

consumption of 138.74 billion gallons. Alaska's projected gasoline consumption was calculated by multiplying the projected nationwide gasoline consumption in 2009 by the ratio of Alaska's gasoline consumption in 2007 to the total U.S. consumption in 2007, based on Table 45, "Prime Supplier Sales Volumes of Motor Gasoline by Grade Formulation, PAD District, and State" gasoline data from EIA's *Petroleum Marketing Annual 2007* (the final rulemaking used data from *Petroleum Marketing Annual 2005*). According to EIA, Prime Supplier data reflects where gasoline is used, rather than where it is produced.² Alaska's projected gasoline consumption in 2009 is 0.27 billion gallons. Subtracting this consumption from the projected nationwide consumption of 138.74 billion gallons in 2009 produces a total consumption of 138.47 billion gallons of gasoline in 2009 in the 48 contiguous states plus Hawaii.

Calculation of $(R_i + RS_i)$, Total Amount of Renewable Fuel Blended Into Gasoline That Is Projected To Be Consumed in the 48 Contiguous States Plus Opt-In States/Territories, in Year i , in Gallons

The projected gasoline consumption in the October 2008 STEO includes

renewable fuel that is blended into gasoline. This volume of renewable fuel must be subtracted from the total volume of gasoline in order to calculate the total consumption of non-renewable gasoline. In Table 8 of the October 2008 STEO, EIA estimates that 0.929 quadrillion Btu of ethanol will be used as transportation fuel in all of the United States in 2009. Dividing this energy usage by the high heating value of ethanol (3.539 million Btu/barrel), and multiplying by 42 gallons/barrel produces a total projected ethanol usage of 11.03 billion gallons nationwide in 2009.

Since Hawaii has opted in, but Alaska has not opted in, to the RFS program for 2009, Alaska's renewable fuels consumption must be subtracted from the nationwide renewable fuels consumption to calculate renewable consumption in the 48 contiguous states plus Hawaii. In Chapter 2 of the Regulatory Impact Analysis for the RFS1 program rulemaking, EPA estimated that ethanol consumption in Alaska would be negligible prior to 2012.³ Thus, calculated projected renewable fuels consumption in the 48 contiguous states plus Hawaii is 11.03 billion gallons in 2009, slightly lower than the RFS for 2009.

Calculation of GE_i , Amount of Gasoline Projected To Be Produced by Exempt Small Refineries and Small Refiners in Year i , in Gallons⁴

In the final rulemaking establishing the RFS1 program regulations, we stated that we would estimate the combined small refinery and small refiner gasoline volume using a constant percentage of national consumption. Using information from gasoline batch reports submitted to EPA, EIA data and input from the California Air Resources Board regarding California small refiners, we estimated this percentage to be 13.5%.⁵

Multiplying the projected nationwide consumption of gasoline in 2009 (138.74 billion gallons) by 13.5% results in a total projected production of 18.73 billion gallons of gasoline from small refiners and small refineries in 2009.

Calculation of $RFStd_i$, Renewable Fuel Standard in Year i , in Percent

Substituting all of the terms calculated above into the equation for $RFStd_i$ results in the following RFS for 2009,

$$RFStd_i = 100 \times \frac{11.1}{138.47 - 11.03 - 18.73} = 10.21\%$$

Therefore, the RFS for 2009 is 10.21%. This is the standard referenced in 40 CFR 80.1105(b) through (d) and which obligated parties apply to determine their renewable volume obligation under 40 CFR 80.1107.

Dated: November 14, 2008.

Robert J. Meyers,

Principal Deputy Assistant Administrator,
Office of Air and Radiation.

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FEDERAL TRADE COMMISSION

Public Hearings Concerning the Evolving Intellectual Property Marketplace

AGENCY: Federal Trade Commission.

ACTION: Notice of Public Hearings

SUMMARY: The Federal Trade Commission will hold a series of public hearings beginning on December 5, 2008, in Washington, D.C., to explore the evolving market for intellectual property (IP). The hearings will examine changes in intellectual property law, patent-related business models, and new learning regarding the operation of the IP marketplace since the FTC issued its October 2003 report, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (the FTC IP Report).¹ Changes and proposed changes in the law, together with evolving business models for buying, selling and licensing IP, could significantly influence a patent's economic value and the operation of the IP marketplace. The hearings will

consider the impact of these changes on innovation, competition and consumer welfare.

The Commission seeks the views of the legal, academic, and business communities on the issues to be explored at the hearings. This notice poses a series of questions relevant to those issues on which the Commission seeks comment. Each hearing will be transcribed. The transcript and any written comments received will be placed on the public record.

DATES: The first hearing will be held December 5, 2008, in the Conference Center of the FTC office building at 601 New Jersey Avenue, N.W., Washington, D.C. All interested parties are welcome to attend. An agenda for that hearing will be posted on the FTC's website, www.ftc.gov. The Commission may hold

² Energy Information Administration, *Petroleum Marketing Annual 2007*, Explanatory Notes, Relationship of Refiner and Prime Supplier Sales Volumes" (p. 393).

³ Table 2.2-21 "2012 Forecasted Ethanol Consumption by State," Regulatory Impact

Analysis: Renewable Fuel Standard Program, April 2007.

⁴ Through 2010 only, unless the exemption is extended under 211(o)(9)(A)(ii) or (B) of the Act.

⁵ "Calculation of the Small Refiner/Small Refinery Fraction for the Renewable Fuel Program,"

memo to the docket from Christine Brunner, ASD, OTAQ, EPA, September 2006.

¹ **Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy** (October 2003), available at (<http://www.ftc.gov/os/2003/10/innovationrpt.pdf>) ("IP Report").

subsequent hearings in Washington, D.C. and other locations. Prior to each hearing, the Commission will publish an agenda on its website.

ADDRESSES: Any interested person may submit written comments responsive to any of the topics identified in this **Federal Register** notice or in any subsequent announcement related to hearings on the Evolving IP Marketplace. Respondents are encouraged to provide comments as soon as possible, but no later than February 5, 2009. The FTC will only accept comments submitted by weblink or in hard copy format. Information about how to submit comments will be posted on the website for the hearings, accessible at (<http://www.ftc.gov/ftc/workshops.shtm>).

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives, whether filed in paper or electronic form. Comments received will be available to the public on the FTC website, to the extent practicable, at <http://www.ftc.gov>. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at (<http://www.ftc.gov/ftc/privacy.shtm>).

FOR FURTHER INFORMATION CONTACT: Erika Meyers, Office of Policy and Coordination, Bureau of Competition, 601 New Jersey Avenue, N.W., Washington, D.C. 20580; telephone 202-326-2076; e-mail, IPMarketPlace@ftc.gov.

SUPPLEMENTARY INFORMATION:

The October 2003 FTC IP Report

The FTC is an antitrust enforcement agency, but it also has a mandate to study issues related to competition policy. In 2002, the agency undertook a study of the patent system under both of these roles in response to the increasing significance of patents in the knowledge-based economy and the role of dynamic, innovation-based considerations in antitrust analysis. In support of the study, the FTC and the Department of Justice held over 24 days of hearings that involved more than 300 panelists, including representatives from large and small business firms; the independent inventor community; patent and antitrust organizations; and

the academic community in economics and antitrust and patent law. In addition, the FTC received about 100 written submissions. Many of the business representatives were from technology-intensive industries such as pharmaceuticals, biotechnology, computer hardware and software, and the Internet. The Report FTC's October 2003 Report on the patent system, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*,² summarizes testimony from the hearings and explains the Commission's recommendations for improving the patent system.

The IP Report found that both competition and patents influence innovation, which drives economic growth and increases standards of living. Patents play an important role in promoting innovation by providing an incentive to develop and commercialize inventions. Without patent protection, innovators that produce intellectual property may not be able to appropriate the full benefits of their innovation when competitors are able to "free ride" on the innovator's efforts. Patents may also encourage firms to compete in the race to invent new products and processes. Patent rights make it easier for inventors to attract funding and enter the licensing and joint-venture arrangements needed to commercialize an invention. Moreover, the public disclosure of scientific and technical information made through a patent can stimulate further scientific progress.

The IP Report explained that competition also plays a critical role in stimulating innovation. Competition drives firms to identify consumers' unmet needs and develop new products and services to satisfy them. In some industries, firms race to innovate in hopes of exploiting first-mover advantages. The IP Report raises concerns that patents of questionable quality—those of questionable validity or having overly broad claims—can hinder competition and innovation in several ways, to the detriment of consumers. For instance, patents of questionable quality can deter follow-on innovation

² I.P. Report, *supra* n.1. In 2007, the Federal Trade Commission and the Antitrust Division of the Department of Justice released a joint report based on these hearings examining the ways in which antitrust analysis should take into account the patent system's incentives to innovate. The report recognizes that the way antitrust law functions at the patent interface can significantly affect IP-driven innovation. **U.S. Dep't of Justice and the Federal Trade Commission, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition** (April 2007) available at (<http://www.ftc.gov/reports/innovation/P040101PromotingInnovationandCompetitionrpt0704.pdf>)

by discouraging firms from conducting research and development in areas that the patent improperly covers, and raise costs when challenged in litigation or unnecessarily licensed. The IP Report made ten recommendations for legislative, judicial and administrative changes to the patent system to address these concerns, several of which have come to pass or received support in Congress. Those recommendations include establishing a more flexible obviousness standard under 35 U.S.C. § 103, raising the requirements for proving willful infringement, and instituting a patent post-grant review procedure in the Patent and Trademark Office.

Recent Changes to the Patent System

The patent system has experienced significant change since the FTC released its first IP Report in October 2003, and more changes are under consideration. The courts and patentees are exploring the full implications of Supreme Court and Federal Circuit decisions on injunctive relief, patentability and licensing issues. Congress has considered sweeping legislative patent reform, and new debates on the appropriate methods for calculating infringement damages have engaged the patent community. New business models for buying, selling and licensing patents have emerged and evolved since 2003. In addition, there is new learning regarding the operation of the patent system and its contribution to innovation and competition.

Three of these recent developments have brought the issues of patent remedies and their impact on innovation and consumers to the forefront. In 2006, the Supreme Court ruled in *eBay v. MercExchange*³ that district courts may no longer automatically grant a permanent injunction barring future infringement following a finding of infringement, but must consider traditional principles of equity. In 2007, in *In re. Seagate Technologies, Inc.*,⁴ the Court of Appeals for the Federal Circuit abandoned its "duty of due care" standard, and held that proof of willful infringement requires "at least a showing of objective recklessness," thus making it more difficult for a patentee to obtain treble damages. While the patent system grapples with the application of those decisions, debate continues in the patent community over the appropriate methods for calculating

³ 547 U.S. 388 (2006).

⁴ 497 F.3d 1360, 1371 (Fed. Cir. 2007).

reasonable royalty damages and whether legislative changes are needed.

Remedies available in patent litigation—a permanent injunction barring future infringement, compensatory damages for past infringement, and trebled damages for willful infringement—play an important role in determining the value of all patents. The parties' assessment of the remedy a court might award heavily influences the settlements that resolve the vast majority of patent infringement actions, and even licensing negotiations that take place without the initiation of a court action. Thus, these changes and proposed changes could have far-reaching effects on the value of patents and the operation of the market for intellectual property.

Three other recent Supreme Court decisions affect the value of patents and the operation of the IP marketplace through rulings on what patents are valid, when licensees may challenge validity, and who may owe royalties. In *KSR International v. Teleflex, Inc.*,⁵ the Supreme Court propounded a flexible approach to obviousness doctrine. In doing so, the Court discussed the detrimental effects of obvious patents, which withdraw from the public what is already known and diminish the resources available to support innovation. In *Medimmune, Inc. v. Genentech, Inc.*,⁶ the Court allowed a patent licensee to challenge a patent's validity through a declaratory judgment action because the harm of paying royalties on an invalid patent generates a "substantial controversy between parties having adverse legal interests."⁷ In *Quanta Computer Inc. v. LG Electronics*,⁸ the Court affirmed the exhaustion doctrine even where the initial patent license purported to limit the rights transferred to subsequent purchasers of a covered product.

Some of the most significant recent changes in markets for intellectual property have occurred not through the courts, but through the emergence of new business models involving the buying, selling and licensing of patents. Companies have always used intellectual property as a strategic asset: sometimes offensively to maintain exclusivity over a technology, to capture royalties from competing products, or to support technology transfer, and sometimes defensively, to stave off potential infringement litigation. New business models have emerged in recent years, however. Some business models

seek to monetize patents based on strategic acquisition and assertion. Others establish a cooperative venture that buys and licenses patents to its members for defensive purposes. Still others seek to create sector-specific funds, similar to mutual funds, that allow investors to earn revenue from royalty streams. There are likely other developing business models that use intellectual property as their primary asset.

Hearings on the Evolving IP Marketplace.

The extent and cumulative impact of these changes and proposed changes on the patent system are poorly understood. They could potentially significantly influence a patent's economic value and a patentee's compensation. If patentees were systematically under-compensated due to legal doctrines that drive down the value received through remedies and licensing, patents would be devalued. This would undermine the patent system's incentives to innovate, to the detriment of consumers who benefit tremendously from innovation. On the other hand, if the relevant legal rules operate to systematically overcompensate patentees, supra-competitive prices for technology would unduly dampen future innovation, and prices for products incorporating patented inventions would increase unjustifiably. Both under- and overcompensation of patentees present the potential for consumer and competitive harm.

The Commission plans to hold a series of hearings that will examine the recent and proposed changes in the IP marketplace and consider the effects of those changes on the alignment of patent and competition policy. The first hearing will occur on December 5, 2008 in Washington, D.C.

The December 5th hearing will include three panels addressing a range of topics related to the valuation of patents and the operation of the market for intellectual property. A primary goal of this first hearing is to identify those issues that require more in-depth study in subsequent hearings. In the first panel, participants will discuss the operation and impact of emerging business models, aspects of the patent system that support those models, and industry responses. The second panel will explore remedies law and the need for economic analysis in this area. In the third panel, participants will examine legal doctrines that affect the value and licensing of patents, such as the recent Supreme Court cases on obviousness, declaratory judgment and exhaustion,

and doctrines that make the scope and enforcement of patents unpredictable. The panel will consider whether the notice function of patents operates to support an efficient marketplace.

The Commission invites public comments discussing the current marketplace for intellectual property, in particular its impact on innovation incentives and competition concerns and the role of economic analysis in this assessment. The Commission will accept comments, as described above, until February 5, 2009. Comments addressing any of the following questions would be particularly helpful.

1. How has the IP marketplace changed in the past five to ten years? What changes are expected in the future? What aspects of the patent system drive those changes? What is the impact of those changes on innovation?
2. What are the new business models involving intellectual property? What has motivated the development of these business models? What is their impact on innovation?
3. What economic evidence is relevant when analyzing whether to grant a permanent injunction following a finding of infringement? What proof have courts required? How should the analysis take into account the incentives to innovate provided by the patent system and the benefits of competition? What is the appropriate remedy when the court has denied a permanent injunction after a finding of infringement?
4. Do the legal rules governing patent damages result in awards that appropriately compensate patentees? Are there circumstances in which they result in overcompensation or undercompensation of patentees? What evidence is there of the extent of these problems? What information would be helpful to better assess whether damage awards appropriately compensate patentees? Are courts and juries able to make damages determinations with sufficient accuracy? To the extent that there are problems resulting from the determination of damages for patent infringement, how should they be addressed?
5. How have changes in willfulness doctrine changed the behavior of patentees and potential infringers? Do recent changes in the law adequately address the concerns with willfulness doctrine identified in the October 2003 FTC IP Report?
6. How will changes in patent law rendered by Supreme Court and Federal Circuit decisions of the past five years affect the value of patents? How will these changes affect the operation of the

⁵ 127 S. Ct. 1727 (2007).

⁶ 549 U.S. 118 (2007).

⁷ Id. at 771.

⁸ 128 S.Ct. 2109 (2008).

IP marketplace? How will they affect innovation and competition?

7. How does uncertainty regarding the validity and scope of patents affect the operation of the IP marketplace? Does the current system adequately fulfill the notice function of patents? How does uncertainty influence the operation of the IP marketplace? What are the sources of uncertainty that affect the value of patents and the operation of the IP marketplace? What could be done to address them?

8. How transparent is the current IP marketplace? Can it be made more transparent? Is that desirable?

9. During the past five years, what new learning has furthered the understanding of the patent system and the IP marketplace?

By direction of the Commission.

Donald S. Clark,
Secretary.

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[BILLING CODE 6750-01-S]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project:

“Reducing Waste and Inefficiency through Process Redesign: Lean/Toyota Production System (TPS) Implementation.” In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by (insert date 60 days after date of publication).

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@ahrq.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT:
Doris Lefkowitz, AHRQ Reports

Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

“Reducing Waste and Inefficiency through Process Redesign: Lean/Toyota Production System (TPS) Implementation” AHRQ, through its contractor, American Institutes for Research (AIR), proposes to investigate the contribution of Lean/TPS to reducing waste in health care delivery systems. Lean is a process-redesign methodology adopted from Toyota Production Systems. The goal of Lean/TPS is to empower front-line staff to apply continuous quality improvement methods to reduce waste and enhance value in workflows and operations (Spear, S. Fixing healthcare from the inside, today. *Harvard Business Rev.*, 2005 83(9), 78-91). AHRQ is interested in assessing and disseminating promising techniques and methodologies for redesigning health care processes to reduce waste and enhance efficiency. Using a purposive sample of health care organizations and projects, AHRQ will describe and assess the ways in which Lean/TPS has been implemented and the related challenges and solutions experienced. The sample will vary in community and market characteristics, type of service (e.g., inpatient/outpatient), and delivery system characteristics (e.g., relationship between physicians and hospitals, ownership). AHRQ plans to disseminate the lessons learned from this project on the implementation of Lean/TPS to health care delivery systems. This project is being conducted pursuant to AHRQ’s statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to: The quality, effectiveness, efficiency, appropriateness and value of health care services; quality measurement and improvement; and health care costs, productivity, organization, and market forces. 42 U.S.C. 299a(a)(1), (2), and (6).

Method of Collection

At least four research locations (i.e., hospitals or other health settings) will be selected to create eight case study reports. Four of the studies will employ a retrospective analytics perspective, while four will employ a prospective analytics perspective. At each location, implementation of Lean/TPS in two departments will be studied: One department with an essentially linear process (clinical laboratory, radiology, or ED) and one department with an essentially non-linear process (cardiology, GI, or med/surg unit). A

linear department is one in which the process is essentially uniform and predictable for most or all services delivered. A non-linear department is one in which the process is much less uniform and predictable. If there is more than one Lean/TPS project in the selected department, we will purposively select a project that appears to have the most information for others about the processes and outcomes of Lean/TPS implementation.

Qualitative data will be collected directly from the four locations selected for this study. The collection will be accomplished using interviews (telephone and in-person), collection of documentation, and digital diaries for the four prospective studies. The “digital diary” is a data collection method using a diary entry guide and a digital recorder to describe key aspects of the implementation process. The total number of in-person interviews to be conducted across the four locations is 100; the total number of telephone interviews is 36. The in-person interviews will be conducted through a multi-day visit to each site. The number of digital diary submissions will depend on the number and duration of the Lean/TPS project within in each department.

Estimated Annual Respondent Burden

Exhibit I shows the estimated annualized burden hours. A total of 25 in-person interviews will be conducted with the administrative and clinical personnel from each of the four participating health care facilities. The estimated time per response is 1.0 hour for a total of 100 burden hours. Additionally, a total of 9 telephone interviews will be conducted with each facility. The estimated time per response is 30 minutes, for a total of 18 burden hours. The digital diaries will be completed once a month for eight months by two personnel from each facility, and will require about 30 minutes each per month for a total of 32 hours. Finally, administrative staff from each site will be asked to provide training materials, reports on Lean/TPS implementation, and/or any other documentation or existing data from previous or current Lean/TPS projects implemented. We anticipate this task will simply consist of forwarding emails and or photocopying and sending documents to the project team one time throughout the course of the project and will take about four hours per facility or 16 hours total. The total estimated burden is 166 hours. Exhibit 2 shows the estimated annualized cost burden for the respondents’ time to provide the requested data. The hourly rate of