New Federal Initiatives Project

Health Care Reform: Implications for the Intellectual Property Community

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On March 23, 2010, President Obama signed H.R. 3590, entitled the "Patient Protection and Affordable Care Act" ("PPACA"), into law as P.L. 111-148. That bill passed the Senate on December 24, 2009, by a vote of 60-39 and the House on March 21, 2010 by a vote of 219-212. A week later, on March 30, 2010, the President signed into law H.R. 4872, entitled the "Health Care and Education Reconciliation Act of 2010" and passed by Congress through the filibuster-proof "reconciliation" process,[1] as P.L. 111-152. [2] The ten titles of PPACA, along with amendments in H.R. 4872, regulate multiple industries, each of which depend heavily on science, technology, and innovation, that make up approximately one-sixth of the national economy.

PPACA Provisions Impacting Intellectual Property:

Title VII

Title VII contains the provisions most obviously impacting innovation and intellectual property. Subtitle A of the Act, entitled the "Biologics Price Competition and Innovation Act of 2009,"[3] addresses biologic drugs – those made from living cells – and provides an abbreviated approval process for follow-on biologics somewhat similar to the Hatch-Waxman procedures for more standard drugs. This legislation accelerates the application process for follow-on biologics, and some say that it encourages patent litigation in a way that is likely to distort price competition and inhibit innovation. Critics argue that these provisions create a regulatory scheme with artificial dates, undefined terms, and paperwork hurdles that will cause inefficiency and litigation, thus imposing additional costs upon, and therefore reducing the productive output of, the companies being regulated.

Title VII also requires the General Accounting Office within eighteen months to address whether Section 340B of the Public Health Service Act, 42 U.S.C. § 256(b), known as the "340B Program," should be expanded.[4] Under the 340B Program, certain entities may purchase drugs at a discount from a federal list. Any expansion of the 340B Program – that is, expanding either the number of entities allowed to purchase discount drugs, expanding the number of drugs available at discount prices, or decreasing the discount price for available drugs – will necessarily reduce payments to drug makers. Critics argue that such expansion will reduce the revenues available to those drug makers for future research and development, thereby limiting future supply. Supporters, though not addressing this criticism directly, have broadly asserted the economic benefits of the health care reform legislation, including reduced overall spending on health care, reducing the inflation rate of health care services, easing strain on overburdened emergency rooms, and providing health insurance to millions of currently uninsured people. Proponents of the health care reform legislation also cite the support of the pharmaceutical industry for the reform efforts. Indeed, some analysts see the reform bill as a boon for the pharmaceutical industry, asserting that although costs per unit can be expected to go down, overall sales will rise considerably as government-funded programs that underwrite prescription drugs expand.[5] Under this scenario, drug companies would be expected to have more funds available for research and development.

Title II

Similarly, critics note that by expanding the Medicaid rebates for prescription drugs,[6] Title II also will reduce the total revenue available to drug makers available for future research and development. Strong property rights proponents argue that such reduced revenue will mean that no drug companies will have the resources or incentive to innovate at the pace seen over the last century. Ultimately, patients will suffer more – and die earlier – as new treatments and cures are delayed or left undiscovered. As noted above, supporters have argued that the reform legislation is a net economic winner for the pharmaceutical industry and that therefore development of new drugs, medical instruments and treatments will not in fact suffer.

Title IX

Title IX's revenue provisions include taxes on branded pharmaceutical and medical device manufacturers and importers. Under these two provisions, the federal government will collect billions of dollars annually from companies that develop or import new drugs and deliver covered medical devices. In the case of the pharmaceutical industry, it will tax at different rates depending on the drug developer or importer's market share of "branded drugs" sold to government medical-related programs. Although Section 9008 of the Act excludes the amount of a covered entity's sales in the private marketplace from the amount of "branded prescription drug sales" used in determining the amount of the fee, critics argue that the Act will still affect overall profitability and incentives by diverting otherwise productive resources to the relatively unproductive, paperwork-heavy tax avoidance industry instead.

Title III

Title III of the Act empowers the Secretary of the Department of Health and Human Services to establish a national strategy "to improve the delivery of health care services, patient health care outcomes, and population health."[7] Even if the national strategy does not literally impact the private sector, the federal government will be the single largest consumer of health care services, and its decisions will dictate the supply of treatments and innovations available to everyone. Supporters, however, contend that the government-as-consumer scenario will permit economies of scale previously unknown in the industry.

Title VI

Similarly, Title VI empowers the Social Security Administration to establish the "Patient-Centered Outcomes Research Institute."[8] PCORI is reputedly not a government agency, but instead is being created to

> assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in

patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a)(2)(B).

Conclusion

Both supporters and critics of the Patient Protection and Affordable Care Act use essentially the same set of facts to make contrary arguments. It is clear that government involvement and regulation will increase. Free market advocates and property rights proponents argue that through the various mechanisms of government control and regulation discussed above, freedom to innovate will be reduced, and the revenue stream essential to fund research and development will be decreased. Supporters see the government involvement differently – as an imposition of certain otherwise absent efficiencies, and the rise of a new, large buyer in the marketplace that will in fact increase the revenue stream of industry players. At bottom, assert critics, the "Patient Protection and Affordable Care Act" both explicitly and implicitly impacts innovation and intellectual property rights, in some ways that are difficult or impossible to predict.

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[1] Under the United States Constitution, no legislative bill can go to the President for signature until passed by both the House of Representatives and the Senate. U. S. Const., Art. I, Sec. 7. The Senate, which styles itself "the world's greatest deliberative body," requires 60 votes to overcome a filibuster. Because neither party currently has the votes needed to bring a conference committee bill to a vote, Democrats used the "reconciliation" process, which does not require a separate Senate vote, to avoid a filibuster. Created in a 1974 budget resolution, see http://www.rules.house.gov/archives/bud_rec_proc.htm, "reconciliation" was not actually used until 1980, and is typically limited to technical changes in "entitlement" spending or tax laws to comply with budget resolutions. It is likely for this reason that H.R. 4872 is entitled "An Act to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13), and that its short title is the "Health Care and Education Reconciliation Act of 2010." H.R. 4872, Sec. 1.

[2] H.R. 4872 was designed to appease House members upset about certain aspects of the Senate bill, derisively called the "Louisiana Purchase," the "Cornhusker Kickback," "Gator Aid," "Handout Montana," "the U Con," and the "Bayh Off," collectively referred to as "Cash for Cloture." *See, e.g.,* Dana Milbank, "On health-care bill, Democratic senators are in states of denial," *Washington Post*, Dec. 22, 2009, at http://www.washingtonpost.com/wp-dyn/content/article/2009/12/21/AR2009122102861.html?hpid=topnews.

[3] H.R. 3590, Sec. 7001 *et seq.*

[4] H.R. 3590, Sec. 7103.

[5] *Big Pharma Wins Big With Health Care Reform Bill*, March 29, 2010, available at http://www.commondreams.org/headline/2010/03/29-8.

[6] H.R. 3590, Sec. 2501.

[7] H.R. 3590, Sec. 3011.
[8] H.R. 3590, Sec. 6301.

Related Links

Full text of the Patient Protection and Affordable Care Act
http://democrats.senate.gov/reform/patient-protection-affordable-care-act-as-passed.pdf

"BIO Statement on Health Care Reform," from Biotechnology Industry Organization
http://www.bio.org/news/pressreleases/newsitem.asp?id=2010_0322_01

"Healthcare Reform Creates Pathway for Biosimilar Biologics," from IPfrontline.com
http://www.cafezine.com/depts/article.asp?id=24198&deptid=4

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