



## CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

September 4, 2007

### **H.R. 1908** **Patent Reform Act of 2007**

*As ordered reported by the House Committee on the Judiciary on July 18, 2007*

#### **SUMMARY**

H.R. 1908 would amend various provisions of current law that regulate how the Patent and Trademark Office (PTO) awards patents. The bill would alter the rule that prioritizes the award of a patent from the “first to invent” to the “first inventor to file.” As a result, PTO would change certain procedures followed in awarding patents and procedures that allow individuals to challenge the validity of patents that have been awarded. The bill would authorize PTO to collect certain fees to offset most of the costs associated with these new procedures. Several provisions of H.R. 1908 would alter intellectual property protections associated with brand name drugs and could affect when competing versions of generic drugs ultimately enter the market. Other provisions would require PTO to prepare several reports for the Congress on the effectiveness of the changes to the patent process that would be made by H.R. 1908.

Subject to appropriation of the necessary amounts, CBO estimates that implementing the bill would have a net discretionary cost of \$3 million in 2008 and \$11 million over the 2008-2012 period. Enacting H.R. 1908 could affect direct spending and revenues, but CBO estimates that any such changes would be negligible over the 2008-2017 period.

H.R. 1908 would impose intergovernmental and private-sector mandates, as defined in the Unfunded Mandates Reform Act (UMRA), on certain patent applicants. Based on information from PTO, CBO estimates that the cost of complying with the mandates would exceed the annual threshold for private-sector mandates established in UMRA (\$131 million in 2007, adjusted annually for inflation) in each of the first five years the mandate is in effect. CBO estimates that the costs to state and local governments of complying with the mandates would not exceed the annual threshold for intergovernmental mandates established in UMRA (\$66 million in 2007, adjusted annually for inflation).

## ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 1908 is shown in the following table. The costs of this legislation fall within budget function 370 (commerce and housing credit).

	By Fiscal Year, in Millions of Dollars				
	2008	2009	2010	2011	2012
<b>CHANGES IN SPENDING SUBJECT TO APPROPRIATION</b>					
Inter Partes Reexaminations					
Estimated Authorization Level	4	17	28	44	57
Estimated Outlays	4	15	26	41	54
Post-grant Reviews					
Estimated Authorization Level	1	4	10	5	2
Estimated Outlays	1	4	9	5	2
Offsetting Collections					
Estimated Authorization Level	-2	-29	-35	-40	-44
Estimated Outlays	-2	-29	-35	-40	-44
Net Changes					
Estimated Authorization Level	3	-8	3	9	15
Estimated Outlays	3	-10	0	6	12

## BASIS OF ESTIMATE

For this estimate, CBO assumes the bill will be enacted near the start of fiscal year 2008.

### Spending Subject to Appropriation

H.R. 1908 would create a new procedure to challenge the validity of a patent and would authorize PTO to collect fees to offset its costs for this activity. Further, PTO expects that the volume of requests for certain other patent review processes would increase as a result of implementing the bill. Under current law, PTO is authorized to collect fees for these activities. The collection and spending of those fees are subject to provisions in annual appropriations acts, and the fees are recorded in the budget as offsets to the discretionary spending of PTO. For 2007, the PTO received a gross appropriation of \$1,771 million, and CBO estimates that amount will be offset by \$1,799 million in fee collections. Assuming appropriation of the necessary amounts, CBO estimates that implementing H.R. 1908 would

increase the PTO's net outlays by \$3 million in 2008 and \$11 million over the 2008-2012 period.

**Inter Partes Reexaminations.** Under current law, an individual may question the validity of an awarded patent through an inter partes reexamination, which allows both the challenger and the patent-holder to participate in the proceedings by submitting arguments and filing appeals.

Inter partes challenges may be raised at any time after a patent has been awarded. Because of certain limitations in the process, however, very few challenges have been raised. The bill would relax these limitations and increase the number of patents that could be challenged. Further, the bill would require the inter partes proceedings to be conducted by an administrative patent judge; under current law, these proceedings are conducted by a patent examiner.

With fewer limitations on future challenges and a larger universe of patents open to challenge, CBO expects that the number of inter partes proceedings would increase under the bill. Based on information from PTO, CBO expects at least 100 additional employees would be necessary to handle that increase in patent challenges. We estimate that implementing the changes to the inter partes reexamination procedures would cost about \$4 million in 2008 to begin hiring and training additional staff, and \$140 million over the 2008-2012 period. PTO is authorized to collect fees that would offset most of the costs of conducting those examinations.

**Post-grant Opposition Procedures.** H.R. 1908 would authorize PTO to initiate a new procedure, at the request of third parties, to review the validity of patents already awarded. This opportunity for a post-grant review generally would be available within 12 months of the date the patent was issued, and would take place in a court-like proceeding where both parties would be involved in developing and presenting information regarding the validity of an awarded patent. The bill also would authorize PTO to collect a fee to offset the cost of this new process.

Based on information from PTO, CBO expects that around 300 requests for post-grant reviews would be made each year once regulations defining the process are complete. CBO estimates that implementing this new process would cost \$1 million in 2008 and \$21 million over the 2008-2012 period, which would be offset by fee collections starting in 2009. The cost would be higher in the early years because we expect that the agency would incur expenses to set up the system before cases would be presented for review.

**Offsetting Collections.** H.R. 1908 would authorize PTO to collect fees to offset the cost of post-grant reviews. In addition, PTO is authorized to collect fees under current law for inter

partes reexaminations. Fees for inter partes reviews are set in current law, and PTO cannot increase the fees beyond an annual adjustment for inflation. CBO expects that fees for inter partes reexaminations would largely but not completely offset the cost of those reviews. Based on information from PTO, CBO expects that most fee collections would begin in 2009 after regulations to implement the legislation are completed. CBO estimates that fee collections would total \$2 million in 2008 and \$150 million over the 2008-2012 period.

## **Direct Spending**

Several provisions of H.R. 1908 would alter intellectual property protections associated with brand name drugs and could affect when competing versions of generic drugs ultimately enter the market. Changing when lower-priced generic drugs would be available to purchasers would affect spending by federal health programs that purchase drugs or provide health insurance that covers drugs. Consequently, CBO expects that direct spending for Medicare, Medicaid, the Federal Employees Health Benefits program, and the Defense Department's TRICARE for Life program could be affected under the bill. However, based on information provided by experts in patent law and the brand and generic drug industry, CBO estimates that net changes in direct spending for those programs would be negligible over the 2008-2017 period.

The potential effects of the bill on the pharmaceutical industry are highly uncertain. Some provisions of the bill could affect patent protections for pharmaceuticals (and the timing of generic entry) in countervailing ways. For example, allowing a party to administratively challenge the validity of a patent through the new post-grant review proceedings at PTO, under certain circumstances, would provide generic firms and other interested parties with a new tool to eliminate patents that block entry of lower priced generic drugs. However, other provisions in the bill, such as one that would modify standards for proving inequitable conduct by patent holders, could make overturning certain patents or the timely launch of their products more uncertain for generic firms in some cases.

CBO anticipates that provisions of the Federal Food, Drug, and Cosmetic Act governing marketing of brand and generic drugs would significantly limit how H.R. 1908 might affect the timing of generic entry over the 2008-2017 period. H.R. 1908 also would make certain new requirements prospective in nature and thereby limit the effect of such changes on the market entry of generic drugs over that period. Because numerous provisions would apply to patent cases initiated and new patents issued after enactment, we expect that the effect of the bill on average drug prices could be significant beyond 2017. The nature and extent of any such long-term effects are unclear, however.

The Chief Judge of the U.S. Court of Appeals for the Federal Circuit has expressed concerns that section 5 of H.R. 1908 could significantly lengthen patent trials and delay their final resolution.<sup>1</sup> CBO expects that the provision relating to damages would infrequently apply to drug cases involving generic competitors and would apply only to cases initiated after enactment. Consequently, any potential budgetary effect from delaying resolution of pharmaceutical patents probably would not be significant over the next 10 years.

## **Revenues**

Enacting H.R. 1908 also could affect federal revenues. Any change to the average cost for prescription drugs available on the market would affect the cost of premiums for private health insurance. CBO anticipates that changes in spending by private health insurance plans would cause a shift in compensation between taxable wages and tax-favored benefits, thereby affecting federal revenue from income taxes and payroll taxes. However, because CBO estimates that enacting the bill would have a negligible net effect on the average price of drugs over the next 10 years, the net effect on federal revenues would also be negligible over that period.

## **INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT**

H.R. 1908 would impose intergovernmental and private-sector mandates, as defined in UMRA, on certain patent applicants. The mandates include following new application requirements and prohibiting tax planning methods from being patentable.

## **Required Search Reports**

The bill would direct the Patent and Trademark Office to establish regulations that would require certain patent applicants to submit a search report, analysis, and other information relevant to receiving a patent. Most patent applicants, including public universities, would be required to follow the new application process. The bill would exempt applications from micro-entities, as defined in the bill, from providing such reports and information. According to PTO, the cost for applicants to research and provide such information would be about \$5,000 to \$10,000 per search report; however, some applicants already provide similar information in their applications. Based on the number of patent applications per

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1. Letter from the Honorable Paul R. Michel, U.S. Court of Appeals for the Federal Circuit, to the Honorable John Conyers Jr. and the Honorable Lamar S. Smith, Chairman and Ranking Member, respectively, of the House Committee on the Judiciary, May 21, 2007.

year, CBO expects that the direct cost to comply with the mandate would exceed the annual threshold for private-sector mandates established in UMRA (\$131 million in 2007, adjusted annually for inflation) in each of the first five years the mandate is in effect. CBO estimates that the costs to public universities of complying with the mandates would not exceed the annual threshold for intergovernmental mandates established in UMRA (\$66 million in 2007, adjusted annually for inflation).

### **Prohibiting Tax Planning Methods**

The bill also would prohibit tax planning methods from being patentable. The prohibition would apply to any application for a new or reissued patent that is filed on or after the date of enactment. While the number of such applicants would likely be small, CBO has no basis for estimating the net income that would be forgone by a patent applicant for not receiving a patent. Therefore, CBO cannot estimate the cost to private entities of complying with this mandate. CBO estimates that the costs of complying with this mandate for state, local, and tribal entities would be small.

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