



## CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

February 15, 2008

### **S. 1145**

### **Patent Reform Act of 2007**

*As reported by the Senate Committee on the Judiciary on January 24, 2008*

#### **SUMMARY**

S. 1145 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.” It also would modify the agency’s authority to collect and spend fees.

CBO estimates that enacting the bill would increase direct spending by \$26.9 billion and revenues by \$25.5 billion over the 2009-2018 period. Much of that change would result from making permanent PTO’s authority to collect and spend certain fees, thus shifting the collections and spending out of PTO’s appropriation account. In total, those changes would increase budget deficits (or decrease surpluses) by \$1.4 billion over the 2009-2018 period.

Pursuant to section 203 of S. Con. Res. 21, the Concurrent Resolution on the Budget for fiscal year 2008, CBO estimates that changes in direct spending and revenues from enacting the bill would not cause an increase in the deficit of more than \$5 billion in any of the 10-year periods between 2018 and 2057.

In addition, CBO estimates that implementing the bill would increase net discretionary spending by \$0.5 billion over the 2009-2018 period, assuming appropriation of the necessary amounts.

S. 1145 would impose intergovernmental and private-sector mandates, as defined in the Unfunded Mandates Reform Act (UMRA), on certain patent applicants, patent holders, and generic drug manufacturers. Based on information from PTO, CBO estimates that the costs of complying with those mandates would exceed the threshold for private-sector mandates established in UMRA (\$136 million in 2008, adjusted annually for inflation) in each of the first five years the mandate is in effect. CBO estimates that the costs to state, local, and tribal governments would not exceed the annual threshold for intergovernmental mandates established in UMRA (\$68 million in 2008, adjusted annually for inflation).

As a result of this legislation, some state, local, and tribal governments would incur higher expenses (estimated to total about \$6 million over the 2008-2013 period) as purchasers of health care for their employees and as providers of health care under Medicaid. Similarly, private-sector entities would incur higher expenses (estimated to total about \$30 million over the same period) as purchasers of health care. Those costs would not result from federal mandates.

## **MAJOR PROVISIONS**

The bill would change certain procedures that PTO follows in awarding patents as well as procedures that allow individuals to challenge the validity of patents that have been awarded. Further, section 15 would make several changes to PTO's authority to set, collect, and spend the fees it charges for activities related to processing applications for patents and trademarks.

Section 14 would eliminate the remedies patent holders have with respect to financial institutions whose use of a "check collection system" constitutes patent infringement. Such systems enable financial institutions to settle checks by transmitting electronic records instead of transporting the paper documents. Based on information from owners of patents who would likely be affected, CBO anticipates that enactment of section 14 would result in litigation against the federal government seeking compensation for a taking of private property.

Finally, section 13 would provide the Director of PTO with new authority to accept certain patent applications filed after statutory deadlines if the applicant petitions PTO within a specified time frame and the Director determines that such delay was unintentional. We expect that enactment of this section would result in PTO granting almost five years of additional patent protection to a particular prescription drug. That added patent protection would increase the net cost for hospitals to perform certain procedures using that drug and would lead to higher net spending on health services by private health plans and certain federal and state health programs.

## **ESTIMATED COST TO THE FEDERAL GOVERNMENT**

The estimated budgetary impact of S. 1145 is shown in the following table. The costs of this legislation primarily fall within budget functions 370 (commerce and housing credit), 550 (health), and 800 (general government).

By Fiscal Year, in Billions of Dollars

2009- 2009-  
2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2013 2018

**CHANGES IN DIRECT SPENDING**

Spending of PTO Fees												
Estimated Budget Authority	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	3.0	11.5	25.5
Estimated Outlays	1.7	2.1	2.3	2.4	2.5	2.6	2.7	2.8	2.9	3.0	11.0	25.0
Spending from Currently Unavailable Balances and Interest												
Estimated Budget Authority	0.8	*	*	*	*	*	*	*	*	*	0.8	0.9
Estimated Outlays	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.5	0.9
Compensation for Patent Holders												
Estimated Budget Authority	0	0	0	0	0	0.2	0.2	0.2	0.2	0.2	0	1.0
Estimated Outlays	0	0	0	0	0	0.2	0.2	0.2	0.2	0.2	0	1.0
Additional Spending for Federal Health Programs												
Estimated Budget Authority	0	0	*	*	*	*	*	*	*	*	*	*
Estimated Outlays	0	0	*	*	*	*	*	*	*	*	*	*
Total Direct Spending Under S. 1145												
Estimated Budget Authority	2.9	2.2	2.3	2.4	2.5	2.8	2.9	3.0	3.1	3.2	12.3	27.4
Estimated Outlays	1.8	2.2	2.4	2.5	2.6	2.9	3.0	3.1	3.2	3.3	11.5	26.9

**CHANGES IN REVENUES**

Reclassification of PTO Fees	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	3.0	11.5	25.5
Effect on Employees' Health Insurance Premiums	0	0	*	*	*	*	*	*	*	*	*	*
Total Changes	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	3.0	11.5	25.5

**NET IMPACT ON REVENUES AND DIRECT SPENDING**

Estimated Increase in Deficit (or Reduction in Surplus)	-0.3	0.0	0.1	0.1	0.1	0.3	0.3	0.3	0.3	0.3	0.0	1.4
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**SPENDING SUBJECT TO APPROPRIATION**

Estimated Budget Authority	0	0	*	*	*	*	*	*	*	*	*	*
Estimated Outlays	0.4	0.1	*	*	*	*	*	*	*	*	0.5	0.5

Notes: \* = spending or revenues of less than \$50 million. Components may not sum to totals because of rounding.

PTO = Patent and Trademark Office.

## **BASIS OF ESTIMATE**

Under current law, PTO is authorized to collect fees from the public for specific activities related to processing applications for patents and trademarks. The agency assesses and collects fees for a number of different activities, and the rate for each is set in law. The collection and spending of those fees are subject to annual appropriation acts. As directed by current law, those fees are recorded in the budget as offsets to the discretionary spending of the PTO. CBO estimates that the agency will collect a total of \$1,989 million in fees in 2008, which will offset an estimated \$1,966 million of appropriated funding for that year, leaving \$23 million in collections unspent.

The treatment of PTO fees as offsetting collections in the budget is required by current law. That requirement would be eliminated under S. 1145, and PTO would be permanently authorized to collect fees, starting in fiscal year 2009, to offset the cost of its operations. Because the collection of those fees would no longer be tied to annual appropriation acts and PTO would be given permanent authority to spend them, the fee collections should be recorded in the budget as revenues (because by charging a fee to confer monopoly rights to patent recipients, the federal government is exercising its sovereign power to regulate and tax).

For this estimate, CBO assumes that the bill will be enacted in the latter half of 2008 and that outlays will follow historical spending patterns for PTO.

### **Direct Spending**

S. 1145 would change PTO's authority to spend the fees it collects and eliminate remedies available to holders of a certain type of patent. It also would extend the patent for a specific drug that CBO expects would affect spending on health services by certain mandatory health programs. CBO estimates that enacting those provisions would increase direct spending by \$1.8 billion in 2009, by \$11.5 billion over the 2009-2013 period, and by \$26.9 billion over the 2009-2018 period.

**Spending of PTO Fees.** Because PTO's spending would no longer be controlled by the availability of appropriated funds, the bill would make all of the agency's fees permanently available for spending. CBO estimates that PTO will collect about \$2.0 billion in fees in fiscal year 2008. Based on historical growth in the number of applications filed for patents and trademarks and historical spending patterns, we estimate that enacting S. 1145 would increase direct spending by about \$11.0 billion over the 2009-2013 period and \$25.0 billion over the 2009-2018 period. (This spending would be roughly offset by a reduction in discretionary spending.)

Those amounts include spending for a new procedure created by S. 1145 to review, at the request of third parties, the validity of patents already awarded. The process would offer third parties two opportunities to request a review. The first, designed as an extension of the examination process, would allow third parties to request a review within 12 months of the date the patent is issued. The second opportunity would be available anytime during the life of the patent, but challengers would face stricter requirements to show that the continued existence of the patent protection causes significant economic harm. The bill would require those reviews to be performed by a panel of three administrative patent judges. Based on information from PTO, CBO estimates that this new procedure would increase direct spending by less than \$50 million per year over the 2009-2018 period.

**Spending from Currently Unavailable Balances and Interest.** The bill also would authorize PTO to spend, without further appropriation, amounts collected in prior years that exceeded the spending authority provided in appropriation acts. Over the 1992-2007 period, PTO collected approximately \$750 million more in patent and trademark fees than it was authorized to spend. Of that amount, about \$230 million is held in a Patent and Trademark Surcharge account (arising from surcharges imposed on certain patent fees for a limited period of time by the Omnibus Budget Reconciliation Act of 1990, Public Law 101-508); the remaining amount, about \$520 million, is held in PTO's appropriation account.

The bill also would authorize PTO to invest its cash balances by purchasing obligations of the United States, or obligations guaranteed by the United States. It would have the authority to spend the interest earned on those balances. Based on information from PTO, we expect that outlays of the newly available amounts would occur slowly and that balances held would be invested in government obligations. CBO estimates that those provisions would increase direct spending by \$440 million over the 2009-2013 period and \$860 million over the 2009-2018 period.

**Compensation for Patent Holders.** Section 14 would eliminate the remedies that certain patent holders currently have with respect to financial institutions whose use of a "check collection system" constitutes patent infringement. By eliminating the remedies that inventors have with respect to a specific use of their inventions, section 14 would effectively eliminate their right to prevent financial institutions from using their inventions. Because a patent is essentially a right to restrict the use of an invention, CBO anticipates that enactment of section 14 would result in litigation against the federal government seeking compensation for a taking of private property. Further, certain patent holders who believe their patents would be infringed have indicated that, if section 14 is enacted, they would immediately file suit against the federal government. CBO generally has insufficient information to assess the likelihood or outcome of litigation against the federal government. In this case, the likelihood of litigation alleging a taking of private property is very high; based on Supreme

Court precedents, there is a high likelihood that the federal government will have to pay damages; and there is a strong basis for estimating those damages.

CBO expects that litigation involving section 14 ultimately would be resolved by the United States Supreme Court, and we assume that the federal government would make no payments during the 2009-2013 period. Further, we assume there is an equal likelihood of compensation payments during each of the following five years. Any damages or settlement amounts would be made from the Judgment Fund (a permanent, indefinite appropriation for claims and judgments against the United States).

To estimate the cost of such compensation, CBO consulted experts on patent litigation who indicated that royalties in patent cases often range from 10 percent to 25 percent of the savings produced by use of the invention. CBO's estimate is based on an expected value of royalty payments equal to 0.5 cents per check (about 3.5 percent of the estimated savings from using such patents) from financial institutions that use such "check collection systems," reflecting the uncertain outcome of future litigation resulting from section 14. The total volume of checks handled by U.S. financial institutions has been decreasing as consumers turn to other payment systems such as debit cards; however, the use of electronic "check collection systems" has been increasing rapidly over the past few years. Based on information from the Federal Reserve Board, CBO estimates that those trends will continue. Hence, we estimate that the expected value of the federal government's liability under section 14 would total about \$1 billion, representing a royalty of 0.5 cents per check on more than 200 billion checks cleared by financial institutions that would be authorized to infringe on the rights of patent holders under the bill. Depending on the outcome of the likely litigation against the government, the cost could be substantially more.

**Additional Spending for Federal Health Programs.** S. 1145 would authorize the Director of PTO to accept certain applications filed after current statutory deadlines if the Director determines that such delay was unintentional and the applicant petitions PTO within a specified time frame. CBO anticipates that enacting this provision would lead PTO to accept an application for extension of the patent term for a drug known by the trade-name Angiomax. (Angiomax is an anticoagulant used in conjunction with certain coronary procedures in hospital settings. The firm that holds the patent for Angiomax missed the statutory filing deadline by one day for its application to restore the patent term authorized under the Drug Price Competition and Patent Term Restoration Act.) Under the bill, we expect that PTO would grant nearly five years of additional patent protection to that product. CBO is currently not aware of any other drug likely to be affected by this provision that also would have an effect on spending by private health plans and federal health programs over the next 10 years.

Under current law, CBO expects that lower-priced generic competitors will first enter the market by January 2011. (The patent on Angiomax will expire in March 2010; however, the drug might receive an additional six months of exclusivity under the FDA's pediatric exclusivity program.) The entrance of generic drugs will reduce the average price paid for the product by private and public purchasers.

CBO anticipates that accepting the late application under the new authority provided by the bill would extend the patent term until December 2014. Assuming that six months of exclusivity ultimately is granted to Angiomax under the FDA's pediatric exclusivity program, we expect that the first generic version of the drug would not enter the market until the middle of calendar year 2015. Delaying the entry of generic versions of Angiomax would have three effects on hospitals' costs. It would:

- Increase the average price paid for the drug by hospitals;
- Increase the number of patients treated with the drug, and therefore, the quantity of the drug purchased by hospitals (because we expect that the manufacturer would continue to market the drug aggressively); and
- Reduce hospitals' costs for services furnished to the additional patients who would be treated with the drug as a result of those marketing efforts. (Total hospital costs for individuals treated with Angiomax for certain procedures tends to be lower than costs for individuals whose treatment involved alternative drug therapies.)

Based on published research and information provided by experts, CBO estimates that, over the 2011-2018 period, hospitals would spend about \$2 billion more for the drug and save about \$1 billion in other patient-care costs for a net increase in hospitals' costs of roughly \$1 billion. That increase in hospitals' costs would result in higher payments by some public and private providers of health insurance. In particular, CBO estimates that enacting S. 1145 would increase direct spending for certain federal health programs—particularly Medicaid and the government's share of retirees' health premiums under the Federal Employees Health Benefits (FEHB) program—by \$2 million over the 2011-2013 period and by \$19 million over the 2011-2018 period. (The bill would not affect Medicare spending because aggregate payments to hospitals are not affected by changes in the costs that hospitals incur.)

Other provisions of S. 1145 would alter intellectual property protections associated with other brand-name drugs and could affect when competing versions of generic drugs ultimately enter the market. Changing when those 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 FEHB program, and the Defense Department's TRICARE for Life program could be affected by the bill. Based on information provided

by experts in patent law and the brand and generic drug industry, CBO expects that those provisions would not have a significant effect on the entry of generic drugs over the next decade. Therefore, CBO estimates that net changes in direct spending for those programs would be negligible over the 2009-2018 period. Although the nature and extent of long-term effects are unclear, we expect that such effects on average drug prices could be significant beyond 2018.

## **Revenues**

S. 1145 would eliminate the requirement that PTO fees be treated as offsetting collections and give the agency permanent authority to set and collect fees for its activities related to processing and reviewing applications for patents and trademarks. Further, by changing the cost of certain drugs and health services (related to altering patent protection for prescription drugs), the bill would reduce federal tax revenues associated with changes in taxable compensation provided by employers that stem from changes in the costs of premiums for employer-sponsored health insurance. CBO estimates that, taken together, those two provisions would increase federal revenues by \$11.5 billion over the 2009-2013 period and \$25.5 billion over the 2009-2018 period.

**Reclassification of PTO Fees.** The bill would authorize PTO to collect and spend fees without further appropriation action. Further, the bill would permanently extend some, but not all, of the fee increases that have been in place since 2005. CBO assumes that PTO would use the fee-setting authority also provided in the bill, combined with the extension of the increase for some fees, to ensure that fee rates would not be reduced from fiscal year 2008 levels.

S. 1145 also would authorize PTO to collect new fees to offset the cost of procedures to review the validity of patents already awarded. Based on information from PTO, CBO estimates that the additional collections resulting from those new fees would be less than \$50 million each year.

Based on information from PTO and historical patterns of collections, CBO estimates that those new authorities would increase revenues by about \$11.5 billion over the 2009-2013 period and \$25.5 billion over the 2009-2018 period. (Those receipts would be roughly offset by a reduction in offsetting collections credited to PTO's appropriation account.)

**Health Insurance Premiums.** Changes to the average cost for prescription drugs and for certain health services would affect the cost of premiums for private health insurance. (See the discussion of the effect of the bill on changes in the average cost for prescription drugs and for certain health services in the section on direct spending under “Federal Health Programs.”) CBO anticipates that the increase in net costs for private health insurance plans would result in higher insurance premiums, thus increasing the amount spent by employers for tax-favored health insurance and reducing the amount spent on taxable wages. That change would reduce federal revenues from income taxes and payroll taxes by an estimated \$3 million over the 2010-2013 period and \$30 million over the 2010-2018 period. Social Security payroll taxes, which are off-budget, would account for about 30 percent of those totals.

### **Spending Subject to Appropriation**

CBO expects that enacting S. 1145 would change the classification of PTO fees from offsetting collections (netted against discretionary appropriations) to revenues. In addition, because the legislation would authorize PTO to spend all fee collections without further appropriation, the need to appropriate funds for PTO’s operations would be greatly diminished or eliminated. Because of the lag between when fees are collected and when they are spent, this reclassification would result in an increase in net discretionary outlays of \$0.4 billion in 2009 and \$0.1 billion in 2010.

Delaying the entry of the generic version of Angiomax also would affect the costs to administer certain discretionary health programs, including those of the Veterans Health Administration, the Indian Health Service, and the Department of Defense. It also would affect payments by federal agencies for health insurance premiums for current employees enrolled in the FEHB program. (See the discussion of the effect of the bill on the average cost for prescription drugs and for providing certain health services in the section on direct spending under “Federal Health Programs.”) CBO estimates that implementing S. 1145 would increase net discretionary spending by those programs by about \$17 million over the 2011-2018 period, assuming appropriation of the necessary amounts.

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

S. 1145 would impose intergovernmental and private-sector mandates, as defined in UMRA, on certain patent applicants, patent holders, and generic drug manufacturers. Based on information from PTO, CBO estimates that the cost of complying with those mandates would exceed the threshold for private-sector mandates established in UMRA (\$136 million in 2008, adjusted annually for inflation) in each of the first five years the mandate is in effect.

CBO estimates that the costs to state, local, and tribal governments would not exceed the annual threshold for intergovernmental mandates established in UMRA (\$68 million in 2008, adjusted annually for inflation).

### **Mandates That Apply to Both Public and Private Entities**

S. 1145 would impose both intergovernmental and private-sector mandates on certain patent applicants by compelling them to follow new requirements and pay fees.

**Reports and Analyses.** The bill would require PTO to establish regulations to require patent applicants to submit search reports, analyses, and other information. (Micro-entities, as defined in the bill, would be exempt from those requirements.) According to PTO, the cost for applicants to research and provide such information would total \$5,000 to \$10,000 per search report. While there are more than 200,000 patent applications each year, some applicants already provide similar information in their applications. CBO estimates that the cost to private-sector entities of complying with the mandate would substantially exceed the annual threshold. We estimate that the costs to public entities—primarily universities—would range from \$30 million to \$60 million annually over the next five years.

**Patent and Trademark Fees.** The bill would allow PTO to set or adjust certain fees and permanently extend other fee increases that are set to expire at the end of fiscal year 2008. The requirement to pay those fees would be a mandate because the federal government controls the trademark and patent systems, and no reasonable alternatives to the systems exist. Based on information from PTO, CBO estimates that the total cost to comply with the mandates would total about \$200 million annually beginning in 2009, with 1 percent to 2 percent (\$2 million to \$4 million) of those costs accruing to intergovernmental entities and the rest accruing to private-sector entities.

### **Additional Mandates That Apply to Private Entities Only**

**Acceptance of Late Filings.** Section 13 would allow the Director of PTO to accept late filings or applications in certain cases of unintentional delay. Currently, the patent for the drug Angiomax is set to expire in 2010. Accepting and approving a late application from Angiomax would delay competition and impose a mandate on generic drug companies. The cost of the mandate would be the forgone net income that generic drug companies would have received under current law. CBO cannot estimate the cost of the mandate because we do not have sufficient information about the distribution of industry costs and revenues.

**Patent Infringement Actions.** Section 14 would impose a mandate on certain patent holders by eliminating their remedies with respect to financial institutions whose use of a “check collection system” constitutes patent infringement. Under UMRA, the cost of that mandate would be the forgone value of licensing fees collected by those patent holders and awards or settlements of infringement claims resolved during the first five years the mandate is in effect. CBO cannot estimate the costs of the mandate because of uncertainty about the timing of current or future infringement claims and whether those claims would be resolved in those first five years. Based on information from the Federal Reserve Board and industry sources, CBO expects that the cost of this mandate could be substantial compared to the annual threshold.

### **Other Impacts**

Provisions of the bill that would extend exclusive patent rights for certain drugs would increase the cost of premiums for health insurance. CBO estimates that state, local, and tribal governments would pay increased premiums for health insurance for their employees totaling about \$5 million over the 2008-2013 period. Similarly, CBO estimates that state spending for Medicaid would increase by about \$1 million over that same period. Private-sector entities also would pay increased premiums for health insurance. We estimate that those costs would total about \$30 million during the 2008-2013 period.

### **PREVIOUS CBO ESTIMATE**

On September 4, 2007, CBO transmitted a cost estimate for H.R. 1908, the Patent Reform Act of 2007, as ordered reported by the House Committee on the Judiciary on July 18, 2007. That bill did not contain provisions to extend or change the budgetary treatment of fees collected by PTO, provisions that would eliminate remedies for certain patent holders, or provisions that would allow PTO to accept certain late filings. H.R. 1908 also would authorize the continuation of certain procedures to challenge patents that would be discontinued under S. 1145. CBO estimated that H.R. 1908 would have a net cost of \$11 million over the 2008-2012 period, subject to the necessary appropriations.

CBO determined that H.R. 1908 also contained intergovernmental and private-sector mandates, including a requirement to submit search reports and a prohibition on patenting tax-planning methods.

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