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IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF FLORIDA Ocala, Florida

DAVID ALLYN, M.D., JAMES V. LYNOTT, M.D., and JOSEPH M. MASESSA, M.D.,

Plaintiffs,

No.: 5:18-CV-355-OC-30PRC

VS.

AMERICAN BOARD OF MEDICAL SPECIALTIES, INC., an Illinois corporation, and AMERICAN BOARD OF DERMATOLOGY, INC., a Delaware corporation, authorized to do business in Massachusetts,

Defendants.

2018 JUL 11 PM 2: 43
CLERK, US DISTRICT COURT
HIDDLE DISTRICT OF FL
GLAN A FLORIDA

PLAINTIFFS' VERIFIED MOTION FOR TEMPORARY RESTRAINING ORDER WITHOUT HEARING AND TEMPORARY INJUNCTION

COME NOW Plaintiffs and Class representatives David Allyn, M.D., James V. Lynott, M.D., and Joseph M. Masessa, M.D. (Plaintiffs), who are suing Defendants the American Board of Medical Specialties, Inc. (ABMS), and the American Board of Dermatology, Inc. (ABD), requesting the Court to enter a Temporary Restraining Order (TRO) without a hearing, pursuant to Rule 65, Federal Rules of Civil Procedure, and Local Rules 4.05 and 4.06, to preserve the status quo until further hearings can be had on this matter, and then entering a preliminary injunction until trial on the merits, stating:

NATURE OF THE ACTION

- 1. This is a class action suit by Plaintiffs against Defendants American Board of Medical Specialties (ABMS) and American Board of Dermatology (ABD), for violations of antitrust laws of the United States and Florida, restraint of trade, unfair and deceptive trade practices, a declaratory judgment, a temporary restraining order, and injunctive relief because of their attempt to create a subspecialty board (referred to herein as the "Mohs Surgery Board") to limit the practice of the procedure known as Micrographic Dermatologic Surgery, "Mohs surgery," or "MDS." Doing so would reduce the availability of Mohs surgery for patients with skin cancer in the U.S.
- 2. This case arises under Section 16 of the Clayton Act, 15 U.S.C. Section 26, to secure equitable relief against a violation by Defendant ABMS of Sections 1 and 2 of the Sherman Act, 15 U.S.C. Sections 1 and 2. Interstate commerce for medical services is substantially affected by Defendants' conduct alleged herein. In addition, this Court has subject matter jurisdiction over these matters pursuant to 28 U.S.C. Section 1332, because there is diversity of citizenship of the parties and the amount in controversy exceeds \$75,000.00. Supplemental jurisdiction exists under 28 U.S.C. Section 1367 for the causes of action based on Florida law.

BACKGROUND AND RELEVANT FACTS

A. The Product/Service: Mohs Surgery

- 3. Mohs surgery¹ is a single surgical procedure in which a physician cuts around and removes a visible skin cancer (a melanoma, basal cell carcinoma, or squamous cell carcinoma) on a patient's-skin.
- 4. Mohs surgery is a simple technique, usually performed using only a local anesthetic, in the physician's office. However, it may be performed in a hospital, as well. It can take from a few minutes to a few hours, depending on how many times the procedure must be repeated during the same surgery. A description of the Mohs Surgery procedure written for patients is set forth in Exhibit "1" attached to the Verified Complaint.

B. Public Demand for and Need for the Mohs Surgery Service

- In 2012, the American Cancer Society estimated that about 5.4 million basal and squamous cell skin cancers are diagnosed each year in the United States.
- 6. The American Cancer Society (ACS) estimates that about 91,270 new melanomas will be diagnosed in 2018 and 9,320 people are expected to die of melanoma.
- 7. Statistics provided by the Medicare Program for 2016 show that 1,395,162 Mohs Surgery procedures were reimbursed by the Medicare Program alone in that year.
- 8. Dermatologists routinely take two (2) rotations (rotations are usually one (1) month in length) in performing Mohs Surgery while in their dermatology residency program.

Mohs surgery was created by Frederic Mohs, M.D., in the 1930's.

- 9. Despite this, ninety-nine percent (99%) of the Mohs surgeries performed in the U.S. are successful in eliminating the cancer.
- 10. In 2018, the American Association of Dermatology ("AAD") estimated that there were at least 20,149 practicing dermatologists in the United States.
- 11. However, in addition to dermatologists, other types of physicians also perform Mohs surgery, such as:

Critical Care, Emergency Medicine, Family Practice, General Practice, General Surgery, Internal Medicine, Neurology, Otolaryngology, Pathology, Plastic and Reconstructive Surgery, and Surgical Oncology physicians.

Mohs surgery is being performed by dermatologists, general surgeons, plastic surgeons, oncologists and other types of physician specialists.

C. Combining, Agreeing, Conspiring and Tying

12. Defendant ABD is conspiring with, agreeing with, and acting in coordination with the ABMS to create the Mohs Surgery Board. It is conspiring with, agreeing with, and acting in coordination with the ABMS to prohibit the performance of Mohs surgery by anyone other than a physician certified by the Mohs Surgery Board.

D. Actions by Defendants to Restrict Availability of Mohs Surgery Physicians

13. Defendant ABD has submitted an application to the ABMS to create the Mohs Surgery Board. Exhibit "2."

- 14. Specifically, Defendant ABMS has conspired, combined, and agreed with other medical specialty organizations, with individual physicians, and with others, to limit the number of physicians who are "board certified" to perform Mohs surgery and thus are allowed to bill and collect for performing the Mohs surgery procedure on patients who need it. ABMS has conspired, combined, and agreed to restrain trade by reducing the availability of an essential skin surgery for skin cancer by creating the Mohs Surgery Board in violation of Sections 1 and 2 of the Sherman Act and state antitrust law.
- 15. At the present time, Mohs surgery is merely one of the many different surgical procedures that physicians in different specialties are taught as part of their residency training programs, mostly in dermatology residency programs. However, general surgeons, oncologists, plastic surgeons, and other specialists may also routinely perform Mohs surgery.
- 16. There are currently only approximately 1,500 fellowship² trained Mohs surgery physicians in the U.S.
- 17. Most of the physicians currently performing Mohs surgery procedures are <u>not</u> fellowship trained in Mohs surgery, as this would require an additional one (1) to two (2) years of training exclusively in Mohs training.

A "fellowship" in graduate medical education (GME) is a specialty training program for a physician who has already completed a medical residency program in a medical specialty. An example would be a fellowship in maternal-fetal medicine, which is considered to be a subspecialty of the medical specialty of obstetrics and gynecology. Fellowships in Mohs surgery are either one year or two years of additional training. Thus, a physician who had already completed a residency program in dermatology and was already board certified as a dermatologist by the American Board of Dermatology, would be required to pursue an additional one or two year fellowship in Mohs surgery in order to become board eligible for certification in the subspecialty of Mohs surgery, as proposed by the Defendants.

- 18. In 2017, there were only 85 physicians in the entire United States who were enrolled in a Mohs surgery fellowship. (See Exhibit "2" of Verified Complaint.)
- 19. In 2018, the number of physicians enrolled in a Mohs surgery fellowship increased to 86. This reflects an increase of only 1.2% from the previous year, which is woefully behind the increasing rates of skin cancer. (See Exhibit "2" of Verified Complaint.)
- 20. Under the program proposed by Defendant ABD to Defendant ABMS, and expected to be approved by ABMS, in order to become board certified ion Mohs surgery, a physician would be required to be: 1) Board certified in dermatology; 2) fellowship trained in an accredited Mohs surgery fellowship program; and 3) meet certain other requirements.
- 21. The Plaintiffs are each board certified dermatologists, each with decades of medical experience, who currently perform Mohs surgery.
- 22. Under the rules of the Mohs Surgery Board as proposed by the Defendants, the plaintiffs would not be able to obtain certification in Mohs surgery.
- 23. Taking Mohs surgery and creating a separate board certification for it would be analogous to creating a separate board for labor and delivery of babies,³ that would require a physician to take an extra one-year or two-year fellowship in labor and delivery of babies, before he or she would be qualified to perform a delivery of a baby.
- 24. The number of dermatologists being produced by dermatology residency programs in the U.S. has not kept up with demand for dermatology services.

³ Currently, delivery of babies in the U.S. is routinely performed by obstetrician/gynecologists, family practice physicians, certified nurse midwives, and midwives, among others.

- 25. The ACS estimates that about 91,270 new melanomas will be diagnosed in 2018 and 9,320 people are expected to die of melanoma. (See Exhibit "4" of Verified Complaint.)
- 26. In 2012, the ACS estimated that about 5.4 million basal and squamous cell skin cancers are diagnosed each-year in the United States. (See Exhibit "5" of Verified Complaint.)
- 27. Statistics provided by the Medicare Program for 2016 show that at least 2,500 physicians performed 1,395,162 Mohs Surgery procedures that were reimbursed by the Medicare Program in that year alone. (See Exhibit "6" of Verified Complaint.)
- 28. A market profile of dermatological services in the U.S. for 2015⁴ showed that over fifty percent (50%) of dermatologists saw more than fifty (50) patients a day. Exhibit "7."
- 29. There is an average of one (1) dermatologist for approximately every 16,165 people in the United States.
- 30. In November 2009 and subsequently, ABMS and several of its member boards obtained the agreement of The Joint Commission (TJC) to require certification and recertification of hospital physicians by the ABMS's member boards, including Defendant ABD, as a condition of obtaining and holding hospital medical staff privileges. TJC is a private company that accredits more than 20,000 health care facilities in the U.S., including more than eighty percent (80%) of all hospitals. (Association of Am. Physicians & Surgeons v. Am. Bd. of Med. Specialties, Case

This market analysis was published by Cegedim Relationship Management of Bedminster, N.J. Exhibit "7" to the Verified Complaint.

No. 14-cv-02705, 2017 U.S. Dist. LEXIS 2105845, pp. 3-4 (N.D. Ill. Opinion of Dec. 13, 2017)).

- 31. TJC accreditation is also a requirement for hospitals in the U.S. to become licensed by the state and maintain their licenses. Additionally, all military hospitals and Veterans Administration hospitals in the U.S. are also accredited by The Joint Commission, in accordance with Federal Regulations.
- 32. There is coordination, combination, conspiracy, and agreement by, between, and among the Defendants, TJC, U.S. hospitals, and others, as detailed below, to require certification of physicians by the Mohs Surgery Board as proposed by Defendants in order for physicians to be able to perform Mohs surgery in U.S. health facilities.
- 33. If a Mohs Surgery Board is approved, then physicians who are not so certified will be prohibited from performing Mohs surgery in their hospitals in the U.S.
- 34. In order to become a member of and be certified by the proposed Mohs Surgery Board, a physician would be required to have a separate fellowship specifically in Mohs Surgery. This is regardless of the number of Mohs surgeries the physician had previously performed or the physician's actual clinical skills and experience in performing Mohs surgery.
- 35. ABMS also falsely implies that the Mohs Surgery Board has or will have governmental approval and academic legitimacy, when it does not. ABMS misleadingly implies that the physicians who would be "board certified" by the Mohs Surgery Board are better qualified to perform the surgery than physicians who are not board certified by the Mohs Surgery Board.
- 36. There is medical evidence showing that there is no difference in the quality of physicians who would be eligible to be certified by the Mohs Surgery Board and those who

currently perform Mohs surgery and who would not be eligible. Furthermore, having a Mohs Surgery Board would cause a reduction-in the number of physicians allowed to perform Mohs surgery, thus reducing the availability of a needed medical service for patients.

- 37. In addition, Defendants are engaging in deceptive trade practices, because ABMS and its co-conspirators, specifically the American College of Mohs Surgery (ACMS), disparages the goods, services, and business of others by false or misleading representations. Specifically, ABMS and ACMS misleadingly disparage physicians who decline to participate in a Mohs surgery fellowship by ABMS's Mohs Surgery Board by falsely implying that such physicians will be of inferior quality to those who do Mohs surgery fellowships and will become certified by the Mohs Surgery Board.
- 38. It is well known that the Medicare Program adopts rules, regulations, and guidelines that require board certification in order to qualify for receiving payment for performing certain medical procedures. Other government payers such as Tricare, state Medicaid programs, the Veterans Administration, and private health insurance companies usually adopt the same guidelines as Medicare.
- 39. If the Defendants and their co-conspirators are successful, they will convince payors for medical services and specifically the Medicare Program, to limit payments for Mohs surgery procedures to only those performed by Mohs Surgery Board certified physicians. This will artificially reduce the number of physicians able to provide such services to patients.
- 40. It is also well known that most hospitals in the U.S. limit the surgical procedures that are allowed to be performed on their premises to those performed by physicians who are

board certified to do so. Most hospitals in the U.S. also limit physicians admitted to their medical staffs to those who are board certified in different medical specialties and subspecialties.

- 41. Plaintiffs seek declaratory relief and injunctive relief to prevent the actions from being pursued by the Defendants, and their Unnamed Co-conspirators, against the members of the Class, as defined below.
- 42. The Plaintiffs have standing in this matter. They are physicians who are experienced in performing Mohs surgery and who each now perform a large number of Mohs surgery procedures on patients every year.
- 43. Plaintiffs each receive payment from the Medicare Program, the Tricare Program, and other government and private health care payors for the Mohs surgery procedures they perform.
- 44. Plaintiffs each have clinical privileges in hospitals that include authorization to perform Mohs surgery procedures in those facilities.
- 45. If the actions of the Defendants are allowed to continue, each Plaintiff will suffer a loss of patients, a loss of income, and will have their ability to provide Mohs surgery procedures for their patients artificially restrained or prohibited.
- 46. The actions of the Defendants will cause the Plaintiffs and other members of the Class to be excluded from insurance networks and the networks of private payors as providers of Mohs surgery.
- 47. The actions of the Defendants will artificially and arbitrarily restrict the income of the Plaintiffs, reduce the number of physicians available to provide Mohs surgery procedures to patients, and reduce patient access to physicians having the ability to provide Mohs surgery.

- 48. Access to Mohs surgery providers by patients will be reduced and restricted by the actions of the Defendants. The price of Mohs surgery will increase because of the reduction in availability of the service. The quality of patient care will not be increased.
- 49. Plaintiffs have an interest in seeing that the availability of physicians who may provide Mohs surgery to patients is not limited or reduced; that the payment for Mohs surgery procedures to patients by government payors and insurers is not controlled or limited by a small group of physicians; that there are a sufficient number of physicians available to provide Mohs surgery procedures to patients across the U.S., especially in Medically Underserved Areas (MUSAs) and Health Professional Shortage Areas (HPSAs); and that physicians who are skilled and experienced in performing Mohs surgery are not restricted from providing such services to patients who need them.
- 50. Plaintiffs have an interest in making sure that the maximum number of physicians who are experienced in or trained in Mohs surgery are allowed to provide it without the restrictions or limitations being placed on them such as those proposed by Defendants.

E. Creating a Board Certification for a Single Procedure Is Unique in the History of Defendant ABMS and Must Be Seen as an Artificial Attempt to Restrain Trade

51. The creation of a separate specialty board in Mohs surgery is a historically unique event in the history of the ABMS. All other specialty boards certify physicians in broad areas of medicine. If Defendants ABMS and ABD succeed in their attempts to create a Mohs Surgery

Board, this will be the first time one individual surgical procedure will be placed under the province of its own board, thus creating an artificial-limitation on it.⁵

- 52. Prior attempts by Defendants to take this type of action failed.
- 53. To date, Defendant ABMS has never created a specialty board for a single isolated medical procedure-such as Mohs surgery. All boards created to date have been-for broad general areas of medicine, such as general surgery and internal medicine.
- a. In fact, creation of a separate specialty board for Mohs surgery was considered by Defendant ABMS in 1987 and rejected, because it centered on only one surgical procedure instead of an area of medicine.
- b. In 2009, the same proposal as the present one was put forth again. However, the subspecialty was called "Procedural Dermatology" to create the false illusion that the subspecialty board would encompass a greater body of knowledge than just Mohs surgery. It was rejected by fifteen (15) state dermatology societies as being too narrow of a field of medicine to deserve a subspecialty board and the ABMS did not approve it.
- 54. Defendant ABD has submitted an application to Defendant ABMS to create the Mohs Surgery Board. A copy of this application is attached as Exhibit "2."
- 55. Defendant ABMS and members of its board of directors will be voting on it shortly after July 6, 2018, to create the new Mohs Surgery Board.

The ABMS considered doing this in 1987 and 2009 and rejected it because the certification would be for a single surgical procedure only and not a broad, general area of medicine. See paragraph 53, supra.

- 56. Defendants ABMS and the Unnamed Co-conspirators have conspired and agreed to create a subspecialty board for Mohs surgery in order to monopolize the Mohs surgery market and are acting to accomplish that end; in order for the physician to obtain clinical privileges in a hospital-or surgical center to perform Mohs surgery procedures.
- 57. Once the Mohs Surgery-Board is formed, Defendants and Unnamed Co-conspirators will act to have the Medicare Program change its requirements so as to require physicians to be board certified by the new Mohs Surgery Board in order for the physician to be reimbursed by Medicare for performing Mohs surgery procedures.
- 58. Once the Mohs Surgery Board is formed, Defendants and Unnamed Co-conspirators will act to have health insurers require physicians to be board certified by the new Mohs Surgery Board in order for the physician to be paid by the health insurer for performing Mohs surgery procedures.
- 59. Defendants' and Unnamed Co-conspirators' actions and agreements, as detailed above and as alleged in further detail below, constitute an illegal agreement in restraint of a trade, an illegal agreement to divide service markets, and an attempt to monopolize under the Sherman Act.
- 60. The proposed requirements to become a member of the Mohs surgery subspecialty board include, among others: a one (1) to two (2) year fellowship in Mohs surgery; a passing score on an examination administered by the Mohs Surgery Board; and payment of fees that would be paid to the Mohs Surgery Board.

F. Defendants' Ability to Fix Prices, Eliminate Competition, and Restrain Trade

- 61. Because skin cancer is most predominant in elderly patients, most Mohs surgery patients have their surgery paid by the Medicare Program.
- 62. Required guidelines for obtaining payments from the Medicare Program are set forth in documents known as National Coverage Determinations (NCDs)-and Local Coverage Determinations (LCDs), the latter covering various geographical regions of the United States. NCDs and LCDs require that the procedures they cover be performed only by physicians trained in and certified to provide the particular service or procedure covered by the NCD and the LCD, or Medicare will not pay for the procedure.
- 63. If board certification by the Mohs Surgery Board becomes authorized, then NCDs and LCDs will be rewritten to require that a physician can only be paid for a Mohs surgery procedure if he or she is certified by the Mohs Surgery Board.
- 64. Other federal and state health care programs such as the Tricare program and the state Medicaid programs, as well as private health insurance companies, usually adopt the same restrictions and payment guidelines as those of the Medicare Program.
- 65. Thus, by controlling board certification for performing Mohs surgery procedures, a Mohs Surgery Board is able to control payments to physicians for performing Mohs surgery. Those who are not board certified by the Mohs Surgery Board will not be able to obtain payment for performing Mohs surgery. This will greatly reduce the number of physicians available to provide Mohs surgery procedures to patients.
- 66. The Defendants and the Unnamed Co-conspirators would restrain trade by acting to have hospitals, surgical centers, health insurers, and government payors (such as the Medicare

Program, the Tricare Program, and the state Medicaid programs) impose the requirement of being certified by the Mohs Surgery Board as a condition for obtaining payment for performing Mohs surgery. This would decrease the number of physicians able to compete for performing Mohs surgery procedures, reduce the availability of Mohs surgery procedures, and increase the prices to consumers in the relevant market.

- 67. Many physicians choose not to undergo a Mohs surgery fellowship because it would impinge on their time to spend caring for their patients. Furthermore, dermatologists are required to complete at least two (2) rotations (months) of training in performing Mohs surgery procedures. Thus all residency trained dermatologists already have training in performing the procedure.
 - 68. Physicians spend more time in training than most other professionals.
- 69. Despite this, the additional burdens on physicians' time imposed by the ABMS's Mohs Surgery Board would be substantial, because physicians will now be forced to undergo an additional fellowship as well as recertification every five (5) years. Exhibit "2."
- 70. It is contrary to public policy for ABMS and ABD, as private entities lacking in public accountability and transparency, to impose their own proprietary product as a condition for patients to have access to Mohs surgery physicians through government programs such as Medicare, insurance networks, and in hospitals.

G. No Improvement in Quality of Care with Mohs Surgery Subspecialty

71. There is no proven benefit to patient care by requiring Mohs surgery physicians to become board certified with a subspecialty board.

- 72. There is no proven benefit to patient care by requiring Mohs surgery physicians to undergo a fellowship in Mohs surgery.
- 73. Medical studies have shown that Mohs surgery currently has a success rate of 99%. This means that 99% of all Mohs surgeries, whether performed by fellowship-trained Mohs surgeons or not, successfully cure the patient of the skin cancer.
- 74. A survey administered in 2017 by the American Academy of Dermatology showed that an overwhelming majority of dermatologists who have not completed a Mohs surgery fellowship (approximately sixty-four percent (64%)) believed that the creation of a Mohs Surgery Board was unjustified and unnecessary.
- 75. Academic physicians have been critical of the lack of benefits from the proposed Mohs Surgery Board, observing that the additional years of fellowship training and board testing do not actually increase the quality of care, that is the quality of the Mohs surgery performed.
- 76. The lack of any genuine value in certification by a Mohs Surgery Board as a measure of professional skill or competence is demonstrated by the high success rates of Mohs surgery when performed by physicians who currently perform it without such certification.
- 77. In 2015, the effort to create a subspecialty board came forth and renamed the proposal as "Micrographic Dermatologic Surgery," which is the proposal that the ABMS will consider on July 6, 2018. This renaming of the application is simply an attempt to trick the ABMS into thinking that the proposal now encompasses a large enough body of knowledge to merit the creation of a subspecialty board; however, it is simply the same proposal that was

⁶ Unnamed Co-conspirator Dr. Coldiron has an article published in 2014 that gives this statistic. See also, Exhibit "3."

brought forth in 1987 and 2009 by a different name. The subspecialty board's only true purpose to is to regulate the Mohs surgery market.

- 78. The proposed Mohs Surgery Board would not admit or certify plastic surgeons, oncologists, general surgeons, or the many other medical specialists who are currently performing Mohs surgery. Control of the performance of this one surgical procedure by one subspecialty board is an unjustifiable restraint of trade.
- 79. Reduction of the number of physicians who can be reimbursed for providing this service is an unjustifiable restraint of trade.

H. Detrimental Impact on Relevant Market; Injury to Market and Harm to Competition

- 80. If payment for Mohs surgery procedures is artificially restricted to physicians certified by the Mohs Surgery Board, then most patients will be required to seek out one of the certified physicians. This will result in a reduced supply of physicians to provide this service.
- 81. The conduct of the Defendants and Unnamed Co-conspirators will reduce the number of physicians able to perform Mohs surgery and receive payment for it. The conduct of the Defendants and Unnamed Co-conspirators will reduce the number of physicians allowed to perform Mohs surgery in U.S. hospitals.
- 82. Thousands of physicians currently providing Mohs surgery will find themselves shut out of the market when government programs and insurers refuse to pay them and hospitals refuse to allow them to perform Mohs surgery as members of the hospitals' staffs.

- 83. The creation of a Mohs Surgery Board reduces the available providers of Mohs surgery by approximately 92.6% of the original service provider market size
- 84. In addition, most patients would be forced to undergo two (2) different physician visits instead of just one (1), to have their skin cancer diagnosed and treated. The patient would ordinarily see a dermatologist (who would diagnose the skin-cancer) and then be referred out to a Mohs surgeon (to have the Mohs surgery performed). This would double the number of required medical visits patients would have to make and would likewise increase the costs of medical care. Currently, the same physician who diagnoses the skin cancer also performs the Mohs surgery.
- 85. The conduct of the Defendants and Unnamed Co-conspirators will decrease the availability of Mohs surgery in the market.
- 86. The actions of the Defendants and Unnamed Co-conspirators are an attempt to artificially fix the supply of the services available by limiting the numbers and specialties of physicians allowed to provide them.
- 87. The actions of the Defendants and Unnamed Co-conspirators are an attempt to fix the demand for services, by acting with and agreeing with the insurance company payors and government programs that pay for such services.
- 88. The conduct of the Defendants and Unnamed Co-conspirators constitutes a horizontal agreement to fix prices and to divide the market.
- 89. The conduct of the Defendants and Unnamed Co-conspirators constitutes an attempt to monopolize the service market and the geographic market.

90. The market will be artificially limited vertically, as well. Hospitals and payors will restrict the number of physicians who will be allowed to perform Mohs surgery to those certified by the Mohs Surgery Board.

I. Verified Complaint and Exhibits Incorporated by Reference

91. Plaintiffs further incorporate the Verified Complaint and its Exhibits, in further support of this motion.

CAUSES OF ACTION BROUGHT BY PLAINTIFFS

- 92. In their Verified Complaint, Plaintiffs have brought suit for:
 - a. Violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §
 1 and 2, which prohibit restraints of trade and attempts to monopolize;
 - Violations of the Florida Antitrust Act, Sections 542.18 and 542.19,
 Florida Statutes, restraint of trade and conspiracy to monopolize;
 - c. Violations of the Florida Deceptive and Unfair Trade Practices Act (FDUTPA), Section 501.204, Florida Statutes;
 - d. Civil conspiracy;
 - e. A request for a declaratory judgment pursuant to pursuant to Rule 57, Federal Rules of Civil Procedure, and 28 U.S.C. Section 2201; and
 - f. A request for injunctive relief, 15 U.S.C. Section 4, and Rule 65, Federal
 Rules of Civil Procedure, and Section 542.23, Florida Statutes.

IMMINENT THREAT

- 93. The ABMS gave the public until July 6, 2018, to provide comments to the proposal made by the ABD to cerate a Mohs Surgery Board. With that period having expired, it is expected that the ABMS will act on the application made by the ABD in the very near future, and approve it.
- 94. The injury alleged in the Verified Complaint and in this Verified Motion is so imminent that notice and a hearing on the application for preliminary injunction is impractical if not impossible.

SECURITY

- 95. Pursuant to Rule 65(c), Federal Rules of Civil Procedure the amount of security which would be proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained, can be determined by the following:
 - At present there is no Mohs Surgery Board or medical specialization in Mohs Surgery.
 - b. In the past such has been considered twice by the Defendant American Board of Medical Specialties, once in 1987 and once in 2009. Both times it was rejected as being unjustified. However, in the past, lobbying efforts and promotion among board certified dermatologists was not nearly as aggressive as it is presently.
 - c. The Defendants will suffer no additional harm if the temporary restraining order and the temporary injunction are entered.

d. On the other hand, if the actions are not restrained and temporarily enjoined, Defendants will proceed to act to approve the application of the Defendant ABD and will create a Mohs Surgery Board with its subspecialty certification in Mohs Surgery. Harm to Plaintiffs and to the market will begin occurring immediately. Defendants will advertise and promote their new specialty and will begin a move to exclude other physicians from performing Mohs Surgery, thus monopolizing the market for the service. Hospitals will prohibit physicians from performing Mohs Surgery unless certified by the Defendants. Government payors and private payors will cease to pay for Mohs Surgery unless performed by a physician certified by the Defendants.

e. The Court should not require any security to be posted by the Plaintiffs,

since the Plaintiffs' actions in bringing this suit are to protect the public's

access to health care.

Regardless, in the alternative, it is respectfully suggested that the only harm that will occur to the Defendants will be the attorney's fees and costs they incur if the Defendants have been found to have been wrongfully enjoined or restrained, which security in the amount of \$10,000 should be appropriate to cover in that event.

MEMORANDUM OF LAW

Rule 65, Federal Rules of Civil Procedure states, in relevant part:

Rule 65 - Injunctions and Restraining Orders

(b) Temporary Restraining Order.

- (1) Issuing Without Notice. The court may issue a temporary restraining order without written or oral notice to the adverse party or its attorney only if:
 - (A) specific facts in an affidavit or a verified complaint clearly show that immediate and irreparable injury, loss, or damage will result to the movant before the adverse party can be heard in opposition; and
 - (B) the movant's attorney certifies in writing any efforts made to give notice and the reasons why it should not be required.
- (2) Contents; Expiration. Every temporary restraining order issued without notice must state the date and hour it was issued; describe the injury and state why it is irreparable; state why the order was issued without notice; and be promptly filed in the clerk's office and entered in the record. The order expires at the time after entry—not to exceed 14 days—that the court sets, unless before that time the court, for good cause, extends it for a like period or the adverse party consents to a longer extension. The reasons for an extension must be entered in the record.
- (c) Security. The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained. . . .

A. No Security Should Be Required Given That Defendants' Actions Seek to Protect an Injury to Public Health and to Make Sure Access to Medical Services Are Not Artificially Restrained.

No security should be required, especially since this matter affects the general health care of the U.S. public. See Bass v. Richardson, 338 F. Supp. 478 (S.D.N.Y. 1971) (no security required where issue was concerns over public's health); cited with approval by Ala. ex rel. Baxley v. Corps of Eng'rs of U.S. Army, 411 F. Supp. 1261, 1275 (N.D. Ala. 1976).

B. Plaintiffs Are Likely to Prevail on the Merits.

It is likely that the Plaintiffs will ultimately prevail on the merits of the claim. Not only are the causes of action pleading antitrust and restraint of trade violations solidly pleaded, there is ample evidence to support the allegations being made. Furthermore, Defendants previously attempted the same actions twice in the past only to have those actions fail because of lack of support from the healthcare community.

C. The Irreparable Nature of the Threatened Injury and the Reason That Notice Cannot Be Given.

As one district court observed:

Other courts have found irreparable harm to result from the wrongful deprivation of arguably less critical services such as dental care, prescription drugs, eyeglasses, and certain diagnostic and rehabilitative services. See Bass v. Richardson, 338 F. Supp. 478 (S.D.N.Y. 1971); Bass v. Rockefeller, [*18] 331 F. Supp. 945 (S.D.N.Y.), remanded on other grounds, 464 F.2d 1300 (1971).

<u>Lewis v. Grinker</u>, 1987 U.S. Dist. LEXIS 16780, at *17-18, Case No. CV-79-1740 (E.D.N.Y. Mar. 5, 1987). Plaintiffs in the present case are bringing suit so as to prevent a reduction in the amount of health services available to the community as a whole.

In the present case, it clearly appears from the facts set forth in the Verified Motion above and in the Verified Complaint and its Exhibits that immediate and irreparable injury will result to the Plaintiffs before the adverse parties or those parties' attorneys can be heard in opposition.

D. No Potential Harm Is Likely to Be Caused to Defendants or Others If the Temporary Restraining Order Issues.

Entering a temporary restraining order may actually prevent the Defendants and applicants for a Mohs Surgery Board from being harmed. If the Defendants proceed with their plans despite this suit, create certification examinations, require applicants to complete lengthy applications and pay application fees, and start certifying physicians, damage will be caused when Defendants are required to unwind it all and reverse their actions and application fees will be required to be returned.

E. The Public Interest Will Be Served by the Entry of a Temporary Restraining Order, as the Purpose of this Suit Is to Ensure That the Availability of Mohs Surgery Is Not Artificially Restrained or Limited and Remains Readily Available to The Public.

The public interest will be served by the entry of a temporary restraining order and temporary injunctions. The whole purpose of this suit is to ensure that Mohs Surgery, a life-saving cancer treatment, remains abundantly available to patients across the United States and is not artificially limited or restrained.

RELIEF-REQUESTED

The Conduct to be restrained and enjoined is:

- A. Action by Defendant ABMS on the ABD's application to create a Mohs Surgery

 Board, and
- B. Action by either Defendant ABMS or Defendant ABD to create a Mohs Surgery
 Board or any other type of subspecialty certification in Mohs surgery.

A proposed Temporary Restraining Order prepared in strict accordance with the several requirements contained in Rule 65(b) and (d), Federal Rules of Civil Procedure, is attached.

CERTIFICATION OF COMPLIANCE WITH COURT RULES

I, undersigned counsel, hereby certify that I have made every effort to comply with all court rules, including but not limited to Rule 65, Federal Rules of Civil Procedure, and Local Rules 4.05 and 4.06.

In addition, a copy of this Verified Motion is being served on both Defendants along with the Summons and Verified Complaint in this case as well as the advance copies served as detailed above.

CERTIFICATION OF COUNSEL AS TO ATTEMPT TO NOTIFY OPPOSING PARTIES

I hereby certify that on July 11, 2018, I sent a letter to the opposing parties, via Federal Express, overnight delivery, containing copies of the filed Verified Complaint and all of its Exhibits, the Summons, and a copy of this Verified Motion. These letters and documents were provided to each of the following:

John C. Moorhead, M.D., M.S., FACEP Chairman, ABMS Board of Directors Oregon Health & Science University Department of Emergency Medicine Mail Code: CDW-EM 3181 S.W. Sam Jackson Park Road Portland, Oregon 97239

Richard E. Hawkins, M.D. President and Chief Executive Officer American Board of Medical Specialties 353 North Clark Street, Suite 1400 Chicago, Illinois 60654

John D. Mandelbaum, Esquire Chief Legal Officer American Board of Medical Specialties 353 North Clark Street, Suite 1400 Chicago, Illinois 60654 Thomas D. Horn, M.D., M.B.A. Executive Director American Board of Dermatology, Inc. 2 Wells Avenue Newton, Massachusetts 02459

Ms. Sharon Hart Registered Agent American Board of Dermatology, Inc. 2 Wells Avenue Newton, Massachusetts 02459

Janet A. Fairley, M.D., President American Board of Dermatology, Inc. 200 Hawkins Drive Unit No. 40025 PFP Iowa City, Iowa 52242

STATE OF FLORIDA)
COUNTY OF LAKE)

VERIFICATION AND DECLARATION

I, the undersigned, having been duly sworn, do hereby depose and state, the facts stated above are true and I have personal knowledge of the same. This Verified Motion is being filled in good faith and not for the purpose of unnecessary delay.

I further certify and declare that immediate less or injury will result of a temporary restraining order and a temporary injunction are not entered to maintain the status quo pending a determination of the case on its merits.

Signature

DAVID ALLYN, M.D.

NOTARIZATION

SWORN TO AND SUBSCRIBED before me this ______ day of July 2018, by David Allyn, M.D., who is personally known to me or who did produce the appropriate identification and is the person who signed above.

- SEAL -

SHAKIRA V BROWN
MY COMMISSION & GG044029
EXPIRES February 05, 2021

NOTARY SIGNATURE

NAME: Shakura V Brown

EXPIRATION: 3/05/

Done this 11th day of July 2018.

/s/ George F. Indest III

GEORGE F. INDEST III, J.D., M.P.A., LL.M.

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ATTORNEYS FOR PLAINTIFFS

Attachment: Proposed Order

S:\001-1699\002\002-ABMS Antitrust Suit\410-Pleadings-Drafts & Pinals\0-Old Copies\Motion for TRO-Final.wpd

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF FLORIDA Ocala, Florida

DAVID ALLYN, M.D., JAMES V. LYNOTT, M.D., and JOSEPH M. MASESSA, M.D.,

No.:

Plaintiffs,

vs.

AMERICAN BOARD OF MEDICAL SPECIALTIES, INC., an Illinois corporation, and AMERICAN BOARD OF DERMATOLOGY, INC., a Delaware corporation, authorized to do business in Massachusetts.

Defendants.	

TEMPORARY RESTRAINING ORDER

THIS MATTER having come before the Court on Plaintiffs' Verified Motion for Temporary Restraining Order and Temporary Injunction, the Court's having also reviewed the Verified Complaint and its exhibits, hereby finds as follows:

THE COURT FINDS:

- 1. This case is one which primarily arises out of Section 16 of the Clayton Act, 15 U.S.C. Section 26, to secure equitable relief against a violation by Defendant ABMS of Sections 1 and 2 of the Sherman Act, 15 U.S.C. Sections 1 and 2.
- 2. Defendants are the American Board of Medical Specialties (ABMS) and American Board of Dermatology (ABD), who are proposing to adopt a subspecialization board for the certification of previously board certified dermatologists in the subspecialty of Mohs surgery.
- 3. Mohs surgery is a medical procedure that has been in existence since the 1930s that involves the removal of skin cancers through a simple surgical procedure that can be performed

in a physician's office or in a hospital.

- 4. Most physicians who are currently performing Mohs surgery in the U.S. are not fellowship trained Mohs surgeons. Many are not even dermatologists, instead being from the medical specialties of plastic and reconstructive surgery, general surgery, oncology, and other medical specialties.
 - 5. In excess of 5.4 million skin cancers are diagnosed annually in the U.S.
- 6. Mohs surgery is ninety-nine percent (99%) effective in curing the skin cancers so treated, whether the Mohs surgery is performed by fellowship trained Mohs surgeons, those physicians who are dermatologists, or from other medical specialties.
- 7. The Plaintiffs are dermatologists who contend that their practices and commerce as a whole would be negatively affected by the actions of the Defendants, and that the proposal of the Defendants is nothing more than an attempt to divide the market and restrict the number of physicians who are able to perform Mohs surgery or receive compensation for performing Mohs surgery.
- 8. Apparently this would be the first time a medical specialization board was created which attempted to regulate and control one specific surgical procedure, instead of a broad area of medicine. The ABMS attempted to create such a board in 1987 and again in 2005, both times failing to convince its member boards of the necessity for such a subspecialization board.
- 9. There are statistics available which show that the quality of Mohs surgery is not improved by being performed by a fellowship trained Mohs surgeon as compared to a non-fellowship trained physician who performs the same surgery.
- 10. Many physicians who are currently performing Mohs surgery would not be able to meet the basic requirements for becoming board certified under the requirements being considered by the ABMS.
- 11. Moreover, once there is a certification offered in a medical specialty or subspecialty, government and private insurance payers usually change their requirements for paying for such procedures, adopting the higher standards implied by such a certification.
- 12. As noted by another court, in November 2009 and subsequently, ABMS and several of its member boards obtained the agreement of The Joint Commission (TJC) to require certification and recertification of hospital physicians by the ABMS's member boards, including Defendant ABD, as a condition of obtaining and holding hospital medical staff privileges. (Association of Am. Physicians & Surgeons v. Am. Bd. of Med. Specialties, Case No. 14-cv-02705, 2017 U.S. Dist. LEXIS 2105845, pp. 3-4 (N.D. Ill. Opinion of Dec. 13, 2017)).

- 13. TJC is a private company that accredits more than 20,000 health care facilities in the U.S., including more than eighty percent (80%) of all hospitals. (Id.)
- 14. TJC accreditation is also a requirement for hospitals in the U.S. to become licensed by the state and maintain their licenses. Additionally, all military hospitals and Veterans Administration hospitals in the U.S. are also accredited by The Joint Commission, in accordance with Federal Regulations, facts of which the Court takes judicial notice.
- 15. Therefore, it is most likely that such coordination, combination, and agreement by, between, and among the Defendants, TJC, U.S. hospitals, and others will result in the requirement that certification of physicians by the Mohs Surgery Board as proposed by Defendants becomes mandatory for physicians to be able to perform Mohs surgery in U.S. hospitals.
- 16. If a Mohs Surgery Board is approved, then physicians who are not so certified will be prohibited from performing Mohs surgery in their hospitals in the U.S.
- 17. In order to become a member of and be certified by the proposed Mohs Surgery Board, a physician would be required to have a separate fellowship specifically in Mohs surgery. This is regardless of the number of Mohs surgeries the physician had previously performed or the physician's actual clinical skills and experience in performing Mohs surgery.
- 18. The actions of the Defendants, if proven, will cause a reduction in the numbers of physicians performing Mohs surgery, which will likely cause an increase in the costs of such surgery.
- 19. The injury that is likely to occur is injury to the public health and to health care trade and business. The number of physicians who will be available to perform Mohs surgery will be reduced since they would not receive payment for performing Mohs surgery. In some cases physicians are likely to be prohibited from performing Mohs surgery, such as in hospitals.
- 20. In areas of the U.S. which are already designated as Healthcare Professional Shortage Areas (HPSAs) and Medically Underserved Areas (MUAs), where it is already difficult to attract skilled physicians, the problem will be exacerbated.
- 21. Statistics from the American Cancer Society project that 9,320 U.S. citizens are expected to die of melanoma alone, and this is just one of the types of skin cancer that Mohs Surgery cures.
- 22. Patients having skin cancer will have less access to the availability of physicians performing Mohs Surgery.
- 23. If payment is artificially restricted to payment to physicians certified by the Mohs Surgery Board, most patients will be required to seek out one of the certified physicians. This will

result in a reduced supply of physicians to provide this service.

- 24. The conduct of the Defendants and Unnamed Co-conspirators will reduce the number of physicians able to perform Mohs surgery and receive payment for it. The conduct of the Defendants and Unnamed Co-conspirators will reduce the number of physicians allowed to perform Mohs surgery in U.S. hospitals.
- 25. Thousands of physicians currently providing Mohs surgery will find themselves shut out of the market when government programs and insurers refuse to pay them and hospitals refuse to allow them to perform Mohs surgery as members of the hospitals' staffs.
- 26. The creation of a Mohs Surgery Board reduces the available providers of Mohs surgery by approximately 92.6% of the original service provider market size
- 27. In addition, most patients would be forced to undergo two (2) different physician visits instead of just one (1), to have their skin cancer diagnosed and treated. The patient would ordinarily see a dermatologist (who would diagnose the skin cancer) and then be referred out to a Mohs surgeon (to have the Mohs surgery performed). This would double the number of required medical visits patients would have to make and would likewise increase the costs of medical care. Currently, the same physician who diagnoses the skin cancer also performs the Mohs surgery.
- 28. The conduct of the Defendants and Unnamed Co-conspirators will decrease the availability of Mohs surgery in the market.
- 29. The actions of the Defendants and Unnamed Co-conspirators are an attempt to artificially fix the supply of the services available by limiting the numbers and specialties of physicians allowed to provide them.
- 30. The actions of the Defendants and Unnamed Co-conspirators are an attempt to fix the demand for services, by acting with and agreeing with the insurance company payors and government programs that pay for such services.
- 31. The conduct of the Defendants and Unnamed Co-conspirators constitutes a horizontal agreement to fix prices and to divide the market.
- 32. The conduct of the Defendants and Unnamed Co-conspirators constitutes an attempt to monopolize the service market and the geographic market.
- 33. The market will be artificially limited vertically, as well. Hospitals and payors will restrict the number of physicians who will be allowed to perform Mohs surgery to those certified by the Mohs Surgery Board.

THE COURT FURTHER FINDS that there is imminent threat. The Defendants provided until July 6, 2018, for public comment on their proposed plan. That date has passed. It is likely that they will take action in the immediate future.

THE COURT FURTHER FINDS that Plaintiffs are likely to prevail on the merits. Not only are the causes of action pleading antitrust and restraint of trade violations solidly pleaded, there appears to be ample evidence to support the allegations being made. Furthermore, Defendants previously attempted the same actions twice in the past, only to have those actions fail because of lack of support from the healthcare community.

THE COURT FURTHER FINDS that the threatened injury is likely to be irreparable such that Defendants' actions should be restrained until a hearing can be held on this matter. The court finds in this case that there is irreparable harm because necessary, lifesaving health care services are at issue. See Lewis v. Grinker, 1987 U.S. Dist. LEXIS 16780, at *17-18, Case No. CV-79-1740 (E.D.N.Y. Mar. 5, 1987), citing Bass v. Richardson, 338 F. Supp. 478 (S.D.N.Y. 1971); Bass v. Rockefeller, [*18] 331 F. Supp. 945 (S.D.N.Y.), remanded on other grounds, 464 F.2d 1300 (1971).

THE COURT FURTHER FINDS that there will be no potential harm to the Defendants or to others if the temporary restraining order issues. The plan has not been adopted and no actions have been taken by the Defendants to implement it at this time.

THE COURT FURTHER FINDS that the public interest will be served by the entry of a temporary restraining order and temporary injunctions. The whole purpose of this suit is to ensure that Mohs Surgery, a lifesaving cancer treatment, remains abundantly available to patients across the United States and is not artificially limited or restrained.

ACCORDINGLY, the Court <u>GRANTS</u> the Plaintiffs' Verified Motion for a Temporary Restraining Order in accordance with Rule 65(c), Federal Rules of Civil Procedure, and Local Rule 4.05.

THE COURT HEREBY ORDERS: Defendants American Board of Medical Specialties, Inc., and American Board of Dermatology, Inc., are hereby prohibited from taking any further action to create, approve, or promote a Mohs Surgery Board, or any other type of subspecialty certification in Mohs surgery, until further hearing can be had by this Court and an Order is entered to that effect.

PERSONS BOUND BY THIS ORDER: This Order binds the following who receive actual notice of it by personal service or otherwise:

a. Defendants American Board of Medical Specialties, Inc., and American Board of Dermatology, Inc.;

- b. The officers, directors, agents, servants, employees, and attorneys, and subordinate boards of Defendants American Board of Medical Specialties, Inc., and American Board of Dermatology, Inc.; and
- c. All other persons or organizations who are in active concert or participation with those described immediately above.

SECURITY: Because the Plaintiffs seek to protect public access to necessary health care services through this suit, the Court hereby finds that it is appropriate that Plaintiffs post NO / security. If security is required, said security may be in the form of a bond by a reputable Florida licensed insurance company.

THIS ORDER shall be promptly filed in the clerk's office and entered in the record.

FURTHER ORDERED, it shall be the responsibility of the Plaintiffs' Counsel to obtain immediate service of process on the Defendants, of all process and papers in this matter.

THIS ORDER expires 14 days after entry unless before that time the court, for good cause, extends it for a like period or the adverse party consents to a longer extension.

THIS ORDER IS ENTERED at _	A.M./P.M. on July, 2018	3, in
chambers/open court in Ocala, Florida.		

U.S. DISTRICT COURT JUDGE	

Copy provided to:

ATTORNEYS FOR PLAINTIFFS:

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