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MEMORANDUM

DATE: May 1, 2017

TO: Brenda J. Erdoes, Legislative Counsel

FROM: Kevin C. Powers, Chief Litigation Counsel **BP**

SUBJECT: Federal constitutional barriers to state price regulation of prescription drugs sold by pharmaceutical manufacturers in interstate commerce.

You have asked for a brief overview of the federal constitutional barriers to state price regulation of prescription drugs sold by pharmaceutical manufacturers in interstate commerce. The two primary federal constitutional barriers are: (1) the Interstate Commerce Clause, also known as the dormant or negative Commerce Clause, which restricts the power of the states to regulate interstate commerce (U.S. Const. art. I, § 8, cl. 3); and (2) the doctrine of federal preemption under the Supremacy Clause, which preempts state laws that conflict with the purposes and objectives of federal laws (U.S. Const. art. VI, cl. 2). With regard to state price regulation of patented prescription drugs sold by pharmaceutical manufacturers, such conflict preemption arises under the federal patent laws governing patented prescription drugs—specifically, the Drug Price Competition and Patent Term Restoration Act of 1984, which is more commonly known as the “Hatch-Waxman Act.”

1. Interstate Commerce Clause.

When a state statute, either directly by its express terms or indirectly by its inevitable and practical effects, substantially burdens interstate commerce occurring beyond the state’s borders, the U.S. Supreme Court has generally found that such a state statute is *per se* invalid under the Interstate Commerce Clause, and the Court has “generally struck down the statute without further inquiry.” Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 579 (1986). Thus, as a general rule, if the inevitable and practical effects of a state statute substantially burden interstate commerce occurring outside the state’s borders—even if the state statute also regulates commerce occurring within the state’s borders—the state statute imposes an unreasonable burden on interstate commerce in violation of the Interstate Commerce Clause. Brown-Forman, 476 U.S. at 579-80; Healy v. Beer Inst., 491 U.S. 324, 336-40 (1989); Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 521-22 (1935) (holding that no state has the power to project its legislation into other states and regulate the prices of wholesale transactions occurring there, even if the products are ultimately sold at retail within the state’s own borders).

A state statutory price regulation will generally violate the Interstate Commerce Clause if the price regulation places limitations on the prices for in-state transactions by tying those in-state prices to out-of-state prices, markets or indexes, including regional, national or foreign prices, markets or indexes. See Healy, 491 U.S. at 336-40 (1989). As explained by the Supreme Court, “[t]his kind of potential regional and even national regulation of the pricing mechanism for goods is reserved by the Commerce Clause to the Federal Government and may not be accomplished piecemeal through the extraterritorial reach of individual state statutes.” Healy, 491 U.S. at 340.

Furthermore, a state statutory price regulation will not escape scrutiny under the Interstate Commerce Clause simply because the statute’s requirements are triggered only by retail sales occurring within the state if the statute’s inevitable and practical effects control or determine prices for transactions occurring outside the state. Brown-Forman, 476 U.S. at 580 (“The mere fact that the effects of New York’s [Liquor] Law are triggered only by sales of liquor within the State of New York therefore does not validate the law if it regulates the out-of-state transactions of distillers who sell in-state.”).

Finally, in determining whether a state statutory price regulation violates the Interstate Commerce Clause, courts will consider how the challenged statute would interact with the legitimate regulatory regimes of other states and what effect would arise if many states, or potentially every state, enacted similar legislation, thereby increasing “the likelihood that a seller will be subjected to inconsistent obligations in different States.” Brown-Forman, 476 U.S. at 583. As explained by the Supreme Court:

[T]he practical effect of the statute must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation. Generally speaking, the Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State.

Healy, 491 U.S. at 336-37.

In applying these constitutional principles to state statutory price regulation of prescription drugs sold by pharmaceutical manufacturers in interstate commerce, federal courts have generally found that such price regulation violates the Interstate Commerce Clause if it regulates the prices of any out-of-state pharmaceutical transactions—such as transactions between pharmaceutical manufacturers and wholesalers—regardless of whether the price regulation arises directly under the statute by its express terms or indirectly by its inevitable and practical effects, and regardless of whether the statute also regulates in-state pharmaceutical transactions. Compare Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 669 (2003), with Pharm. Research & Mfrs. of Am. v. District of Columbia, 406 F. Supp. 2d 56, 67-71 (D.D.C. 2005)

(striking down statute on Interstate Commerce Clause grounds and on federal preemption grounds), *aff'd on federal preemption grounds*, Biotech. Indus. Org. v. District of Columbia, 496 F.3d 1362 (Fed. Cir. 2007), *rehearing and rehearing en banc denied*, 505 F.3d 1343 (Fed. Cir. 2007).

For example, a state statutory price regulation will generally violate the Interstate Commerce Clause if the price regulation requires pharmaceutical manufacturers to sell their drugs to wholesalers for certain regulated prices or otherwise subjects such wholesale transactions to price limitations whose inevitable and practical effects control or determine the prices that pharmaceutical manufacturers may charge or collect for their drugs. Id. In addition, a state statutory price regulation will generally violate the Interstate Commerce Clause if the price regulation places limitations on the prices for in-state pharmaceutical transactions by tying those in-state prices to out-of-state prices, markets or indexes, including regional, national or foreign prices, markets or indexes. Id.

In Pharm. Research & Mfrs. of Am. v. District of Columbia, 406 F. Supp. 2d 56, 67-71 (D.D.C. 2005), these constitutional principles were applied by a federal district court to strike down a District of Columbia law that placed price limitations on certain prescription drugs sold by pharmaceutical manufacturers in interstate commerce.¹ The District's law made it unlawful for pharmaceutical manufacturers to "sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price." Id. at 61 (quoting D.C. Code § 28-4553 (2005)). Under the District's law, a prima facie case of excessive pricing could be established "where the wholesale price of a patented prescription drug" sold in the District of Columbia is "30% higher than the comparable price" in either the United Kingdom, Germany, Canada or Australia, if the prescription drug is protected in those countries "by patents or other exclusive marketing rights." Id. at 61 (quoting D.C. Code § 28-4554 (2005)).

In striking down the law, the federal district court found that the inevitable and practical effects of the District's law substantially burdened interstate commerce occurring outside the District's borders because most transactions between pharmaceutical manufacturers and wholesalers occurred outside the District. Id. at 67-71. Furthermore, even though the District's law was not triggered until a retail sale of the prescription drug was made in the District, the federal district court found that "as soon as that drug is sold in the District, the manufacturer's out-of-state sale [to the wholesaler] becomes the Act's primary target." Id. at 69. Finally, the federal district court found that "it takes little imagination to envision the harm to interstate commerce that could be caused by the domino effect of similar legislation being adopted in many, or every, state." Id. For example, the federal district court posited that similar legislation throughout the country would result in an artificial race to the bottom of the marketplace by state legislatures competing to enact different formulas for determining excessive prices in an attempt

¹ Even though the District of Columbia is not a state, its laws are subject to the same constitutional principles that apply to state laws under the Interstate Commerce Clause. 406 F. Supp. 2d at 67 n.11.

by each state to receive the lowest prices possible for the prescription drugs. *Id.* For all these reasons, the federal district court concluded that the District's law had "a *per se* invalid extraterritorial reach in violation of the Commerce Clause as applied to transactions between manufacturers and wholesalers that occur wholly out of state." *Id.* at 68.

On appeal to the Court of Appeals for the Federal Circuit, the District did not challenge the federal district court's holding that the District's law violated the Interstate Commerce Clause. *Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1366 (Fed. Cir. 2007), *rehearing and rehearing en banc denied*, 505 F.3d 1343 (Fed. Cir. 2007). Furthermore, as will be discussed next, the Federal Circuit affirmed the federal district court's alternative holding that the District's law was preempted under the Supremacy Clause by principles of conflict preemption because the District's law stood as an obstacle to the purposes and objectives of the federal patent laws governing patented prescription drugs. *Id.* at 1372-74.

2. Federal preemption under the Supremacy Clause and the federal patent laws.

Under the Supremacy Clause, conflict preemption occurs when a state law is in direct conflict with a federal law because the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hillsborough Cnty. v. Automated Med. Labs.*, 471 U.S. 707, 713 (1985) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)); *Arizona v. United States*, 132 S. Ct. 2492, 2501 (2012). Under this standard, "[w]hat is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000).

In areas involving unique federal interests, "the conflict with federal policy need not be as sharp as that which must exist for ordinary pre-emption." *Boyle v. United Techs.*, 487 U.S. 500, 507 (1988). Stated another way, "the fact that the area in question *is* one of unique federal concern changes what would otherwise be a conflict that cannot produce pre-emption into one that can." *Id.* at 507-08. Therefore, courts are more likely to find conflict preemption in areas involving unique federal interests. *Id.* at 504-08; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001); *Am. Ins. Ass'n v. Garamendi*, 539 U.S. 396, 416-20 (2003).

Under the Patent Clause, the regulation of patents is a unique federal interest that falls within the delegated powers of Congress. U.S. Const. art. I, § 8, cl. 8; *Graham v. John Deere Co.*, 383 U.S. 1, 5-6 (1966). As a result, when Congress has established national policy in the federal patent laws, state laws cannot stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress in enacting the federal patent laws. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989) As explained by the Supreme Court:

[S]tate regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws. The tension between the desire to freely exploit the full potential of our inventive resources and the need to create an incentive to deploy those resources is constant. Where it is clear how the patent laws

strike that balance in a particular circumstance, that is not a judgment the States may second-guess.

Bonito Boats, 489 U.S. at 152.

To ensure uniformity in the interpretation and application of the federal patent laws, Congress has given the Court of Appeals for the Federal Circuit exclusive subject-matter jurisdiction nationally to review appeals from all federal district courts which arise under the federal patent laws, and that exclusive subject-matter jurisdiction excludes all other federal courts of appeals from entertaining such appeals. 28 U.S.C. § 1295(a)(1); Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 807 (1988); Biotech. Indus. Org. v. District of Columbia, 496 F.3d 1362, 1367 (Fed. Cir. 2007). As a result, the decisions of the Federal Circuit are binding nationally on federal district courts regarding the interpretation and application of the federal patent laws. In re Spalding Sports Worldwide, Inc., 203 F.3d 800, 803-04 (Fed. Cir. 2000); Se. Pa. Transp. Auth. v. Gilead Scis., Inc., 102 F. Supp. 3d 688, 702 (E.D. Pa. 2015).

In Biotech. Indus. Org. v. District of Columbia, 496 F.3d 1362, 1372-74 (Fed. Cir. 2007), the Federal Circuit held that the federal patent laws preempted the District's law that placed price limitations on patented prescription drugs sold by pharmaceutical manufacturers.² In reaching its holding, the Federal Circuit explained that one of the policies adopted by Congress in the federal patent laws is to encourage innovation and invention by enabling patent-holders to reap economic rewards during the patent's period of exclusivity:

[T]he Patent Act creates an incentive for innovation. The economic rewards during the period of exclusivity are the carrot. The patent owner expends resources in expectation of receiving this reward. Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace.

Biotech. Indus. Org., 496 F.3d at 1372-73 (quoting King Instruments Corp. v. Perego, 65 F.3d 941, 950 (Fed. Cir. 1995)).

The Federal Circuit also supported its holding with the legislative history of the Drug Price Competition and Patent Term Restoration Act of 1984, which is more commonly known as the "Hatch-Waxman Act." Biotech. Indus. Org., 496 F.3d at 1373. In that legislative history, Congress "acknowledged the central role of enhanced profits in the statutory incentive scheme," which was designed to advance the congressional purposes and objectives of incentivizing pharmaceutical manufacturers to increase expenditures for research and development into new prescription drugs. Id. Thus, by enabling patent-holders to reap economic rewards during the patent's period of exclusivity, "the patent system provides incentive to the innovative drug companies to continue costly development efforts." Id. at 1372 (quoting Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1383 (Fed. Cir. 2006)).

² Even though the District of Columbia is not a state, its laws are subject to the same preemption principles that apply to state laws under the Supremacy Clause. 496 F.3d at 1371-72.

Given the purposes and objectives of the federal patent laws, the Federal Circuit concluded that the District's law was preempted under the Supremacy Clause because it conflicted with those purposes and objectives in that the law's "effect is to shift the benefits of a patented invention from inventors to consumers." Biotech. Indus. Org., 496 F.3d at 1374. As further explained by the Federal Circuit:

By penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—the District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs. In the District's judgment, patents enable pharmaceutical companies to wield too much exclusionary power, charging prices that are "excessive" for patented drugs. The Act is a clear attempt to restrain those excessive prices, in effect diminishing the reward to patentees in order to provide greater benefit to District drug consumers. This may be a worthy undertaking on the part of the District government, but it is contrary to the goals established by Congress in the patent laws. * * * The District has thus seen fit to change federal patent policy within its borders. The underlying determination about the proper balance between innovators' profit and consumer access to medication, though, is exclusively one for Congress to make. * * * The Act stands as an obstacle to the federal patent law[s'] balance of objectives as established by Congress. Accordingly, we conclude that it is preempted by federal patent law.

Biotech. Indus. Org., 496 F.3d at 1374; see also Se. Pa. Transp. Auth. v. Gilead Scis., Inc., 102 F. Supp. 3d 688, 702-03 (E.D. Pa. 2015) (holding that state-law claims alleging excessive pricing of patented prescription drugs are preempted by the federal patent laws).

3. Conclusion.

The Interstate Commerce Clause imposes significant federal constitutional barriers to state price regulation of prescription drugs sold by pharmaceutical manufacturers in interstate commerce. Given the existing case law to date, the federal courts have generally struck down such state price regulation under the Interstate Commerce Clause because it substantially burdens interstate commerce occurring outside the state's borders.

In addition, with regard to state price regulation of patented prescription drugs, the Supremacy Clause and the federal patent laws also impose significant federal constitutional barriers to state price regulation of patented prescription drugs sold by pharmaceutical manufacturers. Under the nationally binding precedent of the Federal Circuit, such state price regulation is preempted under the Supremacy Clause because it stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress in enacting the federal patent laws.