

THE SUPREME COURT, STATE OF FLORIDA

MYLAN PHARMACEUTICALS INC.,

Petitioner,

vs.

S. Ct. Case No. SC09-1429

L.T.: DCA Case No.: 1D08-602

L.T.: DOAH Case No.: 07-3704R

ABBOTT LABORATORIES,

Respondent.

PETITIONER'S AMENDED BRIEF ON JURISDICTION

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PETITIONER'S BRIEF ON JURISDICTION

Petitioner, MYLAN PHARMACEUTICALS INC. (“Mylan”), pursuant to Florida Rule of Appellate Procedure 9.120(d), respectfully requests that the Court accept jurisdiction of its appeal of the First District Court of Appeal’s decision below based on conflict with *Eastern Airlines v. Department of Revenue*, 455 So. 2d 311 (Fla. 1984). In support of its request that the Court accept jurisdiction, Mylan states as follows:

STATEMENT OF THE CASE AND FACTS

Since April 2008, pharmacies in Florida have substituted generic forms of the drug, Levothyroxine Sodium, for Respondent’s brand name drug as well as other brand name versions of the product. Since that date, there have been approximately five million prescriptions filled with a generic version of Levothyroxine Sodium in Florida, resulting in enormous savings to patients, their insurers and the State. The present case is a dispute between the maker of a generic form of Levothyroxine Sodium tablets and the maker of the most prescribed brand

name form of the prescription drug, Synthroid®. In conflict with this Court's decision in *Eastern Airlines*, involving analogous circumstances, the First District's decision has resulted in Florida reverting to the pre-April 2008 prohibition on generic substitution of Levothyroxine Sodium, requiring pharmacies to dispense the more costly brand name drug instead of being permitted to substitute a less expensive therapeutically equivalent generic version.

This case reached the First District Court on appeal by Abbott Laboratories (“Abbott”) of a summary final order issued by an administrative law judge (ALJ), invalidating the Board of Pharmacy’s rule 64B16-27.500(6), Florida Administrative Code, and requiring removal of an FDA-approved generic medicine, Levothyroxine Sodium, from the Negative Drug Formulary (“NDF”), which prohibits generic substitution of a limited number of prescription drug products considered therapeutically inequivalent to the brand name version of the drug. Mylan, a generic drug manufacturer, challenged the inclusion of Levothyroxine Sodium on Florida’s NDF, as an invalid exercise of delegated legislative authority pursuant to section 120.52(8), Florida Statutes, in the proceedings below. Specifically, Mylan alleged that the Board of Pharmacy’s rulemaking authority to maintain drugs on the NDF is restricted by section 465.0251, Florida Statutes, which requires removal of a drug from the NDF where every commercially marketed generic equivalent of the drug has been “A” rated by

the FDA as listed in the FDA's Orange Book, meaning the product has been found to be therapeutically equivalent to the brand drug or is a reference listed drug. The ALJ concluded that the criteria for removal had been met for Levothyroxine Sodium and that the NDF, rule 64B16-27.500(6), was invalid to the extent it listed Levothyroxine Sodium because all generic versions of the product are listed as "A" rated in the Orange Book. (R. at 732.)

Both the Boards of Pharmacy and Medicine were parties to the administrative proceedings, however, neither chose to appeal the ALJ's order. Instead, only Abbott, the manufacturer of the brand drug product Synthroid®, appealed. Since April 15, 2008, generic substitution of Levothyroxine Sodium has been allowed in Florida based on the ALJ's ruling. It is estimated that over five million prescriptions have been filled with generic Levothyroxine Sodium in Florida since that time.¹ On June 22, 2009, the First District Court issued an opinion reversing and remanding this proceeding to the Division of Administrative Hearings. As detailed below, however, the First District Court's decision in this case and the Florida Supreme Court's decision in *Eastern Airlines* are in direct conflict.

¹ Estimate from IMS National Prescription Audit and National Sales Perspective data.

SUMMARY OF THE ARGUMENT

In the administrative proceedings below, the ALJ relied on the 1984 *Eastern Airlines* decision in determining that the statutory application of the federal consumer price index (CPI) and the statutory application of the FDA's Orange Book ratings were analogous. The ALJ specifically found that the standards which the FDA used in 2001 to determine whether drug products are therapeutically equivalent are essentially the same standards used in 2007. The First District Court, in ruling that current Orange Book drug listings could not be applied under the statute, distinguished the Orange Book from the CPI by finding that "the scientific methodology applied by the FDA for inclusion in editions of the Orange Book is not static and unchanging." (Op. at 29.) The First District Court, however, ignored that the CPI is not "static" but is as the Court stated in *Eastern Airlines*, computed by the Secretary of Labor calling upon other departments of the federal government for data and results obtained by them as he or she deems appropriate.

The essential point is that the Court recognized in 1984 that application of federal indexes is a proper and effective legislative method by which Florida statutes can incorporate revisions to the indexes which occur using accepted equivalent measurements. The statute in *Eastern Airlines* would have been completely ineffective if there had to be a new statute every time the CPI changed, just as the statute at issue will be ineffective in allowing for the substitution of

generic drugs if there has to be a new statute passed every time the Orange Book is updated. This is especially true where, as the District Court noted, the printed version of the Orange Book is supplemented with monthly updates and the electronic version is updated daily. (Op. at 2, fn.1.) The District Court's error was in not applying this Court's later precedent in *Eastern Airlines*, which is the precedent upon which the ALJ made her ruling. The cases upon which the District Court relied were decided earlier than *Eastern Airlines*, and were decisions which the Court itself distinguished in *Eastern Airlines*. It is therefore essential that the Court accept jurisdiction to resolve this inconsistent application of the law governing the validity of the Florida Legislature incorporating reference to federal indexes in applying Florida law.

ARGUMENT

The Court Should Accept Jurisdiction Based on a Direct Conflict With the Florida Supreme Court's Decision in *Eastern Airlines*

The First District Court's decision in this case clearly conflicts with the Court's decision in *Eastern Airlines* because they both interpret the constitutionality of a state agency applying a changing federal index in making a "ministerial decision," and come to opposite legal conclusions. In this case, the First District Court considered whether the current drug ratings in the FDA's Orange Book should be used in determining when a drug is safe and effective for

substitution and therefore must be removed from Florida's NDF pursuant to section 465.0251, Florida Statutes.²

Respondent, Abbott, argued that the current drug ratings in the Orange Book, could not constitutionally be used to determine whether Levothyroxine Sodium must be removed from the NDF under section 465.0251, Florida Statutes, because the index of drugs that are currently listed as therapeutically equivalent, or "A" rated, is different from the index of drugs with an "A" rating as it existed when section 465.0251 was enacted in 2001. The First District Court's decision accepted the Respondent's contention, concluding that "allowing the Orange Book to determine which drugs should be on the NDF would constitute an unlawful delegation of legislative authority to the FDA." (Op. at 30) (citing *Freimuth v. State*, 272 So. 2d 473 (Fla. 1972).). The Court's decision further stated:

While the FDA standards require therapeutic equivalence for drug products to be "A" rated in the Orange Book, and these standards did not change from 2001 to 2007, this fact is not determinative. The record here is clear that the scientific methodology applied by the FDA in approving drug products for inclusion in editions of the Orange Book is not static and unchanging.

² Section 465.0251, Florida Statutes, provides: "The Board of Pharmacy and the Board of Medicine shall remove any generic named drug product from the formulary established by s. 465.025(6), if every commercially marketed equivalent of that drug product is 'A' rated as therapeutically equivalent to a reference listed drug or is a reference listed drug as referred to in 'Approved Drug Products with Therapeutic Equivalence Evaluations' (Orange Book) published by the United States Food and Drug Administration."

(Op. at 29.) This conclusion, however, is in direct conflict with the ALJ's undisputed finding that the FDA's criteria for determining when a drug is therapeutically equivalent to another drug have remained the same since section 465.0251, was enacted in 2001. The ALJ therefore concluded that removal of Levothyroxine Sodium from the NDF does not require the unconstitutional application of any subsequent laws or rules adopted by the federal government or the FDA. Further, consistent with legislative reports precipitating the enactment of section 465.0251, the ALJ concluded, there was no cognizable harm to patients from removing Levothyroxine Sodium from the NDF because once a drug receives an "A" rating from the FDA it may be substituted with the full expectation that it will perform as well as the reference listed or brand name version of the drug. (R. 717-718 at ¶12-13.)

Despite the fact that the First District Court agreed that FDA standards for determining therapeutic equivalence of drugs did not change since section 465.0251 was enacted in 2001, the First District mistakenly applied a line of cases that preceded the Court's *Eastern Airlines* decision in concluding that use of the current index of drugs listed as therapeutically equivalent by the FDA would be unconstitutional. In reaching an opposite conclusion from the Court's decision in *Eastern Airlines*, the First District Court erroneously applied the Court's decision in *Freimuth v. State*, 272 So. 2d 473 (Fla. 1972). Here, unlike in *Freimuth*, the

Legislature did not incorporate a list of drugs into legislation, rather it incorporated FDA standards. This is a critical difference. The First District Court's decision thus is erroneous and results in rendering section 465.0251, Florida Statutes, meaningless.

The Court's decision in *Eastern Airlines*, involved a very similar set of facts as considered by the First District Court in this case. The Court should take jurisdiction of this case and apply the precedent in *Eastern Airlines* to give effect to the Florida Legislature's directive in section 465.0251 that drugs determined to be therapeutically equivalent by the FDA should not be on Florida's NDF, which prohibits access to generic medications. By giving effect to the statute, the Court will ensure Floridians have access to low cost generic medication that has been deemed to be safe and effective for substitution by the FDA and the Florida Legislature and that brand drug manufacturers will not be permitted to maintain de facto monopolies over sales of drugs in Florida.

The *Eastern Airlines* decision is controlling on the question of whether the Legislature may direct an agency to make certain determinations by reference to a constantly changing federal index. In *Eastern Airlines*, the Court considered whether the Legislature had improperly delegated its "power by relating the price adjustment for future periods to the percentage change in the average monthly gasoline price component of the Consumer Price Index [CPI] issued by the United

States Department of Labor.” 455 So. 2d at 315. The CPI referred to in the statute under scrutiny was authorized under a federal statute, which gave the Secretary of Labor broad authority to collect information from other federal bureaus and departments and to publish this statistical information in a manner deemed wise by the Secretary. *Id.* Thus, although the standard for establishing the CPI remained constant, the methodology for collecting, collating and reporting statistics was left to the wise discretion of the Secretary of Labor. *Id.*

The Court held that the statute’s reference to the current CPI, and the Florida Department of Revenue basing tax adjustments on a changing numerical figure, did not amount to an unconstitutional delegation of legislative power because:

Here the Legislature is merely setting forth the manner in which the department is to determine the appropriate total motor fuel and special fuel retail price. The department is directed with precision how to make such a determination. We think the language of *Welch* and *Freimuth* should be interpreted to apply to statutes which incorporate federal statutes or administrative rules which substantively change the law, and not to a statute which incorporates a federal index to provide aid in making a ministerial determination.

Id. (Emphasis added.)

Just as in *Eastern Airlines*, the Board of Pharmacy is directed with precision how to make a ministerial determination—removal of a drug from the NDF--by reference to a federal index that is subject to change. §465.0251, Fla. Stat.

CONCLUSION

There is a direct conflict between the First District Court's decision that reference to the current index of FDA ratings is unconstitutional in aiding the Board of Pharmacy in making a ministerial determination as to which drugs must be removed from the NDF and the Court's decision in *Eastern* that a statute may constitutionally require an agency to refer to a changing CPI in determining whether tax adjustments are required. Either the Legislature may require an agency to refer to a current federal index in making a ministerial determination or it may not. The First District Court's decision here cannot be reconciled with the Court's decision in *Eastern* on this critical issue of law. The only way the Legislature's intent that generic substitution be required where the FDA has made a determination that drugs are safe and effective for substitution is to require reference to the current index of therapeutically equivalent prescription drugs. To allow the First District Court's decision to stand would create the result that drug safety determinations from 2001, which are no longer valid, govern Florida's generic drug substitution laws and deny patients the right to have access to the fourth most dispensed generic prescription drug product in the U.S. The Court should therefore accept jurisdiction to clarify that reference to current Orange Book ratings is appropriate in making determinations of whether generic prescription drug products are safe for substitution.

Respectfully submitted this ____ day of August, 2009.

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CERTIFICATE OF SERVICE

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CERTIFICATE OF COMPLIANCE

I HEREBY CERTIFY that Appellant's Answer Brief complies with the font requirements of Florida Rule of Appellate Procedure 9.210, in that this Brief uses Times New Roman 14-point font.

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