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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
ATHENS DIVISION

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THE NATIONAL ASSOCIATION OF)
BOARDS OF PHARMACY,)

Plaintiff,)

v.)

THE BOARD OF REGENTS OF THE)
UNIVERSITY SYSTEM OF GEORGIA)
and FLYNN WARREN, JR.,)

Defendants.)

CIVIL ACTION NO.:
FILED UNDER SEAL

3-07-cv-84CDL

**PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF
ITS MOTION FOR TEMPORARY RESTRAINING ORDER
AND PRELIMINARY INJUNCTION**

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TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES	i
I. INTRODUCTION	1
II. STATEMENT OF FACTS	1
III. ARGUMENT AND CITATION OF AUTHORITY	15
A. Substantial Likelihood of Success on the Merits.....	16
1. Ownership.	16
2. Copying.	17
3. Vicarious Liability.....	19
B. Irreparable Harm.....	20
C. Balancing the Hardships.	24
D. Public Interest.	24
IV. CONCLUSION.....	26

TABLE OF AUTHORITIES

CASES **Page(s)**

Ass'n of Am. Med. Colls. v. Mikaelian, 571 F. Supp. 144, 154
(E.D. Pa. 1983)16, 17, 18, 20, 21, 23, 24, 25

Bateman v. Mnemonics, Inc., 79 F.3d 1532, 1541 (11th Cir. 1996).....17, 18

Educ. Testing Servs. v. Katzman, 793 F.2d 533, 544 (3d Cir. 1986).....17, 21, 22, 23

Educ. Testing Serv. v. Simon, 95 F. Supp.2d 1081, 1086-87
(C.D. Cal. 1999).....17, 18, 19, 21, 23

Fonovisa, Inc. v. Cherry Auction, Inc., 76 F.3d 259, 261-64 (9th Cir. 1996).....19

Nat'l Conference of Bar Exam'rs v. Multistate Legal Studies, Inc.,
458 F. Supp.2d 252, 256 (E.D. Pa. 2006).....16, 19, 23, 25

Nat'l Conference of Bar Exam'rs v. Saccuzzo, No. 03CV0737BTM, 2003 WL 21467772 *5
(June 10, 2003).....16, 17, 18, 19, 21

Scientific Applications, Inc. v. Energy Conservation Corp.,
436 F. Supp. 354 (N.D. Ga. 1977).....24

Shatel Corp. v. Mao Ta Lumber & Yacht Corp., 697 F.2d 1352, 1354-55
(11th Cir. 1983).....16

STATUTES, TREATISES & OTHER AUTHORITIES

17 U.S.C. § 102(a) 16

17 U.S.C. § 106..... 16

17 U.S.C. § 410(c) 17

17 U.S.C. § 501(a) 16

O.C.G.A. § 26-4-2.....1, 2, 25

GA. COMP. R. & REGS. 480-2-.04(1).....4, 26

4 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 13.02[a].....16

I. INTRODUCTION

Pharmacists, much like physicians and nurses, are professionals in whom the general public invests a significant amount of trust. Mainly, the public trusts that the drugs that pharmacists provide are the right ones, and that they are given in the right dosage, with the right instruction. Most importantly, the public trusts that the pharmacist dispensing the drugs is properly qualified to do so. As the State of Georgia has decreed, “It is further declared to be a matter of public interest and concern that the practice of pharmacy in this state as a learned profession . . . should merit and receive the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy to ensure the quality of drugs and related devices distributed in this state.” O.C.G.A. § 26-4-2.

Professor Flynn W. Warren of the University of Georgia, through the actions described herein, has destroyed that trust. His approach is not a new one, nor is it complicated. He simply provides his students the questions on the pharmacy licensure exam that each will take before they take it. The illicit benefits of such an approach are obvious – surely any licensure examination will be an easier experience if one knows what specific questions will be asked ahead of time. That is why it is cheating. But in this case, it is not only cheating, it is also copyright infringement. And it must be stopped as soon as possible, before the public trust in their pharmacists, and in the drugs they dispense, is negatively impacted.

II. STATEMENT OF FACTS

I. The NABP and its History.

The National Association of Boards of Pharmacy (“NABP”), was incorporated in 1904 to provide a uniform mechanism of licensure transfer among pharmacists moving from state to

state. NABP is a not-for-profit 501(c)(3) Kentucky corporation with headquarters in Mount Prospect, Illinois. NABP membership consists solely of the various state Boards of Pharmacy (or other regulatory agency), and includes the Board of Pharmacy of the State of Georgia. Additionally, international membership includes the governing entities that regulate pharmacists in eight Canadian provinces, the Republic of South Africa, the states of Victoria and New South Wales in Australia, and New Zealand. Unlike professional associations such as the American Pharmacists Association (APhA), individual pharmacists are not eligible for membership in NABP. Catizone Decl. ¶¶ 6, 7, and 8.

NABP assists its member state Boards of Pharmacy in fulfilling their statutory mandates to regulate the pharmacy profession in the interest of protecting the public health. For example, the State of Georgia regulates the practice of pharmacy through Title 6, Chapter 4 of the Official Code of Georgia, O.C.G.A. § 26-4-2, *et. seq.* In fulfilling their legislative mandates, the State Boards provide expertise and advice on pharmacy regulatory matters and legislation and participate in disciplinary hearings. NABP provides programs and services that allow its member Boards of Pharmacy to assess pharmacists' competency prior to licensure and to verify the ongoing competence of licensed pharmacists. NABP also provides input on new and existing laws and related legal matters, and generally assists in the regulation of the practice of pharmacy for the protection of the public. Catizone Decl. ¶ 10.

Over time, NABP has developed various programs and services, generally at the request of its member Boards. Specifically, NABP programs include: the North American Pharmacist Licensure Examination™ (“NAPLEX”, formerly known as “NABPLEX”), the Multistate Pharmacy Jurisprudence Examination® (“MPJE®”), the Electronic Licensure Transfer

Program® (“ELTP®”), and accreditation programs for Internet pharmacies, wholesale drug distributors, and pharmacies providing durable medical equipment through NABP’s Verified Internet Pharmacy Practice Sites™ program (“VIPPS®”), the Verified-Accredited Wholesaler Distributors® program (“VAWD®”), and the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (“DMEPOS”) program. All such programs are intended to assist the member Boards of Pharmacy fulfill their respective statutory mandates to regulate the pharmacy profession in their state in the interest of protecting the public. Catizone Decl. ¶ 11. The NABP program at issue in this litigation is the NAPLEX.

II. The NAPLEX.

A. What is it?

Generally speaking, the NAPLEX is for pharmacists what the Bar Exam is for lawyers. More specifically, the NAPLEX is a computer-adaptive examination that consists of 185 multiple-choice test questions developed by NABP (of the 185 multiple-choice NAPLEX test questions, 150 questions are used to calculate the test score – the remaining 35 items serve as pre-test questions, which do not affect the NAPLEX score, but are administered to statistically evaluate the item’s performance and difficulty level for possible inclusion as a scored question in future examinations) and utilized by all state Boards of Pharmacy as part of their assessment of competence to practice pharmacy. The NAPLEX was developed over many years beginning in 1952, when the concept of a uniform examination to promote the competent practice of pharmacy among jurisdictions and enhance licensure transfer was identified through meetings of NABP member Boards. In 1968, NABP convened a Blue Ribbon Committee of state Board members and educators who developed the examination blueprint, examination items, and other

necessary components for administering and maintaining a valid uniform exam program. The prototype Blue Ribbon Exam was used by 32 states in 1971. In 1975 NABP's exam was named NABPLEX, and was nationally introduced in 1976 when it was used as a licensing criterion by a majority of U.S. state Boards of Pharmacy. By 1986, all state Boards of Pharmacy (except California) used the NABPLEX. In 1997, NABP implemented the North American Pharmacist Licensure Examination (NAPLEX), a computerized successor to the NABPLEX. With the addition of California's use of the NAPLEX in 2004, all state Boards of Pharmacy use the exam as one of a number of criteria a candidate must meet in order to be licensed as a pharmacist. Catizone Decl. ¶ 12. For example GA. COMP. R. & REGS. 480-2-.04(1) states that "For licensure, an individual must successfully pass the NAPLEX, a jurisprudence examination approved by the Board and a practical examination approved by the Board."

B. How is the NAPLEX Developed and Administered?

i. Development.

NABP develops the NAPLEX in compliance with recognized testing standards and practices (as set forth in the *Standards for Educational and Psychological Testing* endorsed by the American Educational Research Association, the American Psychological Association, and the National Council on Measurement in Education), and ensures that the NAPLEX is psychometrically sound, legally defensible, and free of bias. As such, the NAPLEX development process is both time consuming and expensive. Catizone Decl. ¶¶ 13 and 14.

Exam development first requires a national practice analysis to identify and assess the entry-level practice areas that a pharmacy candidate must know for competent practice. Based on an analysis of the national survey responses, a blueprint of the content areas that will need to

be assessed is then developed. Once the blueprint is identified, test items are developed to meet the content areas. Item writing is a learned skill and test-item writers need to be trained. An NABP committee of content experts (called the NAPLEX Review Committee, or “NRC”) convenes several times per year to draft and edit test items and responses. As part of their service on the NRC, every NRC member signs an agreement acknowledging the highly confidential nature of their work and also agreeing that NABP will be the owner of each examination produced. Once approved, an item is pre-tested for statistical analysis to ensure that it meets content and psychometrics standards. Assuming that the item survives, it is then placed in the “item bank” for use. The item bank is a “pool” of questions from which questions are drawn for each administration of the NAPLEX. Catizone Decl. ¶¶ 16, 20, and Ex. B. NABP obtains Certificates of Copyright Registration for its item-bank pool questions – for example the October 2006 Certificate of Copyright Registration No. TXu1-295-893 covers the NAPLEX examination questions that NABP staff have evaluated for purposes of comparison with the Warren materials, and is attached to the Verified Complaint as Ex. B. Catizone Decl. ¶ 27.

As Dr. Walter Steven Pray, who served on the NRC from 1987 until 2002,¹ has attested, security regarding the development of the NAPLEX test questions by the NRC is of paramount importance to NABP. This is due in large part to the nature of the NAPLEX itself. As Dr. Pray has explained, because the knowledge base required to become a competent pharmacist is vast

¹ As a member of the NRC, Dr. Pray’s duties included, but were not limited to: 1) creating new test items (both stand-alone and scenario-based); 2) reviewing items already in the test pool for validity and submitting substantive written comments thereon; 3) reviewing pre-test items and scored items with poor statistics to remedy deficiencies; 4) deciding whether a minimally competent student should be expected to correctly answer each test item in the pool; 5) examining test items in the pool to determine whether they were assigned to the correct competency level; 6) participating in score-setting procedures; 7) reviewing items submitted by other item writers to determine their suitability to become pre-test items; 8) determining whether test items already in the pool deserved to be withdrawn; and 9) assisting in the transition to the computer-assisted version of the NAPLEX. Pray Decl. ¶ 7.

(taught via hundreds of hours of lectures, laboratories, and practical experiences), it is difficult to determine whether a student has mastered all of the information necessary to become a minimally competent pharmacist. Thus there are two available methods of examination for minimal competence in pharmacy. The first method requires that an examiner ask several questions about each and every topic of pharmaceutical information taught to the student, requiring the student to have global knowledge of each topic prior to licensure. But this method is patently impossible due to the enormous amount of knowledge that is required of pharmacists and the time that such an examination would take to perform. For this reason, all standardized pharmacy exams (at least of which Dr. Pray is aware) use a second method, which measures global mastery of the given knowledge base by using a discrete subset of items. Under this method, each test item is meant to represent a larger group of possible items within a particular topic that could be asked. A correct answer to a specific item is interpreted to indicate that the student could have answered the larger group of items correctly. For example, correctly answering one item on the NAPLEX regarding use of antacids in pediatrics is used generally to assume mastery of a hypothesized larger group of potential items testing knowledge of antacid use in pediatric patients. Pray Decl. ¶¶ 8 and 9.

An important potential issue exists with this second method of examination. If potential examinees discover which items will be asked on the NAPLEX examination, they can learn only the answers to those particular items, but will appear to have mastered a larger group of items (when they in fact will have not done so). As a result, an examinee correctly answering a question based on having been “tipped off” about that question could mislead test administrators into rating the student minimally competent when he or she is not. For this reason, all

standardized test items must be kept in the strictest confidence to protect the integrity of the examination results. To that end, specific security measures that Dr. Pray recalls from his NRC membership include:

1. NAPLEX meetings were held in secured areas of hotels or in the NABP building.²
2. All NAPLEX testing materials were closely monitored at all times, and NABP required that all materials be returned when NRC members had finished with them. NABP consistently accounted for all materials distributed to NRC members.
3. Several times each year, NABP mailed item booklets to NRC members for review and comment, prior to a meeting. Members were instructed to keep these materials highly secured at all times.
4. Dr. Pray personally maintained his materials in a locked briefcase in his locked office, in a building that was locked each night. On certain occasions, Dr. Pray requested permission from the Dean's office to allow him to place items in the most highly secured area in the College of Pharmacy, a locked alcohol storage room located inside a locked stockroom. Dr. Pray often took materials home to better control access to them.
5. Dr. Pray shredded materials, at appropriate times, to prevent their misappropriation or dissemination.
6. Dr. Pray never discussed with any individual that he had secure materials at any time when those materials were in his possession.
7. Dr. Pray never discussed NAPLEX items with any person outside of NABP.

Pray Decl. ¶¶ 10 and 11.

ii. Administration.

Administration of the NAPLEX is an ongoing process, meaning that unlike the Bar Exam it is not given only twice a year. Rather, a student can take the NAPLEX by computer at

² Note that in 2004 NABP enhanced its exam security measures by hosting all NAPLEX meetings in the highly secure areas of the NABP building.

any of over 200 testing centers throughout the country, Monday through Saturday during normal business hours. This type of continuous testing provides a valuable service to both the state Boards and the test-takers, and is available due to the strength of the item bank. As items are selected from the item bank, sophisticated software ensures that each administration of the exam includes questions that cover the required various content areas without overexposing questions to similarly situated candidates. The currency, validity, and exposure rates of test items, among other things, are closely monitored to ensure the integrity of the exams. Catizone Decl. ¶ 17.

Security concerns are as paramount with the administration of the NAPLEX as with its development. The exam is administered under highly secure conditions, commencing with the check-in procedures. All candidates are required to have photo IDs for entry, and digital photos and fingerprints are taken at the test center. Candidates are not allowed to bring any materials into the test center. Once admitted to the exam, the candidates are continuously monitored by proctors, and video cameras are located throughout the test centers. Candidates may use only a calculator and a dry-erase board for notes and calculations, and all such calculators and dry-erase boards are provided at the beginning of the exam and then collected at the end by the test-center personnel. Candidates may NOT write or copy exam questions onto paper, diskettes, CDs, or anything else, nor may they have access to emails or engage in other electronic transmissions. Candidates cannot go back to a test item once an answer has been provided. Breaks are limited and monitored. To sit for the NAPLEX candidates must register with NABP and agree and acknowledge that the exam is proprietary, subject to copyright protections, and that activities or behavior that compromise the integrity of the exam will be pursued by NABP and reported to the state Boards of Pharmacy. Catizone Decl. ¶¶ 18 and 21.

As with all regulated professions, review courses designed to prepare candidates for the NAPLEX exam are widespread and generate significant revenue. As part of its security measures, NABP tracks these review courses, as well as the Internet, to ensure that no secure test questions are compromised. NABP staff also participate in NAPLEX review courses to monitor their content. Occasionally, egregious exam security issues such as the one in this case are uncovered. Catizone Decl. ¶ 22.

III. Warren's Repeated Infringement.

A. Mid-1990s.

In the summer of 1994, on the basis of multiple “tips” to NABP, Flynn W. Warren (“Warren”) was identified as an individual possibly gathering NAPLEX items (at the time the exam was referred to as the NABPLEX) through students and otherwise. NABP was told that Warren was asking students to remember NABPLEX items and to tell him about them for placement in review course materials. At the time Warren, though already licensed as a pharmacist in North and South Carolina, was also seeking licensure in Alabama. Rather than relying on “licensure transfer,” whereby his previous NAPLEX results could be used to substantiate competence without the necessity of taking the exam again, Warren had instead elected to sit for the NABPLEX again. Such activity raised concern that Warren was taking the NABPLEX in order to gather items rather than to attempt to “pass” the exam.³ Catizone Decl. ¶¶ 40 and 41.

³ NABP has since adopted exam policies that prohibit individuals who have already passed the test from taking the NAPLEX again, unless it is required by the state into which licensure is sought. Catizone Decl. ¶ 40.

Based on these concerns, NABP undertook an investigation of Warren in mid-1994. This investigation ultimately culminated with a letter to Warren from counsel for NABP, to which Warren responded with a letter from Susan L. Jones, Associate Vice President for Legal Affairs at the University of Georgia. Negotiations ensued and the matter was eventually referred to Georgia Assistant Attorney General Patricia Guilday. The parties ultimately settled the matter in October of 1995. Catizone Decl. ¶ 42 and Ex. G.

B. Present Day.

Unfortunately, Warren has returned to his infringing activities. On July 17, 2007, Professor Walter Steven Pray of Southwestern Oklahoma State University emailed Carmen Catizone, Executive Secretary of NABP, to inform NABP that he had learned that Warren was (again) disseminating NAPLEX exam questions to students in his review courses. Pray Decl. ¶ 21. Specifically, Dr. Pray had reviewed two websites of note:

- The first, “forums.studentdoctor.net,” which offered clues to passing the NAPLEX, discussed an individual named “Flynn” who offered a review course and notes on passing the NAPLEX. Specifically, one correspondent on the website suggested that prospective examinees review the comments sent to “Flynn” by other students, and another provided his address at the University of Georgia.
- The second, “TestMagicForum”, appeared to list actual NAPLEX items. Many of the threads provided detailed information regarding study tips from students who had just taken the NAPLEX, and several threads again referred to a “Dr. Flynn.”

Pray Decl. ¶¶ 15 and 16. Dr. Pray relayed his concerns to a fellow faculty member, Dr. Virgil Van Dusen, a lawyer and pharmacist, who shared with Dr. Pray that a mutual former student, Dr. Alan Spies of Samford University, had indicated to Dr. Van Dusen that Samford University had recently hired a gentleman to visit and prepare students for the NAPLEX, and that Dr. Spies had concerns regarding this individuals’ sharing of what appeared to be actual questions during the

course. Pray Decl. ¶ 18. Dr. Pray then personally contacted Dr. Spies on July 13, 2007 and confirmed that the visiting individual was Flynn Warren from the University of Georgia. Pray Decl. ¶ 18.

Dr. Spies had first learned that Warren was disseminating secure test questions – specifically a series of questions, some 2700 in number, that appeared to be very similar, if not verbatim, to questions asked on the NAPLEX – in May of 2007. Spies Decl. ¶ 7. Curious as to how a single individual had managed to amass such a large bank of test questions, particularly ones identical to the questions which appeared on the NAPLEX, Spies at that point began to investigate the matter in more detail. After discussing the issue with several of his pharmacy students, Dr. Spies was informed that during his review courses Warren encouraged students to not only write down or type all of the questions that they could remember after completing the NAPLEX, but then also to email the questions directly to Warren. Warren would then compile these questions and disseminate them to other students taking the exam. Spies Decl. ¶ 8.

Dr. Spies' suspicions regarding Warren were confirmed in July 2007, when Dr. Spies received an email sent to the entire graduating class of the Samford University School of Pharmacy (as a faculty member, Dr. Spies was included on the listserv to which the email was distributed). Spies Decl. ¶ 9. The email sent to Dr. Spies included an earlier email that had originally been sent by Warren to a Samford student (whose name has been redacted) on June 20, 2007. Pray Decl. Ex. B. The subject heading of the Warren email was “New NAPLEX Questions for 2007 Exam”, and the text of the email read “new questions on this year’s exam that could be forwarded to me”. The email also included an attachment that listed hundreds of NAPLEX questions, apparently sent to Warren by recent examinees, and included comments

from Warren. Pray Decl. ¶ 18 and Pray Decl. Ex. B. Several of the statements from students included in the attachment are as follows:

- “For the NAPLEX, my best advice is to review Flynn’s test questions The following is a list of things I had on my test. . . .”
- “READ WHAT OTHER STUDENTS SENT TO FLYNN. I had at least 20-25 VERBATIM questions.”
- “Make sure to study ALL questions submitted by others – it was a HUGE help (in fact, I probably could have gotten away with just studying old questions). THANK YOU FLYNN!”

Pray Decl. Ex. B (emphasis in original). The content of the email seemed odd to Dr. Spies, considering that the original email from Warren was dated June 20, 2007 and the earliest test takers (schools with early graduation dates) could not have taken the 2007 NAPLEX until approximately a month prior to dissemination of the information. It soon became apparent to Dr. Spies that individuals who had just taken the exam were sending Warren the questions, which he was in turn forwarding to students who had not yet taken the NAPLEX. Spies Decl. ¶ 9. Recognizing the impropriety of this conduct, Dr. Spies immediately (on July 17, 2007) sent the forwarded email to Dr. Pray (who was one of Dr. Spies’ former professors and who Dr. Spies knew had contacts at NABP). Spies Decl. ¶ 10; Pray Decl. ¶ 18. Dr. Pray then contacted NABP by email on July 17th and by telephone on July 20th. Pray Decl. ¶ 21.

Upon learning of Warren’s latest infringing activities, NABP quickly contacted counsel, and on July 30, 2007, Kerri Hochgesang, one of NABP’s attorneys, spoke on the telephone with the continuing education office of the College of Pharmacy at the University of Georgia, which indicated that Hochgesang could purchase course materials for the “Pharmacy Board Review” class offered by Warren at the University of Georgia on August 8, 2007 through August 10, 2007

at the College of Pharmacy for \$100.00. Hochgesang Decl. ¶ 3. On July 31, 2007, Hochgesang went to the fourth floor of the College of Pharmacy at the University of Georgia in Athens, Georgia and provided payment for the course materials. Hochgesang Decl. ¶ 4. In return for the payment, Hochgesang was provided with a packet of materials including: 1) documents; and 2) two CD-ROM disks. Hochgesang Decl. ¶ 5 and Hochgesang Decl. Exs. B, C-1 and C-2, and D-1 and D-2. Highlights from the material provided to Hochgesang include:

- Tab 1 of Hochgesang Decl. Ex. B, entitled “What’s on the Diskette?”, states: “Study guides prepared by students have been edited and comments or changes are often indicated . . . many of these files change as I try to edit them down to reduce unnecessary duplication.” Also, in the category “Info for NAPLEX,” there is a description that reads, “Material from students from prior years.” Hochgesang Decl. ¶ 7. The author of the packet is indicated to be Warren at Tab 2 of Ex. B.
- Tab 3 of Exhibit D-1 is entitled “Information for NAPLEX – May 2006 and Forward.” Paragraph 4 (presumably written by a student), states: “Probably 80% of the questions came straight from the questions submitted by students and Flynn’s review test.” Hochgesang Decl. ¶ 9.
- Numbered paragraph 41 at Tab 4 of Exhibit D-1 shows a student relaying an actual question from the NAPLEX and Warren reading and commenting on it before reproducing it for distribution in the course materials:

Given a situation where a nurse is removing an IV line from an HIV positive patient and gets stuck with the needle. The test gives you a chart and you have to determine what her treatment should be. Essentially, just know that the exposure was through the skin and that she was exposed to blood (which is given in the question), look at the corresponding treatment beside this, and then ensure you select the correct option as your answer. SIMILAR QUESTION WITH MORE PATIENT INFO ... RN stuck herself with a needle while removing an IV line from a patient known to have HIV. Gives you a table on when to offer or not offer prophylaxis. She would be a candidate to offer prophylaxis, however she was already taking HIV medications - Not sure what to do or where they were going with this question. From Flynn – without seeing the table, I would say she WOULD NOT need prophylaxis is she is already responding well to therapy...”

Hochgesang Decl. ¶ 10.

- Numbered paragraph 804 at Tab 5 of Exhibit D-1 states: “I only studied the notes from Flynn’s review, and I felt very good about the exam when I left the testing site. The main packets I studied were the questions from other students and the practice exam. The ques. from students really helped out!” [Sic]. Similarly, numbered paragraph 1492 at Tab 6 of Exhibit D-1 states, “Biggest advice is to be able to do all of Flynn’s calculations and really study “the essentials” b/c I had lots of questions verbatim from it. I only studied his review notebook and glanced through the APhA pharmacy review book and I made a 136!” Hochgesang Decl. ¶ 11.

Further, a comparison of the Warren materials with NABP’s copyrighted NAPLEX test reveals numerous copyrighted NAPLEX examination questions. As of the date of the Catizone Declaration, NABP had assessed approximately 20% of the Warren materials, and the number of substantially similar items contained therein exceeded 150. Catizone Decl. ¶¶ 35, 36, and Ex. D.

IV. The Immediate Harm to NABP from Warren’s Infringement.

Activities such as those of Warren discussed herein are nothing short of devastating for the NAPLEX. Each item that is compromised through publication, or through use in Warren’s course materials, is no longer valid for measuring the competency of pharmacy graduates through use on the NAPLEX. Instead, these items must be discarded. When an item is discarded, it causes a significant loss to NABP. The cost of generating, validating, and reviewing a single item on the exam is incalculable. Many experts, professionals, and support personnel from around the country are involved in these activities, all at significant cost to NABP. As a result, the cost of replacing a single item on the NAPLEX could justifiably be estimated in the tens of thousands of dollars. A loss of hundreds or thousands of items, as it appears has occurred through Warren’s activities, will require NABP to re-populate its item bank to replace compromised items at a significant cost to the association. Re-populating the item

bank without interruption to the NAPLEX creates significant additional hardships to NABP. Of course, if the program must be shut down, applicants for licensure cannot be examined until a new, uncompromised NAPLEX can be created. Pray Decl. ¶ 22.

Further, a student who has attended one of Warren's training courses, who has reviewed his materials, or who has read pirated questions could be suspect in regard to their competency to practice pharmacy. If students without minimal competency have nonetheless passed the NAPLEX, there could be a threat to public health. The state Boards rely upon NABP and the NAPLEX scores in licensing new pharmacists, and Warren's activities could significantly damage the organization's viability and reputation. Pray Decl. ¶ 23.

For these and other reasons discussed in more detail below, NABP now seeks a temporary restraining order to prevent Warren from further disseminating the NAPLEX test questions.

III. ARGUMENT AND CITATION OF AUTHORITY

To obtain a temporary restraining order or preliminary injunction a plaintiff must show:

1. A substantial likelihood of success at trial on the merits;
2. An immediate and real threat of irreparable injury;
3. That the imminent harm to the plaintiff if the relief is not granted is greater than the harm to the defendant if an injunction is imposed; and
4. That granting the injunction is in the public interest.

E.g., Shatel Corp. v. Mao Ta Lumber & Yacht Corp., 697 F.2d 1352, 1354-55 (11th Cir. 1983).

As shown below, NABP has satisfied each of these elements. Furthermore, immediate injunctive relief is particularly appropriate in copyright infringement cases such as this one because irreparable injury or harm to the original creator of the work is inherent. *E.g., Ass'n of Am. Med.*

Colls. v. Mikaelian, 571 F. Supp. 144, 154 (E.D. Pa. 1983). NABP is therefore entitled to a temporary restraining order and preliminary injunction enjoining Warren and the University of Georgia from using any NAPLEX test questions in any manner pending the final outcome of this action.

A. Substantial Likelihood of Success on the Merits.

The Copyright Act provides copyright protection for “original works of authorship fixed in any tangible medium of expression.” 17 U.S.C. § 102(a). The owner of a copyright has the exclusive rights to reproduce its copyrighted work, to prepare derivative works based on the copyrighted work, to distribute copies of the copyrighted work, and to publicly display the copyrighted work, among others. 17 U.S.C. § 106. Anyone who engages in one of these acts without the permission of the copyright owner commits copyright infringement. 17 U.S.C. § 501(a). To establish copyright infringement, a plaintiff must prove ownership of a valid copyright and copying of the original elements of the protected work. *E.g.*, *Nat’l Conference of Bar Exam’rs v. Multistate Legal Studies, Inc.*, 458 F. Supp.2d 252, 256 (E.D. Pa. 2006); *Nat’l Conference of Bar Exam’rs v. Saccuzzo*, No. 03CV0737BTM, 2003 WL 21467772, at *5 (June 10, 2003) (hereinafter “*Saccuzzo*”). Here, NABP has satisfied both elements.

1. Ownership.

NABP is the owner of the copyrights in the NAPLEX questions that are appearing in Warren’s review materials. The October 2006 Certificate of Copyright Registration No. TXu1-295-893 covers the NAPLEX examination questions that NABP staff have evaluated for purposes of comparison with the Warren materials and is attached to the Verified Complaint as Ex. B. This certificate constitutes prima facie evidence of the validity of NABP’s copyright in

the test questions at issue. 17 U.S.C. § 410(c); *see also, e.g., Saccuzzo*, 2003 WL 21467772 at *5; *Educ. Testing Serv. v. Simon*, 95 F. Supp.2d 1081, 1087 (C.D. Cal. 1999) (hereinafter “*Simon*”); *Ass’n of Am. Med. Colls.*, 571 F. Supp. at 149. The certificate thus establishes that the test questions at issue are original and copyrightable and that NABP has complied with the statute in registering them. *Ass’n of Am. Med. Colls.*, 571 F. Supp. at 150.⁴ Further, as part of their service on the NRC, every NRC member signs an agreement that NABP will be the owner of each examination produced. Catizone Decl. ¶¶ 20 and Ex. B.

2. Copying.

To establish the second prong of copyright infringement, the plaintiff must prove, as a factual matter, that the alleged infringer “actually used the copyrighted material to create his own work.” *Bateman v. Mnemonics, Inc.*, 79 F.3d 1532, 1541 (11th Cir. 1996). Proof of copying may be shown either by direct evidence of copying or, in the absence of such evidence, “[c]opying as a factual matter typically may be inferred from proof of access to the copyrighted work and ‘probative similarity.’” *Id.* Moreover, if the plaintiff successfully demonstrates that the portion of the copyrighted work taken satisfies the originality requirement, he must still prove that “the copying of copyrighted material was so extensive that it rendered the offending and copyrighted works substantially similar.” *Id.* at 1542.

In the instant case, Warren obtained access to NABP’s NAPLEX questions through students who had recently taken the exam and provided the information. Spies Decl. ¶¶ 8 and 9;

⁴ In addition, the copyrightability of these types of secure test questions has been repeatedly upheld by the courts. *See, e.g., Saccuzzo*, 2003 WL 21467772 at *8 (“The courts have uniformly found that questions and test forms for secure examinations are subject to copyright protection.”); *see also Educ. Testing Servs. v. Katzman*, 793 F.2d 533, 539-40 (3d Cir. 1986) (rejecting the defendant’s argument that copyright protection could not attach to test questions because the idea or subject of the material being tested merged with its expression, stating: “It is apparent on the face of the materials that ETS’ questions do not represent the only means of expressing the ideas thereon.”).

Pray Decl. Ex. B. Such is sufficient to show access for purposes of establishing copyright infringement. *See, e.g.*, 4 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 13.02[a] (“[E]vidence that a third party with whom both the plaintiff and defendant were dealing had possession of plaintiff’s work is sufficient to establish access by defendant.”). It is irrelevant whether Warren asked the students for this material or whether the students provided it unsolicited. *E.g.*, *Saccuzzo*, 2003 WL 21467772 at *6; *Simon*, 95 F. Supp.2d at 1087. Furthermore, even in the absence of such evidence regarding access, access can be presumed in this case on the basis of the striking similarity between the test questions in Warren’s review materials and the actual NAPLEX test questions (as illustrated below). *E.g.*, *Ass’n of Am. Med. Colls.*, 571 F. Supp. at 151 (“Where the allegedly infringing work is so strikingly similar to the protected work as to preclude the possibility of independent creation, copying may be proved even without the showing of access that has been made in this case.”).

Having shown that Warren had access to NABP’s secure questions, to establish copying NABP must show a substantial similarity between its NAPLEX questions and the questions used in Warren’s review materials. Substantial similarity does not require verbatim copying; a review course such as Warren’s cannot escape copyright liability by claiming that its copying of secure test questions is not word-for-word. Immaterial variations do not alter the conclusion that infringing material is substantially similar to copyrighted material. *E.g.*, *Saccuzzo*, 2003 WL 21467772 at *6; *Simon*, 95 F. Supp.2d at 1088. Nor is there a question in this case that the NAPLEX exam questions copied by Warren would constitute original, copyrighted material. *E.g.*, *Nat’l Conference of Bar Exam’rs*, 458 F. Supp.2d at 259 (“MBE questions may reflect original expression in their wording, particularized facts, and answer choices. . . . Teaching the

legal principles tested on the MBE is permissible. Doing so using the same fact patterns, prompts, and answer-choice combinations is not.”).

In this case, a side-by-side comparison of the Warren materials with NABP’s copyrighted NAPLEX test reveals numerous copyrighted NAPLEX examination questions. As of the date of the Catizone Declaration, NABP had assessed approximately 20% of the Warren materials, and the number of substantially similar items contained therein exceeded 150. Catizone Decl. ¶¶ 35 and 36 and Ex. D.

3. Vicarious Liability.

For all of the foregoing reasons NABP has demonstrated a likelihood of success on the merits of its copyright infringement claim against Warren, the purveyor of the infringing review materials. Further, based on Warren’s liability NABP has also demonstrated a likelihood of success against the Board of Regents of the University System of Georgia for vicarious copyright liability. A copyright defendant will be vicariously liable for the actions of a primary infringer where the defendant: 1) has the right and ability to control the infringer’s acts, and 2) receives a direct financial benefit from the infringement. *See, e.g., Fonovisa, Inc. v. Cherry Auction, Inc.*, 76 F.3d 259, 261-64 (9th Cir. 1996). In the instant case the University of Georgia both had the right and ability to control Warren’s activities and received a financial benefit from his infringement, for all of the following reasons:

- To purchase Warren’s review materials Kerri Hochgesang spoke on the telephone with an employee in the continuing education office of the College of Pharmacy at the University of Georgia. Hochgesang Decl. ¶ 3.
- The “Pharmacy Board Review” class is currently being offered by Warren at the University of Georgia on August 8, 2007 through August 10, 2007 at the College of Pharmacy. Hochgesang Decl. ¶ 3.

- The employee in the continuing education office of the College of Pharmacy at the University of Georgia indicated that Hochgesang could purchase Warren's review materials for \$100.00, and that she would be able to sell them to Hochgesang in an office at the College of Pharmacy. Hochgesang Decl. ¶ 3.
- Hochgesang provided her payment for the Warren review materials in an office on the fourth floor of the College of Pharmacy at the University of Georgia. Hochgesang Decl. ¶ 4.
- Hochgesang's payment receipt for the course materials was from "UGA Pharmacy Cont ED, Pharmacy Building." Hochgesang Decl. ¶ 4 and Ex. A.
- While Warren recently retired from the University of Georgia College of Pharmacy (on July 1, 2007), he plans to continue his Reviews (which he predicts will increase in number), still maintains an e-mail address at the University of Georgia, fwarren@mail.rx.uga.edu, and will likely continue to maintain his University of Georgia office phone number. Hochgesang Decl. ¶ 8 and Ex. B.

All of the foregoing clearly shows that the University of Georgia is vicariously liable for Warren's copyright infringement.

B. Irreparable Harm.

Generally, in any action for copyright infringement, a showing of likelihood of success on the merits raises a presumption of irreparable harm. *E.g., Ass'n of Am. Med. Colls.*, 571 F. Supp. at 154. In addition, in cases such as this one that involve compromised test questions, courts have repeatedly found that the irreparable harm to the copyright holder goes well beyond the basic harm that a typical copyright plaintiff would suffer. Courts have identified at least two types of irreparable harm in such cases. The first can be labeled the "investment" harm. Because secure test questions, which are developed using significant expenditures of time, effort, and money, are rendered worthless through disclosure, and because it requires additional significant expenditures of time, effort, and money to identify and cure previous tests that may have been compromised by the dissemination of secure test questions, infringements such as

those perpetrated by Warren in this case will, if left unchecked, cause irreparable harm to organizations such as NABP. *See, e.g., Educ. Testing Servs. v. Katzman*, 793 F.2d 533, 544 (3d Cir. 1986) (“In this case, there was adequate evidence of the expenditure of significant time, effort, and money directed to the production of copyrighted material. . . . Moreover, there was ample evidence of the effort ETS must undertake when secure questions have been misappropriated, and the inconvenience caused thereby to support the finding of irreparable harm.”); *Saccuzzo*, 2003 WL 21467772 at * 11 (“The disclosure of student recollections of secure test materials by Defendants renders the material worthless to NBCE.”); *Simon*, 95 F. Supp.2d at 1086-87 (“If defendants are not permanently enjoined from copying ETS’s copyrighted test questions and forms, ETS faces the possibility of having to write new questions and undergo similar overhauls of its test forms and questions in the future”); *Ass’n of Am. Med. Colls.*, 571 F. Supp. at 154 (“Obviously, continued use of copyrighted test questions by Multiprep could make worthless AAMC’s stock of MCAT questions. These questions are the result of years of painstaking research and testing. Monetary damages could not compensate AAMC for this damage.”) (citations omitted).

This “investment” harm is as equally applicable in this case as it has been in previous secure test question cases. As Dr. Pray has noted, activities such as those of Warren discussed herein are nothing short of devastating for the NAPLEX. Each item that is compromised through publication, or through use in Warren’s course materials, is no longer valid for measuring the competency of pharmacy graduates through use on the NAPLEX. Instead, these items must be discarded. When an item is discarded, it causes a significant loss to NABP. The cost of generating, validating, and reviewing a single item on the exam is incalculable. Many experts,

professionals, and support personnel from around the country are involved in these activities, all at significant cost to NABP. As a result, the cost of replacing a single item on the NAPLEX could justifiably be estimated in the tens of thousands of dollars. A loss of hundreds or thousands of items, as it appears has occurred through Warren's activities, will require NABP to re-populate its item bank to replace compromised items at a significant cost to the association. Re-populating the item bank without interruption to the NAPLEX creates significant additional hardships to NABP. Of course, if the program must be shut down, applicants for licensure cannot be examined until a new, uncompromised NAPLEX can be created. Pray Decl. ¶ 22.

The second harm that courts have identified in secure test question cases can be labeled the "integrity" harm. Simply stated, when secure test questions (such as the NAPLEX questions in this case) are copied and then disseminated by infringers such as Warren, such actions compromise the entire integrity of the test from which they were taken. Some students – namely those with access to the illicit exam questions – will be afforded an unfair advantage, and the integrity of the exam itself, the organization that administers it, and the profession that it is used to screen applicants for will be called into question. *See, e.g., Katzman*, 793 F.2d at 544 ("Such disclosure of ETS' tests could result in invalidation of certain test scores and thereby undermine the integrity and reputation of ETS and its tests in the eyes of colleges and students."); *Nat'l Conference of Bar Exam'rs*, 458 F. Supp.2d at 262 ("By exposing its students to questions likely to appear on the MBE, PMBR undermined the integrity of the bar examination, possibly causing the admission of unqualified applicants. That the victims of this harm are impossible to identify and the injury impossible to quantify underscores the need to deter would-be copyright infringers."); *Simon*, 95 F. Supp.2d at 1086-87 ("If defendants are not permanently enjoined

from copying ETS's copyrighted test questions and forms . . . it is likely that defendants' customers will enjoy an unfair advantage over other test-takers.").

Absent protection for the integrity of their tests – which is maintained at least in part through the kinds of relief sought here – the harm to testing organizations such as NABP will be irreparable. As Dr. Pray has noted, a student who has attended one of Warren's training courses, who has reviewed his materials, or who has read pirated questions could be suspect in regard to their competency to practice pharmacy. If students without minimal competency have nonetheless passed the NAPLEX, there could be a threat to public health. The state Boards rely upon NABP and the NAPLEX scores in licensing new pharmacists, and Warren's activities could significantly damage the organization's viability and reputation. Pray Decl. ¶ 23.

Moreover, as multiple courts have recognized, for organizations such as NABP the infringement of their test questions is not simply a minor inconvenience that can be quickly and easily addressed. Rather such infringement, if unchecked, will completely destroy the entire secure testing industry. *See, e.g., Ass'n of Am. Med. Colls.*, 571 F. Supp. at 154 (“Monetary damages could not compensate AAMC for this damage. Its procedures would not be capable of replenishing the valid test questions at a rate fast enough to allow continued administration of the MCAT in its present form.”). If the general public, or state Boards of Pharmacy, begin to question the integrity of licensing exams such as the NAPLEX and begin to assume that the results are not reliable, then the utility of such exams as a means of deciding who is and who isn't admitted to a chosen profession will be destroyed.

C. Balancing the Hardships.

The third requirement to obtain a temporary restraining order or preliminary injunction is to demonstrate that the imminent harm to the plaintiff is greater than the harm to the defendant if an injunction is imposed. *E.g., Scientific Applications, Inc. v. Energy Conservation Corp.*, 436 F. Supp. 354 (N.D. Ga. 1977). In the instant case the harm to the Defendants if an injunction is imposed will be slight. Warren, and the University of Georgia, will certainly be able to continue to provide their NAPLEX review course – they simply won't be able to improperly use NABP's secure test questions to do so. *See, e.g., Ass'n of Am. Med. Colls.*, 571 F. Supp. at 154 (“Multiprep certainly has a right to operate its test preparation business in a legitimate manner. Multiprep has no right, however, to profit from copyright infringement.”).

Conversely, the harm that NABP stands to suffer if a TRO is not granted in this case will be substantial. Every day that goes by that Warren is not enjoined could exponentially increase the number of NAPLEX test questions and tests that are compromised. And with each additional compromised test NABP will suffer additional harm, both in terms of lost investment and lost integrity. Thus, the threat of immediate and irreparable harm to NABP greatly outweighs any harm that Warren and the University of Georgia would suffer if required to cease their infringing acts.

D. Public Interest.

The final requirement for a temporary restraining order or preliminary injunction is to show that the relief would be in the public interest. In the copyright context “[i]t is virtually axiomatic that the public interest can only be served by upholding copyright protections and,

correspondingly, preventing the misappropriation of the skills, creative energies, and resources which are invested in the protected work.” *Am. Ass’n of Med. Colls.*, 571 F. Supp. at 156.

However, the public interest in an injunction in this case extends beyond the basic public interest in preventing the infringement of copyrights. Rather, as courts have recognized, the public has a compelling interest in knowing that the exams that are used by state licensing boards to decide who can perform what profession are not compromised. *E.g., Nat’l Conference of Bar Exam’rs*, 458 F. Supp.2d at 262 (“Defendants’ willful and egregious copyright infringement harmed the public as well as the plaintiffs. States have a compelling interest in regulating admission to the bar both to maintain the integrity of the legal system and to protect the safety of their citizens.”).

While not to minimize the importance of reliable licensing procedures in professions such as law or engineering or architecture, it is beyond dispute that the public interest identified in the Bar Exam context in *Nat’l Conference of Bar Exam’rs* is **significantly** increased in cases dealing with the licensing of medical professionals such as physicians and pharmacists. Simply stated, when a customer enters a pharmacy to have a prescription filled, they obviously have a strong interest in knowing that the pharmacist filling their prescription is qualified to do so, and was not licensed simply because he or she was able to obtain licensing by using Warren’s illicit preparation materials. The vehicle that the State of Georgia has chosen to ensure that “only qualified persons be permitted to engage in the practice of pharmacy”, O.C.G.A. § 26-4-2, is the NAPLEX. *See GA. COMP. R. & REGS.* 480-2-.04(1). For this reason it is difficult to imagine **any** case where the public interest in an injunction preventing further copyright infringement would be stronger than it is here.

IV. CONCLUSION

For the foregoing reasons, NABP's Application for Temporary Restraining Order and Motion for Preliminary Injunction should be granted, and both Warren and the Board of Regents of the University System of Georgia should be enjoined from further use of the NAPLEX secure exam questions.

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Respectfully submitted,

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