IN THE SUPREME COURT OF MISSISSIPPI

NO. 2019-IA-00033-SCT

JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER COMPANIES, INC.

v.

LYNN FITCH, ATTORNEY GENERAL OF THE STATE OF MISSISSIPPI EX REL. STATE OF MISSISSIPPI

DATE OF JUDGMENT:	12/18/2018
TRIAL JUDGE:	HON. J. DEWAYNE THOMAS
COURT FROM WHICH APPEALED:	HINDS COUNTY CHANCERY COURT
ATTORNEYS FOR APPELLANTS:	MEADE W. MITCHELL JOHN C. HENEGAN ORLANDO R. RICHMOND MARK A. DREHER CHARLES A. BYRD PETER C. HARVEY ERIN P. LANE
ATTORNEYS FOR APPELLEE:	PATRICK C. MALOUF TA'SHIA S. GORDON TIMOTHY W. PORTER LAUREL LI HARRIS R. ALLEN SMITH, JR. WENDY R. FLEISHMAN PAULINA DO AMARAL GEORGE W. NEVILLE DONALD L. KILGORE JACQUELINE H. RAY
NATURE OF THE CASE:	CIVIL - OTHER
DISPOSITION:	AFFIRMED AND REMANDED - 04/01/2021
MOTION FOR REHEARING FILED:	
MANDATE ISSUED:	

EN BANC.

COLEMAN, JUSTICE, FOR THE COURT:

¶1. The case *sub judice* case comes before the Court on interlocutory appeal. The appeal presents two questions of law concerning the validity of a cause of action brought by the Mississippi Attorney General under the Mississippi Consumer Protection Act, Mississippi Code Section 75-24-5. The first is whether the Act covers the State's claim, and the second is whether that claim is preempted by federal law. The Chancery Court of Hinds County denied the summary judgment motion made by Johnson & Johnson and Johnson & Johnson Consumer, Inc. Johnson & Johnson then filed an interlocutory appeal of the chancellor's decision, which the Court granted.

FACTS AND PROCEDURAL HISTORY

¶2. Johnson & Johnson is a New Jersey corporation and is one of the largest companies in the world. Johnson & Johnson is engaged in the business of, among other things, manufacturing, selling, and marketing consumer products that include talc. One of Johnson & Johnson's most popular products is Johnson's Baby Powder, which it has sold since the 1890s. Up until 2020, one of the primary ingredients of the popular product was talc.

¶3. Talc is a hydrous magnesium silicate, an inorganic mineral that is mined from the earth. Talc has been used in the manufacture of many goods, such as plastic, rubber, ceramics, and cosmetics. Talc is commonly known as talcum powder. For decades, talc has been at the center of controversy. During that time, many studies gave rise to claims of risk of cancer associated with the use of products containing talc.

¶4. In 2014, the State commenced an action against Johnson & Johnson for what it alleged to have been unlawful, unfair, and deceptive business practices related to its cosmetic talcum

powder products. The specific cosmetic products at issue are Johnson & Johnson's Johnson's Baby Powder and Shower to Shower. Specifically, the State alleged that Johnson & Johnson failed to warn of the risk of ovarian cancer in women who used talc. In its complaint, the State relied on "numerous studies over the last several decades" that the State alleged "revealed a significant link between the use of talcum powders with an increased risk of ovarian cancer." The State's complaint sought, among other things, an injunction pursuant to the Consumer Protection Act to require Johnson & Johnson to warn of the hazards associated with talc use. The State further sought a civil penalty of up to $10,000 for each violation of the Act.

¶5. Johnson & Johnson then moved for summary judgment. Johnson & Johnson argued that the chancery court should grant summary judgment because the Act does not apply to the labeling of products regulated by the federal Food and Drug Administration. Additionally, Johnson & Johnson argued that even if the Act applies, summary judgment was still proper because federal law preempts the State's labeling claim. Johnson & Johnson heavily relied on the Administration's consideration of two citizen petitions, one from 1994 and another from 2008. Both petitions requested that the Administration to "require a cancer warning on cosmetic talc products." After careful review, however, the Administration denied both citizen petitions because it "did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer."

¶6. On December 18, 2018, the chancery court denied Johnson & Johnson's motion for

summary judgment. While the chancellor acknowledged Johnson & Johnson's substantive arguments, the chancellor ultimately denied summary judgment because of the existence of factual disputes regarding Johnson & Johnson's knowledge of a link between talc and ovarian cancer and Johnson & Johnson's failure to disclose the risks. Johnson & Johnson now appeals the chancellor's denial of its summary judgment motion.

STANDARD OF REVIEW

¶7. An appellate court in Mississippi applies a *de novo* standard of review when it reviews a trial court's grant or denial of summary judgment. ***WW, Inc. v. Rainbow Casino-Vicksburg P'ship*, *L.P.,*** 68 So. 3d 1290, 1292 (¶ 6) (Miss. 2011) (quoting ***Anderson v. Alps Automotive, Inc.***, 51 So. 3d 929, 931 (¶ 11) (Miss. 2010)). Courts must apply a *de novo* standard when considering "[m]atters of statutory interpretation[.]" ***Chandler v. McKee***, 202 So. 3d 1269, 1271 (¶ 5) (Miss. 2016) (citing ***Wallace v. Town of Raleigh***, 815 So. 2d 1203, 1206 (¶ 7) (Miss. 2016)). Finally, the issue of preemption is a question of law, that is a "legal one for the judge, not a jury," ***Merck Sharp & Dohme Corp. v. Albrecht***, 139 S. Ct. 1668, 1679, 203 L. Ed. 2d 822 (2019), and a court reviews a question of law under a *de novo* standard of review. ***Debrow v. State***, 972 So. 2d 550, 552 (¶ 6) (Miss. 2007) (citing ***Biglane v. Under the Hill Corp.***, 949 So. 2d 9, 14 (¶ 17) (Miss. 2007)).

DISCUSSION

¶8. The State commenced its lawsuit against Johnson & Johnson pursuant to the Mississippi Consumer Protection Act. Miss. Code Ann. § 75-24-5 (Rev. 2016). The Act prohibits acts that constitute "unfair or deceptive trade practices in or affecting commerce[.]"

Miss. Code Ann. § 75-24-5(1) (Rev. 2016). The State argues that by failing to include warning labels on cosmetic talc products, Johnson & Johnson violated the Act by engaging in impermissible "unfair or deceptive trade practices." In response, Johnson & Johnson argues that the State's labeling claim is excluded from the Act and that federal law preempts such a claim. Specifically, Johnson & Johnson argues that since the Act is modeled after the Federal Trade Commission Act, and since the federal Act excludes the regulation of labels, then the Act must also exclude the regulation of labels, and the State's claim is barred. Additionally, Johnson & Johnson contends the federal Food, Drug, and Cosmetic Act (FDCA) preempts the State's labeling claim.

I. The Mississippi Consumer Protection Act governs the State's labeling claim.

¶9. Johnson & Johnson argues that the Act excludes the regulation of labels. Johnson & Johnson first contends that the Mississippi Legislature modeled the Act after the Federal Trade Commission Act. Johnson & Johnson points to Mississippi Code Section 75-24-3(c), which provides that "[i]t is the intent of the Legislature that in construing what constitutes unfair or deceptive trade practices that the courts will be *guided by* the Federal Trade Commission and the federal courts to Section 5(a)(1) of the Federal Trade Commission Act (15 USCS 45(a)(1)) as from time to time amended." Miss. Code Ann. § 75-24-3(c) (Rev. 2016) (emphasis added). Thus, since the words "guided by"are included in the Section 75-24-3(c), Johnson & Johnson argues that "this Court must construe the Act in accordance with its federal 'parent' statute," the Federal Trade Commission Act.

¶10. Next, Johnson & Johnson argues that the Federal Trade Commission Act explicitly

excludes the regulation of labels on cosmetics. Johnson & Johnson contends that the Federal Trade Commission Act defines "[u]nfair or deceptive act or practice" to include "[t]he dissemination or causing to be disseminated of any *false advertisement*[.]" 15 U.S.C. § 52(b) (emphasis added). Johnson & Johnson then provides the Federal Trade Commission Act's definition of false advertisement as "an advertisement, *other than labeling*, which is misleading in a material respect[.]" 15 U.S.C. § 55(a)(1) (emphasis added). By defining unfair or deceptive trade practices to include false advertising and then by defining false advertising to exclude labeling, Johnson & Johnson argues that the definitions exclude labeling from the Federal Trade Commission Act's reach, and since labeling is beyond the Federal Trade Commission Act's reach, Johnson & Johnson argues that it is also beyond the Act's reach.

¶11. As previously noted, Section 75-24-3(c) references 15 U.S.C. § 45(a)(1). The State, however, contends that Johnson & Johnson does not cite 15 U.S.C. § 45(a)(1) to argue the Federal Trade Commission Act excludes labeling from unfair or deceptive trade practices. Instead, the State argues that Johnson & Johnson erroneously cites the Federal Trade Commission Act's separate false advertising prohibition against labeling found in 15 U.S.C. §§ 52(b) and 55(a)(1). The State argues that "[t]he FTC Act's *false advertising* prohibition does not include labeling, but that limit explicitly applies only 'For the purposes of sections 52 to 54,' *not* § 45(a)(1), the section in which the Act instructs courts to be 'guided' by." *See* 15 U.S.C. § 55.

¶12. In construing what constitutes unfair or deceptive trade practices, the Act requires

that courts be "guided by the interpretations given by the Federal Trade Commission and the federal courts[.]" Miss. Code Ann. § 75-24-3(c). Here, the State argues that Johnson & Johnson misconstrues the Act's rule of construction. While the Act provides that courts will be "guided by" the Federal Trade Commission Act, the State contends that "guided by" does not mean that courts are bound by or limited by the federal Act.

¶13. Recently, in ***Watson Laboratories, Inc. v. State***, 241 So. 3d 573 (Miss. 2018), the Court addressed a similar issue involving the interpretation of Section 75-24-3(c). In ***Watson***, the State brought a consumer protection action against prescription drug manufacturers under the Act. ***Id.*** at 576. There, the State alleged that the manufacturers inflated reported prices which, in turn, caused the Mississippi Division of Medicaid to reimburse pharmacies at the inflated prices. ***Id.*** The chancellor agreed with the State in that case, but on appeal, Watson argued that the chancellor applied the incorrect legal test or standard. Relying on the "guided by" language in Section 75-24-3(c), Watson argued that a different test or standard, one that the Federal Trade Commission adopted, must be applied. ***Id.*** at 577, 590 In rejecting Watson's argument, the Court announced that

> Nothing in Section 75-24-3(c), though, delegates the chancellor's determination to the federal courts, nor does the statute bind Mississippi judges to varied, changing decisions at the federal level. The judges, as factfinders in bench trials, and the juries of the State of Mississippi are perfectly capable of determining—while being "guided" by federal authority—what are deceptive practices. That is exactly what the chancellor did here.

Id. at 590.

¶14. Johnson & Johnson argues that the case *sub judice* is unlike ***Watson*** because it involves one federal standard, namely that the Federal Trade Commission Act excludes

cosmetic label regulation, so the Act must also exclude such regulation. Johnson & Johnson distinguishes ***Watson*** because it involved a choice between two different federal standards. Here, however, the State contends that the Court's reference in ***Watson*** to "varied, changing decisions at the federal level" does not isolate ***Watson*** to cases only involving two or more federal standards.

¶15. ***Watson*** merely emphasized the principle that Section 75-24-3(c) does not wholly limit a Mississippi judge's determination to federal law. ***Id.*** If judges in Mississippi were bound by the federal Act, then Mississippi would be left without a legal mechanism to address labeling issues. Unlike Mississippi, the federal system assigns the regulation of labeling issues to the Food and Drug Administration. There is even an agreement between the Federal Trade Commission and the Administration that delegates the regulation of labels to the Administration. No such dual system exists in Mississippi. Instead, the Act is the legal mechanism available to govern the regulation of labels.[1]

¶16. Like the chancellor in ***Watson***, the chancellor here is not bound by a federal court or Federal Trade Commission interpretation of the Federal Trade Commission Act. Instead, a chancellor is to be guided by such interpretations, just as Section 75-24-3(c) commands. Accordingly, the Act does not preclude the State's claim.

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[1]In 1971, the Federal Trade Commission and the Food and Drug Administration entered into a Memorandum of Understanding. Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18,539 (Sept. 16, 1971). The agreement between the two agencies provided that, with the exception of prescription drugs, the Commission regulates "the truth or falsity of all advertising (*other than labeling*) of foods, drugs, devices, and cosmetics." *Id.* (emphasis added). Then the Food and Drug Administration regulates "all matters regulating the *labeling* of foods, drugs, devices, and cosmetics." *Id.* (emphasis added).

II. Federal law does not preempt the State's claim.

¶17. Additionally, Johnson & Johnson argues that the chancellor should have granted summary judgment because federal law preempts the State's talc labeling claim. Specifically, Johnson & Johnson contends that the State's claim is expressly preempted under the FDCA's express preemption for cosmetic labels. Also, Johnson & Johnson argues that a Food and Drug Administration regulation impliedly preempts the State's claim.

A) An Overview on Preemption

¶18. The Supremacy Clause of Article VI of the United States Constitution provides that "the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Thus, as the Supreme Court of the United States has stated, "since our decision in ***M'Culloch v. Maryland***, 17 U.S. (4 Wheat.) 316, 427, 4 L. Ed. 579 (1819), it has been settled that state law that conflicts with federal law is 'without effect.'" ***Cipollone v. Liggett Grp., Inc.***, 505 U.S. 504, 516 (1992) (quoting ***Maryland v. Louisiana***, 451 U.S. 725, 746 (1981)). "Consideration of issues arising under the Supremacy Clause 'start[s] with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress.'" ***Id.*** (alterations in original) (quoting ***Rice v. Santa Fe Elevator Corp.***, 331 U.S. 218, 230 (1947)). Therefore, "'[t]he purpose of Congress is the ultimate touchstone' of pre-emption analysis." ***Id.*** (quoting ***Malone v. White Motor Corp.***, 435 U.S. 497, 504 (1978)).

¶19. Congress may show "preemptive intent through a statute's express language or through its structure and purpose." ***Altria Group, Inc. v. Good***, 555 U.S. 70, 76 (2008). If Congress gave an express preemption provision, the provision does not automatically end the inquiry because a court must still determine the question of "the substance and scope of Congress' displacement of state law[.]" ***Id.***

B) Federal law does not expressly preempt the State's claim.

¶20. Johnson & Johnson argues that federal law expressly preempts the State's talc labeling claim. Specifically, Johnson & Johnson contends that the FDCA includes a provision that expressly preempts state law regulation of cosmetics labels.

¶21. In 1997, to ensure that federal requirements are not frustrated by state law, Congress added an express preemption provision to the FDCA that specifically covered cosmetics. ***Id.*** (citing Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 752, 111 Stat. 2296, 2376 (1997)). That provision provides:

> Except as provided in subsection (b), (d), or (e), no State or political subdivision of a State may establish or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, *a requirement specifically applicable* to a particular cosmetic or class of cosmetics under this chapter, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

21 U.S.C. § 379s(a) (emphasis added).

¶22. The State sought to require Johnson & Johnson to establish an ovarian cancer warning on Johnson & Johnson's talc cosmetic products. Johnson & Johnson argues that the action is expressly preempted by § 379s(a). While an express preemption provision indeed applies

to cosmetics regulation, as stated previously, in order for the provision to fully apply, the Court must determine whether the State's sought requirement falls within the provision's scope. *See* ***Altria***, 555 U.S. at 76. The express preemption provision preempts state requirements that "establish or continue in effect [a] requirement for labeling or packaging of a cosmetic that is different from or in addition to . . . *a requirement specifically applicable* to a particular cosmetic or class of cosmetics under this chapter[.]" 21 U.S.C. § 379s(a) (emphasis added). However, in the case *sub judice*, there was no requirement by the Food and Drug Administration.

¶23. As previously noted, the FDCA vested the Administration with the authority to require labels for cosmetics. 21 U.S.C. § 371(a). Johnson & Johnson argues that the Food and Drug Administration's decision in two citizen petitions establishes preemption.

¶24. Several Administration regulations within Title 21 of the Code of Federal Regulations govern the Administration's citizen petition process. First, the Food and Drug Administration provides that:

> (a) An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. A petition must be either:
>
> (1) In the form specified in other applicable FDA regulations, e.g., the form for a color additive petition in § 71.1, for a food additive petition in § 171.1, for a new drug application in § 314.50, for a new animal drug application in § 514.1, or
>
> (2) in the form for *a citizen petition in § 10.30*.

21 C.F.R. § 10.25(a)(1)-(2) (West, Westlaw through Mar. 4, 2021) (emphasis added).

¶25. Second, 21 C.F.R. § 10.30 specifically outlines the citizen petition process - a process

that is subject to judicial review. *See* 21 C.F.R. § 10.30(k) (West, Westlaw through Mar. 4, 2021). Finally, "[u]nless otherwise provided, the Commissioner's final decision constitutes *final agency action* (reviewable in the courts under 5 U.S.C. 701 et seq. and, where appropriate, 28 U.S.C. 2201) on a *petition* submitted under § 10.25(a)[.]" 21 C.F.R. § 10.45(d) (West, Westlaw through Mar. 4, 2021) (emphasis added). The regulations establish that a final decision by the Food and Drug Administration on a citizen petition constitutes a final agency action that is subject to judicial review.

¶26. In 2014, in accordance with the above regulations, the Administration responded by letter to the Cancer Prevention Coalition's 1994 and 2008 citizen petitions. Both citizen petitions requested "that the Food and Drug Administration (FDA or the Agency) require a cancer warning on cosmetic talc products" because of the risk of ovarian cancer after applying talc "in the female genital area." In its letter, the Food and Drug Administration denied the citizen petitions' request for ovarian cancer warnings because the "FDA did not find that the data submitted presented conclusive evidence of a casual association between talc use in the perineal area and ovarian cancer." In order to be binding on the public, the Food and Drug Administration must follow the notice and comment rule making process. U.S. Food & Drug Admin., The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961, 1997 WL 79385 (Feb 27, 1997). While the Food and Drug Administration letter is considered a final agency action, it does not follow the notice and comment rule making process. In a similar case, a letter written by the commissioner of the Food and Drug Administration was deemed inaction, and the United

States Court of Appeals for the Third Circuit held, "the FDA has not acted to regulate it in a manner that could preempt [the plaintiff's] claims." ***Fellner v. Tri-Union Seafoods, L.L.C.***, 539 F.3d 237, 253 (3d Cir. 2008). Additionally, the United States Supreme Court has held that courts "have a duty to accept the reading that disfavors pre-emption." ***Bates v. Dow Agrosciences LLC***, 544 U.S. 431, 449 (2005). Through its inaction, the Food and Drug Administration declined to make a requirement regarding cancer warnings for cosmetic products that contain talc.

¶27. "Where a statute is unambiguous, the Court must apply the statute according to its plain meaning, refraining from principles of statutory construction." ***Carver v. Pub. Emps.' Ret. Sys. of Miss.***, 306 So. 3d 694, 698 (¶ 12) (Miss. 2020) (internal quotation marks omitted) (quoting ***OXY USA, Inc. v. Miss. State Tax Comm'n***, 757 So. 2d 271, 274 (¶ 12) (Miss. 2000)). By its plain language, § 379s(a) only applies if the Food and Drug Administration adopts "a requirement specifically applicable" to a given cosmetic. Accordingly, the Food and Drug Administration's decision not to act cannot be deemed to be a requirement for purposes of § 379s(a). In other words, the preemption statute requires the existence in federal law of a positive expression of regulation applicable to a specific product. The Food and Drug Administration's decision not to adopt any such regulation cannot, as it were, fit the bill. Accordingly, the State's claim is not expressly preempted under 21 U.S.C. § 379s(a).

¶28. Johnson & Johnson also argues that the State's claim is barred by principles of implied preemption. Johnson & Johnson argues that obstacle preemption bars the State's claim,

citing ***International Paper Co. v. Ouellette***, 479 U.S. 481, 494 (1987). "[T]he state law . . . is preempted if it interferes with the methods by which the federal statute was designed to reach this goal." ***Id.*** However, the Food and Drug Administration has declined to create a requirement, either positive or negative, regarding the cosmetic or class of cosmetics listed in the State's claim, thus no interference could occur. There is no need to guess what Congress' goal was when § 379s(a) was enacted. The statute clearly prohibits states from having a requirement that is different from or in addition to a requirement that is already in place by the Food and Drug Administration. However, in the case *sub judice*, there is no existing requirement in place. Accordingly, the Food and Drug Administration chose not to exercise its regulatory authority, allowing the states the freedom to regulate cosmetics instead.

CONCLUSION

¶29. The Act does not exclude the State's talc labeling claim. Additionally, because of the lack of any specific requirement by the Food and Drug Administration, the State's claim is not barred by the principles of express or implied preemption. Therefore, the judgment of the Chancery Court of Hinds County is affirmed, and the case is remanded.

¶30. **AFFIRMED AND REMANDED.**

RANDOLPH, C.J., KITCHENS AND KING, P.JJ., MAXWELL, BEAM, CHAMBERLIN, ISHEE AND GRIFFIS, JJ., CONCUR.