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File Name: 14a0018p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

BETH ANN MILLER, Personal Representative of the Estate of Beth Ann Kelly,
Plaintiff-Appellant,

v.

MYLAN INC., MYLAN PHARMACEUTICALS INC., and MYLAN TECHNOLOGIES INC.,
Defendants-Appellees.

No. 12-2502

Appeal from the United States District Court
for the Eastern District of Michigan at Detroit.
No. 2:12-cv-11684—Paul D. Borman, District Judge.

Argued: October 8, 2013

Decided and Filed: January 21, 2014

Before: MERRITT, GIBBONS, and McKEAGUE, Circuit Judges.

COUNSEL

ARGUED: S. Jay Ahmad, ISHBIA & GAGLEARD, P.C., Birmingham, Michigan, for Appellant. Clem C. Trischler, PIETRAGALLO GORDON ALFANO, Pittsburgh, Pennsylvania, for Appellees. **ON BRIEF:** S. Jay Ahmad, ISHBIA & GAGLEARD, P.C., Birmingham, Michigan, for Appellant. Clem C. Trischler, PIETRAGALLO GORDON ALFANO, Pittsburgh, Pennsylvania, for Appellees.

MERRITT, J., delivered the opinion of the court in which GIBBONS, J., joined. GIBBONS, J. (pp. 8–10), delivered a separate concurring opinion. McKEAGUE, J. (pp. 11–19), delivered a dissenting opinion.

OPINION

MERRITT, Circuit Judge. Beth Ann Kelly died after receiving a fatal dose of fentanyl. Her estate subsequently brought this lawsuit alleging that the defendant's fentanyl patch caused Kelly's death. The defendant pleaded immunity under a Michigan statute that immunizes manufacturers of "drugs" from suit. The district court determined that the fentanyl patch was a "drug" and consequently granted the defendant's motion to dismiss the complaint. We conclude that the district court's analysis was incomplete and that a factual question remains as to whether the fentanyl patch was a "combination product," the manufacturers of which do not enjoy immunity under Michigan law. We therefore reverse the judgment of the district court and remand for further proceedings.

I. Background

Defendant Mylan is the manufacturer of a fentanyl patch that is the generic version of Duragesic. The product is intended to treat pain. It essentially has two parts: fentanyl (its active ingredient) and a "transdermal system" (i.e., the patch that delivers the drug). The patch is affixed to the patient's skin and is designed to deliver a regulated dose of fentanyl to the patient for a prolonged period. According to the complaint, the defendant's patch caused Kelly's death by delivering an excessive amount of fentanyl.

Kelly's estate brought suit in Michigan state court, alleging counts based on common law and statutory torts, i.e., strict products liability, negligence, negligent misrepresentation, fraud, warranty, and the Michigan Consumer Protection Act. The defendant removed the case to federal court and subsequently moved to dismiss the complaint for failure to state a claim upon which relief can be granted. As is relevant here, the defendant based its motion on Mich. Comp. Laws § 600.2946(5), which provides that manufacturers of "drugs" are immune from suit. The district court

concluded that the fentanyl patch is a "drug" and dismissed the complaint in its entirety. The correctness of this conclusion is the sole issue on appeal.[1]

II. Analysis

Mich. Comp. Laws § 600.2946(5) grants immunity from suit to drug manufacturers. In pertinent part, the statute reads:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

As the statute plainly states, a manufacturer is immune only if the product at issue is a "drug." Michigan defines "drug" as the term is defined in federal law: "'Drug' means that term as defined in section 201 of the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 321." Mich. Comp. Laws § 600.2945(b). In turn, the federal Act defines "drug" to mean:

> (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

21 U.S.C. § 321(g)(1). Michigan's definition of "drug" also provides that a "drug" is not a "medical appliance or device," though the statute neither defines "medical

[1]Before the district court, the plaintiff consented to dismissal of her claim under the Michigan Consumer Protection Act and her products-liability claim insofar as it was premised on a failure to warn. These particular claims are not before us.

appliance or device" nor refers to the federal definition of "device."[2] Mich. Comp. Laws § 600.2945(b).

Before the district court, the plaintiff argued that the patch is not a drug even if fentanyl, the product's active ingredient, is. The district court disagreed, holding that "there is no factual or legal basis to disassociate the pharmacologically active and inactive components of the [fentanyl patch]," and that the fentanyl patch, "including all its system components, is an FDA-approved drug." The court determined that the patch was akin to a time-release capsule in a pill and that it qualified as an "article intended for use as a component of any article specified in clause (A), (B), or (C)."

The district court's conclusion is problematic for two reasons. First, it is unclear that the patch is an "article intended for use as a component" of fentanyl, as that phrase is most naturally understood. The phrase applies to certain inactive ingredients such as "coatings, binders, and capsules." *See United States v. Generix Drug Corp.*, 460 U.S. 453, 454 (1983). We are not entirely convinced that it applies to a product, like the patch, that appears to have a mechanical (rather than chemical) effect on the human body.

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[2]Federal law defines "device" as follows:

> The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
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> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> (3) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h).

Second, and more importantly, the district court failed to take full account of the statutory scheme governing federal drug regulation. *See K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988) ("In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole."). The court assumed a binary scheme whereby a particular item is defined as either a "drug" or "device" and is regulated accordingly. That is how things used to work, but no longer. In 1990, Congress amended the federal Act to add a third category of products known as "combination products." Pub. L. No. 101-629, § 16, 104 Stat. 4511, 4526 (1990) (codified as amended at 21 U.S.C. § 353(g)). The apparent purpose of this law was to determine whether ambiguous products would be regulated as drugs or as devices. (The approval process is different for each.) The law gives the Secretary authority to determine a combination product's "primary mode of action" and to regulate the product accordingly. Simultaneously, Congress deleted language in the definition of "drug" stating that drugs do not "include devices or their components, parts, or accessories." The deletion reflected the replacement of the binary scheme with a tripartite scheme.

The effect of the 1990 amendment was to create a distinction between how a product is *defined* and how that product will be *regulated*. In many cases, it will be obvious that a product should be defined as a statutory "drug" or a statutory "device" and will be regulated as such. In other cases, a product is neither a statutory "drug" nor "device" but rather is a "combination product." Whether a combination product is regulated as a drug or a device is left to the Secretary's discretion.

The defendant argues that it is irrelevant whether the fentanyl patch is labeled a "combination product" or a "drug" because the FDA actually regulated the patch as a drug. This argument ignores the plain language of the Michigan immunity statute. A manufacturer is only immune if the suit regards a "product that is a drug" (i.e., if it is *defined* as a drug) *and* "if the drug was approved for safety and efficacy by the United States food and drug administration" (i.e., if it is *regulated* as a drug). Mich. Comp. Laws § 600.2946(5). In turn, a product is a "product that is a drug" only if it falls within

the federal definition of "drug." Mich. Comp. Laws § 600.2945(b). It follows that if a product is better defined as a "combination product" than a "drug" under federal law, then its manufacturer is not immune from suit in Michigan.

At best, Michigan law is ambiguous as to whether the manufacturer of a combination product should be immune from suit. Accepted canons of statutory construction require this ambiguity to work against immunity for manufacturers of combination products. "It is axiomatic that statutes in derogation of the common law should be narrowly construed." *Badaracco v. Comm'r*, 464 U.S. 386, 403 n.3 (1984) (Stevens, J., dissenting). Put in a slightly different form, "statutes will not be interpreted as changing the common law unless they effect the change with clarity." Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 318 (2012). There was no immunity such as this at common law (and indeed, Michigan appears to be the only state that provides immunity in this fashion). In light of the Michigan legislature's failure to clearly immunize manufacturers of "combination products," the statute should not be construed to exempt those manufacturers from suit.

The remaining question is whether the fentanyl patch is indeed a "combination product" rather than a "drug." The federal Act does not explicitly define "combination product" except to say that such products "constitute a combination of a drug, device, or biological product." 21 U.S.C. § 353(g)(1). FDA regulations more thoroughly define "combination products" to include "product[s] comprised of two or more regulated components, i.e., drug/device, . . . that are physically, chemically, or otherwise combined or mixed and produced as a single entity." 21 C.F.R. § 3.2(e)(1).

Whether the fentanyl patch meets this definition is a question of fact that we are unprepared to answer in the first instance. Therefore, we find that a remand is appropriate. In light of the now tripartite division of products into drugs, devices, and combination products, the district court shall determine whether the fentanyl patch should be designated as only a "drug" for purposes of the Michigan statute.

Accordingly, the judgment of the district court is reversed and the case remanded for further proceedings consistent with this opinion.

CONCURRENCE

GIBBONS, Circuit Judge, concurring. I agree that we must reverse the district court's dismissal of the complaint and remand for further proceedings. And I agree that there may well be an issue on remand about whether the patch was a "combination product." My additional reasons for reversal, however, are broader than a focus on that single issue and are more procedurally based.

Miller carefully crafted her complaint to make clear that it is the manner in which the patch delivers fentanyl that she alleges was defective and unreasonably dangerous in its design, manufacture, and marketing. Similar, it is the manner in which the patch delivers fentanyl that is the basis for the negligence and other claims. The district court did not focus on the complaint as pled, however, but instead focused on documents submitted by Mylan in support of its motion to dismiss. The district court justified its consideration of the documents by saying that *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007), authorizes the court, in ruling on a motion to dismiss, to consider letters from a federal agency and matters of public record whose authenticity cannot be questioned, when those documents are incorporated by reference into or are central to the claims set forth in plaintiff's complaint. The court secondarily relied on our opinion in *Greenberg v. Life Insurance Co. of Virginia*, 177 F.3d 507, 514 (6th Cir. 1999), which found that documents attached to a motion to dismiss that are referred to in the complaint and central to the claim are deemed to form part of the pleadings. The district court apparently determined that the documents were referenced in the complaint and central to the claim because the complaint "specifically refers to the warnings and labels that accompanied MFTS" and because neither party questioned their authenticity.

No documents were attached to plaintiff's complaint, and it did not mention any specific document or its contents. The documents submitted by Mylan included a letter from the Director of the Office of Generic Drugs in the Food and Drug Administration

with the date of January 28, 2005, stamped on it, that approves the patch as "safe and effective for use as recommended in the submitted labeling;" a number of medication guides dealing with, among other things, appropriate use of MFTS and Duragesic; and some labeling materials. Mylan made no effort to authenticate the documents.

The documents considered by the district court appear quite different from the sorts of documents approved in *Tellabs* and *Greenberg* for use in connection with a motion to dismiss. The plaintiff does generally refer to labeling in her complaint. But no specific reference is made to the labeling of the patch used by plaintiff's decedent Kelly, and there is no indication that the labeling submitted by Mylan was labeling provided to Kelly or submitted to the FDA. Nor is there any indication that the medication guides were submitted to the FDA or that they would have been provided to the ultimate user of the product. The relevance, if any, of these documents to the complaint is unknown at this time. The letter from the Office of Generic Drugs does provide some support for Mylan's arguments that the FDA considered the entire patch to be a drug, as it refers to Mylan's "abbreviated new drug application" and refers to the patch as a "drug." But it is not clear that the FDA was doing anything other than using a natural way of referring to the product since it was in fact approving a drug application. Clearly, this document is in no way referenced in the complaint, and it is not central to *plaintiff's* claim. If anything, it seems central to the defense. It is precisely the sort of document on which defendant could properly rely in a motion for summary judgment, along with appropriate authentication supporting its admission. That motion would of course be made after plaintiff had an opportunity for discovery about all the exchanges between Mylan and the FDA with regard to the patch. Moreover, there is some question whether the letter should be considered at all in connection with a motion to dismiss, regardless of whether it is central to the plaintiff's claim. *See Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1197 (3d Cir. 1993) (discussing whether written correspondence subject to FOIA requests are public records for purposes of a motion to dismiss and holding that they are not).

Rather than taking the complaint as it was, the district court and, in this court, the dissent immersed themselves in drawing conclusions from the documents and the relevant statutes. At a later point in this litigation, that might be appropriate. But from my perspective it is inappropriate to use the documents submitted by Mylan as if they were a part of plaintiff's pleadings. Submission of the additional materials should have likely triggered conversion of the motion to a motion for summary judgment, which would have required Mylan to provide some evidentiary basis for their admission and would have required the district court to permit presentation of all evidence pertinent to the motion.

One may fairly question why this court should embark on a discussion of the procedural error when plaintiff did not brief it before the district court or this court. And certainly, we should generally avoid issues not raised by the parties. *See generally Barney v. Holzer Clinic, Ltd.*, 110 F.3d 1207, 1213 (6th Cir. 1997) (citing *Hines v. United States*, 971 F.2d 506, 508–09 (10th Cir. 1992)). But this case presents one of those exceptions—it implicates an important nonjurisdictional concern that transcends the interests of the parties. *See Hines*, 971 F.2d at 508. Maintaining the integrity of the procedures contemplated by the Federal Rules of Civil Procedure is an important goal, one which is best advanced here by pointing out the irregularity.

DISSENT

McKEAGUE, Circuit Judge, dissenting. The Majority finds that there remains a factual determination as to whether the fentanyl patch is a "combination product" under the Food, Drug, and Cosmetic Act. I disagree with the Majority's interpretation of the Michigan immunity statute and would instead hold that Mylan's Fentanyl Transdermal System is a "drug" under 21 U.S.C. § 321(g)(1) and therefore Mylan is immune from suit under Michigan law. I respectfully dissent.

Determining whether the Mylan Fentanyl Transdermal System should be considered a "drug," a "device," or "combination product" requires first looking at the definition of "combination products."[1] As the Majority correctly notes, one must look to the FDA regulations, 21 C.F.R. § 3.2(e)(1),[2] to find a definition. Under the regulations, a combination product is simply "two or more regulated components," comprising either a "drug" and "device" or a "drug" and "biologic," etc. *Id.* There is

[1] As a preliminary matter, the parties never mention the term "combination product" in their initial briefs before this Court. Furthermore, the parties did not argue that Mylan's Fentanyl Transdermal System was a "combination product" before the district court. Plaintiff does not allege that the product was a "combination product" in the Complaint. R. 1-7, Complaint, *et seq*. The term "combination product" was *sua sponte* raised by this Court, when it asked the parties to address whether Mylan's Fentanyl Transdermal System is a "combination product" and whether the manufacturer of a "combination product" is immune from suit under Michigan law. The Plaintiff had an opportunity to amend her complaint when Defendants filed their motion to dismiss based on Michigan's immunity statute, to allege that Mylan's Fentanyl Transdermal System was a "combination product" and therefore was not immune from suit; Plaintiff took no such course of action. Accordingly, I would not even address the question of whether this product is a "combination product" because Plaintiff has waived raising this argument in the district court. *See Scottsdale Ins. Co. v. Flowers*, 513 F.3d 546, 551 (6th Cir. 2008). And, while this Court can consider novel questions for the first instance on appeal in exceptional circumstances where a miscarriage of justice would otherwise occur, the "novel issue," of whether the fentanyl patch is a "combination product," was not even raised by the parties. *Friendly Farms v. Reliance Ins. Co.*, 79 F.3d 541, 545 (6th Cr. 1996) (providing the standard for when the court of appeals may entertain issues not raised in the district court). Accordingly, I do not think this Court should even be addressing the legal issue of whether this product is a "combination product," as the issue was waived by the Plaintiff in the district court and this case does not present exceptional circumstances where a miscarriage of justice would otherwise occur.

[2] 21 C.F.R. § 3.2(e)(1) provides the definition of "combination product:"

> (1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined and produced as a single entity; . . . .

no claim that the transdermal patch includes a "biologic." Following our invitation, Plaintiff now argues that the transdermal patch comprises a drug (fentanyl) and a device (the patch), and that the device malfunctioned. Pl.'s Br. at 12–13. The Michigan immunity statute does not define "device" but simply provides that "drug does not include a medical appliance or device." Mich. Comp. Laws § 600.2945(b). As the Michigan immunity statute relies on the federal Act for its definition of "drug" and the regulation defining "combination product" relies on the federal Act for defining "drug"[3] and "device"[4] I turn to those definitions to see if Mylan's Fentanyl Transdermal System is a "combination product."

Mylan's Fentanyl Transdermal System's "components" are described in the official labeling of the product, which is approved by the FDA. *See* R. 12, Dist. Court Op. at 4, PageID # 283; R. 5-3, Mylan's Labeling at 2, Page ID # 125. The components are described as follows:

> **System Components and Structure**. The amount of fentanyl released from each system per hour is proportional to the surface area (25mcg/hr per 6.25 cm). The composition per unit area of all system sizes is identical.

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[3] 21 U.S.C. § 321(g)(1) provides the definition of "drug," as:

> (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

[4] 21 U.S.C. § 321(h) provides the definition of "device," as:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
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> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

> Fentanyl transdermal system is a translucent rectangular patch with rounded corners comprising a protective liner and two functional layers. Proceeding form the outer surface toward the surface adhering to the skin, these layers are: 1) a backing layer of polyester film; and 2) fentanyl containing silicone adhesive layer. Before use, a protective liner that is attached to and covering the adhesive layer is removed and discarded.
>
> Fentanyl transdermal systems are packaged with additional pieces of protective film above the system within each pouch. These are also discarded at the time of use.
>
> The active component of the system is fentanyl. The remaining components are pharmacologically inactive.

Id.

After considering the definition of "device" and "drug," I conclude that the patch does not include a "device." While the fentanyl patch could possibly be considered an "instrument" or "apparatus," because the patch achieves its "primary intended purposes" of relieving pain through some "chemical action within or on the body" and fentanyl must be metabolized in order for it to be effective, the patch does not fit the definition of "device." 21 U.S.C. § 321(h)(3). A "device" may not achieve its "primary intended purpose" through "chemical action" or metabolization. *Id.* As indicated in the labeling of the Mylan Fentanyl Transdermal System, the fentanyl patch achieves its "primary intended purpose" through both means, and therefore does not meet the definition of "device." R. 5-3, Mylan's Labeling at 2, Page ID # 125. Furthermore it is noteworthy that the labeling for the Mylan Fentanyl Transdermal System, approved by the FDA, includes absolutely no suggestion that the system includes a device or is a combination product.[5] There is nothing to suggest that the FDA, when approving the label thought

[5]The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label. 21 U.S.C. § 355. In general, a manufacturer may only change a drug label already approved by the FDA by filing a "supplemental application" with the FDA. *Wyeth v. Levine*, 555 U.S. 555, 568 (2009); *Strayhorn v. Wyeth Pharms., Inc.*, 887 F. Supp. 2d 799, 809 (W.D. Tenn. 2012) (noting that in order for a drug manufacturer to change the label, the manufacturer must go through a formal process through the FDA). Regulations provide that the FDA must approve the labeling in order for a new drug to be "approved." 21 C.F.R. § 314.105 (2008). Therefore, the language included in the label is approved by the FDA. This Court should not begin second-guessing labels approved by the FDA, which has primary jurisdiction over labeling such products.

any part of Mylan's Fentanyl Transdermal System was a device. Furthermore, Mylan's Fentanyl Transdermal System does accurately fit the FDA's definition of "drug." As defendants articulate in their brief, the FDA's definition of "drug" includes "articles intended for use as a component of any article," where an "article" may be any of the three earlier described categories for "drugs." The Mylan Fentanyl Transdermal System could be considered either an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man" or an article "intended to affect the structure or any function of the body of man," as the fentanyl patch is designed to alleviate long-term pain. Furthermore, the FDA describes the adhesive matrix and the pharmacologically inactive ingredients as "components" of the product in the labeling. R. 5-3, Mylan's Labeling at 2, Page ID # 125. Accordingly, because the Mylan Fentanyl Transdermal System is a "drug," and the system does not include a "device," it is not a "combination product" under the FDA's definition.

My interpretation of the term "combination product" and conclusion that the Mylan Fentanyl Transdermal System is a "drug" and not a combination product is further supported by the FDA's statutory scheme and limited caselaw.

The statutory scheme of "combination products" and evidence before the district court, in particular, support my conclusion that the Mylan Fentanyl Transdermal System consists of only a "drug." The FDA promulgated the final rule defining "combination products" on November 21, 1991. "Assignment of Agency Component for Review of Premarket Applications," 56 FR 58754-01, Nov. 21, 1991; *see* 21 C.F.R. § 3.2(e). The rule sets forth the process by which the FDA designates the agency that has primary jurisdiction over a combination product. 21 C.F.R. § 3.7.[6] In order for "combination

[6]The regulation provides, in part, that an applicant requesting that his product be designated, as either a "drug," "device," or "combination product":

> (a) Who should file: the sponsor of:
> (1) Any combination product the sponsor believes is not covered by an intercenter agreement; or
> (2) Any product where the agency component with primary jurisdiction is unclear or in dispute.
> (b) When to file: a sponsor should file a request for designation before filing any application for premarket review, whether an application for marketing approval or a

products" to obtain FDA approval two steps must be met. First, the applicant files a "request for designation" with the FDA. *Id.* Second, the FDA issues a "letter of designation," informing the applicant which FDA division has primary jurisdiction over the product. *See* 21 C.F.R. § 3.2(I) ("Letter of designation means the written notice issued by the product jurisdiction officer specifying the agency component with primary jurisdiction for a combination product."). The "letter of designation" constitutes an "agency determination," and the division which has primary jurisdiction is only subject to change by the product jurisdiction officer, as specified by the procedures in the regulations. *See* 21 C.F.R. § 3.9.

In designating the division that will have primary jurisdiction over the product, the FDA determines the "primary mode of action" of the product. 21 C.F.R. § 3.4. The "primary mode of action" determination involves the technical application of the definition provided in 21 C.F.R. § 3.2(k) to ascertain the means by which a product achieves an intended therapeutic effect. For example, where the primary mode of action is determined to be through a "drug," then the division of the FDA that is in charge of regulating drugs has primary jurisdiction over the product.

In this case, after reviewing the record before the district court, it appears that the defendants did not file a "request for designation," nor did they receive a "letter of designation" from the FDA. This is important, as the FDA is the agency primarily responsible for categorizing "combination products." 21 U.S.C. § 353(g); *see also Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973) (holding that the FDA has primary jurisdiction to determine that a product is a 'new drug,' subject to review in the court of appeals).

Moreover, the one letter from the FDA in the record, a letter from the FDA approving the fentanyl patch, only uses the word "drug." *See* R. 5-2, Approval Letter

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> required investigational notice. Sponsors are encouraged to file a request for designation as soon as there is sufficient information for the agency to make a determination.

21 C.F.R. § 3.7.

to Mylan at 2-4, Page ID # 121–23. There is no mention of the terms "combination product" or "device." *Id.* The division responsible for sending the letter of approval was the "Office of Generic *Drugs*, Center for *Drug* Evaluation and Research." *Id.* at 4, PageID # 123. Accordingly, even if the defendants had requested a "letter of designation" to determine which unit of the FDA had primary jurisdiction, the fact that the Office of Generic *Drugs* approved Mylan's Fentanyl Transdermal System suggests that the FDA determined that the primary mode of action of fentanyl was that of a "drug." The FDA was acutely aware of the various designations under which the fentanyl patch could be classified.[7] There was no indication before the district court, or before this Court, that fentanyl was designated as any product other than a "drug."[8]

The Majority's approach leads to courts second-guessing the FDA's designation of a given product. As in this case, the only evidence in the record shows that the FDA designated the fentanyl patch as a "drug." In my view, the inquiry stops there. While the letter may is not a "formal" agency action, intended to have the force of law, the FDA's designation of a product as a "drug," "device," or "combination product," is entitled to deference as it comes from the agency charged with making such nuanced

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[7] If the Office of Combination Products determined that the product was a "combination product," the "letter of designation" could specify any of the following divisions having primary jurisdiction over the product : "Center for Drug Evaluation and Research"; "Center for Devices and Radiological Health"; or the "Center for Biologics Evaluation and Research." The "Office of Generic Drugs" is a subpart of the "Center for Drug Evaluation and Research." Combination Products, "Capsular Descriptions of Jurisdictional Determinations," http://www.fda.gov/CombinationProducts/JurisdictionalInformation/RFDJurisdictionalDecisions/CapsularDescriptions"One-Liners"/default htm (last visited Jan. 14, 2014). It is not clear whether any of the divisions exercising jurisdiction over the "combination product" would refer to the product as a "combination product" or would rather simply refer to the product by its primary mode of action. Accordingly, the only clear indication of whether the FDA considers a product to be a "combination product" is its designation in the "letter of designation."

[8] It is also worth noting that the district court recognized the significance of the FDA's Office of Generic Drugs approving Mylan's Fentanyl Transdermal System:

> [I]t appears beyond dispute that the FDA deemed and approved the MFTS (the system–not some discrete part of the system) as a drug. As noted above, on January 29, 2005, the FDA issued its approval of Mylan's Abbreviated New Drug Application for "Fentanyl Transdermal Systems," concluding that "the drug is safe and effective for use as recommended in the submitted labeling." . . . There is no question that in considering Mylan's ANDA [Abbreviated New Drug Application], the FDA deemed the MFTS, the patch, to be a drug; not a device and not something less than its whole.

See R. 12, District Court Op. at 11, PageID # 290.

designations. *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 643 (6th Cir. 2004). The Majority's approach appears to give little or no deference to the FDA's designation, instead opting for courts to make an independent evaluation of whether a product is a "drug," "device," or "combination product." As the FDA is the agency with the authority to make such designations and has far greater expertise in this area than courts, I would continue to give deference to the FDA's determinations and not grant courts the purview to begin making their own designations, particularly where the complaint does not even allege that the product is anything other than a drug.

The Majority's biggest criticism of the district court's determination that the fentanyl patch is a "drug," for purposes of the Michigan immunity statute, is that it failed to take "full account of the statutory scheme governing federal drug regulation." Maj. Op. at 5. The Majority argues that the district court did not consider the 1990 amendment to the federal act adding combination products as a third category of products to the FDA's regulatory scheme. Because Michigan's immunity statute was passed in 1995 and the changes to the FDA's statutory scheme occurred prior to the Michigan legislature's enactment of the Michigan immunity statute, the Majority finds the omission of the term "combination product" in Michigan's immunity statute to be significant. As courts often employ the canon that inclusion of one definition implies the exclusion of the other, *Nationwide Mut. Ins. Co. v. Cisneros*, 52 F.3d 1351, 1357 (6th Cir. 1995), the Majority seems to say that this Court should presume that the Michigan legislature knew that there was a distinction between "drugs" and "combination products" and therefore, chose to not provide immunity for "combination products." Because I conclude that Mylan's Fentanyl Transdermal System is not a "combination product," I would not reach the question of whether the district court erred in not taking full account of the "statutory scheme" governing federal drug regulation.

The Majority also takes issue with the district court's refusal to distinguish the pharmacologically active and inactive components of the fentanyl patch in considering whether the fentanyl patch is a "drug" or includes a "device." Maj. Op. at 3–4. The Majority states that it is not convinced that the phrase "article intended for use as a

component" applies to a product that "appears to have a mechanical (rather than chemical) effect on the human body," like the patch. Maj. Op. at 4. First, there is no support for that conclusion whatsoever in the record. Morever, the limited caselaw addressing products with features similar to the fentanyl patch have not drawn such distinctions. In *Lake-Allen v. Johnson & Johnson, L.P.*, No. 08-cv-930, 2009 WL 2252198 (D. Utah Jul. 27, 2009), a Utah district court specifically addressed the fentanyl patch. The case involved a products liability action against the manufacturer of Duragesic,[9] "an FDA-approved prescription transdermal pain medication containing fentanyl." *Id.* at *1. Plaintiff claimed that the decedent's death was "due to a deadly dose of fentanyl introduced into his body via the reservoir system of a Duragesic patch." *Id.* Defendant moved to dismiss all causes of action that were based on design defect liability, based on Utah's strict liability design defect jurisprudence. Plaintiff argued that the Duragesic patch is more akin to a "drug container and is therefore not exempt from any design defect claims." *Id.* at *2. The district court rejected plaintiff's argument, stating:

> Plaintiffs' argument that the patch is more akin to a container is unpersuasive. The Duragesic patch was approved by the FDA as a drug and to categorize it as a container is akin to categorizing any substance available in a time release capsule as a container. In the case of prescription pharmaceutical patches, it is nonsensical to separate the liability of the overall product and the substance that it releases.

Id. at *3; *see also* R.12, District Court Op. at 14, PageID # 293 (quoting same language); *Bowers v. Johnson & Johnson*, 795 F. Supp.2d 672 (N.D. Ohio 2011).[10]

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[9] Mylan's Fentanyl Transdermal System is the generic version of Duragesic.

[10] In *Bowers v. Johnson & Johnson*, 795 F. Supp.2d 672 (N.D. Ohio 2011), the district court reviewed a motion for summary judgment in litigation involving the Ortho Evra birth control patch. The suit involved a products liability claim. It is unclear from the opinion what specific type of defects the plaintiff was alleging with the patch. The district court held, after considering plaintiff's claims in the context of the Michigan immunity statute "and there being no dispute that Ortho Evra was subject to and successfully completed the FDA approval process," that plaintiff's products liability claims were precluded as a matter of Michigan law. *Id.* at 677. Accordingly, the court in *Bowers* held that the fact that the "drug" was approved by the FDA, immunity attached.

Accordingly, based on the statutory scheme for "combination products" and caselaw addressing fentanyl transdermal systems and similar products, I do not agree with the Majority's conclusion that Mylan's Fentanyl Transdermal System is a "combination product." Instead, I would hold that Mylan's Fentanyl Transdermal System is a "drug" and that immunity attaches in this case, and I would not reach the question of whether immunity attaches to "combination products" under Michigan's immunity statute.

I respectfully dissent.