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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.

that the brand drugs enjoy some degree of monopoly as result of patents and other forms of protection.

Of course, the patent system serves an important purpose by providing an incentive for pharmaceutical companies to research and test new drugs, but this incentive must be carefully structured to ensure that it is encouraging research and innovation and not just rent-seeking at the expense of the rest of society. The AIA was an effort to recalibrate the system to limit the incentives for such rents. The specific purpose of the Inter Partes Review process established under the AIA was to allow for a relatively low-cost mechanism through which the validity of patents could be challenged. It replaced the Inter Partes Reexamination process which had been in place prior to the passage of the AIA.

The logic of this process is straightforward: if a patent has been improperly awarded it is best to have this fact determined as quickly as possible. Consumers should not have to pay patent protected prices for an item that should be available in a competitive market without a patent monopoly. Also, competing firms benefit from knowing as quickly as possible if a patent is valid. They may have incentive to try to invent around a valid patent in order to share in a portion of the patent rents. This can lead to misdirected investment if it subsequently turns out that the patent is not valid. In addition, it is much cheaper and quicker if the decision on a patent's validity can be made by a patent review panel rather than bringing the issue into federal court. For these reasons, the Inter Partes Review process is sound policy.

It is important to recognize that the Tillis Amendment is not intended to end the Inter Partes Review (IPR) process in general, just to exclude patents related to pharmaceutics and biological products from process. There is not an obvious reason why these patents would be singled out for special treatment. While the review process is relatively new, it does not appear that the pharmaceutical industry has been singled out for harassment by this process. In the first two years that the review process has been in place, pharmaceutical patents accounted for 5.6 percent of the patents for which review petitions were filed.[7] By comparison, these patents have accounted for 3.1 percent of all patents issued over the years 2008−2012, the most recent period for which data is available.[8] This indicates that pharmaceutical patents are more likely to face an IPR than patents more generally, but their risk of review is not hugely out of line with the risk faced by other patent holders. Furthermore, based on past trends, there would have been more than 16,000 pharmaceutical patents issued in this period. With a total of 114 petitions, less than 0.8 percent of pharmaceutical patents have faced review petitions in this period.

7 USPTO (2014a).
8 USPTO (2014c).

The USPTO does not provide data on the outcomes of IPRs by category, but it appears that most of the petitions for review have not been frivolous. In the first two years after the AIA was passed, the review board agreed to hear 3,344 claims out of 5,045 claims that were challenged, or just over 66 percent as shown in **Table 1**.

TABLE 1

Outcome of Inter Parte Review Petitions	
(as of September 2014)	
Patent claims challenged	5045
Patent claims reviewed	3344
Patent claims withdrawn	606
Patent claims found unpatentable	999
Challenged claims removed	31.8 percent
Reviewed claimed removed	48.0 percent

Source: USPTO (2015).

Of this group, 999 claims were found to be unpatentable while 606 claims were cancelled or disclaimed.[9] This means that of the claims challenged, almost one-third (31.8 percent) were subsequently removed in one manner or another. Unless the quality of patents issued for pharmaceutical patents is markedly higher than for other patents, the IPR process would appear to be an efficient mechanism for reducing the number of unwarranted patent claims.

There are certainly many issues that have been and could be raised about the validity of pharmaceutical patents. Other countries that have considerably stricter standards for patents have denied patents for drugs that are patented in the United States and therefore can command a high price due to monopoly power.

For example, India refused to grant a patent for the cancer drug Glivec.[10] As a result, a generic version of the drug is available in India at a cost of $2,500 a year. The patent protected version in the United States sells for $70,000 a year, nearly thirty times as much.[11] Similarly, Gilead Sciences was unable to win a patent in India for its Hepatitis C drug, Sovaldi.[12] The patent protected version of the drug sells in the United States for $84,000 for a three month course of treatment. Doctors Without Borders estimated that a generic version could be produced for just over $100 a year.

9 These data are taken from USPTO (2015).
10 Kulkarni et al. (2013).
11 Harris et al. (2013).
12 Silverman (2015).

These are, of course, extreme cases involving unusually expensive drugs. Also, India has among the strictest patent standards in the world (i.e. it is difficult to get a patent), but they do illustrate the sort of money that could be at stake with an improperly granted patent in the pharmaceutical industry. But it is not necessary to make comparisons with India's patent system to find important examples of potentially improper patents. There are plenty of cases of questionable cases of important patents where issues have been raised in U.S. courts.

For example, AstraZeneca made modest alterations to its heartburn drug Prilosec just as its patent protection was expiring in 2001. It repackaged the drug and sold it as Nexium, on which it was able to enjoy patent protection until 2014.[13] The drug Clarinex, which was marketed by Schering-Plough, provides another example of this sort of patent abuse which is sometimes referred to as "evergreening." Schering-Plough brought Clarinex to the market just as the patent on its incredibly successful allergy drug Claritin was about to expire. Clarinex was essentially the same drug, with extremely minor modifications. (One of Schering-Plough's main claims for the superior benefits of Clarinex was that it could be taken with grapefruit juice.[14]) Shering-Plough's claims for the patentability of Clarinex were eventually rejected by the courts, but the process effectively extended the life of its patent on Claritin by 46 months since patents generally are treated as being in effect through the life of a dispute.

This situation points to the benefits of the sort of early intervention allowed by IPR process. There is a fundamental asymmetry in the stakes between the party defending and the party attacking a pharmaceutical patent, if it pertains to a drug that is already being successfully marketed. The company defending the patent stands to make monopoly rents for the whole time that the patent remains in effect. By contrast, the party attacking the patent only stands to gain the right to sell the drug in a competitive market.[15]

Since the monopoly profits are much larger than the profits from selling the drug in a competitive market, the holder of the patent has far more incentive to defend its patent than a potential generic competitor has in contesting the patent. The threat of high legal costs can discourage many potential competitors from even trying to enter the market since they may conclude that the profits would not justify the expenses even if they won their suit.[16] This asymmetry in the incentives facing patent

13 The case of Nexium is discussed in Midha (2015).

14 This case is discussed in Bansal et al. (2009).

15 They may enjoy six months of market exclusivity, which would allow them some amount of extra-normal profits, although even this benefit has been eroded by recent court decisions that allow the seller of the brand drug to market its own generic in the period of exclusivity.

16 This asymmetry can also lead to outright corruption since the patent holder can share some of its profits with a potential competitor in order to keep them out of the market. For example, Warner Chlicott allegedly made payment to two generic manufacturers to keep them producing a drug in competition with its oral contraceptive Loestrin (see Chiem (2013)).

holders and challengers is problematic from a larger economic perspective, since the monopoly profits earned by the patent holder come at the expense of the rest of the economy. Specifically, insurance companies, governments, and patients will all pay far more for drugs if they are improperly subject to patent protection.

While it is not plausible that the IPR process will eliminate all improper patents, or improper claims within patents, it is clearly desirable to have a process such as this in place so that patents can be contested at a point where the stakes are more balanced between the parties. It is also hugely beneficial that improper patents be identified as early as possible. This is not only because of the potential for inappropriate patent rents earned by the patent holders, but also due to the misplaced incentives created by an improperly awarded patent. If a patent is wrongly granted for a potentially important drug then competitors may waste resources attempting to invent around the patent in order to share in the rents. However, if the patent should not have been granted, then competitors would be able to enter the market without incurring these needless research expenses.

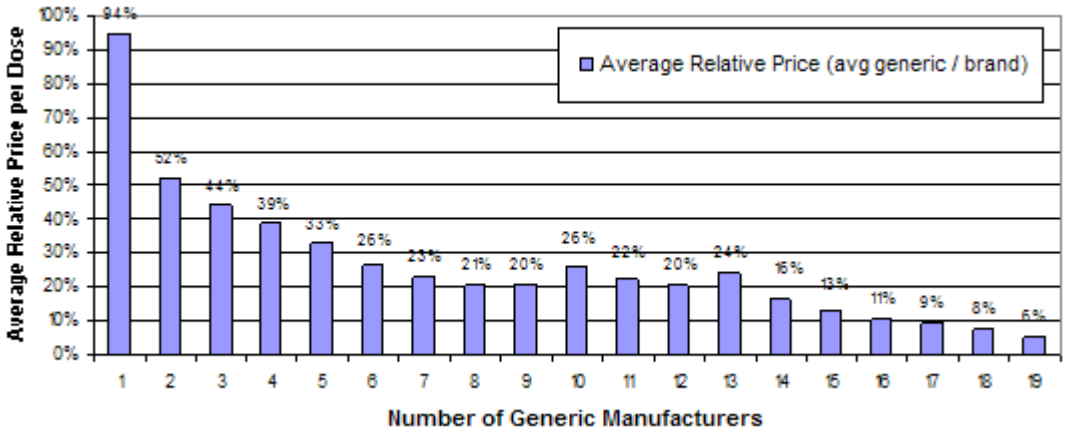
Quantifying the Costs of Eliminating the IPR Process for Pharmaceuticals

The examples given above (and many other instances that could be cited) suggest that the United States has a serious problem with patents being improperly granted to pharmaceutical companies. Wrongly awarded patents can impose substantial costs on patients, insurers, and the government. As noted in the cases of Gilvec and Sovaldi, the difference between the patent protected price and the generic price could be on the order of 10,000 percent.

Even with less expensive drugs, the price of the generic version will typically be just 10 to 20 percent of the price of the brand drug. The extent of the price difference will depend on both the cost of the patent protected brand drug and the number of generics that have entered the market. The latter usually increases with the amount of time since the expiration of patent protection.

FIGURE 1

Generic Competition and Drug Prices



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005. Figure from FDA (2015).

An analysis by the Food and Drug Administration found that average generic prices fell to around 20 percent of the patent-protected price when eight or more generics were in the market and to less than 10 percent for drugs where the number of producers exceeded seventeen. In short, there are very substantial savings associated with generic competition.

The major potential expense that would be associated with providing an exemption to the pharmaceutical industry to the IPR process is that an exemption would allow a drug to get or keep patent protection when a fair interpretation of the law would deny patent protection. As noted above, because of the asymmetry in the incentive for patent holders to defend a patent compared with the incentives for a potential generic entrant to challenge the patent, it is reasonable to believe that among drugs brought to market, some number of improper patents will be allowed to stand. The main cost from exempting the pharmaceutical industry from IPR will depend on the likelihood that improper patents would have been prevented by the IPR and therefore some number of drugs will wrongly be granted patent protection.

To get some idea of the amount of money potentially at stake from improperly granted drug patents, we can look at the revenue from top selling drugs. The average sales revenue for the top 100 drugs for which data are available was $1,780 million in 2013.[17]

17 Drugs.com (2015).

It is not possible to know the number of drugs based on improper patents the IPR would prevent that would otherwise survive later patent challenges. As noted before, the share of pharmaceutical patents that have been subject to review has been just under 0.8 percent. Of the claims in these patents, almost one-third ended up being cancelled or removed as a result of the review. (More than half of the petitions resulted in at least one claim being removed.) This means that just over one quarter of one percent of pharmaceutical patents were removed due to the IPR process in the first two years that it has been in place if they were cancelled at the same rate as other patents.

However, this figure almost certainly understates the importance of IPR petitions to the industry. Presumably the patents that were targeted were chosen not only because the claims were dubious, but also because potential competitors saw them as being commercially important. It is therefore reasonable to believe that some of these claims would have resulted in drugs wrongly benefiting from patent monopolies.

This benefit can take two forms. The first would be where a drug benefits from a patent monopoly where it really is not based on an innovation that is worthy of a patent. Glivec would arguably be an example of such a case. In this instance, the full sales revenue for the drug would be an excessive payment. The second form of benefit would be in cases where the manufacturer of a brand drug is able to extend its effective patent for a period of time with the use of questionable second patents, or submarine patents. Clarinex and Claritin provide one such example. In these cases, a drug company may be able to get somewhere between 2 to 4 years of additional patent protection for their drug.

To try to get an estimate of how much the elimination of the IPR process for the pharmaceutical industry will cost the country in higher drug prices, we can set a range on the number of drugs that will be improperly receiving patent protection at a point in time due to the elimination of the IPR process. At the low end, it is reasonable to assume that the equivalent of at least one of the top 100 selling drugs will be improperly benefitting from patent protection. This could mean that, at a point in time, either that one of the top 100 fits into this category, or that several less popular drugs with sales equivalent to the average of 1 of the top 100 are wrongly benefiting from patent protection as a result of the ending of the IPR process. Under the middle assumption, two of the drugs will be improperly benefitting from patent protection. Under the high assumption, three of the drugs will be improperly benefiting from protection, with one of the three taking the form of a major drug like

Glivic. This will be important not only for the price of the drug but for directing research in the industry.

Table 2 shows projections of additional drug costs under each of the three scenarios described above. In each case, it is assumed that the annual sales of for major drugs rise at the same pace as projected by Center for Medicare and Medicaid Services (CMS) for the drug spending as a whole.[18] The additional cost is based on the assumption that generics would sell for an average of 15 percent of the price of the patent-protected brand drug.

TABLE 2

Cost in Higher Drug Prices from Ending IPR

(millions of dollars)

Year	Low-Cost Scenario	Middle-Cost Scenario	High-Cost Scenario
2018	2,005.1	4,010.2	6,015.3
2019	2,123.0	4,246.0	6,368.9
2020	2,258.1	4,516.2	6,774.3
2021	2,392.7	4,785.3	7,178.0
2022	2,536.1	5,072.2	7,608.4
2023	2,684.6	5,369.2	8,053.8
2024	2,841.7	5,683.5	8,525.2
2025	3,008.1	6,016.2	9,024.3
2026	3,184.2	6,368.4	9,552.6
2027	3,370.6	6,741.2	10,111.8
2028	3,567.9	7,135.8	10,703.7
2029	3,776.8	7,553.5	11,330.3
2030	3,997.9	7,995.7	11,993.6
2031	4,231.9	8,463.8	12,695.7
2032	4,479.6	8,959.3	13,438.9
2033	4,741.9	9,483.7	14,225.6
2034	5,019.5	10,038.9	15,058.4
2035	5,313.3	10,626.6	15,939.9
2036	5,624.3	11,248.7	16,873.0
2037	5,953.6	11,907.2	17,860.7
Total	73,110.8	146,221.6	219,332.4

Source: Center for Medicare and Medicaid Services and author's calculations, see text.

18 CMS (2014), Table 11. The projections only run to 2023; the rate of growth of revenue for major drugs in subsequent years is assumed to be 5.9 percent annually—the same as the rate CMS projected for the growth from 2022 to 2023.

In the low-cost scenario, the effect of an exemption of the pharmaceutical industry from IPR would be to raise annual payments for drugs by $2 billion in 2018, the first year in which the elimination of this process could plausibly have an effect on drug prices. The projected cost rises rapidly, based on the projection from CMS that spending on prescription drugs will increase rapidly. By 2028, the additional cost is projected to be almost $3.6 billion and in 2037 it is projected to be almost $6.0 billion. The cumulative increase in spending on drugs over the 20-year period from 2018−2037 is projected to be more than $73 billion.

The projections in the middle-cost scenario are twice as high by construction. Under the assumptions in the additional cost in 2018 from exempting the pharmaceutical industry from the IPR process would be over $4 billion. In 2037, they would be over $11.9 billion. The cumulative increase in spending on drugs in this scenario would be more than $146 billion over the 20-year period. In the high-cost scenario, the addition spending on drugs in 2018 would be $6.0 billion. The cumulative increase would be more than $219 billion.

These projections of higher drug prices are substantial, but this primarily reflects the large and rapidly growing amount of spending on drugs. Even in the high-cost projection, the additional spending assumed due to the end of the IPR process for prescription drugs is increasing total spending on drugs by less than 2 percent.

The Impact of the IPR Exemption on Research Spending

The above discussion only dealt with the potential impact of improperly granted patents, due to the pharmaceutical industry's exemption from the IPR process, on higher drug prices. However, if a pharmaceutical company is wrongly granted a patent which turns out to be central in the production of a major selling drug, then it can be expected that it will also lead to a major distortion in research spending. Other pharmaceutical companies will try to gain a share of the patent rents by attempting to innovate around the wrongly issued patent. This can lead to large amounts of money being misspent.

To be clear, in the case where a pharmaceutical company has a valid patent, this sort of innovation is beneficial since it can bring down the price of the drug before the patent expires and generics can enter the market. This appears to be happening in the case of Sovaldi, the Hepatitis C drug. There are several pharmaceutical companies developing comparable products which either have already gained FDA approval or are likely to do so in the near future. This should lead to a situation in

which effective treatments for Hepatitis C are available for a considerably lower price than Gilead Sciences, the patent-holder, was initially charging for Sovaldi.

However, if the initial patent was wrongly granted, then this research will have been largely wasted. The drug should have already have been available as a generic, and therefore there would be no patent rents to be shared.[19] This misdirection of research is an important cost associated with improperly granted patents. If the pharmaceutical industry's exemption from IPR increases the probability of improperly awarded patents, then we should expect more misdirected research as a result.

The cost of researching new drugs has been rising dramatically, so even a modest amount of misdirected research would imply a considerable degree of waste. A recent analysis by Joe Dimasi at Tufts University calculated that the cost of developing a new drug was $2.6 billion in 2014.[20] Furthermore, he calculated that the cost was rising at annual rate of 8.5 percent. If this rate of increase is assumed to continue into the future, and it is assumed that patents wrongly granted because of the industry's exemption from the IPR process lead to the development of two new drugs (in 2025 and 2035) it would imply $20.8 billion in wasted research spending in the high-cost scenario over the twenty years from 2018−2037.

This would be another cost in additional to the additional expense associated with paying patent protected prices for drugs. It is important to note that this $20.8 billion would be largely a source of pure economic waste, since it involves a misdirection of resources. By contrast, the higher drug prices are primarily a transfer from patients, insurers, and the government to the pharmaceutical industry. This is a form of redistribution of resources, as opposed to a waste of resources.[21]

Another way in which improperly granted patents can lead to a waste of resources is by providing pharmaceutical companies a way to mislead doctors and the public about the safety and effectiveness of their drugs. Because patent monopolies allow them to sell their drugs at prices far above their marginal cost of production, they have an enormous incentive to sell as much of a patent protected as possible. There have been numerous instances where drug companies have

19 The misdirected research is not likely to be completely wasted. Some patients will likely have a bad reaction to a specific drug or the drug may not mix well with other drugs hey are taking. For these reasons it will often be beneficial to have multiple drugs to treat a specific condition. However, from the standpoint of the economy as a whole it would typically be better to devote resources to conditions where no effective treatment currently exists.

20 Dimasi (2014).

21 Drug companies are also likely to spend more money marketing drugs that have been improperly granted patents. There is little point in spending much money marketing generic drugs since the profit margins are too small to justify major expenditures. These marketing expenses are also a direct waste of resources, since capital and labor are being diverted from productive purposes. In other words, the people flying around the country trying to get doctors to use their employers' drugs could be engaged in productive work.

allegedly misrepresented their drugs benefits in order to increase sales. This can impose enormous costs on society in the form of increased mortality and morbidity. A recent study looked at the cost from five prominent instances of drug companies misrepresenting their products over the period 1994−2008. It put the figure at $382 billion (in 2014 dollars).[22]

In this case, it would also be difficult to construct a basis for determining how much cost society is likely to incur from drugs being mismarketed as a result of wrongly granted patents. However, it is clear that any patent, whether properly or improperly granted, provides an incentive for this sort of mismarketing. There will undoubtedly be more mismarketing if more patents are granted, and some of them are improper.

Who Pays the Cost?

The analysis of drug spending by CMS provides a basis for determining which parties will pay the higher drug prices that would result from an exemption for the pharmaceutical industry from the IPR process. **Tables 3a**, **3b**, and **3c** shows the breakdown for the additional drug costs by payer in the low-cost, middle-cost, and high-cost scenarios, respectively. The table assumes the same projected breakdown for any additional spending resulting from the exemption of the pharmaceutical industry from the IPR process as for other drug spending.[23]

22 Katari and Baker (2015).

23 For years after 2023 it is assumed that the division of spending between payers remains the same as in 2023. These data are taken from Table 11 in the CMS (2014).

TABLE 3a

Distribution of Higher Drug Cost (Low-Cost Scenario)

(millions of dollars)

Year	Out-of-Pocket Payments	Private Health Insurance	Medicare	Medicaid	Other Health Insurance Programs	Other Third Party Payers
2018	268.0	840.2	610.5	195.7	70.6	20.0
2019	279.1	881.3	658.9	207.4	74.5	21.1
2020	292.5	929.7	714.0	219.6	79.5	22.8
2021	305.8	974.2	771.8	233.0	84.5	23.9
2022	319.2	1,020.3	835.2	246.9	89.5	25.6
2023	332.5	1,065.9	902.5	261.3	95.1	27.2
2024	352.0	1,128.3	955.3	276.6	100.6	28.8
2025	372.6	1,194.4	1,011.2	292.8	106.5	30.5
2026	394.4	1,264.3	1,070.4	310.0	112.8	32.3
2027	417.5	1,338.3	1,133.1	328.1	119.4	34.2
2028	441.9	1,416.7	1,199.4	347.3	126.4	36.2
2029	467.8	1,499.6	1,269.6	367.7	133.8	38.3
2030	495.2	1,587.4	1,343.9	389.2	141.6	40.6
2031	524.2	1,680.3	1,422.6	412.0	149.9	43.0
2032	554.9	1,778.7	1,505.9	436.1	158.7	45.5
2033	587.3	1,882.8	1,594.0	461.6	167.9	48.1
2034	621.7	1,993.0	1,687.4	488.6	177.8	50.9
2035	658.1	2,109.7	1,786.1	517.2	188.2	53.9
2036	696.6	2,233.2	1,890.7	547.5	199.2	57.1
2037	737.4	2,363.9	2,001.4	579.6	210.9	60.4
Total	9,118.7	29,182.3	24,363.9	7,118.4	2,587.4	740.6

Source: Center for Medicare and Medicaid Services and author's calculations, see text.

TABLE 3b

Distribution of Higher Drug Cost (Middle-Cost Scenario)

(millions of dollars)

Year	Out-of-Pocket Payments	Private Health Insurance	Medicare	Medicaid	Other Health Insurance Programs	Other Third Party Payers
2018	536.0	1,680.4	1,221.1	391.5	141.2	40.0
2019	558.3	1,762.7	1,317.8	414.8	149.0	42.3
2020	585.0	1,859.4	1,427.9	439.3	159.0	45.6
2021	611.7	1,948.4	1,543.6	466.0	169.0	47.8
2022	638.3	2,040.7	1,670.4	493.8	179.0	51.2
2023	665.0	2,131.9	1,804.9	522.7	190.2	54.5
2024	704.0	2,256.7	1,910.6	553.3	201.3	57.7
2025	745.2	2,388.8	2,022.4	585.7	213.1	61.1
2026	788.8	2,528.6	2,140.8	620.0	225.6	64.6
2027	835.0	2,676.6	2,266.1	656.2	238.8	68.4
2028	883.8	2,833.3	2,398.8	694.7	252.7	72.4
2029	935.6	2,999.2	2,539.2	735.3	267.5	76.7
2030	990.4	3,174.8	2,687.9	778.4	283.2	81.1
2031	1,048.3	3,360.6	2,845.2	823.9	299.8	85.9
2032	1,109.7	3,557.4	3,011.8	872.2	317.3	90.9
2033	1,174.7	3,765.6	3,188.1	923.2	335.9	96.3
2034	1,243.4	3,986.0	3,374.7	977.3	355.6	101.9
2035	1,316.2	4,219.4	3,572.3	1,034.5	376.4	107.9
2036	1,393.3	4,466.4	3,781.4	1,095.0	398.4	114.2
2037	1,474.8	4,727.8	4,002.8	1,159.1	421.7	120.8
Total	18,237.4	58,364.7	48,727.8	14,236.8	5,174.8	1,481.2

Source: Center for Medicare and Medicaid Services and author's calculations, see text.

TABLE 3c

Distribution of Higher Drug Cost (High-Cost Scenario)

(millions of dollars)

Year	Out-of-Pocket Payments	Private Health Insurance	Medicare	Medicaid	Other Health Insurance Programs	Other Third Party Payers
2018	804.0	1,680.4	1,221.1	391.5	141.2	40.0
2019	558.3	1,762.7	1,317.8	414.8	149.0	42.3
2020	585.0	1,859.4	1,427.9	439.3	159.0	45.6
2021	611.7	1,948.4	1,543.6	466.0	169.0	47.8
2022	638.3	2,040.7	1,670.4	493.8	179.0	51.2
2023	665.0	2,131.9	1,804.9	522.7	190.2	54.5
2024	704.0	2,256.7	1,910.6	553.3	201.3	57.7
2025	745.2	2,388.8	2,022.4	585.7	213.1	61.1
2026	788.8	2,528.6	2,140.8	620.0	225.6	64.6
2027	835.0	2,676.6	2,266.1	656.2	238.8	68.4
2028	883.8	2,833.3	2,398.8	694.7	252.7	72.4
2029	935.6	2,999.2	2,539.2	735.3	267.5	76.7
2030	990.4	3,174.8	2,687.9	778.4	283.2	81.1
2031	1,048.3	3,360.6	2,845.2	823.9	299.8	85.9
2032	1,109.7	3,557.4	3,011.8	872.2	317.3	90.9
2033	1,174.7	3,765.6	3,188.1	923.2	335.9	96.3
2034	1,243.4	3,986.0	3,374.7	977.3	355.6	101.9
2035	1,316.2	4,219.4	3,572.3	1,034.5	376.4	107.9
2036	1,393.3	4,466.4	3,781.4	1,095.0	398.4	114.2
2037	1,474.8	4,727.8	4,002.8	1,159.1	421.7	120.8
Total	18,505.4	58,364.7	48,727.8	14,236.8	5,174.8	1,481.2

Source: Center for Medicare and Medicaid Services and author's calculations, see text.

As can be seen, private insurers are projected to see the largest share (roughly 40 percent) of the increase in costs associated with the industry's exemption from the IPR process. Medicare comes in next, with more than 30 percent of the costs. Medicaid would also pick up just under 10 percent of the additional costs.

In the low-cost scenario the additional spending would increase the costs for Medicare by $600 million in 2018, $1.2 billion in 2028, and $2.0 billion in 2037. The total additional cost for the program over the 20-year period would be $24.4 billion. In this scenario, the cost for Medicaid would rise by $200 million in 2018, $350 million in 2028, and $580 million in 2037. The total additional cost to Medicaid over the 20-year period would be $7.1 billion.

In the middle-cost scenario, the additional cost to Medicare in 2018 would be $1.2 billion and in 2037 it would be $4 billion. The total increase in costs over the 20-year period would be $48.7 billion. The increase in costs to Medicaid would be $14.2 billion over the 20-year period. In the high-cost scenario, the increase in costs to Medicare over the 20-year period would be $73.1 billion, with the increase to Medicaid being $21.4 billion.

The projections in the Tables 3a, 3b, and 3c, suggest that the government run health care programs could incur substantially higher costs as a result of exempting the pharmaceutical industry from the IPR process.

Conclusion

This paper projects the potential consequences from exempting the pharmaceutical industry from the IPR process. It indicates that the failure to remove improperly awarded patents at an early date could lead to substantially higher drug costs. These costs will translate into higher payments from government run health insurance programs like Medicare and Medicaid.

The improper award of patents is also likely to lead to misdirected research, potentially wasting billions of dollars in spending in pursuit of patent rents based on the improperly awarded patents. In addition, these patents will provide incentives to mismarket drugs, a process that has led to substantial costs in the form of increased morbidity and increased mortality in the past. This analysis suggests that there could be substantial costs associated with exempting the pharmaceutical industry from the IPR process.

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