

Legal Issues Raised by Rx Council's Compulsory Licensing Proposal

The West Virginia Pharmaceutical Cost Management Council has proposed a program under which the state would contract with a single wholesaler to purchase prescription drugs purchased by state employees and West Virginians covered by programs like Medicaid and PEIA. Manufacturers would be required to sell their drugs to the wholesaler at a "reasonable" price. If a manufacturer does not agree to sell a drug at a "reasonable" price, the state would "license" other manufacturers to produce generic versions of the drug. Any price in excess of the price paid by the Australian Pharmaceutical Benefits Scheme would be presumed to be unreasonable. The generic manufacturers would be required to obtain FDA approval to market their versions of the drug. The Council suggests the possibility of extending this program to include all West Virginians.

As discussed below, the compulsory licensing aspect of the Council's proposal is unconstitutional.

- States have no power to "license" others to make a patented product.

The Patent Clause of the Constitution gives Congress power to "secure[] for limited Times to . . . Inventors the exclusive Right to their . . . discoveries." Const. art. I, § 8, cl. 8. This is an exclusively federal power. *McClurg v. Kingsland*, 42 U.S. (1 How.) 202, 206 (1843) ("[T]he powers of Congress to legislate upon the subject of patents is plenary by the terms of the Constitution."). Hence, states can neither grant patents nor interfere with the rights a patent confers on the holder. *Webber v. Virginia*, 103 U.S. 344, 347 (1880). West Virginia can no more "license" others to make a patented drug than it can issue or invalidate passports, or regulate commerce with Indian tribes.

- The proposed licensing scheme would conflict with and be preempted by federal law.

The Council's compulsory licensing scheme would also conflict with the patent system established by Congress, and would therefore be preempted under the Supremacy Clause of the Constitution. The federal patent system strikes the balance between exclusive use and public use that Congress deemed necessary to encourage invention. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989). States are not free to strike a different balance: "state regulation of intellectual property must yield to the extent it clashes with the balance struck by Congress." *Id.* at 152. Just as a state cannot provide patent-like protection for unpatented goods, *id.* at 159-60, so a state cannot limit the patent protection afforded by the federal government.

- The proposed licensing scheme would violate the Takings Clause.

The Takings Clause of the Fifth Amendment to the Constitution specifies that “private property shall [not] be taken for public use without just compensation.” Patents are a form of property, 35 U.S.C. § 261; *see Fla. Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 642 (1999), and “a State, by ipse dixit, may not transform private property into public property without compensation,” *Webb’s Fabulous Pharmacies, Inc. v. Beckwith*, 449 U.S. 155, 164 (1980). Congress recognized this principle when it enacted legislation under which the federal government may arrange for a patented drug to be made for it by a government contractor; the statute provides that the patent holder can sue the government for “reasonable and entire compensation.” 28 U.S.C. § 1498.¹

The Council’s proposal does not appear to contemplate that West Virginia would compensate drug manufacturers for the “taking” of their patent rights; the proposal would therefore violate the Takings Clause on its face. *See Sweet v. Rechel*, 159 U.S. 380, 399 (1895) (“[I]t is a condition precedent to the exercise of [the power of eminent domain] that the statute make provision for reasonable compensation to the owner.”). Moreover, if West Virginia were to compensate patent holders, the upshot of the Council’s proposal would simply be to shift the cost of patented drugs from specified government programs to taxpayers generally. And the Commonwealth undoubtedly would have to agree to indemnify the generic manufacturer for any costs that it might incur in the event of an infringement action by the patent holder.

- A generic manufacturer could not obtain FDA approval.

The Council recognizes that a generic manufacturer could not market its version of a patented drug without obtaining FDA approval. The Council therefore specifies that a generic manufacturer that receives a license “will be responsible for FDA approval.” Presumably, the generic manufacturer would seek FDA approval by filing an Abbreviated New Drug Application (“ANDA”) with FDA. 21 U.S.C. § 355(j). As part of its ANDA filing, the generic manufacturer would need to certify that the branded product’s patent is either invalid or non-infringed by the generic applicant. 21 U.S.C. § 355(j)(2)(A)(vii). As a matter of federal law, the generic manufacturer could not make the required certification because the patent would still be valid; and, as far as federal law is concerned, the manufacturer’s production of the drug would infringe that patent.

¹ Section 1498 also underscores the exclusively federal nature of the patent, which the United States grants and over which the United States (and the United States alone) can exercise eminent domain. *See W.L. Gore & Assocs., Inc. v. Garlock*, 842 F.2d 1275, 1283 (Fed. Cir. 1988) (“The patentee takes his patent from the United States subject to the government’s eminent domain rights to obtain what it needs from manufacturers and to use the same.”).

If the generic manufacturer certified non-infringement (*e.g.*, on the theory of holding a state license), the patent holder would be entitled to bring an infringement suit in federal court. The filing of the lawsuit would automatically prevent FDA approval of the generic drug for up to 30 months while the lawsuit is pending. 21 U.S.C. § 355(j)(5)(B)(iii).² Moreover, because a federal court would likely agree that West Virginia lacks the power to abrogate a manufacturer's patent rights or that such abrogation is preempted, the generic manufacturer's assertion of non-infringement would likely fail. As a result, the generic manufacturer would not be able to obtain marketing approval from FDA, and would therefore be precluded both under the Federal Food, Drug, and Cosmetic Act and the Council's proposal from selling the product.

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For all of these reasons, the compulsory licensing aspect of the Council's proposed program is unconstitutional.

² In addition, under federal law, a generic manufacturer may not file an ANDA for a new chemical entity ("NCE") until five years after the NCE's approval, or four years if the ANDA is filed with a so-called paragraph IV certification challenging the innovator's patents. 21 U.S.C. § 355(j)(5)(F)(ii).