STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

MYLAN PHARMACEUTICALS INC.,

Petitioner,

v. Case No. 07-003704RX

STATE OF FLORIDA, DEPARTMENT OF HEALTH,
BOARD OF PHARMACY AND BOARD OF MEDICINE,

Respondents,

and

ABBOTT LABORATORIES,

Intervenor.
_____/

MYLAN'S RESPONSE TO ABBOTT'S
MOTION FOR CLARIFICATION AND FOR STAY

Mylan Pharmaceuticals Inc. ("Mylan"), by and through undersigned counsel submits this response in opposition to Abbott Laboratories' ("Abbott") Motion for Clarification and for Stay, and in support of its opposition states as follows:

1. On February 6, 2008, subsequent to the Administrative Law Judge's ("ALJ") issuance of a Summary Final Order in this proceeding invalidating the Board of Pharmacy's existing rule 64B16-27.500(6), Florida Administrative Code, Abbott filed a motion for clarification of the Summary Final Order and motion for stay. Both motions should be denied for lack of legal support as stated below.

Objection to Motion for Clarification

2. Abbott's motion for clarification improperly requests that the ALJ issue a form of declaratory statement that section 120.56(3), Florida Statutes, requires that rule 64B16-27.500(6)

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remain valid until Abbott's appeal of the Summary Final Order is concluded. Abbott's argument is that since it has filed an appeal of the Summary Final Order and section 120.56(3)(b), states that a rule "shall become void when the time for filing an appeal expires," that the time for filing an appeal never actually expires and the rule remains valid throughout the appeal proceedings. If Abbott's argument were accurate, however, Florida Rule of Appellate Procedure 9.310, requiring certain conditions to be met before a stay is granted, would be meaningless.

3. Despite the inherent flaws in Abbott's legal argument, the most compelling reason for denial of the relief Abbott seeks is that it is beyond the jurisdiction of the Division of Administrative Hearings ("Division") to make such a ruling. First, since Abbott has already filed its appeal of the ALJ's Summary Final Order with the First District Court of Appeal, that court has exclusive jurisdiction regarding all matters relating to the subject of the appeal aside from consideration of a motion for stay. *See Stoppa v. Sussco, Inc.*, 943 So. 2d 309 (Fla. 3d DCA 2006); *Bailey v. Bailey*, 392 So. 2d 49, 52 (Fla. 3d DCA 1981) (determining that a lower tribunal does not have jurisdiction to modify a final order once an appeal has been filed).

4. Second, in these proceedings the Division of Administrative Hearings only has jurisdiction to determine the invalidity of an administrative rule, and not the meaning and effect of a statute on a party's rights, as has been requested by Abbott. As specifically set forth in the ALJ's Summary Final Order, the Division has jurisdiction over the parties and the subject matter of this proceeding under sections 120.56(1) and (3), Florida Statutes. (Summary Final Order, ¶ 20.) Section 120.56(1), Florida Statutes, provides: "Any person substantially affected by a rule or proposed rule may seek an administrative determination of the invalidity of the rule on the ground that the rule is an invalid exercise of delegated legislative authority." Section 120.56(3), Florida Statutes, provides in pertinent part: "A substantially affected person may seek an

administrative determination of the invalidity of an existing rule at any time during the existence of the rule." If Abbott wishes to obtain a declaratory statement as to the meaning of section 120.56(3), Florida Statutes, it may only file this request with the appropriate Article V court, and not the Division. *See* §86.011, Fla. Stat. (2007) (vesting jurisdiction to issue declaratory judgments concurrently in the circuit and county courts).

5. There is no provision in either the Administrative Procedure Act or the Uniform Rules of Procedure authorizing a motion for clarification, and thus granting such a motion is not within the jurisdiction of the Division of Administrative Hearings.

6. In addition to the jurisdictional bar against the ALJ granting Abbott's motion for clarification, the motion should be denied because there is no legal authority for such relief.

7. In this case, Abbott, along with the Board of Medicine, opposed Mylan's petition seeking to invalidate rule 64B16-27.500(6), and require removal of the drug Levothyroxine Sodium from the negative drug formulary. Recently, as Abbott is surely aware, both the Board of Medicine and Board of Pharmacy ("Boards") separately met on February 2, 2008 and February 5, 2008, respectively, and determined not to appeal the Summary Final Order holding the challenged rule to be invalid. Thus, Abbott will serve as the sole appellant in appeal proceedings before the First District Court of Appeal. Without a governmental entity filing its own appeal of the final order herein, no automatic stay of the summary final order arises, and thus, absent Abbott otherwise obtaining a stay, rule 64B16-27.500(6) will become void by operation of law on February 28, 2008. *See* §120.56(3)(b), Fla. Stat. (2007).

8. Abbott's argument that the time for filing an appeal never expires when any party to a rule challenge files an appeal is both non-sensical and unsupported by case or statutory law or applicable procedural rules. Abbott's interpretation would mean that even when a

non-governmental party appeals, a stay is put in place, instead of an automatic stay only occurring under rule 9.310(b)(2), Florida Rules of Appellate Procedure, when a governmental entity files an appeal.

9. Section 120.68(2)(a), Florida Statutes, provides that an adversely affected party may appeal a final order within thirty days of the date of the order. Consistent with section 120.68(2)(a), Florida Statutes, the Summary Final Order provided that, "A party who is adversely affected by this Final Order is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. . . The Notice of Appeal must be filed within 30 days of rendition of the order to be reviewed." (Summary Final Order at 26.) Thirty days means thirty days. This time is not somehow tolled by Abbott filing its appeal so that the thirty days never expires. At the end of thirty days, if Abbott has not obtained a stay of the Summary Final Order, rule 64B16-27.500(6) will be rendered void by operation of law under section 120.56(3)(b), Florida Statutes, which provides that when an administrative law judge has declared a rule invalid, "The rule or part thereof declared invalid shall become void when the time for filing an appeal expires. The agency whose rule has been declared invalid in whole or part shall give notice of the decision in the Florida Administrative Weekly in the first available issue after the rule has become void." This is consistent with the provisions of section 120.68(3), Florida Statutes, which provides that the filing of an appeal " . . . does not itself stay enforcement of the agency decision . . ." The First District Court of Appeal's opinion in *Board of Optometry v. Florida Society of Opthalmology*, 538 So. 2d 878 (Fla. 1st DCA 1988), cited by Abbott, does not lend support to Abbott's argument that rule 64B16-27.500(6) should remain in effect for the duration of the appeal process. The *Board of Optometry* case dealt with an appeal by an administrative agency,

not a private party. The appeal in that case by the Board of Optometry triggered the automatic stay provisions of rule 9.310(b)(2), Florida Rules of Appellate Procedure. In its opinion, the court simply held that even though it affirmed the ruling of the ALJ that the contested rule was invalid, such a ruling did not render the rule either void *ab initio* or retroactively invalid. *Id.* at 889. To do so, the court found, would cause "chaotic uncertainty" as to the validity of prior agency actions taken pursuant to the contested rule. *Id.* The finding in *Board of Optometry,* that the rule became void on the date the court's decision became final, was simply a recognition that under rule 9.310(e), Florida Rules of Appellate Procedure, a stay expires upon issuance of a mandate from the court. There is no such issue here. The Boards have determined not to appeal the ALJ's ruling, and as a result, no automatic stay will arise under the appellate rules. There is no suggestion anywhere in the record of this proceeding that actions taken pursuant to rule 64B16-27.500(6) prior to the invalidation of the rule by the ALJ would be somehow rendered invalid. Abbott's hope that it may prevail on appeal and have the rule reinstated is not similar to the situation in *Board of Optometry* and does not merit the same relief. Thus, for the numerous reasons stated above, Abbott's Motion for Clarification should be denied.

Objection to Motion for Stay

10. In its motion, Abbott has also requested a stay of the Summary Final Order issued in this case. The reasons advanced by Abbott, however, fail to satisfy the requirements for obtaining the requested stay.

11. To obtain a stay of a final order, the movant is required to demonstrate: 1) that it has a likelihood of success on the merits of its appeal; and 2) a likelihood of harm to the movant should the stay be denied. *See Mitchell v. State*, 911 So. 2d 1211 (Fla. 2005) (citing *Perez v. Perez*, 769 So. 2d 389, 391 n. 4 (Fla. 3d DCA 1999)).

12. Abbott's motion fails to demonstrate a likelihood of success. In its motion for stay Abbott simply regurgitates the points made in its motion for summary final order, each of which were thoroughly considered and properly rejected by the ALJ.

13. Specifically, Abbott argues that the ALJ's legal conclusion that the most recent version of the Orange Book should be used to determine whether all commercially marketed versions of Levothyroxine Sodium are "A" rated to a reference listed drug is erroneous because it violates the non-delegation doctrine. (Abbott's Motion at 12-13.) This argument was specifically rejected in the Summary Final Order, in which the ALJ stated: "When drug products meet the criteria listed in Section 465.0251, Florida Statutes, the removal becomes a ministerial duty." (Summary Final Order, ¶ 35.) The ALJ further found that the criteria employed by the FDA for classifying drug products as therapeutically equivalent "are essentially the same criteria that existed in 2001" when section 465.0251, Florida Statutes, was enacted. (*Id*., ¶ 14.) Thus, it was appropriate to use current FDA ratings in determining whether Levothyroxine Sodium should be removed from the negative drug formulary.

14. A second argument advanced by Abbott is that the Legislature's use of the word "a" in section 465.0251, is ambiguous. This argument was also rejected by the ALJ. As accurately stated in the Summary Final Order, subsection 425.0251(1), Florida Statues, "is clear and unambiguous." (*Id*., ¶ 26.) The "plain and obvious meaning of subsection 465.0241(1), Florida Statutes, is that a generic named drug product is to be removed from the negative drug formulary if the generic equivalent is 'A' rated as therapeutically equivalent to a reference listed drug as referred to in the Orange Book . . . 'A' is singular, meaning one." (*Id*., ¶ 27.) There is no colorable claim advanced by Abbott to suggest that the ALJ erred in this regard and

absolutely no showing that an appellate court would likely reverse the ALJ and rule in Abbott's favor on this issue.

15. Further, Abbott's motion for stay should be denied because Abbott fails to allege that its own interests will in any way be harmed if a stay of the Summary Final Order is not granted. Throughout these proceedings, Abbott has argued that generic substitution of Levothyroxine Sodium will cause harm to patients sufficient to justify the granting of a stay. Abbott, however, lacks standing to raise issues of harm on behalf of Florida patients sufficient to justify the granting of a stay. Abbott has not been charged by the Florida Legislature with the duty of protecting patients as have the Boards of Medicine and Pharmacy, neither of which will be challenging the ALJ's Summary Final Order. Further, Abbott does not purport in this proceeding to represent any patient groups claiming a negative effect from allowing generic substitution of Levothyroxine Sodium. The ALJ specifically determined in the Summary Final Order that there was no cognizable harm to patients from removing Levothyroxine Sodium from the negative drug formulary 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 drug. (Summary Final Order, ¶ 12-13) Abbott is the manufacturer of the brand-name Levothyroxine Sodium product, Synthroid®, and has indicated they have approximately 61% of the market share for Levothyroxine Sodium in Florida. (Abbott's Response to Mylan's Motion for Summary Final Order at 10.) The only possible harm Abbott could suffer is to its profit margins resulting from competition by generic manufacturers (an argument it does not advance in its motion).

16. The Board of Medicine and Board of Pharmacy are charged with ensuring patient safety relating to generic drug substitution. *See* §465.025(6), Fla. Stat. (2007) (Boards determine

when generic substitution of drugs "would pose a threat to the health and safety of patients receiving prescription medicine."). It is extremely revealing that neither of these Boards independently filed motions for summary final order or actively opposed Mylan's motion for summary final order. Further, neither Board chose to challenge the ALJ's determination that Levothyroxine Sodium should be removed from the negative drug formulary. If either of these Boards were concerned for Florida patients' safety resulting from the generic substitution of Levothyroxine Sodium, they could have temporarily prevented such substitution by the filing of an appeal thus activating the automatic stay arising under rule 9.310(b)(2), Florida Rules of Appellate Procedure.

17. Even if potential harm to patients were relevant in disposing of Abbott's request for a stay (and it is not), further evidence of a lack of patient harm resulting from generic substitution of Levothyroxine Sodium is that this drug may already be substituted in Florida institutional pharmacies. *See* §465.025, Florida Statutes (2007) (Only community pharmacies, such as CVS or Walgreens, are governed by the negative drug formulary.). Thus, there should be no expectation that allowing community pharmacies the same substitution rights will result in patient harm. Additionally, generic forms of Levothyroxine Sodium may already be dispensed where a physician simply writes "Levothyroxine Sodium" on a prescription. *See* 465.025(6)(b), Fla. Stat. (2007) (negative drug formulary only applies where the physician prescribes a "brand name" drug product). No party to these proceedings has raised a concern that this type of substitution has resulted in patient harm. Abbott's claims of potential patient harm, therefore are irrelevant, speculative and insufficient to merit a stay of the Summary Final Order.

18. In conjunction with its argument that patient safety requires that the ALJ enter a stay, Abbott's motion presents a discussion indicating its opinion that Florida pharmacists lack

"professional judgment" and are not competent to properly substitute generic drugs in certain circumstances based solely on a selected discussion from a Board of Pharmacy meeting. (Abbott's Motion at 8-11.) Not only is this characterization insulting to the Board and other Florida pharmacists, it is irrelevant to a determination of whether Levothyroxine Sodium meets the statutory requirements for removal from the negative drug formulary set forth by the Legislature in section 465.0251, Florida Statutes. As correctly determined by the ALJ in the Summary Final Order, ". . . the Legislature has set out specific standards, which when met require the removal of a drug product from the negative drug formulary . . . When drug products meet the criteria listed in Section 465.0251, Florida Statutes, the removal becomes a ministerial duty." (Summary Final Order, ¶ 35.) The mere fact that Abbott disagrees with the ALJ, the Florida Legislature, the United States Food and Drug Administration, and now the Boards of Pharmacy and Medicine, does not mean that Abbott is likely to prevail on appeal, and certainly falls far short of entitling Abbott to an undeserved stay.

19. Even if Abbott had presented sufficient reasons to warrant a stay of the Summary Final Order, it has failed to state how it will satisfy rule 9.310(c), Florida Rules of Appellate Procedure, requiring a supersedeas bond. Mylan fully expects it would suffer damages from any stay of the Summary Final Order due to loss of sales of Levothyroxine Sodium during that time period. These damages would need to be covered by an appropriate bond if Abbott were granted a stay.

20. Abbott's failure to set forth a sufficient basis to establish that it has a likelihood of success on appeal or that it will suffer harm if a stay of the Summary Final Order is not imposed mandates denial of Abbott's motion for stay.

WHEREFORE for the reasons set forth above, Mylan Pharmaceuticals Inc. respectfully requests that the ALJ deny Abbott's Motion for Clarification and for Stay and grant Mylan such additional relief as the ALJ deems just and proper.

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been served this 13th day of February, 2008, by electronic delivery to the following:

Deborah Loucks, Assistant Attorney General
Office of Attorney General
The Collins Building
107 West Gaines Street, Room 332F
Tallahassee, Florida 32399-1050
Telephone: 850-414-3300
Facsimile: 850-922-6425
deborah.loucks@myfloridalegal.com
Attorneys for Board of Pharmacy

Edward A. Tellechea
Senior Assistant Attorney General
Office of the Attorney General
Administrative Law Bureau
PL-01, The Capitol
Tallahassee, Florida 32399-1050
Telephone: 850-414-3300
Facsimile: 850-922-6425
ed.tellechea@myfloridalegal.com
Attorneys for Board of Medicine

Michael J. Glazer, Esq.
Ausley & McMullen
P. O. Box 391
227 South Calhoun Street
Tallahassee, Florida 32302
Telephone: 850-224-9115
mglazer@ausley.com
Attorneys for Abbott Laboratories

Peter Witty
Abbott Laboratories
100 Abbott Park Road
Abbott Park, Illinois 60064
Peter.witty@abbott.com
Attorneys for Abbott Laboratories

/s/ William E. Williams
William E. Williams (Fla. Bar No. 0132989)
Amy W. Schrader (Fla. Bar No. 0621358)
GrayRobinson, P.A.
301 South Bronough Street, Suite 600 (32301)
Post Office Box 11189
Tallahassee, Florida 32302-3189
850/577-9090 (telephone)
850/577-3311 (facsimile)
Email: wwilliams@gray-robinson.com
aschrader@gray-robinson.com

Attorneys for Petitioner, Mylan Pharmaceuticals Inc.