In the

United States Court of Appeals

For the Seventh Circuit

No. 16-3071

LEGATO VAPORS, LLC, et al.,

Plaintiffs-Appellants,

and

RIGHT TO BE SMOKE-FREE COALITION, INC.,

Intervenor-Appellant,

v.

DAVID COOK, et al.,

Defendants-Appellees.

Appeal from the United States District Court for the Southern District of Indiana, Indianapolis Division.
No. 1:15-cv-00761-SEB/TAB — **Sarah Evans Barker**, *Judge*.

ARGUED DECEMBER 8, 2016 — DECIDED JANUARY 30, 2017

Before MANION, KANNE, and HAMILTON, *Circuit Judges*.

HAMILTON, *Circuit Judge*. In 2015 the State of Indiana enacted the Vapor Pens and E-Liquid Act to regulate the manufacture and distribution of vapor pens and the liquids used in so-called e-cigarettes. 2015 Ind. Acts 1870, Ind. Code §§ 7.1-7-1-1 *et seq*. The Act is written so as to have extraterritorial reach that is unprecedented, imposing detailed requirements of Indiana law on out-of-state manufacturing operations. The Act regulates the design and operation of out-of-state production facilities, including requirements for sinks, cleaning products, and even the details of contracts with outside security firms and the qualifications of those firms' personnel. Imposing these Indiana laws on out-of-state manufacturers violates the dormant Commerce Clause of the United States Constitution.

The federal Constitution leaves Indiana ample authority to regulate in-state commerce in vapor pens, e-liquids, and e-cigarettes to protect the health and safety of its residents. For example, the Act's prohibitions on sales to minors, its requirements for child-proof packaging, ingredient labeling, and purity, and requirements for in-state production facilities pose no inherent constitutional problems. Indiana may not, however, try to achieve those health and safety goals by directly regulating out-of-state factories and commercial transactions. As applied to out-of-state manufacturers, the challenged provisions of the Act violate the dormant Commerce Clause prohibition against extraterritorial legislation.

We reverse the judgment of the district court dismissing this case and remand with instructions to enjoin enforcement of the challenged provisions against the plaintiffs and to declare the challenged provisions unenforceable against out-of-state manufacturers. To explain our reasons, we first review the statutory provisions and procedural history of the case. Then we apply the Commerce Clause analysis to three categories of challenged provisions: security terms, clean room specifications, and audit requirements.

I. *Factual and Procedural Background*

In 2015, the Indiana legislature passed the Vapor Pens and E-Liquid Act, regulating the production and sale of e-liquid solutions. E-liquid solutions—generally consisting of a mixture of propylene glycol, vegetable glycerin, flavorings, water, and a range of nicotine concentrations—are ingested by the consumer using an e-vapor device. E-vapor devices are often shaped like cigarettes. They use a battery and atomizer to turn an e-liquid solution into an aerosol that can be inhaled through a mouthpiece, simulating the act of smoking a cigarette. The popularity of "vaping" has increased dramatically since its introduction to the United States market in 2007. Currently, there are an estimated 138 brick-and-mortar "vape" shops in Indiana, and products are also available online to Indiana consumers. Total annual sales of vape devices and e-liquids in the state are more than $77 million.

In some ways, the Act is unremarkable and uncontroversial. It regulates in-state sales of e-liquids with requirements for tamper-evident and child-proof packaging, as well as labels designating active ingredients, nicotine content, and expiration dates. Ind. Code § 7.1-7-4-6(b)(1)–(7). The Act prohibits sales to minors. § 7.1-7-6-2(a)(1). The Act itself explains that its purpose is to protect public health and safety in the use of these products "in the absence of federal regulations," § 7.1-7-1-2, since the federal government has not adopted comparable regulations for safety and purity of e-cigarette products.

What is remarkable, however, is the Act's extensive regulation beyond the manufacture and sale of e-liquid solutions in Indiana. The statute requires not just that in-state and out-of-state manufacturers meet stringent security standards, but it also goes so far as to require the manufacturer to contract with an independent security firm rather than provide the security services in-house. It requires the manufacturer to enter a service agreement with a security firm that is valid for five years after the date of permit application. Ind. Code §§ 7.1-7-4-1(d)(2)(B), (d)(3). The security firm must meet stringent certification standards and provide 24-hour video monitoring and high-security key systems. § 7.1-7-4-6(b)(12)–(13). The Act also dictates details for the construction, design, and operation of the manufacturing facility, including requiring a "clean room" for mixing and bottling that adheres to requirements of the Indiana Commercial Kitchen Code. §§ 7.1-7-4-1(d)(1), 7.1-7-2-4(3).

The Act imposes each of these substantive requirements governing manufacturing processes and facilities as a condition of obtaining and keeping a permit. If a manufacturer's products are sold in Indiana, the manufacturer must obtain a permit from the Indiana Alcohol and Tobacco Commission. § 7.1-7-4-1(a). To obtain a permit, the substantial requirements for security and clean room facilities must be met, and audit provisions apply to ensure compliance after the permit is granted. See, e.g., § 7.1-7-4-6(b)(17). A permitted manufacturer "must submit to random audits," § 7.1-7-4-6(b)(16), defined as procedures "performed by the commission, including inspection of manufacturing facilities and preparation areas, review of required records, compliance checks, and auditing of samples of e-liquid," § 7.1-7-2-3. The Act defines a "manufacturer" as "a person or cooperative, located inside *or outside Indiana*, that is engaged in manufacturing e-liquid." § 7.1-7-2-15 (emphasis added).

The plaintiffs are three out-of-state manufacturers of regulated products: Legato Vapors, Rocky Mountain E Cigs, and

Derb E Cigs. They filed suit in the district court for injunctive and declaratory relief against members of the Indiana Alcohol and Tobacco Commission on several state and federal grounds. The parties filed cross-motions for summary judgment on stipulated facts. The district court granted summary judgment for the defendants. *Legato Vapors LLC v. Cook*, — F. Supp. 3d —, 2016 WL 3548658 at *18 (S.D. Ind. June 30, 2016).

Where the district court has decided cross-motions for summary judgment on stipulated facts, our review on appeal is *de novo*, without deference to the legal analysis of the district court. On appeal, plaintiffs have narrowed both their theory and the scope of their challenge. They have narrowed their legal theory to the argument that the Act, as applied to out-of-state manufacturers, violates the dormant Commerce Clause prohibition on extraterritorial state regulation of commerce. Plaintiffs have narrowed their challenges to the Act's direct regulations applicable to manufacturing facilities, including those regulating the physical manufacturing facility, security and cleaning arrangements, and facility audits.

II. *The Dormant Commerce Clause*

The Commerce Clause gives Congress the power to regulate commerce "among the several States." U.S. Const. art. I, § 8, cl. 3; see *Gibbons v. Ogden*, 22 U.S. 1 (1824); *Wilson v. Black-Bird Creek Marsh Co.*, 27 U.S. 245 (1829). While the clause expressly grants power to Congress, since before the Civil War it has been settled that it also has an implicit or "dormant" dimension: "Although the Clause thus speaks in terms of powers bestowed upon Congress, the Court long has recognized that it also limits the power of the States to erect barriers against interstate trade." *Lewis v. BT Investment Managers, Inc.*, 447 U.S. 27, 35 (1980); see also, e.g., *CTS Corp. v. Dynamics*

Corp. of America, 481 U.S. 69, 87 (1987), citing *Cooley v. Board of Wardens*, 53 U.S. 299 (1851).

For many years, dormant Commerce Clause jurisprudence drew a distinction between States' direct and indirect regulation of interstate commerce. Direct interference with interstate commerce was invalid as a violation of the dormant Commerce Clause, but legislation having indirect effects remained permissible. See, e.g., *Di Santo v. Pennsylvania*, 273 U.S. 34, 36–37 (1927) (state law seeking to prevent fraud by requiring state license to sell steamship tickets was invalid as direct regulation of foreign and interstate commerce).

The distinction between direct and indirect regulation proved to be less a bright line and more a matter of degree. The Supreme Court then began to rely more on a balancing test that weighs the regulating state's interests against the burdens on interstate commerce (at least when the state does not actually discriminate against interstate commerce). See *Southern Pacific Co. v. Arizona*, 325 U.S. 761, 770–71, 783–84 (1945) (applying balancing test to hold that state law restricting length of interstate trains was invalid burden on interstate commerce); *California v. Thompson*, 313 U.S. 109, 116 (1941) (overruling *Di Santo*); *South Carolina State Highway Dep't v. Barnwell Bros.*, 303 U.S. 177, 196 (1938) (upholding state limits on size and weight of trucks on state highways).

Despite the fading reliance on the direct-indirect distinction and the further development of balancing tests for nondiscriminatory state laws, the Supreme Court has never held that a state may impose truly direct and burdensome state regulation of commerce beyond the state's boundaries. See, e.g., *Brown-Forman Distillers Corp. v. New York State Liquor Au-*

thority, 476 U.S. 573, 584 (1986) (invalidating state's price-affirmation law that directly regulated "interstate commerce"); *Edgar v. MITE Corp.*, 457 U.S. 624, 642 (1982) (plurality opinion) ("[A] state statute which by its necessary operation directly interferes with or burdens [interstate] commerce is a prohibited regulation and invalid, regardless of the purpose with which it was enacted."), quoting *Shafer v. Farmers Grain Co.*, 268 U.S. 189, 199 (1925). The dormant Commerce Clause continues to prohibit "the application of a state statute to commerce that takes places wholly outside of the State's borders, whether or not the commerce has effects within the State." *Healy v. Beer Institute, Inc.*, 491 U.S. 324, 336 (1989), quoting *Edgar*, 457 U.S. at 642–43. When a state directly regulates interstate commerce, it "exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature." *Id*.

Generally, courts will strike down a statute that "directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests," without engaging in the more permissive balancing tests applied to non-discriminatory legislation. *Brown-Forman Distillers*, 476 U.S. at 578–79; *Edgar*, 457 U.S. at 640, 643. See, e.g., *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970). Laws that discriminate directly against interstate commerce are subject to what amounts to strict scrutiny. *Maine v. Taylor*, 477 U.S. 131, 138 (1986). "[O]nce a state law is shown to discriminate against interstate commerce either on its face or in practical effect, the burden falls on the State to demonstrate both that the statute serves a legitimate local purpose, and that this purpose could not be served as well by available nondiscriminatory means." *Id*. (internal quotation marks and citations omitted).

In this case, plaintiffs do not contend that the Indiana Act discriminates against interstate commerce. They argue that the law violates the Commerce Clause by directly regulating commercial activity outside Indiana. Where the issue is the extraterritorial effect of a law, the focus is on its "practical effect." *Healy*, 491 U.S. at 336. The practical effect is assessed by considering both the consequences of the law itself and how the law may interact with the legitimate regulatory regimes of other states—potential inconsistent legislation. *Id*.

Here, plaintiffs argue that the Indiana Act violates the Commerce Clause as extraterritorial regulation because it dictates how out-of-state manufacturers must build and secure their facilities, operate assembly lines, clean their equipment, and contract with security providers, if any of their products are sold in Indiana. Plaintiffs also argue that the Act puts out-of-state manufacturers at risk of inconsistent regulations imposed by other states. The defendant state officials argue that the transactions regulated by the Act are not wholly outside Indiana and that the Act is facially neutral, without discriminating against interstate commerce. The Act applies equally to in-state and out-of-state manufacturers.

We assess only whether particular provisions of the Indiana Act, as applied to out-of-state manufacturers, are invalid as direct extraterritorial regulation. To figure out which provisions plaintiffs challenge, we note their general claim that "the security, clean room, and audit requirements" violate the Commerce Clause, their list of twenty-two challenged provisions in the first amended complaint, and the imprecise disclaimer that plaintiffs are not challenging, or at least are no longer challenging, "local sales rules" in Ind. Code § 7.1-7-4-6. The result, as we see it, is that plaintiffs continue to challenge the following sixteen provisions: Ind. Code §§ 7.1-7-4-1(d)(1)–(3), (6), (8)–(10); 7.1-7-4-6(b)(8), (10)–(16), and (19). See *Legato Vapors*, 2016 WL 3548658, at *1 n.1 (district court's observation that exact provisions plaintiffs challenged were not clear in the filings).

With almost two hundred years of precedents to consider, our review of prior dormant Commerce Clause decisions has not revealed a single appellate case permitting any direct regulation of out-of-state manufacturing processes and facilities comparable to the Indiana Act. The Supreme Court has issued a number of decisions in closer cases, such as challenges to price-affirmation laws and laws regulating in-state segments of interstate transportation. At first glance, both types of laws seem to regulate only in-state commerce. Those lines of cases reveal two facets of the basic rule prohibiting extraterritorial legislation. Price-affirmation laws can violate the Commerce Clause because they have ripple effects in other states, effectively setting the price for a commodity in transactions outside the regulating state. See, e.g., *Healy*, 491 U.S. 324; *Brown-Forman Distillers*, 476 U.S. 573. State regulation of in-state segments of interstate railroad and highway traffic can violate the Commerce Clause because national uniformity is "practically indispensable to the operation of an efficient and economical national railway system," *Southern Pacific*, 325 U.S. at 771, and the effect of one state's regulation can place a "substantial burden on the interstate movement of goods," *Raymond Motor Transp., Inc. v. Rice*, 434 U.S. 429, 445 (1978). Implicit in both lines of cases is the more general principle that a state may not impose its laws on commerce in and between other states.

This court has struck down as extraterritorial state laws much less intrusive than the Indiana Act. For example, we invalidated a state law that attempted to regulate loan transactions entered into entirely out-of-state. In *Midwest Title Loans, Inc. v. Mills*, the plaintiff challenged an Indiana law that deemed a loan transaction to take place in Indiana and thus subject to Indiana law if the out-of-state lender advertised in Indiana, even if an Indiana resident entered into the transaction entirely in Illinois. 593 F.3d 660, at 661–62, 669 (7th Cir. 2010). Indiana's attempt to regulate loan transactions occurring wholly outside the state constituted impermissible extraterritorial regulation. *Id.* at 669. Similarly, in *Dean Foods Co. v. Brancel*, a Wisconsin law prohibited payment of volume premiums for bulk purchases of milk produced in Wisconsin. 187 F.3d 609 (7th Cir. 1999). We held that Wisconsin could not apply its law to regulate the price of sales of milk produced in Wisconsin but where the sales took place outside the state, after the producers had transported the milk beyond the state boundary. *Id*. at 620.

In *National Solid Wastes Management Association v. Meyer*, a Wisconsin statute prohibited both in-state and out-of-state generators of solid waste from dumping certain materials in Wisconsin landfills unless they resided in a community that had adopted an "effective recycling program." 63 F.3d 652, 653–54 (7th Cir. 1995). We held that the law violated the Commerce Clause as extraterritorial regulation. *Id*. at 661–62. The law controlled the conduct of those engaging in commerce occurring wholly outside the state when it conditioned the "use of Wisconsin landfills by non-Wisconsin waste generators on their home communities' adoption and enforcement of Wisconsin recycling standards," such that all persons in those communities outside Wisconsin had to "adhere to the Wisconsin standards whether or not they dump[ed] their waste in Wisconsin." *Id*. at 658. That Wisconsin law also directly regulated out-of-state commerce and was invalid. *Id*. at 661.

It is useful to compare these cases on extraterritorial legislation to decisions dealing with state laws imposing product labeling requirements for in-state sales, even when the product is produced out-of-state. The Second Circuit upheld a Vermont law requiring special labels for light bulbs containing mercury in *National Electrical Manufacturers Association v. Sorrell*, 272 F.3d 104 (2d Cir. 2001). The court found that the law was not extraterritorial in scope. Although the law may have required out-of-state manufacturers to "modify their production and distribution systems to differentiate" between light bulbs bound for Vermont and those bound elsewhere, the law was not invalid. *Id*. at 110. Nor did it matter that the law might compel manufacturers to withdraw from the Vermont market, or alternatively, to sell light bulbs with labeling conforming to Vermont's requirements in other states. *Id*. at 110–11. The Second Circuit found that no conflict with other state regulatory schemes had been shown, so that the labeling law did not pose a risk of inconsistent regulation. *Id*. at 112.

The Sixth Circuit took a similar approach to uphold a state-specific labeling requirement in *International Dairy Foods Association v. Boggs*, 622 F.3d 628, 647–49 (6th Cir. 2010). An Ohio law said that labels on milk sold in the state could not carry certain claims about the absence of artificial hormones and had to include a disclaimer for claims about the absence of artificial hormones in production processes. *Id*. at 632–34.

The Sixth Circuit held that the law was not invalid as extraterritorial despite out-of-state producers' claims that it would burden interstate commerce. *Id*. at 649–50. The Sixth Circuit reasoned that the law had only indirect effects on out-of-state manufacturers, who may have needed to adjust their labels, and did not impede the flow of milk across state lines. *Id*. at 647–48.

The contrast between the labeling laws and the extraterritorial laws we have struck down helps to mark the extent of the dormant Commerce Clause prohibition. When we compare the challenged provisions of the Indiana Act here, it becomes clear that they cannot be applied to out-of-state manufacturers of vaping products.

A. *Security Provisions*

We first consider the requirements for security contracts, beginning with Indiana Code § 7.1-7-4-1(d), which governs initial applications for e-liquid manufacturing permits. Paragraph 7.1.-7-4-1(d)(1) requires the permit application to include plans "for the construction and operation of the manufacturing facility that demonstrate that the facility design is … capable of meeting … the security requirements." Paragraphs (d)(2) and (d)(3) make explicit the requirements referenced in (d)(1): the applicant-manufacturer must have entered into a service agreement that is valid for five years after the date of application, renewable for the entire duration the applicant holds a permit, and with a security firm that can certify that it meets the requirements of § 7.1-7-4-6(b)(10)–(15).

The provisions of § 7.1-7-4-6(b)(10)–(15) in turn require the manufacturer to "take reasonable steps to ensure that all ingredients used in the production of e-liquid are stored in a secure area accessible only by authorized personnel," and "that only authorized personnel have access to secured areas;" to have "a remotely monitored security system" and "an exclusive high security key system;" to record 24-hour video surveillance; and to maintain samples from each production batch for not less than three years in areas with "recorded video surveillance."

In remarkably specific provisions, § 7.1-7-4-1(d)(3) requires an applicant for a manufacturing permit to provide "verified documents" demonstrating that the "security firm has continuously employed" for not less than one year at least one employee certified by the Door and Hardware Institute and at least one employee certified as a Rolling Steel Fire Door Technician. The security firm must also have at least one year of commercial experience with "video surveillance system design and installation with remote viewing capability from a secure facility," owning and operating a security monitoring system with redundant offsite backup, and operating "a facility that modifies commercial hollow metal doors, frames, and borrowed lights with authorization to apply the Underwriters Laboratories label." § 7.1-7-4-1(d)(3).

From the perspective of the dormant Commerce Clause, these are extraordinary provisions, at least as applied to out-of-state manufacturers. At the most basic level, one might wonder why Indiana cares whether an out-of-state manufacturer provides for security at its facilities through a contract with an independent company rather than through its own employees. The specific provisions for the forms of security, including the types of systems and the use of on-site or off-site monitoring, raise more questions. The astoundingly specific provisions for the qualifications of the security firm that the manufacturer must commit to hire for at least five years raise still more questions that go well beyond the Commerce Clause.

Another district court decision in Indiana recently found that only one company in the entire United States, located not so coincidentally in Indiana, satisfied the criteria of the Indiana Act and has the approval of the Indiana Alcohol and Tobacco Commission. *GoodCat, LLC v. Cook*, — F. Supp. 3d —, 2016 WL 4734588 at *5–6 (S.D. Ind. Aug. 19, 2016). In fact, prior to an amendment to the bill that became the Act, not even that favored company would have met the Act's requirements. *Id*. at *5. That lone company was neither required nor had the capacity to accept all contract applications. The result has been that the one security company serves six companies who sought security contracts with it. *Id*. at *5–6. Only those six companies may lawfully sell their vaping products in Indiana. Before the Act went into effect, ninety percent of e-liquid revenue in Indiana came from e-liquids manufactured out-of-state. Now, only six manufacturers—compared to the more than one hundred selling in Indiana before the Act—supply e-liquids to Indiana retailers. Four of those six are in-state companies. *Id*. at *15.

These circumstances raise obvious concerns about protectionist purposes and what looks very much like a legislative grant of a monopoly to one favored in-state company in the security business. We can decide this case without pursuing all of those questions, however. As applied to out-of-state manufacturers, the security provisions of the Indiana Act violate the Commerce Clause for a more basic reason. They operate as extraterritorial legislation, governing the services and commercial relationships between out-of-state manufacturers and their employees and contractors. With two hundred years of Commerce Clause precedents to draw from, the defendant state officials have offered no authority supporting such extraterritorial legislation.

We understand the State's arguments that good security for manufacturing facilities is vital to protect vaping products from contamination. The Commerce Clause does not prohibit Indiana from imposing reasonable and even-handed purity requirements on vaping products sold in Indiana. It may not try to achieve that goal by direct extraterritorial regulation of the manufacturing processes and facilities of out-of-state manufacturers.[1]

Consideration of potential inconsistent regulation only reinforces our conclusion that, as applied to out-of-state manufacturers, the challenged provisions violate the Commerce Clause. Plaintiffs argue that now, ten years after the launch of the e-liquid market, states have had the opportunity to adopt their own distinct regulatory regimes for e-liquids. Plaintiffs point us to less stringent e-liquid laws in Arkansas and Utah, for example, but the threat of inconsistent regulation, not inconsistent regulation in fact, is enough to show why Indiana

[1] The Supreme Court has said that extraterritorial laws, like laws that discriminate against interstate commerce, are "virtually *per se* invalid" under the Commerce Clause. *Brown-Forman Distillers*, 476 U.S. at 579; see also *International Dairy Foods*, 622 F.3d at 644–45. We understand the qualifier "virtually" to refer to unusual circumstances where the state law serves an important purpose and the state can show that no less restrictive or intrusive measures could serve that purpose, so that the law survives strict scrutiny, as in *Taylor*, 477 U.S. at 138 (upholding discriminatory state law under strict scrutiny). Indiana has not tried to satisfy that standard here.

cannot impose these security requirements on out-of-state manufacturers. See *Dean Foods*, 187 F.3d at 615.

The potential for conflicts in the remarkably specific security requirements is obvious. Suppose another state chose to enact a similarly specific security provision tailored to one of its own in-state security firms. Or suppose another state simply required manufacturers to provide adequate security through their own employees, without trying to contract out the service. Indiana responds that the e-liquid market is new and states are just beginning to regulate it, making the possibility of inconsistent regulation slight. We reject this argument. The very youth of the market and of state health and safety regulations cuts the other way. In the absence of preemptive federal laws, we can expect more states to enact their own laws (and to treat existing laws in other states, like Indiana, as models). In any event, the obvious risk of inconsistent regulation is enough here. See *Healy*, 491 U.S. at 336.

Taken together and individually, the security provisions amount to direct and unconstitutional extraterritorial regulation of out-of-state e-liquid manufacturers' production facilities and their purchases of services in their home states. These requirements are not like the labeling cases, where an out-of-state producer may comply by making minor adjustments to its production processes so that labeling will conform to the governing state's requirements. The direct regulation of out-of-state facilities and services has effects that are not comparable to mere incidental effects of a facially neutral law regulating labels, such as those on light bulbs or milk. Compare *National Electrical Manufacturers Ass'n*, 272 F.3d 104, and *International Dairy Foods Ass'n*, 622 F.3d 628, with Ind. Code § 7.1-

7-4-6(b). More than just posing a significant threat of inconsistent regulation, the Indiana Act directly regulates specific elements of any security contract made by out-of-state manufacturers. These provisions control conduct "beyond the boundaries of the state" and tell out-of-state companies how to operate their businesses. See *Edgar*, 457 U.S. at 643 (citation omitted).

The defendant state officials have not tried to show that they can satisfy the "strictest scrutiny" that would be needed to uphold a discriminatory or extraterritorial law. See *Taylor*, 477 U.S. at 144 (citation omitted). The defendants simply assert without support that "for a product such as e-liquids there is no practical way to regulate the quality of it without regulating the manufacturing process." The asserted purpose of the statute—protecting the health and safety of Hoosiers who consume e-liquids—is of course legitimate. But the defendants have failed to offer any evidence that less intrusive alternatives to these unprecedented extraterritorial provisions are incapable of serving that purpose. See *Taylor*, 477 U.S. at 138. Such direct extraterritorial legislation is invalid as applied to the plaintiffs and other out-of-state manufacturers. See *Healy*, 491 U.S. at 336.

B. *Clean Room Requirements*

The clean room provisions challenged by the plaintiffs require that the permit application include plans "for the construction and operation of the manufacturing facility that … include a clean room space where all mixing and bottling activities will occur." Ind. Code § 7.1.-7-4-1(d)(1). "The manufacturing facility must conduct all mixing and bottling activities in a clean room."[2] § 7.1-7-4-6(b)(8). The cleaning and sanitizing of equipment must be consistent with the Indiana standards for commercial kitchens in Indiana, and the equipment used in the production process must be "easily cleanable." § 7.1-7-2-4; 410 Ind. Admin. Code § 7-24-1 *et seq.*; § 7-24-27(a). The commercial kitchen standards referenced in the Act impose detailed requirements for everything from physical facilities such as the type of sinks and required cleaning equipment, 410 Ind. Admin. Code § 7-24-270), to production materials such as types of cleansers and utensils used, 410 Ind. Admin. Code §§ 7-24-294, -303).

Like the security provisions, the clean room provisions directly regulate the physical plants of out-of-state manufacturers. The clean room provisions also directly regulate the production processes of out-of-state manufacturers. Akin to telling out-of-state communities how to run their recycling programs, Indiana has gone so far as to order out-of-state e-liquid manufacturers to wash their equipment with specific cleansers in specific sinks. Compare *National Solid Wastes Management Ass'n*, 63 F.3d 652, with 410 Ind. Admin. Code §§ 7-24-270, -294, -303. And again, the potential for inconsistent regulation is obvious. Of the many requirements, from sink size to cleanser type, there are countless possible variations. That one state might demand double-basin steel sinks and another demand single-basin porcelain sinks is just one example. The clean room provisions directly regulate interstate commerce

[2] The statute defines "clean room" as any part of the facility where "the mixing and bottling activities are conducted in secure and sanitary conditions in a space that is kept in repair sufficient to prevent e-liquid from becoming contaminated." Ind. Code § 7.1-7-2-4.

and, as applied to out-of-state manufacturers, are invalid as extraterritorial laws.

C. *Audits and Additional Provisions*

The remaining provisions of the Indiana Act challenged by the plaintiffs fall into the loose category of "audits." Indiana Code § 7.1-7-4-1(d)(10) requires the applicant-manufacturers to give their consent to the Indiana Alcohol and Tobacco Commission "to enter during normal business hours … to conduct physical inspections, sample the product … and perform an audit." See also § 7.1-7-4-6(b)(16). Paragraph 7.1-7-4-1(d)(9) requires the manufacturers to consent to state or national criminal background checks on anyone listed in the permit application, and § 7.1-7-4-6(b)(19) prohibits the manufacturer or any other person listed on the permit application from having been "convicted of a felony or an offense involving a controlled substance." Another challenged provision is § 7.1-7-4-1(d)(6), which requires a permit application to include the "projected output in liters per year of e-liquid of the manufacturing facility," perhaps as the basis for a future audit.

The record and parties' arguments with respect to the audit provisions are not well developed. The record is sufficient for us to conclude, however, that audits and on-site inspections of out-of-state manufacturers are invalid direct regulations of interstate commerce insofar as they relate to enforcement of Indiana's requirements for facility design and production operations. We leave room for future challenges, based on better developed records and arguments, to audit provisions such as taking product samples or other inspections not relating as directly to manufacturing facilities and production processes.

D. *Commercial Transactions Outside the State*

Our conclusion that the Act is an impermissible "attempt to regulate activities in other states," see *Midwest Title*, 593 F.3d at 665, is supported by further analysis of commercial transactions taking place wholly outside the governing state. The plaintiffs argue that not only are the regulations direct extraterritorial regulations, as explained above, but also that three categories of commercial sales are impermissibly regulated by the Act because they take place wholly outside the state. See *Healy*, 491 U.S. at 336. The parties have agreed that the Act regulates: (1) sales by an out-of-state manufacturer to an out-of-state distributor if the distributor resells the e-liquids to Indiana retailers; (2) sales by an out-of-state manufacturer to an out-of-state online retailer if the online retailer sells the e-liquid to Indiana consumers; and (3) direct online sales by out-of-state manufacturers to Indiana consumers. Although not explicitly regulated, these transactions fall within the scope of the statute because in each case, the Indiana Alcohol and Tobacco Commission could enforce the provisions against a manufacturer whose product, either intentionally or unintentionally, reaches Indiana vape shops for sale. To avoid violating the Act, an out-of-state manufacturer who wishes to avoid regulation by Indiana and has not obtained an Indiana permit would need to include in its contracts with distributors and online retailers an effective, perhaps even foolproof, guarantee ensuring the e-liquid would not be resold to anyone in Indiana.

The first two categories of transactions are like the loan transactions in *Midwest Title* or milk sales in *Dean Foods*. They occur entirely outside the regulating state. Indiana's governance of these transactions is impermissible extraterritorial regulation. See *Midwest Title*, 593 F.3d 660; *Dean Foods*, 187 F.3d 609. Whether the third category—the producer-as-online-retailer selling directly to an Indiana consumer—occurs wholly outside the state may be a more complex question. See generally Ind. Code § 26-1-2-401(2) (under UCC sales provision, title to goods passes at time and place of shipment unless otherwise specified); *Quill Corp. v. North Dakota*, 504 U.S. 298, 311–13 (1992) (dormant Commerce Clause requires out-of-state seller to have substantial nexus with taxing/purchaser state in order for taxing state to collect taxes from out-of-state seller). In any event, the other extraterritorial aspects of the challenged provisions are sufficient to hold that they may not be applied to out-of-state manufacturers, so the answer to the online sales question would not change our ultimate conclusion.

The regulations of clean rooms and security systems for e-liquid manufacturers are akin to an attempt by Ohio to regulate not just milk labeling but also the heating, cooling, ventilation, plumbing, and locks for out-of-state barns where the cows are milked. The Indiana Act directly regulates the production facilities and processes of out-of-state manufacturers and thus wholly out-of-state commercial transactions. It poses the clear risk of multiple and inconsistent regulations that would unduly burden interstate commerce. As applied to out-of-state manufacturers, the challenged extraterritorial laws violate the Commerce Clause.

* * *

For these reasons, we REVERSE the district court's grant of summary judgment to the defendant state officials and REMAND to the district court to declare the challenged provisions unenforceable against out-of-state manufacturers and to enjoin their enforcement against the plaintiffs. These instructions apply to the following provisions: Indiana Code §§ 7.1-7-4-1(d)(1)–(3), (6), (8)–(10); 7.1-7-4-6(b)(8), (10)–(16), and (19).