Healthcare Reform's Impact on Drug Patents

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Adam Mossoff*: Well, I want to thank you, Dean Maddox, and to thank the Federalist Society here at George Washington for inviting me to talk about drug patents. It's really a privilege debating John Duffy, whom I've been reading for a long time. I'm a big admirer of his work, and I have to confess, I feel a bit like a welterweight getting into a boxing ring with Mike Tyson. So, Professor Duffy, as long as you promise not to bite off my ear, I think we're going to have some fun here.

I'm really interested in healthcare reform and its impact on drug patents. I'm interested in this issue from the perspective of whether there is a constitutional problem with any restrictions on pharmaceutical patents that will follow from, and perhaps be a logical result of, the federal government's push for healthcare reform. Since we don't yet know exactly what the healthcare law will be, I will use here as my reference point some proposals that have been floated in Congress.

One actually is a bill for drug reimportation that Dean Maddox hinted at. These bills have been floated in Congress every year for a long time now. They permit reimportation of drugs from countries like Canada and other industrialized countries that have socialized healthcare systems and express price controls.

The way these bills work is that they eviscerate a patentee's ability to impose restrictions on wholesalers in other countries that prohibit them from reselling back to the United States. It's called territorial restrictions. So they sell to the Canadian bulk purchaser, stating that you can only sell your drugs in Canada and that you can't resell them in the United States. The reimportation bills work by eviscerating—prohibiting—pharmaceutical companies' rights to include those types of restrictions and other types of restrictions, like sale quantity and use restrictions and even price restrictions, in their sales contracts.

And also there is a great possibility down the road, especially if they adopt some sort of nationalized healthcare system here or the public option, of outright price controls. You can see the justification for this. If the federal government is paying for drugs, then it's going to be plainly justified in regulating the amount of money that private pharmaceutical companies can take from the public fisc, and it's going to eventually assert this as a price control measure.

I'm interested in whether the pharmaceutical companies may assert a regulatory takings claim in response to these types of legislative or regulatory restrictions on prices or sale restraints. Within regulatory takings law and patent law there's actually sound doctrine to suggest that these types of legal moves by Congress would actually result in a taking of the pharmaceutical companies' property rights in their drugs. In other words, they may seek protection under the Takings Clause of the Fifth Amendment. Depending upon what you think of the pharmaceutical companies, you can maybe just hum Darth Vader's imperial march theme in the background as I'm talking. Yes, I am here defending the pharmaceutical companies!

So I'm going to look to regulatory takings doctrine, the famous *Penn Central* inquiry,[1] as a framework in my remarks today to identify what I think are the essential property rights in drug patents, and therefore determine if there could there be a takings claim in response to price controls or other restrictions on these patents. It's important to note that I'm interested in this as a matter of doctrine, and I readily concede as a matter of practical politics that it's unlikely that the Court would actually rule in this way. As I fully expect Professor Duffy to note, there are strong countervailing policy considerations outside of the doctrine of both patent law and takings law on which the Court could rely in reaching the result that price controls on patented drugs are not a taking, and takings doctrine is nebulous enough to permit this type of decision. But I think there is still value in recognizing both the conceptual and normative standards that are built into the doctrine itself.

But even conceding that if you don't buy my story—as the saying goes, we're all legal realists now—then hopefully my remarks today will at least make you realize that you can't just quickly jump to the conclusion that these types of regulations are constitutional. There are many commentators who think there's no problem with this whatsoever. Actually, they have to engage in substantially more doctrinal and normative heavy-lifting than they assume. It's not as easy a decision as many see it.

All right, so let me start with a few important baseline observations. Patents are *intellectual property*, right? Why make this seemingly obvious point? It's important because in cases dealing with *intangible property* interests, the Court in regulatory takings cases seems to shift instinctively as to what it thinks is the essential nature of the property that's affected by the regulation. In several cases throughout the twentieth century involving intangible property rights, such as in *Armstrong v. United States*,[2] in which the U.S. destroyed the value in liens on boats owned by a bankrupt shipbuilder, in *Hodel v. Irving*[3] and in *Babbitt v. Youpee*,[4] in which a federal escheat statute eliminated the right to devise, and of course in *Monsanto v. Ruckelshaus*,[5] in which an FDA regulation forced the disclosure of trade secrets, the Court has consistently held regulatory restrictions to be a taking. I particularly like *Monsanto* because the Supreme Court cites John Locke as authoritative precedent that labor is the source of property.[6]

In these cases, the Court conceives of property in terms of the substantive rights of use, enjoyment, and disposal. And it is these rights that take central place in the takings analysis of the property interest that is affected by the regulation. What's most notable about these cases involving intangible property rights—liens, the right to devise, and trade secrets—is that the property owners have won.

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Now this is in stark contrast with the traditional land cases that many people think of when they think of regulatory takings. In these cases, such as *Lingle v. Chevron*,[7] *Palazzolo v. Rhode Island*,[8] and the Lake Tahoe case,[9] the Court doesn't define property in terms of the rights of use, enjoyment and disposition, but instead focuses on the *right to exclude* as the sole right that makes something "property" under the Takings Clause. Once it determines that the right to exclude is unaffected by the regulation, it then discounts regulations restricting use and disposition against the overall social benefits that come from regulations. And it's not surprising in these particular land cases, the government always wins.

Now this is why the context of a patent as an intellectual property right is important, because this suggests that it will lead the Court to shift instinctively in the way that it thinks of the property. In such a case, it will shift to the substantive conception of property consisting of the rights of use, enjoyment, and disposition. As a result, the Court may then feel compelled to provide stricter constitutional protection, as it did in the other cases involving intangible property rights, for the substantive rights of use and disposition in drug patents. In particular, it will view licensing rights and the rights to control how a purchaser and a follow-on user of a patented invention—the drug in this case—may be able to use it as essential rights of the property right.

So the starting point for dealing with an intangible property right in a regulatory takings case would be to look at it from the perspective of the property owner, determining how a restraint affects the core expectations of the property owner.

Here I'm going to go walk through the multi-factor *Penn Central* inquiry, although I'm not going to walk through the factors literally because the Court doesn't even do this. Even though the Court says the *Penn Central* inquiry is the "polestar" for its regulatory takings jurisprudence,[10] it doesn't treat it literally as such. It mixes and matches the factors depending on the nature of the property interests at issue, as I've identified in the two conflicting lines of cases.[11] That's probably why this area of law is called an "inquiry" and not a "test."

All right, so the Court will think about the intangible property from the perspective of the importance of the rights of use and disposition. The question then becomes: how much does the government action interfere with the patent owner's expectations? In other words, what's the *character of the government action* and does it interfere with expectations secured under current law? Or does it simply enforce a limitation already built into the title, i.e., limitations that already exist in doctrine and that directly relate to the affected property interest?

Well, this is a tough question, as it is in all regulatory takings cases, but I don't think that price controls or reimportation laws can look to pre-existing patent law for support—as something that just reflects limitations already built into the title in the patent. The primary patent doctrine that delimits patentees' rights to dispose of their property is patent exhaustion doctrine. Even in the Supreme Court's recent decision in 2008 in *Quanta Computer, Inc. v. LG Electronics, Inc.*,[12] which announced a very stringent, mandatory rule on patent exhaustion—that patentees, when they dispose of their inventions in the market, exhaust all their property rights and thus they can't control downstream third-party uses of the patented inventions—it still recognized that patentees could impose restrictions directly on licensees, such as wholesalers, who are in privity with the patentee himself.

Thus—this is very important—a drug reimportation law would directly remove the licensing rights that patentees have long used with their wholesalers and licensees in foreign jurisdictions, like Canada. Moreover, price controls or other rate regulations would directly prohibit the free pricing of the property in a sale between a pharmaceutical company and a wholesaler or distributor, whether it's a public one or a private one. So the basic point here is that patentees have within patent law long-standing use and disposition rights—licensing rights—going back to the nineteenth century.[13] They have long been free to exploit their substantive rights of use and disposition in their property as they see fit to maximize their commercial return.

Now there may be perhaps doctrines that are external to patent law that might reflect a pre-existing limitation built into the title that could serve as a basis for justifying reimportation laws or price controls. For instance, one might think that antitrust has changed the expectations here. But I don't think so. Again, it is a difficult question, but the quick answer is that drug reimportation and price controls would not implicate a limitation that finds support in antitrust limits on drug patents.

In its application to patents, as a general matter, antitrust prohibits things like patent misuse, tie-in arrangements, and price-fixing. But patentees are generally insulated from antitrust liability for contractual restraints with licensees or wholesalers when it involves a *single* patent. In fact, it's in antitrust cases that you get some of the strongest statements about the importance of the substantive use and disposition rights of patentees. Thus, for instance, in *United States v. General Electric*,[14] the Supreme Court declared that the patentee had broad powers to condition sales by licensees and wholesalers in terms of territorial restrictions and other types of restraints, because—to use Chief Justice Taft's words for a unanimous Court—such rights all serve "the reward which the patentee by the grant of the patent is entitled to secure."[15]

Thus, the character of the government action—here, we're talking about a price control or a drug reimportation law—would be a radical shift in the nature of the types of rights that patentees have long expected to enjoy as part of their property. As part of their title, when they've obtained a patent, they have been able to go out into the world and impose territorial restrictions, impose sale quantity restrictions, and impose all sorts of other types of restrictions on their immediate purchasers in order to maximize the profit that they can obtain for the term of their patent, and this is the reward that the patent system intended to secure for them.

Lastly, of course, the factor I haven't talked about, the one that most people think about when they think of regulatory takings is *economic losses*. What are the losses that result from the regulation? And here, the pharmaceutical industry is highly specialized. It is one of the few industries that's actually built on the dynamic efficiency of intellectual property; that is, on the research and development of new molecules that it then turns

around and patents—it turns it into property—and then goes into commercial markets with it.

In fact, studies show repeatedly that the drug industry is the most research-intensive of all industries in the United States.[16] This has been true throughout most of the twentieth century when the drug industry engaged in traditional screening methodologies, where it has gone out and collected slime and screened it for whether it has molecules that are active against diseases or genetic defects. And this heavy research and development has only increased in the past twenty years with the rise of what's known as structure-based design methodologies, which has been part of the biotech revolution in which drug companies now design molecules from the protein up to provide treatments to patients.

As a result of this research-intensive environment, the average R&D costs behind each patented drug that is brought to market are between approximately $500 million to $1 billion, and sometimes as high as $1.1 billion.[17] Now why is this? I mean, just because you have heavy R&D, it doesn't necessarily mean that you're going to have $1.1 billion in sunk costs behind a single drug that comes on the market.

Well, one primary reason is that each drug is not only paying for itself, it's paying for thousands of dry wells in the research and development process. I don't know how many people know this, but on average, out of ten thousand compounds that are initially researched by a pharmaceutical company, only five are approved by the FDA for clinical trials. And out of those five that are approved by the FDA for clinical trials, only one actually gets approved for use in patients. Thus, one out of every ten thousand drug compounds that goes through research and development by pharmaceutical companies—and through the testing gauntlet imposed upon them by FDA—ultimately becomes a commercial product in the healthcare market.[18] Once out in the market, there's not even a guarantee of success. Studies show that only three out of ten FDA-approved drugs that reach the market provide enough money for a pharmaceutical company to recoup its basic R&D expenditures.[19]

Now these economic losses are really significant. They're really significant, but not in the way that they're normally framed in regulatory takings cases. The nature of the economic losses for the pharmaceutical company in the use of its property is unlike in land cases in which the Court adopts the idea of property as the right to exclude. In the land cases, it determines the right to exclude is unaffected by regulations that restrict the rights of use and possession, which is then deemed to be a relatively small price that we pay for the overall social benefits achieved by the regulations that are enacted according to a state's police powers.

This attitude is supported by the nature of the economic losses in land cases. In most land cases, you have single, one-time losses. One of the most significant losses in a modern regulatory takings case involving land was in *Palazzolo*, in which the landowner claimed that he lost $3.1 million as the result of an environmental regulation that prohibited development of a parcel of land in Rhode Island.[20] But this $3.1 million was a static, one-time loss. He said I will lose this amount if I try to sell my land on the market under this new regulation.

In a restriction on a drug patent, you actually have ongoing and continuing losses, so it's not a static efficiency loss. It's a dynamic efficiency loss. The research and development that pharmaceutical companies are paying for is tens of millions of dollars on a day-to-day, year-to-year basis, and thus they'd be looking at tens of millions in losses, not just a one-time $3.1 million loss. It thus becomes harder to discount these economic losses against generalized social benefits that might accrue to the rest of the country.

Moreover, there are clearly identifiable and substantial stakes at issue with a drug patent. As I said, $3.1 million seems like a lot of money, but to a pharmaceutical company, that's chump change. One pharmaceutical company, Vertex Pharmaceuticals in Boston, burned through $3 million in just two to three months before it brought its very first successful product to market, one of the first AIDS treatment drugs in the mid-1990s. And by then it had already spent $200 million, and that was in the early 1990s,[21] and so the costs are even higher today.

Now this economic data is significant but not because it will play a significant role in the regulatory takings analysis as such. It's interesting to note that in the regulatory takings cases involving intangible property rights—as I indicated, *Armstrong*, *Hodel*, *Youpee*, and *Monsanto*—the Court didn't talk very much about the economic losses. Why? Because in these cases, the Court emphasized that it must look at the substantive property rights under the Takings Clause—the rights of use and disposition—and thus it didn't engage in the discounting against the right to exclude that one sees in land cases.

And this is why these massive economic losses matter. Because they increase pressure on the Court to shift in its thinking about the nature of the property: it is not simply a bare right to exclude that's untouched by a regulation, but rather it is the substantive conception of the essential rights of use and disposition. When a pharmaceutical company has sunk costs of $500 million to $1.1 billion behind a single product, the rights of use and disposition—the right to make a profit in the marketplace—matter in a very dramatic way.

Of course, until we actually know what the healthcare legislation actually says, rather than the conceptual language that keeps being presented to us in the summaries of the 2000-page bills, it will be anyone's guess as to what impact ultimately will fall on the drug companies and how the Court might resolve a regulatory takings claim.

Thank you.

Professor Mossoff Response: I'll just quickly respond to each of Professor Duffy's points. First, I agree with Professor Duffy that there is massive distortion in the healthcare market right now, such as cost-shifting. In fact, most people don't realize how much healthcare in this country is already paid for by the government. When they talk about the failure of our free market system, people don't realize that about 50% of all healthcare costs in this country are paid for by the federal, state and local governments.[22] When 50% of your healthcare is being paid for by the government, you don't have a free market in the healthcare system.

If you talk to doctors and companies that work in the healthcare market, all of the inefficiencies of government are imposed upon them, from excessive bureaucracy to excessive paperwork,[23] and ultimately to the government strong-arming them to accept certain payments for services and products that are less than what they would accept normally. This occurs repeatedly with Medicare and Medicaid, and in fact, one reason why, if you have private healthcare insurance, you pay so much, is because hospitals and doctors do not receive as much to cover the actual costs under Medicare. They actually get less than marginal cost payments from Medicare for products and services. In hospitals, the doctors have to cover their expenses, so they just cover that extra cost by tacking it on to the other services and products that are paid for by private insurance companies.

So again, we have massive dislocations in the system, like cost-shifting, and I entirely agree with that, but I strongly doubt that the pharmaceutical industry is a winner in this. They are universally reviled and looked at as bad people, along with the insurance companies, and I admit that some of this is deserved. Like everyone else, they lobby for benefits, like Medicare Part D. In the run-up to the legislative debates, President Obama last spring got the pharmaceutical industry to support the proposed bills for national healthcare reform with a public option by promising that price control and reimportation provisions would not be considered as part of the reform bills. And now six months later, these provisions are already being considered, which explains why it's now lobbying against it, because the government has gone back on its promises about it. My attitude about this is that if you make a deal with the devil—the government—don't be surprised that the devil may stab you in the back.

On drug reimportation, I also agree that it's a public choice problem. In Canada, the government imposes price controls knowing full well that pharmaceutical companies will raise their prices in the United States to make up the difference because they have certain costs that they need to cover, and it's not the marginal costs. Covering the marginal costs will not make the least bit of difference in an R&D-based industry that needs to recoup its upfront expenses. In Canada, if it imposes price controls, the prices are just transferred to someone else, like us.

This has been happening in all the countries throughout the world, and it's a great example of a public choice problem because politicians in other countries are not responsive to the concerns of the American voter. They don't care if American voters are paying too much. All they care about is that Canadian voters are paying less so that they can get voted into office in Canada. Well, the buck stops with America. We're the last major country that doesn't impose price controls.

What will happen when the United States adopts price controls or reimportation laws is that prices are not going to rise in these other countries because those governments don't care what happens in our country. I mean, at the end of the day, you don't negotiate with a government like it's another private entity. When you're a drug company and you have a conversation with the government about how much it's going to pay in its socialized healthcare program, this is not like you sitting down with a homebuyer and having a negotiation with him about how much he's going pay for your house. The government says, we're going to pay you this much, and you're going to have to accept it because we're the only game in town.

Why then do pharmaceutical companies agree to this in other countries? Well, they would rather accept one penny than nothing at all because that's still something that they can get back on their sunk costs because the marginal costs, like I said, are not what is driving the price of their products. The pharmaceutical industry is not a marginal-cost industry; it costs almost nothing to make a pill. With their massive research investments behind their drugs, it's these costs that have to get covered for past and future R&D, and pricing at marginal cost isn't going to do that. As I said, this is an industry driven by dynamic efficiency, not static efficiency.

Lastly, the reason why it's only estimates on total R&D costs, with the opponents of the pharmaceutical industry claiming that R&D is $400-$500 million and the pharmaceutical industry saying that it's $800 million to over $1 billion, is that the R&D data is secret. They don't want to expose it, because this would reveal trade secrets and other commercial secrets. So we don't really know what their R&D is going to, but everyone assumes that it's all going to end-of-life treatments: drugs for the last two years of someone's life, like an elderly person with terminal cancer. But it's not just that, it's also going to treatments of major diseases that are killing all people, like AIDS. Vertex Pharmaceuticals, the company I had mentioned in my talk, was the first company to bring out a treatment for AIDS, which has saved countless numbers of lives, and ultimately led to the famous drug cocktails that people with AIDS now take. So young people who thought they were going to be dead in a couple of years are now still alive today, like Magic Johnson. So don't think all of the R&D expenses are entirely for end-of-life medical treatments for old people who are just buying a little more time to avoid the inevitable.

Endnotes

1 Penn Central Transp. Co. v. New York City, 438 U.S. 104 (1978).

2 364 U.S. 40 (1960).

3 481 U.S. 704 (1987).

4 519 U.S. 234 (1997).

5 467 U.S. 986 (1984).

6 *Id.* at 1003 (citing Locke's *Second Treatise* for the proposition that property arises from "labour and invention").

7 544 U.S. 528 (2005).

8 533 U.S. 606 (2001).

9 Tahoe-Sierra Preservation Council v. Tahoe Regional Planning Agency, 535 U.S. 302 (2002).

10 *Tahoe-Sierra Preservation Council*, 535 U.S. at 336 ("Our polestar . . . remains the principles set forth in *Penn Central* itself and our other cases that govern partial regulatory takings.").

11 I learned of this divide within the regulatory takings case law from Eric R. Claeys, *The* Penn Central *Test and the Tension between Classical- and Modern-Liberal Theories of Property*, 30 Harv. Envtl. L. Rev. 339 (2006).

12 128 S. Ct. 2109 (2008).

13 *See* Adam Mossoff, *A Simple Conveyance Rule for Complex Innovation*, 44 Tulsa L. Rev. 707, 711-720 (2009); Adam Mossoff, *Exclusion and Exclusive Use in Patent Law*, 22 Harv. J. L. & Tech. 321, 347-60 (2009).

14 272 U.S. 476 (1926).

15 *Id.* at 489.

16 *See* F.W. Scherer, *The Pharmaceutical Industry—Prices and Progress*, 351 New Eng. J. Med. 927, 927 (2004) ("The pharmaceutical industry is the most research-intensive of U.S. industries that support their research and development with private funds (as distinguished from defense and space contractors).").

17 *See* Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151, 181 (2003) (projecting total R&D costs for drugs approved in 2001 to be $1.1 billion). The pharmaceutical industry claims that the average R&D cost in 2000 was $800 million. *See What Goes into the Cost of Prescription Drugs? . . . and Other Questions About Your Medicines* 2 (2005), *available at* http://www.phrma.org/files/attachments/Cost_of_Perscription_Drugs.pdf (last visited Nov. 4, 2010).

18 *See What Goes into the Cost of Prescription Drugs? . . . and Other Questions About Your Medicines* 2 (2005), *available at* http://www.phrma.org/files/attachments/Cost_of_Perscription_Drugs.pdf (last visited Nov. 4, 2010).

19 *See* Henry G. Grabowski & John Vernon, *Returns to R&D on New Drug Introductions in the 1980s*, 13 J. Health Econ. 383, 404 (1994).

20 *Palazzolo*, 533 U.S. at 616.

21 Barry Werth, The Billion-Dollar Molecule 253-54 (1994).

22 Lin Zinser & Paul Hsieh, *Moral Health Care vs. "Universal Health Care*," 2 The Objective Standard 9, 17 (Winter 2007-2008) (citing 2006 U.S. Census Bureau report).

23 *See id.*; Stella Daily Zawistowski, *A Prescription for America's Health Care Ills*, 3 The Objective Standard 27, 29 (Fall 2010) (reporting that "regulation-strewn interactions with insurance companies" impose an extra $23 to $31 billion per year in costs on physicians).