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Hearing on H.R. 1706, the *Protecting Consumer Access to
Generic Drugs Act of 2009*

Before the U.S. House of Representatives Subcommittee on Commerce, Trade
and Consumer Protection, of the Committee on Energy and Commerce

March 31, 2009

Chairman Rush, Ranking Member Radanovich, and Members of the Subcommittee:

Good morning. My name is Diane Bieri and I am the Executive Vice President and General Counsel of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA's member companies are leading research-based pharmaceutical and biotechnology companies that are devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. In 2008, PhRMA's member companies invested an estimated \$50.3 billion in research and development – an increase of over \$2 billion from 2007 – and were developing or seeking regulatory approval for 2,900 molecules that might eventually be used to treat U.S. patients. PhRMA companies are leading the way in the search for new and better treatments for patients. PhRMA appreciates the invitation to participate in today's hearing on H.R. 1706 and biopharmaceutical companies' settlements of patent disputes.

The biopharmaceutical companies that constitute PhRMA's membership range in size from small start-up research firms to multi-national, multi-billion dollar corporations, and encompass both research-based pharmaceutical and biotechnology companies. Regardless of their size, these companies face significant challenges relating to the discovery, development, testing, production, and commercialization of new medical treatments. Yet, data show that the drive for innovation remains strong, and the sector's R&D focus provides considerable value to the U.S. economy. At a time when many industries are seeking help just to stay afloat, pharmaceutical research companies are expending the vast majority of their R&D investment within America. In fact, PhRMA member companies dedicated roughly 70 percent of their \$50.3 billion R&D investment domestically last year.

In order to continue to foster this economic growth and the much-needed medical breakthroughs that will save lives and lower overall health care costs, we must continue to pursue public policies that promote innovation, and that requires the protection of legitimate patent rights. Patents allow biopharmaceutical companies and their investors an opportunity to recoup and secure the benefits of their significant investments. Two years ago, PhRMA President and CEO – and cancer survivor – Billy Tauzin submitted testimony to this Subcommittee about the critical role of patents in stimulating pharmaceutical innovation and the importance of preserving options to reach pro-consumer settlements of expensive and time-consuming patent litigation among brand and generic pharmaceutical companies. These points still hold true today, and PhRMA remains confident that a case-by-case approach to analyzing patent settlements serves the best interests of patients, health care, and competition.

Courts and experts have stated unequivocally and in increasing numbers that settlement of litigation – including patent litigation – should be encouraged and

can benefit consumers. Blanket prohibitions on certain types of settlements could force both sides to spend valuable resources that could be used for investing in innovation or bringing generics to market rather than litigating their patent disputes to judgment. Statistics show that innovators will win a significant number of those cases. In fact, innovator companies have prevailed in approximately 53 percent of the cases in which appeals were decided between 2004 and 2008. And a win by the patent holder means the generic almost certainly would not be able to enter the market before the patent expires unless it obtained permission from the patent holder. In addition, both innovator and generic companies would have to absorb – or pass on to consumers – the costs of increased litigation. In the face of these alternatives, it is better for companies, the courts and consumers if the parties are permitted to negotiate settlements that could bring the generic product to consumers before the patent expires and save considerable litigation costs.

H.R. 1706 envisions a per se ban on nearly all settlements in which the brand company gives something of value to the generic. This could stop pro-consumer settlements, reduce the value of patents, and reduce incentives for innovation. The sweeping prohibition could also have the unintended consequence of reducing generic companies' incentives to challenge patents in the first place, as they will have to consider that their options of settling patent litigation will be dramatically reduced.

Instead of an across-the-board ban, enforcement agencies and courts should continue to evaluate patent settlements on a case-by-case basis, looking at all relevant facts including the scope of the patent. In the Medicare Prescription Drug, Improvement, and Modernization Act, Congress expanded the ability of the Federal Trade Commission and the Department of Justice to evaluate patent settlement agreements between brand and generic companies before the generic is due to come on the market. This approach gives the agencies and courts the chance to consider all the relevant facts and circumstances and address settlements that would harm consumers without eliminating those that will promote competition.

I. Patents Are Essential To Pharmaceutical Innovation

Intellectual property protection has deep roots in the United States, all the way back to the protection authorized by Article I of the U.S. Constitution. Patents are crucial because they make it possible for society to realize the benefits of genius, creativity and effort. Since our patent system was created in 1790, it has been key to critical advances in science and technology. Of all of the advances in the last century, from aviation to the Internet, few have been as important and valuable to the preservation and enhancement of life as pharmaceutical innovations. According to University of Chicago economists, "Over the last half century, improvements in health have been as valuable as all other sources of

economic growth combined.”¹ New medicines have contributed to significant breakthroughs in the treatment of diseases such as cancer, HIV/AIDS and cardiovascular disease that formerly led often to death or significant disability.²

Innovators across industries rely on patents to ensure that their inventions are protected and that they will be given an opportunity to recover their research investments. For reasons explained in more detail below, patents are particularly important to the biopharmaceutical industry as compared to other industries. According to one commentator, without patent protection, an estimated 65 percent of pharmaceutical products would not have been brought to market, while the average across all other industries was 8 percent.³ Indeed, it is well-established that patents are significantly more important to pharmaceutical firms than for firms in other sectors in part due to the very high costs of development.⁴

Today, the United States is the clear global leader in biopharmaceutical investment, jobs, and product development, offering opportunities for high-quality and robust economic growth. However, the industry faces increasing challenges that reinforce the importance of robust patent protection to biopharmaceutical companies. In 2008, there were more than 2,900 molecules in development or awaiting approval for use by U.S. patients.⁵ Development of new medicines is a long and high-risk process, and it has become more costly and complex over the last decade. Without strong patent protection, biopharmaceutical companies, including many smaller companies, could neither make nor attract the significant investments that are needed to develop these new medicines.

Between 1960 and 2007, the average development time for new medicines increased from approximately eight years to between 10 and 15 years.⁶ At the same time, costs to bring new discoveries from laboratory to bedside have also increased. A recent study from the Tufts University Center for the Study of Drug Development estimates the average cost of developing a new medicine at \$1.3

¹ Kenin Murphy, Ph.D., and Robert Topel, Ph.D., *Measuring the Gains from Medical Research: An Economic Approach* (Chicago: The University of Chicago Press, 2003).

² See, e.g., American Society of Clinical Oncology, *Clinical Cancer Advances 2008: Major Research Advances in Cancer Treatment, Prevention and Screening*, *Journal of Clinical Oncology*, 22 December 2008 (9 advances relating to new medicines, better ways of using existing medicines, or newly discovered benefits of approved medicines are among 12 major advances in treatment of cancer in 2008 which “significantly altered the way cancer is understood or had an important impact on patient care”); Center for Disease Control and Prevention, National Center for Health Statistics, *Health, United States, 2008 with Chartbook*, Table 41, (Hyattsville, MD: 2009) (since the approval of highly active anti-retroviral treatments in 1995, annual number of AIDS deaths has dropped by over 70 percent); DM Cutler, G Long, ER Berndt, et al., *The Value of Antihypertensive Drugs: A Perspective on Medical Innovation*, *Health Affairs*, 26 (2007): 97-110 (use of antihypertensive medicines prevented 86,000 premature deaths from cardiovascular disease in 2001, and 833,000 hospitalizations for heart attack and stroke in 2002).

³ Edwin Mansfield, *Patents and Innovation: An Empirical Study*, *Management Science* (February 1986) at 173-181.

⁴ Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 *JOURNAL OF INT’L ECONOMIC LAW* 849-60 (2002).

⁵ PhRMA, *Profile 2008* (2008), available at <http://www.phrma.org/files/2008%20Profile.pdf>.

⁶ *Id.*; Joseph A. DiMasi, *New Drug Development in the U.S. 1963-1999*, 69 *Clinical Pharmacology & Therapeutics* 286, 292 (2001).

billion (in 2005 dollars), including the cost of failures and capital. The same study estimates the cost to develop a biologic (a large molecule treatment produced by a biological system) at \$1.2 billion (in 2005 dollars).⁷ These staggering figures include the cost of the thousands of once-promising but ultimately failed initiatives—products that never made it to market. For every 5,000-10,000 compounds that enter the R&D pipeline, only 250 reach the pre-clinical stage. Of those compounds, only five progress to clinical study in humans, and ultimately only one receives regulatory approval.^{8/} Figure 1 illustrates this challenging path.

Figure 1. The Research and Development Process

Further, for those drugs or biologics that do reach human clinical trials, those trials have become more complex and more costly to perform. Today, clinical trials are longer, have more participants (who are difficult to recruit and retain), and involve more demanding and complex trial design and clinical protocols (including more procedures per patient and difficult-to-measure clinical endpoints). In addition, there is an increasing challenge of developing new therapies for complex diseases and more testing against comparator drugs.⁹ In light of these complexities, it may not be surprising that only two in 10 approved medicines bring in enough revenue to recoup the average cost of development.¹⁰ These dynamics reinforce the importance of strong intellectual property protection and appropriate incentives to ensuring a vital, innovative biopharmaceutical sector.

In addition, the regulatory environment for biopharmaceutical products has grown increasingly complex over the past decade, with significant new requirements introduced as recently as two years ago. For example, enhanced post-market surveillance requirements and the creation of Risk Evaluation and Mitigation Strategies enacted as part of the Food and Drug Administration Amendments Act of 2007 increase required investments associated with many marketed products.¹¹ These increased investments, while appropriate to promote regulatory compliance, also enhance the importance of patent protection to provide an opportunity to recoup increased costs for marketed drug products.

⁷ 5J. A. DiMasi, and H. G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?" *Managerial and Decision Economics* 28 (2007): 469–479.

⁸ PhRMA, *Drug Discovery and Development: Understanding the R&D Process* (2007), available at http://www.innovation.org/drug_discovery/objects/pdf/RD_Brochure.pdf.

⁹ Tufts University Center for the Study of Drug Development, *Growing Protocol Design Complexity Stresses Investigators, Volunteers*, Tufts Impact Report (Jan./Feb. 2008), available at http://csdd.tufts.edu/_documents/www/Doc_309_65_893.pdf.

¹⁰ John Vernon, Joseph Golec & Joseph DiMasi, *Drug Development Costs When Financial Risk Is Measured Using the FAMA-French Three Factor Model* (Jan. 2008) (submitted to the *Journal of Health Economics*).

¹¹ See generally Pub. L. No. 110-85.

II. Congress Has Attempted To Strike a Balance Between Policies That Foster Innovation and Those That Promote the Availability of Generic Pharmaceuticals

Patents are given due respect in the law. By Congressional enactment, an issued patent is afforded the presumption of validity.¹² In the antitrust context, courts have held that the antitrust laws should be interpreted not to supplant legitimate patent rights.¹³ Indeed, courts recognize that antitrust and intellectual property are “two bodies of law [that] are actually complementary, as both are aimed at encouraging innovation, industry, and competition.”¹⁴ Consistent with the antitrust laws, a patent holder may exclude others from producing a patented article, or may grant limited licenses.¹⁵ Generally, antitrust laws are implicated only when a restriction on use goes “outside the scope of the patent grant.”¹⁶

Even as we discuss the critical role of patents in pharmaceutical innovation, it is important to recognize that pharmaceutical products in effect receive a shorter period of useful patent term than other types of products. The basic patent term in the U.S. is 20 years from the date the patent application is filed. Innovators in other industries -- who don't have to wait for regulatory approval before going to market -- can benefit from the patent as soon as it is granted.

By comparison, pharmaceutical companies are required to obtain FDA approval before they can market their products. The R&D process takes an average of 10 to 15 years and involves many discrete steps and activities, including early discovery, to pre-clinical work, to clinical trials, to FDA review, and finally, to FDA approval.¹⁷ Even if we assume that a pharmaceutical company is in a position to file for a patent within the first few years of that process and that a patent issues about two and half years later, the additional time consumed by the FDA approval process means that the time the medicine is actually on the market before the patent expires will be less than the effective patent life of other products.

Congress has taken some steps to address this dilemma. The Drug Price Competition and Patent Term Restoration Act of 1984 (better known as “the Hatch-Waxman Act”)¹⁸ was designed to balance the interests of innovative and

¹² 35 U.S.C. § 282.

¹³ See *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964) (“[T]he patent laws . . . are in *pari materia* with the antitrust laws and modify them *pro tanto*.”).

¹⁴ *Atari Games Corp. v. Nintendo, Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990).

¹⁵ See, e.g., *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 456 (1940).

¹⁶ *Monsanto v. McFarland*, 302 F.3d 1291, 1298 (Fed. Cir. 2002); see also *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) (“The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent.”).

¹⁷ J. A. DiMasi, “New Drug Development in U.S. 1963–1999,” *Clinical Pharmacology & Therapeutics* 69, no. 5 (2001): 286–296; M. Dickson and J. P. Gagnon, “Key Factors in the Rising Cost of New Drug Discovery and Development,” *Nature Reviews Drug Discovery* 3 (May 2004): 417–429; and J. A. DiMasi, R. W. Hansen, and H. G. Grabowski, “The Price of Innovation: New Estimates of Drug Development Costs,” *Journal of Health Economics* 22 (2003): 151–185.

¹⁸ Pub. L. No. 98-417, 98 Stat. 1585 (1984), 21 U.S.C. 355, 35 U.S.C. 156, and 35 U.S.C. 271.

generic companies and granted innovator products market exclusivity for limited periods and restored some of their effective patent time lost during the clinical research and FDA regulatory review of the product. However, commentators examining the evolution of the pharmaceutical market post Hatch-Waxman have found the market exclusivity period (defined as the time from innovator approval to first generic entry into the market) for new molecular entities was in the range of 12 to 15 years, with products with larger sales at the time of first generic entry having lower average market exclusivity periods.¹⁹ For medicines with annual sales of more than \$100 million (which account for 90 percent of the sales of medicines exposed to generic competition) whose generic competitors entered the market in 2005, the average time on the market before generic competition was 11.5 years.²⁰ These market exclusivity periods “represent relatively short product life cycle return periods for products that typically take more than a decade to develop and whose sales revenues are critical to the returns to R&D for the overall portfolio of new drug introductions.”²¹

It is important to remember that, while a patentee holds an exclusive right to manufacture, distribute and sell the patented invention for a period of time, patents do not provide immunity from competition. As the Supreme Court recently held, citing to the actions of Congress and the antitrust enforcement agencies, a patent does not translate into presumed market, let alone monopoly, power in a relevant economic market.²² Pharmaceutical manufacturers always are free to – and often do – research and bring to market different innovative medicines to treat the same disease, and increasingly, there is strong competition between different patented products within the same therapeutic class. A recent study by the Tufts Center for the Study of Drug Development showed that the amount of time between the entry of the first and second drug in a class has fallen by about 78 percent since 1970.²³ In fact, the average length of time before a first-in-class drug faces its first direct competitor has dropped from 8.2 years in the 1970s to 1.8 years in 1995.²⁴

And of course, there is increasing and earlier competition among brand companies and generic companies as well. The same Hatch-Waxman Act that restores some of the patent life for innovative medicines also provides mechanisms to speed the development and approval of generic copies of those medicines. The law created the Abbreviated New Drug Application (ANDA), under which a generic product needs only to be shown to be “bioequivalent” to an innovator drug and can be approved without any additional research once the

¹⁹ Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 *Managerial and Decision Economics* 491-501 (2007).

²⁰ *Id.*

²¹ *Id.* at 497.

²² *Illinois Tool Works, Inc. v. Independent Ink., Inc.* 547 U.S. 28, 45-46 (2006) (“Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee. Today, we reach the same conclusion”).

²³ DiMasi JA, Paquette C. The Economics of Follow-On Drug Research and Development: Trends in Entry Rates and the Timing of Development, *Pharmacoeconomics* 2004, 22, suppl. 2, 1-13.

²⁴ *Op. Cit.*

innovator's patent and exclusivity periods have expired.²⁵ In addition, the Hatch-Waxman Act created a unique exception to patent law by allowing generic manufacturers to use innovator medicines still under patent to obtain bioequivalency data for their FDA applications (a use that otherwise was considered patent infringement).²⁶ This allows the generic company to forego the burden and expense of performing its own studies on safety or efficacy and puts it in a position to be ready to market its copies as soon as the innovator patents expire. The generic company may even seek approval to market a generic version of a drug prior to the expiration date of the innovator's patents, provided it certifies that the patents are invalid or will not be infringed by the manufacture, use, or sale of the generic drug.²⁷ This certification, known as a Paragraph IV certification, may be filed as early as four years after FDA approval of the brand product.

The Hatch-Waxman Act stimulated the development of a robust generic pharmaceutical industry in the U.S. Since the law's passage, the generic industry share of the prescription drug market has jumped from less than 20 percent to 71 percent today²⁸, up from about 60 percent when we testified before the Subcommittee just two years ago.²⁹ Before the 1984 law, it took three to five years for a generic copy to enter the market after the expiration of an innovator's patent. Today, generic copies often come to market almost as soon as the patent on the innovator product expires.³⁰ Prior to Hatch-Waxman, only 35 percent of top-selling innovator medicines had generic competition after their patents expired.³¹ Today, many more innovator medicines face such competition.³² In addition, there are increasing examples of generic companies challenging innovator patents before patent expiration. According to one commentator, "[m]ost ... patent challenges [brought by generic companies against the innovator's patents] now occur four years after market approval which is the earliest point in time that a generic firm can submit an ANDA filing with a [P]aragraph IV certification."³³ And when a generic version of a medicine becomes available for the first time, it can capture as much as 86 to 97 percent of the market within the first month.³⁴ This dramatic and rapid impact on brand

²⁵ 21 U.S.C. 355(j).

²⁶ 35 U.S.C. 271(e)(1).

²⁷ 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

²⁸ IMS Health, National Prescription Audit, Dec 2008

²⁹ Prepared Statement of Billy Tauzin, President and Chief Executive Officer, PhRMA, Regarding H.R. 1902, before this Subcommittee on May 2, 2007 (citing Generic Pharmaceutical Association, "Statistics", available at [http://www.gphaonline.org/Content/Navigation Menu/About Generics/Statistics.default.htm](http://www.gphaonline.org/Content/Navigation%20Menu/About%20Generics/Statistics.default.htm) (accessed January 15, 2007)).

³⁰ Congressional Budget Office. *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (Washington, D.C., July 1988) ("1998 CBO Report").

³¹ 1998 CBO Report (citing Henry Grabowski and John Vernon, Longer Patents for Lower Imitation Barriers: The 1984 Drug Act, *American Economic Review*, vol. 76, no. 2, pp.195-98 (May 1986)).

³² *Id.*

³³ Henry G. Grabowski, *Data Exclusivity for New Biological Entities*, Duke University Department of Economics working paper (Jun. 2007) at 28, available at <http://www.econ.duke.edu/Papers/PDF/DataExclusivityWorkingPaper.pdf>.

³⁴ Medco, 2008 Drug Trend Report (2008) at 9, available at <http://medco.mediaroom.com/file.php/162/2008+DRUG+TREND+REPORT.pdf>

market share increases the risk and uncertainty involved in innovative drug development.

III. Public Policy Favors Settlements of Expensive, Burdensome Patent Litigation

In this climate of increasing costs associated with discovering and bringing new innovative medicines to market, juxtaposed with growing brand-to-brand and generic-to-brand competition, research-based pharmaceutical companies obviously have strong incentives to defend their patents against potential infringers. Generic companies also have strong incentives to challenge the innovators' patents, particularly because the Hatch-Waxman statutory scheme permits them to mount such challenges without first bringing their product to market. Therefore, it should come as no surprise that patent litigation among brand and generic pharmaceutical companies is both common and costly.

Numerous courts have recognized that "public policy wisely encourages settlements."³⁵ Courts and experts likewise have stated unequivocally that settlement of patent litigation can benefit consumers. As the Eleventh Circuit has stated there is "no question that settlements provide a number of private and social benefits" when compared to the costs of litigation.³⁶ The Court of Appeals for the Federal Circuit agrees that "[t]here is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation."³⁷ And leading antitrust expert Herbert Hovenkamp explains that the general principle encouraging settlements is so strong that some agreements that would be unlawful outside of the litigation context may be lawful when used to settle a bona fide patent dispute.³⁸ In the words of the Federal Circuit, "[a] settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled – a monopoly over the manufacture and distribution of the patented invention."³⁹

It is basically a truism that patent litigation is complex, lengthy and extremely expensive for all concerned. U.S. patent litigation overall was estimated 10 years ago to cost about \$1 billion annually.⁴⁰ Another study found that the median expense for patent litigation with more than \$25 million dollars at risk is \$5 million.⁴¹ The costs of patent litigation in the pharmaceutical industry likewise are significant. And it is not uncommon for a patent dispute to last several years.⁴² Settlements allow both litigants and the court system to conserve resources that

³⁵ *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994).

³⁶ *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056, 1072 (11th Cir. 2005).

³⁷ *In re Ciprofloxacin*, 544 F.3d at 1333.

³⁸ Settlements Resolving Intellectual Property Disputes, 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2046, at 265-66 (1999).

³⁹ *In re Ciprofloxacin*, 544 F.3d at 1337.

⁴⁰ Steven C. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 Yale J. Reg. 359, 380 (1999).

⁴¹ Am. Intellectual Prop. Law Ass'n, Report of the Economic Survey 2007, at 26 (2007).

⁴² Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration," July 2002, at iii ("On average, the time between the filing of a patent infringement lawsuit and a court of appeals decision in the case was 37 months and 20 days.").

can then be put to more efficient use, including, in the case of the innovator companies, further investment in developing new treatments.

Aside from these direct costs of patent litigation, the uncertainty surrounding an ongoing patent dispute can stall a company's business activities indefinitely. Particularly at early stages of a case, litigants face uncertainty over how the case will be resolved, because that resolution is dependent on a myriad of unknown factors, including a judge's interpretation of difficult legal questions and unpredictable juries. This uncertainty can chill productive activities that are affected by a case even if they are not directly implicated by it. For example, a pharmaceutical company with even a strong patent nevertheless might face an uncertain judgment in a case brought by a generic challenger, and therefore may delay or forego innovative activity because of the prospect of an adverse judgment.

Settlements create an environment of certainty, which allows parties to make business planning decisions with more efficiency and flexibility than can be achieved in the midst of an all-or-nothing legal dispute that may take years to resolve. It is therefore important that PhRMA members continue to have options to enter into procompetitive settlements, which allow them to get on with the business of developing new medicines for patients.

IV. A Rule That Bans The Transfer Of Anything of Value From a Brand to A Generic in Connection with Patent Settlements Would Make Settlements Less Likely and Less Efficient and Would Threaten Both Innovation and Generic Drug Development

H.R. 1706's ban against patent settlements where the brand company transfers something of value to the generic would chill all patent settlements. In fact, as Judge Richard Posner has pointed out, this broad description could almost cover any settlement agreement because a generic challenger logically would only settle in exchange for something of value.⁴³ And a law restricting parties' ability to settle their patent dispute would have significant adverse consequences for brand and generic companies and ultimately for patients. Fewer options for settlement would raise the cost of patent enforcement (and patent challenges) by forcing both sides to incur additional litigation costs. It could also reduce generic manufacturers' incentives to challenge patents in the first place by reducing their options in litigation against patent holders.

The narrow exceptions carved out from the sweeping prohibition in H.R. 1706 will not alleviate the bill's chilling effect on settlements. Similarly, the fact that the bill

⁴³ *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003); see also Letter from U.S. Department of Justice Office of Legislative Affairs, Office of the Assistant Attorney General to Senator Jon Kyl, Feb. 12, 2008 (2008 DOJ Letter) at p.2 ("[I]n any patent litigation, the principle means available to the patent holder to induce the generic company to settle the litigation is to offer something of value").

authorizes the FTC to undertake rulemaking to exempt additional settlements does not provide sufficient certainty that litigants' options for pro-consumer settlements will be preserved.

Settlements are not easily crafted or achieved. Often — as in the context of patent infringement litigation involving pharmaceuticals — the parties have a different risk-reward calculus, a different appetite for risk, and different litigation costs. Consider the incentives of the parties in a patent dispute within the Hatch-Waxman framework. The innovator and generic are likely to face significantly different risks and rewards from patent litigation. For example, the innovator stands to lose the market exclusivity through which it has the chance to recoup the hundreds of millions of dollars invested in making new products available to patients. On the other hand, the generic may risk losing comparatively little. The generic's development costs are just a fraction of the innovator's costs because the generic takes advantage of much of the innovator's development efforts.

Moreover, the generic typically is not exposed to liability for any infringement damages as a result of the Hatch-Waxman statutory scheme.⁴⁴ As described in a recent study by noted economists Laura D'Andrea Tyson, Jonathan Orszag and Bret Dickey, in a typical patent case outside of the Hatch-Waxman context, a patent infringer markets the product prior to being sued by the patent holder for infringement. The alleged infringer would owe significant damages if found liable, but the parties may agree to a settlement where the alleged infringer pays damages to the patent holder that are far less than the amount the patent holder claimed in the litigation. In these circumstances, the alleged infringer pays the patent holder, but value in fact flows from the patent holder to the infringer (measured in the reduced amount of damages the innovator accepts in order to resolve the case). So-called “[r]everse payment settlements can be thought of in the same way, but the Hatch-Waxman framework means the patent holder typically does not incur any damages from sales of the infringing products, and so the net payment flows from the branded manufacturer to the generic manufacturer.”⁴⁵

The innovator and generic can also face lopsided benefits from winning. If the innovator wins, it merely maintains the status quo. If the generic wins, however, it is rewarded by profits from the sale of a new product.

The parties' differing risk exposure, however, should not suggest that the innovator always has more at stake, or that the innovator is always more willing

⁴⁴ *Schering-Plough*, 402 F.3d at 1074 (explaining that “the Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from any possible infringement....Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude”).

⁴⁵ B. Dickey, J. Orszag, L. Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, p.27 (Dec. 2008), available at http://www.compasslexecon.com/highlights/Pages/_12_17_08.aspx?year=2008 (“Dickey, Orszag & Tyson”).

to settle. For example, the innovator may be less willing to settle precisely because of the value of the market exclusivity conferred by its patent. The innovator may be willing to take the risk of losing in return for a chance of a court judgment securing its entitlement to market exclusivity for the full life of its patent. On the other hand, the generic may have significant incentives to settle because it may not be able to afford the staggering costs of patent infringement litigation.

The parties' risk exposure and perceptions affect their willingness to settle as well as the settlement terms each party is willing to accept. When the parties' risk exposure and perceptions differ, as they are likely to in the context of brand-generic litigation under the Hatch-Waxman framework, settlement may be very difficult to achieve.⁴⁶ As the Chairman and CEO of generic manufacturer Barr Pharmaceuticals testified before the Senate Judiciary Committee in 2007, the ability to reach an agreement that provides for some consideration in addition to generic entry prior to patent expiration can be useful in "bridging the gap" that may exist based on different risk exposure and perceptions held by the parties.⁴⁷

Patent litigation — and settlement of patent cases — also cannot be viewed in a vacuum. Companies generally, and drug companies involved in patent litigation specifically, are often interacting on multiple levels, involving separate deals and perhaps disputes. Many times, they also have assets that are not involved in the suit that are more valued by the other party. For example, one of the parties may possess technology that can be more effectively marketed by the other party. The ability to license this technology, and offer that as part of a settlement, can facilitate the parties' efforts to reach and structure a mutually acceptable – and procompetitive – settlement. This has in fact been demonstrated in the very cases that have come before the courts.⁴⁸ It has also been borne out in statements by Barr Pharmaceutical's Downey, who testified that collateral agreements on some asset that is separate from the patented product in dispute often provide value to the patent holder and the generic challenger and also serve consumers by allowing the parties to reach a settlement that brings the generic product to market before patent expiration.⁴⁹ Likewise, Theodore Whitehouse, an attorney testifying before this Subcommittee in 2007 on behalf of generic manufacturer Teva Pharmaceuticals USA, Inc., explained that Teva had been able to achieve through settlements benefits for consumers that it could not have achieved by litigating the case to judgment, including early entry on

⁴⁶ *Schering-Plough*, 402 F.3d at 1073 ("Schering presented experts who testified to the litigation truism that settlements are not always possible. Indeed, Schering's experts agreed that ancillary agreements may be the only avenue to settlement.").

⁴⁷ Testimony of Bruce Downey, Senate Committee on the Judiciary Hearing, "Paying off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?", p.7, January 17, 2007 ("Downey Testimony").

⁴⁸ See, e.g., *Schering-Plough*, 402 F.3d at 1059-61 (discussing settlements in which assets were exchanged).

⁴⁹ Downey Testimony, pp. 7-9

products in addition to the one that was the subject of the suit.⁵⁰ Similarly, Tyson, Orszag and Dickey explain that “the parties’ valuations of the components of a collateral business arrangement may be quite different. This difference in valuation could be used to offset different expectations in the patent litigation to arrive at a settlement.”⁵¹

The parties to a patent dispute are, in short, often repeat players that have interactions or potential interactions on a number of different levels. Foreclosing the ability of innovators and generics to exchange assets that may or may not be involved in the litigation, as would be the case if there was a blanket prohibition on the exchange of *anything of value*, would put a straight jacket on the settlement negotiations. Not only would it make settlements less likely, but it also would make them less efficient. It would also harm consumers, since “Hatch-Waxman settlements . . . which result in the patentee’s purchase of a license for some of the alleged infringer’s other products may benefit the public by introducing a new rival into the market, facilitating competitive production and encouraging further innovation.”⁵²

Finally, a broad ban on payments of anything of value would open *any* transaction between the innovator and generic up to scrutiny. It is not hard to imagine an argument that a wholly separate license deal or other business transaction was in fact part of a patent settlement and therefore should be deemed illegal. Opening up this Pandora’s box of litigation would be expensive and wasteful.

For these reasons and others, courts and competition experts have expressed significant concerns about a rule that broadly condemns all settlements where the innovator transfers something of value to the generic. As the Eleventh Circuit stated in the *Schering-Plough* case:

Given the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements, we fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic’s entry date, and, in an ancillary transaction, pays for other products licensed by the generic. Such a result does not represent the confluence of patent and antitrust law.⁵³

⁵⁰ Testimony of Theodore Whitehouse, House Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy & Commerce Hearing on H.R. 1902, Hearing Tr. p. 145, May 2, 2007) (“Whitehouse Testimony”).

⁵¹ Dickey, Orszag & Tyson, p. 36.

⁵² *Schering-Plough*, 402 F.3d at 1075.

⁵³ *Schering-Plough*, 402 F.3d at 1076.

The Eleventh Circuit's concern that a ban on all payments from an innovator to a generic will have negative effects on settlements was echoed by the United States in its *amicus curiae* brief on the FTC's petition for *certiorari* in the *Schering* case and by the Department of Justice in its 2008 comments on proposed Senate legislation regarding patent settlements. In both its *amicus* brief and comments on the Senate legislation, the government stressed that "the public policy favoring settlements, and the statutory right of patentees to exclude competition within the scope of their patents, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation."⁵⁴ It further recognized that the Hatch-Waxman Act creates a unique litigation dynamic that makes some settlements reasonable.

Given the importance of settlement and the obstacles to reaching settlement, any limit on the ability of parties to achieve settlement must be approached with great caution. Any categorical limit on settlement options increases the risk that the parties may not be able to reach settlement or that the settlement will be less efficient – and ultimately worse for consumers – than prohibited alternatives.

Categorical limits on the ability to settle brand-generic lawsuits also increase the uncertainty over the scope and duration of patent protection. Faced with this increased uncertainty, innovator pharmaceutical companies likely will be less willing to make the astronomical investments necessary for developing and testing novel pharmaceuticals. Innovators, large and small, can only afford to make these investments because they have the opportunity to recoup them through market exclusivity guaranteed by patent protection. Innovators can therefore be expected to develop fewer new products under a regime that constrains settlement options.⁵⁵

This effect on innovators has been recognized by the courts and has been one of the key drivers in their refusal to find that competition principles compel a rule that would effectively prohibit nearly all transfers of value (including, but not limited to, reverse payments). As one court put it, "the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product."⁵⁶

The consequences of reduced innovation likely would in turn be felt throughout the health care system. Medicines represent just 10.5 cents of each dollar that is spent on healthcare, and only seven cents of that is attributable to brand name

⁵⁴ 2008 DOJ Letter at p.2; Letter Brief for the United States as Amicus Curiae, *FTC v. Schering-Plough Corp.*, No. 05-273 (filed May 17, 2006).

⁵⁵ Dickey, Orszag & Tyson, p.37

⁵⁶ *Schering-Plough*, 402 F.3d at 1075.

medicines.⁵⁷ Yet evidence shows that new medicines *reduce* the cost of healthcare. One study found that for every dollar spent on newer medicines in place of older medicines, total healthcare spending is reduced by \$6.17.⁵⁸ Another found that every additional dollar spent on healthcare in the U.S. over the past 20 years has produced health gains worth \$2.40 to \$3.00.⁵⁹

Overly broad limits on the ability to settle patent litigation may also have detrimental effects on generics. As Judge Posner recognized, limits on settlement structure, like a rule prohibiting reverse payments, “would reduce the incentive to challenge patents by reducing the challenger’s settlement options should he be sued for infringement, and so might well be thought anticompetitive.”⁶⁰ Counsel for generic manufacturer Teva Pharmaceuticals testified before this Subcommittee in 2007 that Paragraph IV cases at that time “involve[d] more difficult issues than they typically did a few years ago and may be more difficult for generic companies to win.”⁶¹ Similarly, Barr Pharmaceuticals CEO testified before the Senate Judiciary Committee that “[t]he generic challenger will lack the necessary resources to litigate every patent challenge to final judgment upon appeal, particularly when there is the risk that the challenger might ultimately win nothing.... A generic challenger’s ability to bring a Hatch-Waxman challenge depends in significant measure upon its having the flexibility to decide when, and on what terms, to compromise the litigation.”⁶² Moreover, limits on settlement will limit a generic’s ability to gain access to technology or other assets in the innovator’s possession that may improve the generic’s ability to bring to market other substitutes for brand-name products.

Similarly, sweeping limits on settlements will increase the possibility of a court ruling of infringement. An infringement ruling prevents a generic from making any sales until patent expiration and thus delays its ability to recoup its investment in developing its product. Generic manufacturers may, therefore, develop fewer generic drugs and may take longer to bring those drugs to market under a legislative regime which constrains settlement options.

Finally, fewer settlements mean that litigants will spend more time and money litigating. By spending more time and money on litigation, the litigants presumably will have to make corresponding cuts in other expenditures, including expenditures invested in new drug development.

⁵⁷ http://www.innovation.org/index.cfm/ImpactofInnovation/Controlling_Healthcare_Costs (accessed March 29, 2009).

⁵⁸ F. Lichtenberg, *Benefits and Costs of Newer Drugs: An Update*, National Bureau of Economic Research Working Paper, No. 8996 (Cambridge, MA, NBER June 2002).

⁵⁹ MEDTAP Int’l, Inc., *The Value of Investment in Health Care: Better Care, Better Lives* (Bethesda, MD: MEDTAP 2003), <http://www.medtap.com/Products/policy.cfm> (accessed February 8, 2005).

⁶⁰ *Asahi Glass Co. v. Pentech Pharm.*, 289 F.Supp.2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation).

⁶¹ Whitehouse Testimony, Hearing Tr., p.146.

⁶² Downey Testimony, pp. 9-10

V. A Case-By-Case Approach By Courts And Enforcement Agencies Will Allow Procompetitive Patent Settlements to Proceed and Still Deter Settlements That Harm Consumers On Balance

We understand that the Subcommittee continues to question the best way forward in addressing the competitive nature of brand-generic settlements in patent litigation. PhRMA respectfully submits that a legislative solution may not be necessary, and, more importantly, a broad *per se* ban on almost all settlements involving transfer of anything of value from the innovator to the generic is not in the best interests of patients or competition. The antitrust agencies and courts are in the best position to evaluate the facts of particular cases and determine whether particular settlements are truly anticompetitive.

We urge the Subcommittee and other policymakers to continue to make policy choices that will balance patent and antitrust considerations and provide for both innovation and a strong generic industry. While the role of generics is important to our health care system, the existence of generics is dependent upon innovative pharmaceuticals being developed. Policies that incentivize research and development and allow innovator companies time to recoup their significant investment, while encouraging generic entry at the appropriate time, are essential to the lifeblood of both industries.

Fundamentally, a policy that would provide for a *per se* ban on all settlements that contain some payment from a brand manufacturer to a generic company would put additional stress on the drug development system. It would decrease the value of patent protection generally and decrease incentives for taking the risks necessary to develop new products. One court noted, “a rule prohibiting settlements of Hatch-Waxman litigation can have grave consequences for R&D and, in turn, severe consequences for consumers...”⁶³

Instead of a blanket rule banning certain types of patent settlements, enforcement agencies and courts should continue to evaluate these patent settlements on a case-by-case basis. Courts are in the best position to balance the deeply-instilled policy of settlements against a claim that a patent settlement unreasonably restrains trade and therefore harms consumers. Whether a particular patent settlement is appropriate turns on whether the settlement excludes competition beyond the scope of the patent’s protection. As Hewitt Pate, the former head of the Department of Justice’s Antitrust Division, has recognized, “[i]f a patent is valid and infringed, then any competitive entry allowed by a settlement is up to the patent holder.”⁶⁴ This kind of analysis can only be done on a case-by-case basis.

⁶³ *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d at 256.

⁶⁴ R. Hewitt Pate, Assistant Attorney General, Antitrust Division, Address to the American Intellectual Property Law Association, January 24, 2003.

And, of course, the enforcement agencies already have the authority and ability under current law to review and evaluate individual patent settlements. Under the Medicare Modernization Act, brand and generic companies settling patent litigation arising out of the generic company's Paragraph IV certification must file a copy of their settlement agreement or a written description of it with FTC and with the DOJ's Antitrust Division before the date when the generic product may enter the market. Thus, Congress has already given enforcement authorities the ability to review and evaluate patent settlement agreements between a brand and generic company on a case-by-case basis. Reports in the press and the FTC's own public reports indicate that the FTC maintains its interest in monitoring these agreements, and it retains the power to challenge any agreement that it deems anticompetitive. If the Subcommittee feels legislative action is necessary, additional steps could potentially be taken to facilitate agency or judicial review. But the proposed ban on an entire category of settlements would chill all settlements, even those that would allow generic entry before patent expiration or contain other provisions that facilitate the availability of products to help patients live longer, healthier lives.

Thank you again for the chance to speak with you today. PhRMA and its member companies believe it is crucial for this Subcommittee and other policymakers to find public policy solutions that will strike a balance between patent and antitrust considerations and will foster innovation while still allowing for a strong generic industry. We welcome your interest in this issue, and look forward to working with members of the Subcommittee and others in Congress as you address these and other important policy issues relating to innovation and access to medicines.