 was to expire on Feb. 20, 1990
- * Second patent issued Jan 8, 1980 was set to expire Jan. 8, 1997
- * Patent was extended under provisions of the GATT treaty to May 22, 1998
- * Patent was extended again under provisions of the Hatch-Waxman Act to May 22, 2000

* The BSM market exclusivity was then extended under provisions of the Pediatric Studies law to Nov. 22, 2000

* The new Metabolite patent obtained on Nov. 21, 2000, asbsent de-listing, will expire on June 6, 2020

Financial impact of the BuSpar® ordeal on BMS and Mylan

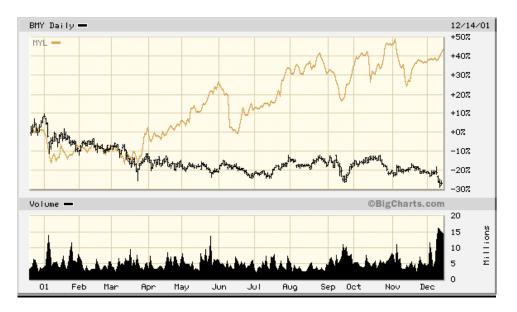
The FDA's March 28, 2001 approval to Mylan to sell its generic version of BuSpar® has certainly had an impact on the sales, profit and stock prices of both BMS and Mylan from the March 28 date up until the present time.

In fact, it is important to remember that BuSpar® had been BMS' most profitable drug in recent years since it offered the company the highest profit margin of all its drug portfolio, yielding almost an 85-90% profit per dollar of sales. BuSpar® indeed generated almost \$200 million dollars in revenue for BMS per quarter, and \$750 million annually as of 2000.

BMS's financial results for the 2nd and 3rd quarters of 2001 in regards to BuSpar® stand in stark contrast to the above mentioned financial figures of the recent past. In fact, during the 2nd quarter of this year, sales of BuSpar® declined to \$89 million from \$194 million during the 3rd quarter of 2000 mostly due to generic competition by Mylan. During the 3rd quarter of this year, sales of BuSpar® declined 84% to \$28 million from \$175 million in the same period of 2000, once again due to generic competition, mostly generated by Mylan.

In contrast to the above results for BMS, Mylan's 2nd and 3rd quarter results for 2001 seems to present a trend opposite to that of BMS. In fact, Mylan's generic net revenues for the 2nd quarter of 2001 were \$209.8 million compared to \$132.5 million for the prior year quarter, a \$77.3 million increase or 58.3 % increase. New products launched subsequent to June 30, 2000 resulted in increased net revenues for the quarter of \$37.6 million, primarily Buspirone, which contributed \$33.7 million. Also, Mylan generic net revenues for the quarter ended September 30, 2001 (3rd quarter) were \$252.8 million compared to \$168.9 million for the prior year quarter, an \$83.9 million or 49.7% increase, mostly due to the sales of Buspirone, whose net revenues for the 3rd quarter 2001 were \$36.8 million.

A close look at the common stock prices of BMS and Mylan over the past year (Jan 2001 to present) also shows the impact that the March 28, 2001 FDA decision has had on the stocks of the two companies considered. In fact, BMS started the year (Jan. 2, 2001) at a per-share value of \$71.50 and has a current per-share price of \$50.00. In contrast, Mylan's share price on January 2, 2001 was \$24.69 while its current share price is \$36.06. The below graph clearly depicts the stock price trend over during 2001 for both BMS and Mylan (where BMY and MYL are the trading symbols for BMS and Mylan, respectively).



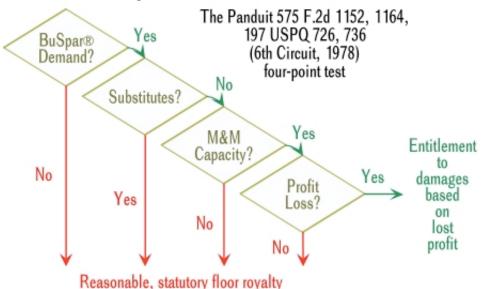
Patent Infringement Damage Calculation 4-Point Test

The 1978 Panduit Corp. vs Stahlin Bros. Fibre Works, Inc. case turned patent infringement damage calculation into all or naught. In fact, according to the Panduit 575 F.2d 1152, 1164, 197 USPQ 726, 736 (6th Circuit, 1978) four-point test, BMS must show the following in order to qualify for entitlement damages based on lost profit:

As opposed to the traditional royalty damages calculations, Panduit introduced two significant breaks from past reasoning: (1) it ruled that the Hypothesis of voluntary negotiations between willing parties was intolerable; and (2) it furthered the Court's reliance on market-based analyses by providing a market-based test with which a patent holder could prove entitlement to lost-profit. The Panduit approach to royalties, therefore, suggests that an analyst should consider patentee and licensee relative bargaining power and profit expectations at the time of the infringement. In addition, the patentee must be made whole regardless of whether or not the infringer earned ex post profits. In other words, the royalties may exceed the maximum amount the infringer may have been willing to pay at the time of the hypothetical negotiation.

In regards to the four-point test mentioned above, the patent owner must demonstrate: (1) demand for the patented product (2) an absence of acceptable non-infringing substitutes (3) the marketing and manufacturing capability to exploit demand (4) the amount of profit it would have been made in absence of the infringement. With this test, damage calculation is an all or nothing issue. If all four points are proven, lost-profit damages may be awarded; If any one of the four points is not proven, damages are limited to a reasonable royalty-the statutory floor.

Figure 2 How the 1978 Panduit Corp. vs Stahlin Bros. Fibre Works, Inc. case turn patent infringement damage calculation into an all or naught decision situation



BMS is entitled to patent infringement damages under Panduit because its satisfies the four-point test. In detail:

(a) <u>BuSpar® Demand</u>

BuSpar® has generated exceptional demand ever since its launch on the market. In fact, as mentioned earlier, BuSpar® indeed generated almost \$200 million dollars in revenue for BMS per quarter, and \$750 million annually as of 2000. Also, BuSpar® has been BMS' most profitable drug in recent years since it offered the company the highest profit margin of all its drug portfolio, yielding almost an 85-90% profit per dollar of sales.

(b) <u>Substitutes</u>

There are no true substitutes for BuSpar®, which is considered the best prescribed antianxiety medication. In fact, other "possible" substitutes, represented by the Benzodiazepines family of anti-anxiety drugs (such as Xanax, Klonopin, and Ativan) carry a significant risk for drug dependence and are prescribed by doctors only for the first two or three weeks of treatment. In contrast, BuSpar® is a nonhabit-forming medication, and is usually safe and effective in relieving both the emotional and physical symptoms of generalized anxiety disorder.

(c) Marketing and Manufacturing (M&M) Capacity

BMS, through its divisions and subsidiaries, is a large producer and distributor of consumer medicines, pharmaceuticals, nutritionals, medical devices & beauty care products. As a large multi-million dollar corporation, with current market capitalization of \$96.7 billion, BMS certainly has all the necessary M&M to support BuSpar®.

(d) Profit Loss

As mentioned earlier, BMS has sustained significant revenue losses due to Mylan's launch of Buspirone, as BMS's financial results for the 2nd and 3rd quarters of 2001 in regards to BuSpar® illustrate. In fact, during the 2nd quarter of this year, sales of BuSpar® declined to \$89 million from \$194 million during the 3rd quarter of 2000 mostly due to generic competition by

Mylan. During the 3rd quarter of this year, sales of BuSpar® declined 84% to \$28 million from \$175 million in the same period of 2000, once again due to generic competition, mostly generated by Mylan.

These revenue losses are certainly reflected in BMS' current and future profits, due to importance of BuSpar® to BMS. In fact, from the below table, one can see the below table that BMS's 2002 estimated earnings growth rate will be practically one-half of that of 2001, with the decline in profits of BuSpar® playing a major role in such earnings estimate.

Earnings Growth Rates	Last 5 yrs.	FY 2001	FY 2002
BMS	10.30%	14.60%	7.50%
Industry	21.90%	15.50%	26.60%
S&P 500	8.40%	-20.40%	14.20%

(e) <u>Reasonable statutory-floor royalty</u>

The general royalty rate in the pharmaceutical industry is 50%

Conclusion

Based on the above points (a) through (d), BMS satisfies all the necessary criteria to be entitled to damages based on lost profit. Bristol has the right to sue Mylan for patent infringement damages for the whole thirty month period of the '365 patent expansion, which covers from March 14 2001 when Mylan's generic Buspirone was launched in the market until May 21 2001 ('365 patent expiration date)

Punitive damages may also apply for Mylan's misuse of its legal rights to sue, however this paper does not address this issue in the damages calculation.

Decision Choices

Due to the recent court ruling in favor of Bristol-Myers Squibb, the company is faced with several possible choices regarding how they should proceed. The following four choices are discussed below:

0 = Stop generic and regain full market power, losing goodwill

Stopping the production of the generic drug is one of the more simple scenarios and, most likely, one of the most profitable options. However, the loss of goodwill could be severely detrimental. In a press release dated December 12, 2001, it was stated that Attorney General Hardy Myers had joined 29 other states and Puerto Rico in suing Bristol-Myers Squibb Company for allegedly making false statements to a federal agency concerning its patent of BuSpar® in order to prevent manufacturers of generic drugs from marketing it. The multi-state lawsuit was filed in the U.S. District Court for the Southern District of New York. Therefore, simply preventing the generic from being produced might be a difficult option to execute under the current circumstances.

1 = Stop generic and sue for damages, including goodwill.

This option, if successful, could be more favorable to Bristol-Myers Squibb. If the company could convince a court that they were correct in suing the maker of the generic drug, it

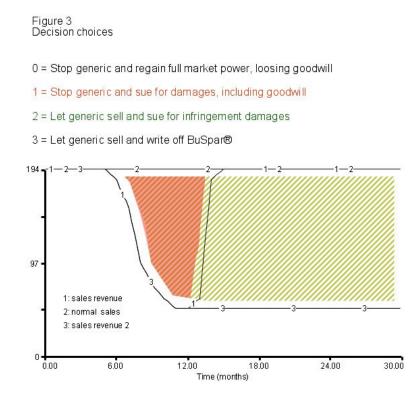
would be highly unlikely that the aforementioned lawsuit would come to fruition. The company would remain the market leader without any damage to its reputation.

2 = Let generic sell and sue for infringement damages

Although this scenario is damaging to Bristol-Myers Squibb's future revenue, there will be minimal loss of goodwill. This choice mainly depends on Bristol's belief that they can prove that the infringement did occur. It also depends on the products that are currently in the pipeline and whether or not they can afford the significant loss of revenue that will be incurred by allowing the generic to sell.

3 = Let generic sell and write off BuSpar

Again, this option will damage future revenue, but will in no way create a loss of goodwill. If the company is most concerned with the overall image they are trying to protect and maintaining its customer base, this may be the most viable option. As stated above, this will depend on the impact the severe loss of revenue will have on the overall outlook for the company and the success rates of the products in the pipeline.



EXPECTED ECONOMIC DAMAGES EXPLAINED

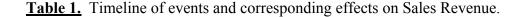
System Dynamics for Damages

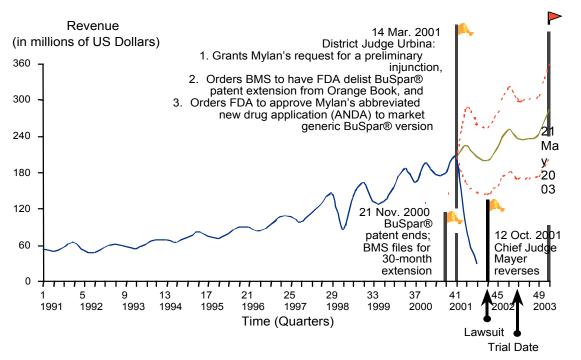
Utilizing System Dynamics specifically for determining economic damages offers an easy way to calculate all the damages necessary. Rather than having to separately calculate every potential damage and then combine them for a total, System Dynamics allows you to create a model that addresses every potential situation and then calculates the damages automatically. With system dynamics you create a model that includes all variables and then graphs the desired results.

Patent Life Remaining

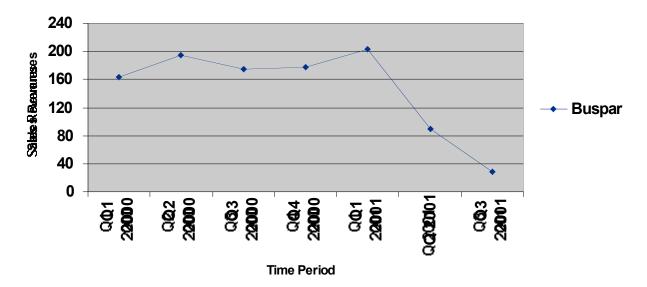
As mentioned in the statement of facts, on November 21, 2000 BMS sued and received a 30-month patent extension for BuSpar® as set forth in the Hatch-Waxman Act. This would have allowed BMS patent exclusivity for selling BuSpar until May 21, 2003. Unfortunately, Judge Urbina decided on March 14, 2001 that BMS de-list its patent for BuSpar®, which would allow the FDA to review generic versions of buspirone. On March 28, 2001 Mylan was approved to sell its generic version of buspirone. BMS then appealed the ruling and Chief Judge Mayer reverses the order of District Judge Urbina, stating that the judge went beyond the scope of his power.

BMS in essence should never have lost the right to sell BuSpar® with patent exclusivity until May 21, 2003. Due to the over zealousness of District judge Urbina, BMS lost patent exclusivity only four months into the 30-month extension. With the October 12 reversal BMS has approximately 19 months left to the original 30-month extension. BMS loses those seven months of patent, even though they were unable to sell their product exclusively because generics entered the marketplace. BMS is now faced with a difficult choice in moving forward.



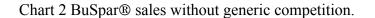


The chart below shows the difference in revenues BMS was generating for BuSpar leading up to the first quarter 2001 and subsequent quarters. Chart 1



As you can clearly see from the chart above BMS suffered dire losses due to the entrance of generic buspirone. In fact, from the period between March 2001 and October 2001, BMS lost an estimated total of \$289MM. This revenue loss is gone and can never be regained.

Let us look at a projected trend over the next thirty months, if Mylan was never allowed to introduce its generic buspirone.



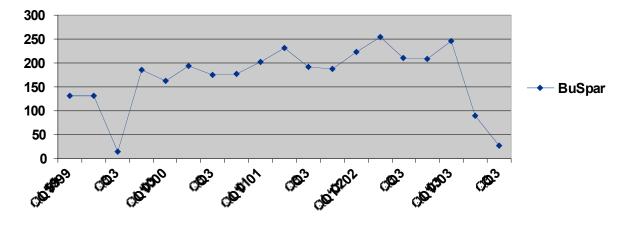


Chart 2 provides an overview of potential sales revenues for BuSpar® following a past trend of an average 10-12% growth annually. Had Mylan not been allowed to produce generic buspirone until May 21, 2003, BMS would have been able to generate an additional \$1.75bn in gross sales revenue.

Moreover, there is no certainty as to when BMS would have lost the actual patent. The 30-month cooling off period occurred because BMS sued Mylan for patent infringement, this 30 months of patent extension is simply for BMS to put together its case. At the end of the thirty months if BMS proves that a further extension of patent is warranted they could be awarded up to an additional 14 years. This is why this has been a very difficult position for BMS.

Infringement Damages

The damages assessed become very difficult to accurately measure. It is very easy to see how much revenue has been lost since Mylan launched its generic (Chart 3). But the tricky part comes into play when you need to figure out how to assess for the patent infringement and future value of sales revenues (Chart 4&5).

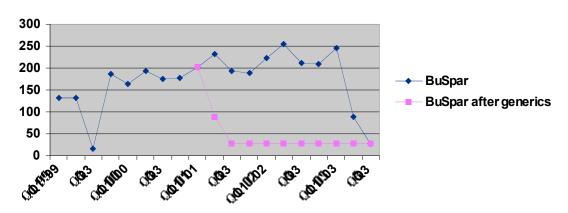


Chart 3. BuSpar® Revenue comparison with and without Generic competition.

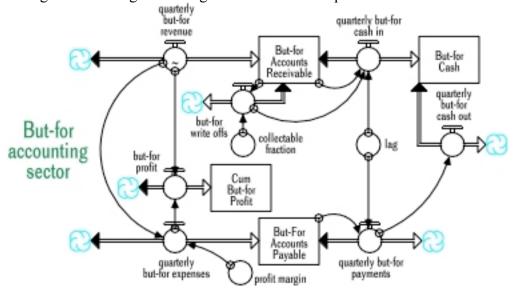
This chart demonstrates the severity of the intrusion of generic buspirone on the market. As the chart clearly shows BuSpar® sales have dropped off by 85% in just under six months.

The net dollar amount of sales revenue lost is \$307MM in first six months, but overall the net revenue loss would be greater than \$1.45bn over the course of the next 24 months. This will cause a significant impact on the bottom line of the entire company.

When you look at charts 4 and 5 you will notice the many categories associated with patent infringement damages. This is where System Dynamics truly proves its value. To calculate the damages we must look at Past Profit loss, Future profit loss, Profit loss if generic stops, Incremental cost, Profit loss, and then we must calculate the future values and present values of all those mentioned variables. It seems challenging, but with system dynamics it becomes manageable.

(See next page for chart 4 and the next page for chart 5).

Chart 4. Infringement Damages with regards to Generic Buspirone



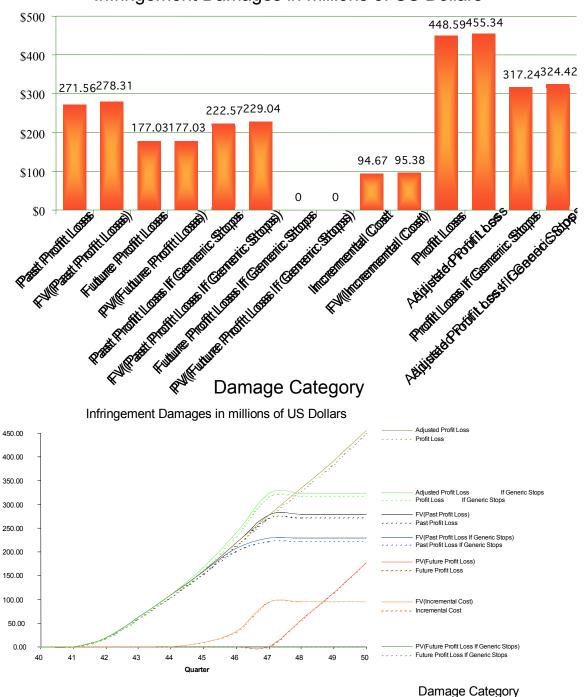


Chart 5. Dollar value Bar chart of Infringement Damages Infringement Damages in millions of US Dollars

Total Damages

Total Damages are determined by assessing the real damages, the actual loss of sales revenue due to generic competition, and another variable determined by the company's course of action. BMS has basically four choices to make and they are outlined in the following.

I. Stop generic and regain full market power, loosing goodwill.

As explained earlier, BMS would request removal of the generic products from the shelf and they would then replace the shelves with the branded BuSpar® product. This poses a slight problem: What damages does the company sue for?

First, the firm has to account for the incremental cost it will incur to get operations up to full speed to regain market power. This is best illustrated in Graph # 9 from the model. The graph shows the calculations over a period of quarters that it would take to get back to full market power. Total incremental cost to regain full market power is \$95MM. Incremental cost is only one portion of the equation; we must also look at lost revenues throughout the entire period.

This is best explained by Graph # 10 in the Systems Dynamic model. You will notice the chart demonstrates the sales revenue generated prior to generics, then shows the rapid decline of revenue after generics. What is most important is the return curve upward; this illustrates the period of time it will take to get BuSpar® back to full manufacturing capacity. This chart forms a teacup illustration; this teacup represents all damages the firm would be eligible to receive. This graph approximates the damages at \$1.5bn, for revenues lost during the period generics were on the market.

II. Stop generic and sue for damages, including goodwill.

This option presents the greatest challenge to BMS. Stopping generics and suing for damages, including goodwill but not replacing BuSpar® to market, could severely tarnish the credibility of the firm. As it stands there are no safe alternatives to BuSpar® on the market and if the firm pulls generic without replacing BuSpar® the consumer will have to do without the benefits the product provides.

BMS would then sue to acquire real sales loss and future sales loss. Best illustrated by Graphs 1,5&6. BMS would have to calculate actual revenue lost, future revenue lost, past and future profit lost.

III. Let generic sell and sue for infringement damages.

This represents one of BMS greatest alternatives. This option allows them to keep the goodwill of its customers in tact, by allowing generics to remain on the market, but also provides them an avenue to regain its corporate stature, by suing Mylan for infringement damages.

The course of action BMS would take here is best illustrated by Graph # 5 & 6. Graph 5 calculates past profit loss, the future value of past profit loss and the change in future value of past profit loss. In other words, even though the firm has lost sales in the past and presently, that loss affects future earnings for BMS. You not only account for those real revenue losses, but what each dollar would have been worth in the future.

Secondly, the company must account for future profit loss, as described by Graph # 6. Here the graph accounts for Future Profit loss, the present value of that future profit loss and the change in present value of the future profit loss. Again, you not only need to account for the real losses but also the impact of those losses both in the present and the future. For every dollar BMS losses today it has a greater loss tomorrow and conversely, for every dollar they lose next year it has a significant impact on the firm today. According to the calculations the PV of future profit loss will equal \$177MM.

The last part of this calculation would be the addition of a licensing agreement. In essence when Mylan sued for the right to sell generics they infringed upon the patent that BMS held for BuSpar®. When the Federal appeals court overturned it, Mylan had involuntarily entered into a licensing agreement with BMS. The licensing agreement would most likely be a profit sharing agreement. BMS would take 50% of the profits generated by Mylan for the 26 months it sold generic buspirone in the period of patent infringement. This would then be added to the adjusted profit loss of \$455.34MM.

IV. Let generic sell and write off BuSpar®

This option is self-explanatory, BMS would just write off the product looking forward for new opportunities for investment. In an effort to repair any damage suffered to the reputation and goodwill of the firm, BMS would choose to not sue either. They in essence recoup zero dollars in damages.

Conclusion

Taking all things into consideration it appears BMS has only one course of action, to let generics remain on the market and sue them for patent infringement. Any other option would place BMS' reputation at risk. From the data it is easy to see that the possibility of gaining full market power in the remaining time left on patent would be more costly than profitable, both monetarily and professionally. By leaving generics on the market BMS can retain its reputation and avoid certain public pitfalls, but at the same time allow them to recoup losses suffered by suing Mylan.

¹ Rapp, Richard T., Patent Damages: Updated Rules on the road to Economic Rationality, Patent Litigation 1999.

Appendix: The Math

Adjusted losses adjusted profit loss = FV of Past Profit Loss + PV_of_Future_Profit_Loss adjusted profit loss with stay = FV Past Profit Loss with Stay + PV Future Profit Loss with Stay + FV Incremental Cost profit loss without stay = Past Profit Loss + Future Profit Loss profit loss with stay = Past Profit Loss with Stay + Future Profit Loss with Stay + Incremental Cost Loss With Stay Sector Future Profit Loss with $Stay(t) = Future Profit Loss with <math>Stay(t - dt) + (future profit loss w stay \setminus q) * dt$ INIT Future Profit Loss with Stay = future profit loss w stay \setminus q **INFLOWS:** future profit loss w stay $\setminus q = IF (TIME > trial date)$ THEN (net profit margin * revenue loss w stay \setminus q) ELSE(0)FV Past Profit Loss with Stay(t) = FV Past Profit Loss with $Stay(t - dt) + (fv past profit loss w stay \setminus q)^*$ dt INIT FV Past Profit Loss with Stay = fv past profit loss w stay $\setminus q$ **INFLOWS:** fv past profit loss w stay $\langle q = MAX(0, past profit loss w stay \rangle q * (1 + real quarterly prime)^(trial date -$ TIME)) FV Incremental Cost(t) = FV Incremental Cost(t - dt) + (change in FV of incremental cost) * dtINIT FV Incremental Cost = change in FV of incremental cost **INFLOWS:** change in FV of incremental $cost = MAX(0, quarterly incremental cost * (1 + real quarterly prime)^{}$ (trial date - TIME)) Incremental Cost(t) = Incremental Cost(t - dt) + (quarterly incremental cost) * dtINIT Incremental Cost = quarterly incremental cost **INFLOWS:** quarterly incremental cost = IF (TIME \geq 44) AND (TIME \leq 47) THEN (incremental cost margin * revenue w stay $\langle q \rangle$ ELSE(0)Past Profit Loss with Stay(t) = Past Profit Loss with $Stay(t - dt) + (past profit loss w stay \setminus q) * dt$ INIT Past Profit Loss with Stay = past profit loss w stay $\setminus q$ **INFLOWS:** past profit loss w stay \setminus q = IF (TIME <= trial date) THEN (net profit margin * revenue loss w stay \setminus q) ELSE(0)PV Future Profit Loss with Stay(t) = PV Future Profit Loss with Stay(t - dt) +(change in PV of future profit loss with stay) * dt INIT PV Future Profit Loss with Stay = change in PV of future profit loss with stay **INFLOWS:** change in PV of future profit loss with stay = MAX(0, future profit loss w stay $\langle q * (1 / (1 +$ real quarterly discount) ^ (TIME - trial date))) Revenue Loss with $Stay(t) = Revenue Loss with <math>Stay(t - dt) + (revenue loss w stay \setminus q) * dt$ INIT Revenue Loss with Stay = revenue loss w stay \setminus q **INFLOWS:** revenue loss w stay $\langle q = max(0, revenue forecast absent infingement - revenue w stay <math>\langle q \rangle$ incremental cost margin = NORMAL(0.3848, 0.0127, 321) revenue forecast absent infingement = GRAPH(TIME) (1.00, 52.5), (2.00, 48.9), (3.00, 55.8), (4.00, 62.8), (5.00, 50.8), (6.00, 47.3), (7.00, 54.0), (8.00, 60.8), (9.00, 57.2),(10.0, 53.3), (11.0, 60.9), (12.0, 68.5), (13.0, 67.5), (14.0, 62.9), (15.0, 71.8), (16.0, 80.8), (17.0, 74.4), (18.0, 69.3), (19.0, 79.1), (20.0, 89.1), (21.0, 88.2), (22.0, 82.2), (23.0, 93.8), (24.0, 106), (25.0, 106), (26.0, 98.4), (27.0, 112), (28.0, 127), (29.0, 145), (30.0, 84.0), (31.0, 138), (32.0, 164), (33.0, 132), (34.0, 132), (35.0, 155), (36.0, 186),

(37.0, 163), (38.0, 194), (39.0, 175), (40.0, 177), (41.0, 203), (42.0, 224), (43.0, 204), (44.0, 200), (45.0, 220), (46.0, 250), (47.0, 234), (48.0, 236), (49.0, 241), (50.0, 283) revenue w stay \setminus q = GRAPH(TIME) (1.00, 52.5), (2.00, 48.9), (3.00, 55.8), (4.00, 62.8), (5.00, 50.8), (6.00, 47.3), (7.00, 54.0), (8.00, 60.8), (9.00, 57.2), (10.0, 53.3), (11.0, 60.9), (12.0, 68.5), (13.0, 67.5), (14.0, 62.9), (15.0, 71.8), (16.0, 80.8), (17.0, 74.4), (18.0, 69.3), (19.0, 79.1), (20.0, 89.1), (21.0, 88.2), (22.0, 82.2), (23.0, 93.8), (24.0, 106), (25.0, 106), (26.0, 98.4), (27.0, 112), (28.0, 127), (29.0, 145), (30.0, 84.0), (31.0, 138), (32.0, 164), (33.0, 132), (34.0, 132), (35.0, 155), (36.0, 186), (37.0, 163), (38.0, 194), (39.0, 175), (40.0, 177), (41.0, 203), (42.0, 89.0), (43.0, 28.0), (44.0, 20.0), (45.0, 28.0), (46.0, 89.0), (47.0, 234), (48.0, 236), (49.0, 241), (50.0, 283) Loss without stay sector Future Profit Loss(t) = Future Profit Loss(t - dt) + (quarterly future profit loss) * dt INIT Future Profit Loss = quarterly_future_profit_loss **INFLOWS:** quarterly future profit loss = IF (TIME > trial date) THEN (net profit margin * quarterly revenue loss) ELSE(0)FV of Past Profit Loss(t) = FV of Past Profit Loss(t - dt) + (change in FV of past profit loss) * dt INIT FV of Past Profit Loss = change in FV of past profit loss **INFLOWS:** change in FV of past profit loss = MAX(0, quarterly past profit loss * (1 + real quarterly prime) ^ (trial date -TIME)) Past Profit Loss(t) = Past Profit Loss(t - dt) + (quarterly past profit loss) * dt INIT Past Profit Loss = quarterly_past_profit_loss **INFLOWS:** quarterly past profit loss = IF (TIME <= trial date) THEN (net profit margin * quarterly revenue loss) ELSE(0)PV of Future Profit Loss(t) = PV of Future Profit Loss(t - dt) + (change in PV of future profit loss) * dt INIT PV of Future Profit Loss = change in PV of future profit loss **INFLOWS:** change in PV of future profit loss = MAX(0, quarterly future profit loss * $(1/(1 + real quarterly discount)^{1})$ (TIME - trial date))) Revenue Loss(t) = Revenue Loss(t - dt) + (quarterly revenue loss) * dtINIT Revenue Loss = quarterly revenue loss **INFLOWS:** quarterly revenue loss = max(0, revenue forecast absent infingement - actual quarterly revenue)net profit margin = NORMAL(0.2632, 0.0159, 123)trial date = 47actual quarterly revenue = GRAPH(TIME) (1.00, 52.5), (2.00, 48.9), (3.00, 55.8), (4.00, 62.8), (5.00, 50.8), (6.00, 47.3), (7.00, 54.0), (8.00, 60.8), (9.00, 57.2),(10.0, 53.3), (11.0, 60.9), (12.0, 68.5), (13.0, 67.5), (14.0, 62.9), (15.0, 71.8), (16.0, 80.8), (17.0, 74.4), (18.0, 69.3), (16.0, 80.8), (17.0, 74.4), (18.0, 69.3), (17.0, 74.4), (18.0, 69.3), (17.0, 74.4), (18.0, 69.3), (17.0, 74.4), (18.0, 69.3), (17.0, 74.4), (18.0, 69.3), (17.0, 74.4), (18.0, 69.3),(19.0, 79.1), (20.0, 89.1), (21.0, 88.2), (22.0, 82.2), (23.0, 93.8), (24.0, 106), (25.0, 106), (26.0, 98.4), (27.0, 112), (28.0, 127), (29.0, 145), (30.0, 84.0), (31.0, 138), (32.0, 164), (33.0, 132), (34.0, 132), (35.0, 155), (36.0, 186), (37.0, 163), (38.0, 194), (39.0, 175), (40.0, 177), (41.0, 203), (42.0, 89.0), (43.0, 28.0), (44.0, 20.0)Rates sector quarterly discount = annual discount / quarters per year quarterly inflation = annual inflation / quarters per year quarterly prime = annual prime / quarters per year quarters per year = 4real quarterly discount = MAX(0, (quarterly discount - quarterly inflation) / (1 + quarterly inflation))real quarterly prime = MAX(0, (quarterly prime - quarterly inflation)) / (1 + quarterly inflation))annual discount = GRAPH(TIME)(40.0, 0.06), (41.0, 0.0511), (42.0, 0.0383), (43.0, 0.0306), (44.0, 0.0247), (45.0, 0.0235), (46.0, 0.0229), (47.0, 0.0227), (48.0, 0.022), (49.0, 0.0223), (50.0, 0.0223) annual inflation = GRAPH(TIME)

(40.0, 0.0315), (41.0, 0.0266), (42.0, 0.0266), (43.0, 0.0266), (44.0, 0.0266), (45.0, 0.0263), (46.0, 0.0263), (47.0, 0.0263), (48.0, 0.0263), (49.0, 0.0262), (50.0, 0.0262) annual_prime = GRAPH(TIME) (40.0, 0.095), (41.0, 0.0862), (42.0, 0.0734), (43.0, 0.0657), (44.0, 0.0598), (45.0, 0.0602), (46.0, 0.0624), (47.0, 0.0636), (48.0, 0.0652), (49.0, 0.0648), (50.0, 0.0649)

¹ Rapp, Richard T., Patent Damages: Updated Rules on the road to Economic Rationality, Patent Litigation 1999.