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The Impact of Exempting the Pharmaceutical Industry from Patent Reviews

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Executive Summary

This paper analyzes the impact of an amendment to Senate Bill 1137, offered by Senator Thomas Tillis, which would exempt patents related to pharmaceuticals and biological products from the Inter Partes Review (IPR) process. The IPR process was established in the America Invents Act, which was passed and signed into law in 2012. The process is intended to provide a quick and low-cost way in which dubious patent claims can be challenged by those who might be affected. In the first two years in which it was in place, almost one-third of challenged claims were canceled or removed according to data from the United States Patent and Trademark Office (USPTO).

Based on this data, the paper argues that the IPR process appears to be an effective mechanism for quickly removing dubious patent claims before they impose major costs on the economy.

It notes that many drug companies have made dubious patent claims on drugs that were both medically important and involved substantial sales revenue. Such claims have often been rejected by patent offices in other countries as well as the USPTO. However, since patent law in the United States is very friendly to patent holders, those making dubious claims have often benefited even when these claims are eventually overturned. Also, because there is an asymmetry between the potential benefits to a patent holder who gets to maintain a monopoly on their drug and a generic producer who is trying to gain the right to sell a drug in a competitive market, it is likely that many dubious claims end up going unchallenged.

The paper notes research showing large gaps between patent protected drug prices and the prices of generics. The later typically sell for just 10 to 20 percent of the price of the former and in some extreme cases, less than one percent. This means that if patents are improperly granted, the public could end up paying far higher prices for drugs.

A set of calculations shows that in a low-cost scenario the additional costs from improperly granted patents could be over $73 billion in the 20-year period from 2018−2037. In a middle-cost scenario, the higher cost would be almost $146 billion and in the high-cost scenario it would be almost $220 billion.

Much of this additional cost would be borne by public sector health care programs, most importantly Medicare and Medicaid. In the low-cost scenario, Medicare would pay $24 billion over this 20-year period while Medicaid would pay an additional $7 billion. In the middle-cost scenario, Medicare would pay an additional $48 billion and Medicaid would pay $14 billion more. In the high-

cost scenario, Medicare would pay an additional $72 billion over this 20-year period while Medicaid would pay $21 billion.

The paper also points out that if the exemption of the pharmaceutical industry from IPR allows for improperly granted patents it is also likely to lead to misdirected research spending, as drug companies attempt to innovate around these patents in order to share in the patent rents.

Introduction

In the summer of 2011, a large bipartisan majority in both houses of Congress approved the Leahy-Smith America Invents Act (AIA), which President Obama signed into law on September 16, 2011. The purpose of the law was to modernize the patent system in order to better foster innovation and to reduce the extent to which patent suits can improperly impede technological progress. The problems in the prior system were widely recognized, which is why the bill was able to gain such broad-based support.

One of the main provisions of the AIA was the creation of the Inter Partes Review process. This process allows third parties to contest the validity of patent within nine months of its issuance before the Patent Trial and Appeal Board. The basis for review must relate to either Section 102 or Section 103 of Title 35 of the United States Code. These sections refer the requirement that a patent be novel and non-obvious, respectively. The purpose of this provision is to provide a relatively low-cost mechanism for challenging inappropriate patents so that they can be revoked before there are substantial commercial consequences.

The need for such reviews stems from the fact that the United States Patent Office is under enormous pressure to grant patents and may often error on the side of the applicant. In 2014, there were over 618,000 patent applications filed.[1] With just 9,300 examiners, this translates into almost 70 patents per examiner per year.[2] Many of the applications are hundreds or even thousands of pages, mostly in technical language. Under such circumstances, mistakes are inevitable. The ease of getting a patent was famously demonstrated in 1997 when two inventers were able to get a patent on a peanut butter and jelly sandwich.[3] The Inter Partes Review process was established to provide a

1 USPTO (2014b), Table 2.
2 *Ibid*, p. 11.
3 USPTO (1999).

timely and low-cost mechanism to counter the pro-applicant bias inherent in the patent issuing process.

An amendment to Senate Bill 1137 offered by Senator Thomas Tillis would exempt patents related to pharmaceuticals and biological products from the Inter Partes Review process established by the AIA. This study examines the implications of this proposed exemption for the pharmaceutical industry. Specifically it discusses the likelihood of patents being granted improperly in this sector and the potential implications in terms of higher drug costs for the government and the private sector.

Patent Protection and Drug Prices

Spending on prescription drugs has grown rapidly both as a share of health care spending and as a share of GDP. Prescription drugs rose from just 0.3 percent of GDP in 1959 to 2.1 percent of GDP ($373.6 billion) in 2014.[4] One of the reasons that prescription drugs were not originally covered under Medicare when it was established in 1965 is that the cost was small enough so that it did not impose a major burden on most seniors. This rapid growth in drug spending has continued even as other the growth in other health care costs has slowed. Over the last four years spending on prescription drugs has increased at average annual rate of 6.7 percent, with an increase of 10.9 percent in the year from 2013 to 2014. By comparison, spending on health care services, the category which accounts for the vast majority of health care spending, has increased at just a 4.3 percent annual rate since 2010 and a 4.0 percent rate in the last year. [5]

The main reason that drugs are expensive is patent protection and other forms of protection for intellectual property.[6] In the absence of these protections, the vast majority of drugs would sell at relatively low prices. Chain drugs stores sell hundreds of generic drugs at prices of less than $10 per prescription. As a group, these drugs are not necessarily simpler or easier to manufacture than the brand drugs that sell for hundreds or even thousands of dollars per prescription. The difference is

4 These data are taken from the BEA (2015), Table 2.4.5U, Line 121, divided by Table 1.1.5, Line 1.
5 *Ibid*., Table 2.4.5U, Line 168.
6 In addition to patent protection, many drugs enjoy effective monopolies through data exclusivity, which prohibits competitors from establishing the safety and effectiveness of their product by using the test results filed with the Food and Drug Administration (FDA) by the first company gaining approval. In addition, the first generic drug to enter a market is granted a six-month period as the sole generic competitor, which allows the manufacturing to charge a higher price than in a market fully open to competition.

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