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Innovations in Healthcare Financing Policy

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State Prescription Drug Affordability Board
Legislative Proposals
Interactions with Federal Patent Law

Introduction

This document examines a key federal appeals court decision that is the existing legal precedent for limiting state drug cost containment policy. The decision found in favor of the industry finding that a District of Columbia law violated both the Dormant Commerce Clause and the Supremacy Clause of the Constitution because the DC law ran afoul of federal patent law. This paper looks specifically at the patent law ruling and provides newer analysis of why the ruling falls short – but falls short because many important federal health policies laws were not brought to bear in the case.

Background on PhRMA BIO v District of Columbia Patent Issues[i]

The US Court of Appeals for the District of Columbia Circuit found ruled consistent with the lower District Court's finding the District of Columbia law (the Prescription Drug Excessive Pricing Act) unconstitutional on both dormant commerce clause violations and supremacy clause violations based on federal patent law.

The DC law limited the price at which a manufacturer could sell its product in the District. That limit was the mathematical average price of a product in five OECD countries. The Court found that the DC law conflicted with federal patent law (specifically patent-holder rights) which triggered a violation of the Supremacy Clause of the Constitution.

In brief, the lower Court and then the Appeals Court interpreted federal patent law as an expression of congressional intent that patent holders have unlimited rights to unlimited profits from the unbounded pricing of their inventions. Any state action to control the price at which an innovator sells the innovation is not consistent with the intent of Congress (inferred from federal patent law). This perceived inconsistency is then a violation of the Constitution's Supremacy Clause. This patent law issue is the focus of this document.

The pharmaceutical industry has raised the specter of a legal challenge to any state that enacts a strong and meaningful Prescription Drug Affordability Board (PDAB), a board that would have authority to set limits on what patients and state-licensed healthcare suppliers and providers *pay and charge* for a drug in the state.

PDAB Model in Brief

In brief, the model state PDAB legislation creates a Board of non-conflicted people with expertise in various economic and clinical aspects of pharmaceuticals. The PDAB is modeled on long standing, public utility rate setting commissions that have existed in every state since the beginning of the 20th century.

A PDAB has authority to set upper payment limits on what state-licensed suppliers, providers, payers and patient may charge and pay for a prescription drug for which the PDAB has set an upper payment limit.

The PDAB uses its authority after determining that the cost of drug in the state is creating affordability problems; the drug is expensive to such a degree that payer have difficulty financing care and patient access to the drug is limited owing to cost. Not every drug would come under review by the PDAB, and not every drug under review would be moderated with an Upper Payment Limit.

Like a state public service commission, a PDAB would exist to ensure affordability of products and services that are vital to the health and safety of state residents. An increasing number of drugs maintain monopoly position in a dysfunctional segment of the US marketplace. The ability to monopoly price to the detriment of state residents occurs for a host of reasons beyond the scope of this paper and beyond the ability of state governments to change. Thus, a public utility approach is one of the very few options for meaningful resident relief available to state governments.

In that context, this document looks at the decades of healthcare payment rate setting by the federal government which do *directly* impact patent holder profits by reducing the prices charged for drug products. These federal laws and federal prescription drug price controls have never been challenged and are very relevant for discerning congressional views of the rights of patent holders to unfettered pricing and profiteering.

Issues that Should be Brought to Bear in the Next PhRMA Legal Challenge

The federal healthcare laws and general market standard operating procedures that specifically limit the revenue an innovator can receive for their prescription drug innovation. These examples were not introduced in the PhRMA BIO v District of Columbia litigation. These federal healthcare laws are bit obscure to most patent attorneys.

Direct Federal Price Control Where the Government is Not a Market Participant

At Section 340B of the Public Health Services Act, Congress decided to impose direct price controls on every drug on the US market for all sales to 340B designated entities. This is a very substantial price control, and in this case, the government is not a market participant. There are an estimated 53,000 340B designated entities[ii] (private and public hospitals, hospital satellite clinics, free standing clinics) and about 102,000 of their contracted pharmacies[iii]. 340B providers/participating entities can order as much of any and all prescription drug products as they can use. They can bill payers at market price

and retain the margin as entity revenue. The program provides $24 billion in drug sales through 340B channel in 2018, and the amount of the price control is based on the Medicaid, discussed below.

PhRMA believes this program is quite out of control to the point of abuse. The industry has complained repeatedly and asked repeatedly over the last seven or so years for Congress to scale it back. Congress has never undertaken to limit the scope of the law or the drugs flowing through it. In fact, Congress expanded the number of healthcare facilities eligible to participate in the program during the years of PhRMA's expressed concerns.

The federal agency administering the program has only undertaken to verify provider program eligibility and ensure that manufacturers are providing the correct discounts required by law.

Direct Federal Price Controls Where Government is a Market Participant Regulating Drug Price and Profits on Behalf of Itself and Other Market Participants at the Same Time

Medicaid

The Medicaid program exists to provide healthcare coverage to the poorest people in America. It is jointly funded by states and the federal government. The federal government sets most of the programs that guide state administration of the program. There are about 72 million people enrolled in the Medicaid program.

Even before the creation of the 340B program, Congress created the Medicaid Drug Rebate Program (MDRP) for the express purpose of limiting pharmaceutical company patented product profits at the expense of the program that finances the healthcare of the poorest people in America.

In this case, the federal government price control is in the form of rebates to each and every state Medicaid program and Puerto Rico for each unit of a drug paid for by Medicaid in each calendar quarter.

Congress has *increased* the level of rebate required for each and every drug periodically over the years. The minimum rebate required is 23.1 percent of the market price in quarter, up from 15.1 percent.[iv] There is also a 'best price' rebate, which requires manufacturers to rebate to each state Medicaid program, and amount equal to the very price the manufacturer gave to *any* healthcare entity. The best price may be provided to only one entity in the country, but that doesn't change the law's requirement. There is also now an inflation/price increase penalty rebate which is a rebate add on amount based on the price increase in each quarter relative to the drug price when it entered the market. Finally, there is also a rebate calculation specifically for drugs that get patents or patent extensions for merely simple innovations (referred to as line-extensions in the industry).

Clearly Congress did not have patent holder rights on its mind in thinking about the Medicaid program. PhRMA supported the original law and there is no evidence it raised a concern with patent rights in subsequent changes to the law.

Veterans Administration

The branded pharmaceutical industry is required to provide discounts for the direct pharmaceutical purchases of the Veteran's Administration (VA). The discount is 24 percent off the non-federal average manufacturer price (24 percent of the average price offered by manufacturers to non-government purchasers and payers. The VA treats nine million veterans each year and there are 22 million veterans nationally.

Medicare Part B Multi-Drug Average Price Payment Limit

Medicare Part B covers drugs administered to outpatients by physicians. It is funded by a combination of general federal tax revenues and enrollee premiums. The amount of the premium varies by enrollee income. There are about 58 million Medicare beneficiaries.

Medicare Part B reimburses physicians or clinics for the cost of a drug administered to a patient. Congress has set limits on how much Medicare reimbursement providers for the drugs purchased and dispensed.

In 2015, the federal agency that administers Medicare, set Part B reimbursement for a type of group of drugs called biologics, at the average price of all the biologics in a class. In other words, innovator biologic which is has the highest price, and any biosimilars of the innovator (first in class) drug, were reimbursed based on the average price of *all* the biologic products in the class – so a provider choosing the innovator would likely not be reimbursement full cost and a provider choosing the lowest cost biosimilar could earn a profit. These are all patented products. The federal agency was trying to incent the use of lower cost biosimilars and forcing innovators to drop their price to stay competitive. Biosimilars are expected to come to market with prices at least 15 percent lower than the innovator biologic. Congress took no action to stop the agency, even though certain patent holders had their price constrained. CMS was ultimately convinced by the biologics industry to drop the program in 2018.[v]

Importantly, health insurers around the country based their payment formulas and rates on what Medicare does, so a policy that limits price can have a big impact on the pharmaceutical industry.

Medicare Part B Reimbursement Based on the Average of Lower Prices in Other Countries.

In 2018, the Trump Administration announced its intent to rein in drug prices by paying no more than lowest price of the drug in the world. The US Health and Human Services Department announced it will propose a draft rule to reimburse Part B biologics drugs at 126% of the average of the (lower) price-controlled prices in Europe. Congress has not taken any steps to stop the implementation of the program. This reimbursement formula, if applied to Medicare, will migrate to the private sector where the government is not a market participant. PhRMA is likely to sue on the basis that the Department is exceeding its authority. Congress has taken no action to stop the HHS price control initiative.

House-Passed Drug Price Control Bill and Senate Finance Committee- Passed Price Limit Legislation

The Democratic-lead House bill, which is awaiting action in the Republican-led Senate, would require the federal government to negotiate with drug makers for lower prices for Medicare Parts B and D. That negotiated price would be made public for all other health insurers and providers to use in setting their payment rates. There are extreme financial penalties for manufacturers who refuse to participate.

The Senate Finance Committee has its own bill awaiting a full vote of the Senate. This bill is less sweeping in scope than the House but still limits manufacturer prices for drugs used in the Medicare and Medicaid programs.

Other Considerations on the Validity of Statewide Drug Upper Payment Limits

Upper Payment Limits/Reimbursement Rate Setting is Ubiquitous in the US Healthcare System

Establishing uniform *statewide* upper payment/reimbursement limits that apply to all state-licensed healthcare payers, suppliers, providers as well as patients is unique. However, the concept of limiting reimbursement payments (aka upper payment limits) is ubiquitous in the US healthcare system. There are numerous examples of payment rates that are less than a manufacturer's price. These routine insurer upper payment limits have never been equated to price controls. Hospitals limit what they will pay for supplies, new technology and drugs. Public and private health insurers have payment limits for almost all covered services.

For drugs, upper payment limits can be: Maximum Allowable Costs, Federal Upper Payment Limits, Average Sales Price, Average Manufacturer Price, Best Price, 340B ceiling price.

The point of these widely used upper payment limits is to drive negotiations in the private sector so that providers force better deals when they purchase the drugs that are used for patient care.

Statewide Drug Cost Rate Setting is not a Price Control.

Statewide healthcare prescription drug payment rate setting does not change a manufacturer's ability to maintain their list price and does not change a manufacturers' ability to provide greater or lesser price concessions to any other payor or purchaser in the country. The upper limit relies on the same market behavior that occurs everyday in the pharmaceutical market – discount negotiations and agreements that are fulfilled through the supply chain on behalf the manufacturer and the purchaser or payer with the price concession agreement.

Statewide Drug Cost Rate Setting Will Increase Product Sales

The point of PDAB and its rate setting authority is to increase sales of a product by making it affordable to payer and patients. That should not be viewed as an impediment to the patent law scheme, which is balance ability to profit from an innovation.

The pharmaceutical industry business model relied almost exclusively on sales volume driven by market share. Today, the business is more reliant on price and less on sales volume, (BCBS and other citations). Statewide drug cost rate setting will generate more sales that would occur in the model based on price and price increases with no expectation that revenues under a rate setting model would decline relative to status quo of profits based on price.

Patent Rights No Longer Operate in a Well-functioning Pharmaceutical Market

The PhRMA BIO v District of Columbia court decision is based on the expectation that the patent law balances public good and innovator rights within a well-functioning economic market. There is a wealth of peer reviewed literature and mainstream economic analysis that demonstrates that the healthcare marketplace does not function well, and that the subset of the pharmaceutical is particularly dysfunctional. Pharmaceutical companies regularly abuse the patent system to extend drug patents decades beyond the original expiry date.

States and the federal government regulate monopolies that have impacts over the health and safety of residents.

States have a tradition and indeed a responsibility to protect the health and welfare of residents. There are very few ways to protect people from unaffordable drugs and pricing that is literally causing death. Statewide upper payment limits leverage all existing features of the pharmaceutical negotiations and supply to create affordability for some important, but otherwise unaffordable drugs.

Conclusion

A review of Medicare, Medicaid and 340B law should demonstrate the actual intent of Congress regarding how patent protections are to be viewed in the context of assuring affordability. The U.S. tradition of healthcare payment rate setting and upper payment limits demonstrates that statewide rates and upper payment limits for certain drugs is perhaps the best approach to assuring affordability while still rewarding innovation.

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[i] (US Court of Appeals for the District of Columbia Circuit, No. 2006-1593, August 1, 2007)

[ii] Rough estimate based on HRSA.gov website which lists 67,000 covered entities [9/16/2019] and assuming 20% of entities are listed but terminated from the program

[iii] Rough estimate based on HRSA.gov website which lists 135,000 contract pharmacies [9/16/2019] and assuming 25% of listed entities are terminated from the program

[iv] The description of the MDRP is general, without all the complex calculations and definitions that are not necessary for the discussion in this paper.

[v] https://www.cov.com/-/media/files/corporate/publications/2017/11/cms_revises_medicare_part_b_biosimilar_coding_and_payment_policies.pdf, accessed 1/22/2020.