Intellectual Property

Impediments to Innovation: Implications of National Health Care Legislation for the Intellectual Property Community

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The move toward a national health care plan in the United States has taken three major steps: passage of the Social Security Act under President Franklin D. Roosevelt in 1935;[1] passage of Medicare and Medicaid as amendments to the Social Security Act under President Lyndon B. Johnson in 1965;[2] and passage of the "Patient Protection and Affordable Care Act" under President Barack H. Obama in 2010. Although contemporaneous litigation may stop or slow its implementation,[3] and implementing regulations have not yet been drawn up or been published, it is safe to say that any legislation that regulates an estimated one-sixth of the national economy—and a segment that is particularly sensitive to and dependent upon innovation—will necessarily affect innovation and intellectual property rights.[4] The general merits (or, indeed, the constitutionality) of a national health care scheme are not the focus of this paper. Instead, we offer observations about the likely effect of this recently-passed legislation on the most significant driver of American economic growth in the twenty-first century, innovation and corresponding intellectual property rights.

I. Brief Legislative History

On March 23, 2010, President Obama signed H.R. 3590, entitled the "Patient Protection and Affordable Care Act," into law as P.L. 111-148. That bill had passed the Senate on December 24, 2009 by a vote of sixty to thirty-nine and the House on March 21, 2010 by a vote of 219 to 212. Immediately after voting on H.R. 3590, the House also passed H.R. 4872, entitled the "Health Care and Education Reconciliation Act of 2010," by a vote of 220-211, and President Obama signed it into law on March 30, 2010 as P.L. 111-152.[5] The analysis below focuses primarily on H.R. 3590, enacted as P.L. 111-148, with amendments by H.R. 4872, enacted as P.L. 111-152, as noted.

II. Overview of the "Patient Protection and Affordable Care Act"

The PPACA is divided into ten titles that regulate multiple industries, each of which depend heavily on science, technology, and innovation. Title I includes new statutes governing the health insurance industry, such as prohibiting certain coverage limits, extending dependent coverage, standardizing language and forms, and prohibiting preexisting condition exclusions; addresses costs; and attempts to achieve universal health care coverage by creating state insurance exchanges, providing tax credits, and requiring individuals to obtain health insurance or to pay a fine enforceable by the Internal Revenue Service. Title II amends existing government-run programs such as Medicaid, the Children's Health Insurance Program (also known as "CHIPs"), and the Medicaid prescription drug program. Title III attempts to address the quality and efficiency of health care. Title IV attempts to address chronic disease and overall public health, and Title V addresses the health care workforce.

Title VI addresses the "transparency and integrity" of the Act, Title VII addresses access to innovative medical technologies such as biologic drugs, and Title VIII addresses community living assistance. Title IX addresses funding for the Act. Finally, Title X contains a variety of amendments to the above sections based on the "Manager's Amendment" to H.R. 3590 added shortly before the Senate's December 24, 2009 vote. Of greatest interest here are Titles VII, II, and IX, although Titles III and VI also deserve a look.

III. PPACA Provisions Impacting Intellectual Property

A. 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,"[6] addresses biologic drugs—those made from living cells—and provides an abbreviated approval process for follow-on biologics similar to the Hatch-Waxman procedures for conventional drugs. Specifically, Section 7002 provides twelve years of exclusivity for the inventors of biologic drugs while providing an expedited pathway to approval for follow-on drug makers.[7] This legislation accelerates the application process for follow-on biologics and regulates certain kinds of patent litigation.

1. Biosimilar Application Process

Title VII defines a "biologic drug" as "biosimilar" to a branded company's biologic drug ("reference product") if it is (a) "highly similar" to the reference product (b) with no clinically meaningful differences in terms of safety, purity, and potency.[8] A "biological product" is "interchangeable" with the reference product if: (1) the biological product is determined to be "biosimilar" and (2) the biological product meets safety and efficacy standards compared to the reference product.[9]

Assuming the applicant thinks it meets one of these standards—to be defined later, in rules and regulations promulgated and codified in the Federal Register—an applicant must wait at least four years after the FDA first approves the reference product to file its biosimilar application, which the FDA then has eight to eight and a half years to approve. (The FDA may not approve the biosimilar application until at least twelve years after its first approval of the reference product, and may extend the term by six months if the FDA requests,

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and the brand company completes, certain pediatric clinical studies.)[10]

The FDA will then reward the first biosimilar applicant to establish interchangeability with the reference product with marketing exclusivity for a period ranging from twelve months after its first commercial marketing to eighteen months after approval (unless that applicant is involved in ongoing patent litigation), based on the earlier of:

- one year after first commercial marketing of first interchangeable biological product;
- eighteen months after approval, if no patent litigation had been instituted against the first interchangeable biological product,
- eighteen months after a final court decision of all patents in suit or dismissal with or without prejudice on litigation over the first interchangeable biological product; or
- forty-two months after approval if there is still ongoing patent litigation on the first interchangeable biological product.[11]

2. Biosimilar Patent Litigation

Before a biosimilar applicant and the brand company can pursue patent litigation, the parties must first exchange information such as the biosimilar application, manufacturing information, lists of potentially infringed patents, and arguments regarding infringement, validity, and enforceability. The parties must then follow detailed negotiation procedures during which the applicant decides the total number of patents that can be litigated. There is no automatic stay of FDA approval during any ensuing litigation. And failure to follow these procedures, such as failing to provide potentially confidential information, will have significant consequences, such as barring the brand company from seeking an injunction before the applicant commercializes its follow-on product.[12]

3. 340B program discounted drugs

Title VII of the Act also requires the General Accounting Office to report within eighteen months regarding the scope of section 340B of the Public Health Service Act, 42 U.S.C. § 256(b), known as the "340B Program."[13] Under the 340B Program, certain entities may purchase drugs at a discount from a federal list. The GAO report must address whether the 340B program "should be expanded since it is anticipated that the 47,000,000 individuals who are uninsured as of the date of enactment of this Act will have health care coverage once this Act is implemented."[14] Any expansion of the 340B Program—that is, expanding either the number of entities allowed to purchase discount drugs (or the number of drugs available at discount prices), or decreasing the discount price for available drugs—will necessarily reduce payments to drug makers.

B. Title II

Title II will expand the scope of Medicaid rebates for prescription drugs.[15] Title II is therefore likely to reduce the total revenue available to drug makers available for future research and development. Because U.S. drug manufacturers implicitly subsidize the health care systems of other nations by virtue of being the world's leading innovators, patients in Europe, Canada, and Japan have in the past been able to benefit from new drugs developed by American drug companies.[16] By equilibrating the cost of such subsidies, the Act will reduce the resources and incentive of drug companies to innovate at the pace seen over the last century. Ultimately, patients are likely to suffer more—and die earlier—as new treatments and cures are delayed or left undiscovered.

C. Title IX

Title IX's revenue provisions include taxes on branded pharmaceutical and medical device manufacturers and importers. In particular, Section 9008 of the Act, as amended, allocates an escalating multi-billion dollar annual tax among branded drug manufacturers and importers based on the absolute amount of their "branded prescription drug sales" to certain government programs[17] and their adjusted market share,[18] and Section 9009 imposes a 2.3% excise tax on medical device makers or importers.[19] The amount of the fee is based on the percentage that a specified percentage of the entity's branded prescription drug sales "taken into account" during the preceding calendar year bears to the "aggregate branded prescription drug sales" of all covered entities "taken into account" during the preceding calendar year, applied to an amount that varies from year to year.[20]

Basic economics teaches that taxing something (*i.e.*, raising its price) is likely to yield less of it, while subsidizing something (*i.e.*, reducing its price) creates demand for more. Although Section 9008 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, it will still affect overall profitability and incentives, in at least two ways.

The first order effects on both the pharmaceutical and the medical device industries will be to increase the price (cost) of their products, to leave fewer resources for research and development, and thereby to reduce the incentive of some companies in the industry to stay in business at all. Because of the disparate effective rates of the health care excise tax on pharmaceutical companies, the second order effect of these provisions on the pharmaceutical industry is more problematic, and at this stage difficult to quantify.

For example, the specified percentage of sales to government programs on which the excise tax is based varies with the amount of branded prescription drug sales the entity makes. For covered pharmaceutical entities with not more than $5 million in aggregate branded prescription drug sales during the calendar year that percentage is zero; for those with more than $5 million but not more than $125 million in such aggregate sales it is ten percent; for those with more than $125 million but not more than $225 million in such aggregate sales it is forty percent; for those with more than $225 million but not more than $400 million in such aggregate sales it is seventy-five percent; and for those with more than $400 million in such aggregate sales it is one hundred percent.[21]

To understand the second order effects of this approach, consider that in 2009 the total size of the U.S. pharmaceutical

market was an estimated $315-321 billion, with thirty active pharmaceutical companies, including Pfizer, GlaxoSmithKline, Johnson & Johnson, and Merck.[22] Thus, we could say that the "average" annual revenues of these companies, if apportioned equally, would be approximately $10.65 billion. Yet unless these revenues are evenly distributed, or unless all participants are above the $400 million annual sales threshold for branded prescription drugs, then the annual excise tax will work to the advantage of some and to the disadvantage of others.

Imagine, for example, that the entire U.S. pharmaceutical industry has $2.5 billion in covered "branded prescription drug sales" to the specified government programs in 2011, exactly equal to the initial aggregate amount of the excise tax. (This would be less than eight-tenths of one percent of the total pharmaceutical market for that year.) Imagine further that the distribution of such sales to the specified government programs is unequal, such that Merck has $401 million in branded prescription drug sales to government medical programs in 2011 and each of the remaining twenty-nine competitors has an equal share of the balance, or $72.38 million each.

Because Merck's covered branded prescription drug sales in this example would exceed $400 million, Section 9008(b) would require Merck to take one hundred percent of its covered sales into account for purposes of the excise tax. Because their covered sales would be less than $125 million, each of its twenty-nine competitors would have to take only ten percent of its covered sales into account. Thus, for excise tax purposes, Merck would account for $401 million in covered sales, and each other market participant would account for $7.238 million (ten percent of $72.38 million). Accordingly, although total covered sales to the specified government agencies would be $2.5 billion, the amount of sales taken into account for purposes of the excise tax would be only $610.9 million (Merck's $401 million plus the other twenty-nine competitors' aggregate $209.9 million).

Merck's hypothetical share of the $2.5 billion excise tax would therefore be roughly 65.64% of the total industry tax ($401 million/$610.9 million), notwithstanding that its share of the total branded sales to the specified government agencies would be only about sixteen percent ($401 million/$2.5 billion). Conversely, Merck's twenty-nine competitors would pay in the aggregate only 34.36% of the excise tax—or about 1.18% each—even though their aggregate share of the total branded sales to the government would be about eighty-four percent ($2.099 billion/$2.5 billion)—or about 2.9% each. In other words, Merck's effective tax rate on "branded prescription drug sales" would be more than eight times that of its competitors, because Merck would be paying at four times its proportionate share of the market and the competitors at less than one-half.

In this example, what would these numbers mean for the bottom line? They would mean that Merck's 65.64% share of that year's $2.5 billion excise tax is $1.64 billion. Because we have assumed, in this example, that total pharmaceutical industry sales (not restricted to "covered" sales to government agencies) are evenly distributed among the industry's twenty-nine participants, or approximately $10.65 billion each, Merck's revenues for the year net of the excise tax are reduced to $9.01 billion ($10.65 billion – 1.64 billion). Each of its competitors, however, would pay "only" about $29,619,950 ([$2.5 billion – $1.64 billion] / 29) in excise tax for the year, so their revenues for the year net of the excise tax would be approximately $10.62 billion each ($10.65 billion minus 29.62 million).

The net effect in this example, then, would be that total covered sales of branded prescription drugs to government agencies that constitute less than eight tenths of one percent of the total pharmaceutical market for brand name drugs that year would put one competitor at a $1.61 billion disadvantage—roughly fifteen percent of its total revenues—relative to its competitors. Because the excise tax is not deductible for income tax purposes, this difference would go straight to the bottom line.

In sum, a very small share of the total market that is disproportionately large in relation to "branded prescription drug sales" could have a dramatic effect on the bottom line of the pharmaceutical company that dominates the "branded prescription drug sales" market. Participants in this particular market would therefore have an economic incentive either to minimize their sales to the "specified government programs"—namely Medicare, Medicaid, TRICARE, and certain Veterans and Defense Department programs—or to form cartels to ensure that their relative participation were roughly equal.

The exact effects of Section 9008's excise tax will depend upon total "branded prescription drug" sales, their distribution among the companies in the market, and the aggregate amount of the tax each year. But if the federal income tax system is any guide, this sort of unequal treatment will divert otherwise productive resources to the relatively unproductive, paperwork-heavy tax avoidance industry instead. Tax lawyers and accountants thus may benefit at the expense of innovation in the health care industry.

D. 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."[23] This provision does not appear to extend as far as the "comparative effectiveness research center" proposed in earlier health care reform bills. Nevertheless, the Secretary is empowered to work with federal and state agencies to deliver health care in line with a national strategy developed under this provision rather than allowing market forces alone to set health care priorities. 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. The federal government's decisions thus will dictate the supply of treatments and innovations available to everyone.

E. Title VI

Similarly, Title VI empowers the Social Security Administration to establish the "Patient-Centered Outcomes Research Institute."[24] PCORI is reputedly not a government agency and is being created for the following purposes:

> [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).[25]

IV. Conclusion

At bottom, 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. Directly, the Act imposes a complicated regulatory scheme, details yet to be provided, concerning intellectual property protection of biologic drugs. Indirectly, the Act takes resources of drug companies and medical device makers and importers that otherwise might fund research and development or directly lower product costs. It remains to be seen, in other words, whether the recently-passed national health care legislation will violate the first and oldest rule in medicine: first, do no harm.

Endnotes

1 Social Security Act, ch. 531, 49 Stat. 620 (now codified at 42 U.S.C. ch.7).

2 Social Security Amendments of 1965, Pub. L. No. 89-97, 42 U.S.C. ch. 7, subch. XVIII, §§ 1395 *et seq*.

3 For a by-no-means exhaustive complaint against the constitutionality of PPACA, see the complaint in *State of Florida v. U. S. Dept. of Health & Human Services*, Case 3:10-cv-00091-RV-EMT, (N.D. Fla. March 23, 2010), which argues that the Act violates the Commerce Clause and the Taxing and Spending Clause (Art. I, Sec. 8), the prohibition against unapportioned capitation or direct taxes (Art. I, Secs, 2, 9), the sovereign rights of states to a republican form of government (Art. IV, Sec. 4), and the Tenth Amendment. Other arguments advanced elsewhere include objections under the First Amendment's Free Exercise Clause and the Fifth Amendment's Takings Clause. *See* Peter Urbanowicz & Dennis G. Smith, Federalist Soc'y for Law & Pub. Policy Studies, Constitutional Implications of an "Individual Mandate" in Health Care Reform 5 (2009), *available at* http://www.fed-soc.org/doclib/20090710_Individual_Mandates.pdf.

4 *See* H.R. 3590, 111th Cong., § 1501(a)(2) (2010) (enacted), spelling out findings regarding the national economic importance of health care and stating that spending on health insurance and health care services constituted 17.6% of the economy in 2019. For a statement that national health care is likely to retard innovation, see the remarks of former Clinton Administration Secretary of Labor Robert Reich given at the University of California at Berkeley on September 26, 2007, available at http://www.youtube.com/watch?v=IT7Y0TOBuG4.

5 H.R. 4872 was designed to appease House members upset about certain aspects of the Senate bill which the press and political critics have dubbed 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, Wash. Post, Dec. 22, 2009, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2009/12/21/AR2009122102861.html?hpid=topnews.

6 H.R. 3590, § 7001 *et seq*.

7 *Id.* § 7002(k) (7).

8 *Id.* § 7002(k) (2) (A) (i) (I).

9 *Id.* § 7002(k) (4).

10 *Id.* § 7002(k) (7).

11 *Id.* § 7002(k) (6).

12 *Id.* § 7002(l).

13 *Id.* § 7103.

14 *Id.* § 7103(b) (1).

15 *Id.* § 2501.

16 The United States has the largest pharmaceutical industry in the world, with calendar year 2007 revenues totaling approximately $315 billion. The combination of market competition, patent protection of new medicines, an aging population, the emergence of bio-pharmaceutical technology, and fierce global competition have led to increasing research and development since the year 2000. This includes a 3.16% annual increase even during the global financial crisis year of 2008, when U.S. pharmaceutical R & D expenditures totaled a reported $65.2 billion. Approximately 2,900 drugs are currently undergoing research and testing in the United States, including approximately 750 for cancer treatment, 312 for heart diseases, 150 for diabetes, 109 for AIDS, and ninety-one drugs for Alzheimer's disease and related dementia. *See* US Pharmaceutical Industry Report, 2008-2009 (2009) (summary available at http://www.reportlinker.com/p0118600/US-Pharmaceutical-Industry-Report-2008-2009.html).

17 H.R. 3590, § 9008 defines a "covered entity" as "any manufacturer or importer with gross receipts from branded prescription drug sales," H.R. 3590, § 9008(d), 111th Cong. (2010) (enacted), and "branded prescription drug sales" as sales of "branded prescription drugs" to "any specified government program" or "pursuant to coverage under any such program." *Id.* § 9008(e) (1). "Specified government program" means Medicare Parts B and D; Medicaid; Department of Veterans Affairs and Department of Defense programs that procure "branded prescription drugs"; and the TRICARE retail pharmacy program, formerly part of what was known as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), a health care program of the United States Department of Defense Military Health System, that provides civilian health benefits for military personnel, military retirees, and their dependents, and some members of the reserves. *Id.* § 9008(e) (4).

18 H.R. 3590, § 9008, requires each "covered entity" in the "business of manufacturing or importing branded prescription drugs" to pay a "fee" to the Secretary of the Treasury no later than September 30 each year. *Id.* § 9008(a). For Internal Revenue Service purposes, the "fee" is treated as an "excise tax" with respect to which only civil actions for refunds under Subtitle F of the Internal Revenue Code apply, so that such fees are not deductible. *Id.* § 9008(f).

19 Originally, H.R. 3590, § 9009 imposed a fee on medical device makers or importers calculated in much the same way as that of § 9008(b), but based on an aggregate $2 billion fee, "gross receipts" rather than "sales taken into account," and with only three size classes of "covered entities": those with aggregate "gross receipts" of not more than $5 million (zero percent); those with aggregate "gross receipts" of more than $5 million but not more than $25 million (fifty percent); and those with aggregate "gross receipts" of more than $25 million (one hundred percent). H.R. 3590, § 9009(b), 111th Cong. (2010) (enacted). Before Congress even passed the bill, § 10904 amended § 9009(b) to increase the aggregate amount of the "fee" to $ 3 billion after 2017. H.R. 3590, § 10904(a), 111th Cong. (2010) (enacted). That is the way matters stood for exactly one week following President Obama's signing H.R. 3590 into law. On March 30, 2010, however, H.R. 4872 repealed § 9009 of H.R. 3590, as amended, retroactively effective to its enactment date, and replaced it with a 2.3% tax on the sales price of "any taxable medical device sold by the manufacturer, producer, or importer." H.R. 4872, § 1405(d), 111th Cong. (2010) (enacted).

20 H.R. 4872, § 1404(a) (2), 111th Cong. (2010) (enacted). As discussed later in this article, the specified percentage of sales taken into account for covered entities with not more than $5 million in aggregate branded prescription drug sales during the calendar year is zero; for those with more than $5 million but not more than $125 million in such aggregate sales it is ten percent; for those with more than $125 million but not more than $225 million in such aggregate sales it is forty percent; for those with more than $225 million but not more than $400 million in such aggregate sales

it is seventy-five percent; and for those with more than $400 million in such aggregate sales it is one hundred percent. H.R. 3590, § 9008(b) (2), 111th Cong. (2010) (enacted). Originally, the aggregate fee imposed on the pharmaceutical industry was to be $2.3 billion. *Id.* § 9008(b) (1). Under the reconciliation bill, however, the aggregate industry fee begins at $2.5 billion with calendar year 2011 and increases to $2.8 billion in 2012 and $3 billion in 2014. There it remains until after the 2016 presidential election year, when it increases to $4 billion in 2017 and $4.1 billion in 2018. In 2019 and thereafter, it returns to its 2012 level of $2.8 billion per year. H.R. 4872, § 1404(a) (2) (b), 111th Cong. (2010) (enacted).

21 H.R. 3590, § 9008(b) (2), 111th Cong. (2010) (enacted).

22 *See supra* note 22.

23 H.R. 3590, § 3011, 111th Cong. (2010) (enacted).

24 *Id.* § 6301.

25 *Id.*