UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

K & S ASSOCIATES, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**No. 3:09-1108**
	)	**JUDGE SHARP**
AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE,	)	
	)	
	)	
Defendant.	)	

FINDINGS OF FACT AND CONCLUSIONS OF LAW

From February 5, 2013, to February 11, 2013, the Court held a bench trial on Plaintiff K&S Associates, Inc.'s ("K & S'") request for injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, based upon Defendant American Association of Physicists in Medicine's ("AAPM's") alleged violation of Section 1 of the Sherman Act, 15 U.S.C. §1. At the conclusion of the bench trial, the parties were provided the opportunity to provide proposed findings of fact and conclusions of law, and responses and replies thereto. The last of those filings was made on April 16, 2013.

Having reviewed the parties' proposed findings and conclusions, their arguments, the record, the exhibits received in evidence, and the testimony of the witnesses, after considering their interests and demeanor, the Court enters the following Findings of Fact and Conclusions of Law in accordance with Rule 52(a) of the Federal Rules of Civil Procedure. Except where the Court discusses different testimony on a specific issue, any contrary testimony on a specific matter has been rejected in favor of the specific fact found. Further, the Court omits from its recitation facts which it deems to be immaterial to the issues presented.

I. FINDINGS OF FACT

1. The AAPM is a non-profit, 501(c)(3) scientific and professional society comprised of approximately 8,000 medical physicist members. Formed in the 1950s, the AAPM has since expanded to include numerous committees and task groups promoting scientific research in the field of medical physics.

2. Among other things, and most pertinent to this case, the AAPM controls the accreditation process for "Accredited Dosimetry Calibration Laboratories" ("ADCLs")[1] in the United States. The "Calibration Laboratory Accreditation" subcommittee of the AAPM ("CLA") has the primary responsibility for overseeing, accrediting, and periodically re-accrediting the ADCLs.

3. The voting membership of the CLA is referred to as the "CLA-X," and is comprised of AAPM volunteer members who are supposed to have no personal, employment-related, or financial interest in any ADCL. CLA-X members are tasked with making recommendations to the AAPM Board of Directors on the accreditation of ADCLs.

4. ADCLs calibrate a line of commercial products broadly classified as "dosimetry" equipment that (generally) is designed to determine precise doses of radiation, and assess the extent to which tissues have absorbed radiation during the course of radiation therapy. As such, clinical physicians depend on ADCL calibrations of dosimetry equipment to provide accurate information, particularly in the cancer treatment field.

5. Virtually every major medical facility in the United States that provides radiation therapy treatment requires periodic calibration of its dosimetry equipment. Presently, there are approximately 2,500 such end users of calibration services in the country. The only practical way

[1] Previously, ADCLs were known as RCLs, or Regional Calibration Laboratories.

to have the dosimetry equipment properly calibrated is through a laboratory accreditation by the AAPM.[2]

6. K&S was incorporated in 1972 and began business as a physics consulting group. In 1982 it built a dosimetry equipment calibration laboratory, became accredited that year by the AAPM, and has remained so accredited to this date.

. 7. The first ADCLs were located at the M.D. Anderson Cancer Center in Houston, Texas, Memorial Sloan-Kettering in New York City, and Victoreen, in Cleveland, Ohio.

8. Victoreen also manufactured dosimetry equipment and when concerns were raised about the quality of calibrations and the influence placed on it because of its manufacturing interests, Victoreen elected to discontinue its involvement in calibrating dosimetry equipment. At some point (apparently in the early 2000s), Memorial Sloan also left the field. The AAPM has not accredited any new ADCLs since 1983, and, apparently, the only application for accreditation (from the U.S. Army Calibration and Repair Center) received by the AAPM was rejected.

9. Presently then, there are three ADCLs in the United States: K&S, the University of Wisconsin, in Madison ADCL ("UW ADCL"), and the M.D. Anderson Cancer Center ADCL in Houston, Texas ("MDA ADCL"), which is affiliated with the University of Texas.

10. The UW ADCL has approximately 60% of the market (based upon the number of required dosimetry equipment calibrations performed in a given year), followed by K&S at approximately 34%, and MDA ADCL at approximately 6%. Those percentages of market shares have remained relatively constant since 2005.

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[2] Theoretically, the National Institute of Standards and Technology ("NIST") could perform the calibrations, but, as a practical matter, it is without the resources to do so, and has deferred to the AAPM to regulate calibrations.

11. The director of the UW ADCL is, and was at all relevant times, Larry DeWerd, Ph.D. Dr. DeWerd was a founder and also owns one-third of Standard Imaging, Inc. ("Standard Imaging"), a Wisconsin corporation that manufactures dosimetry equipment. He is also a member of Standard Imaging's Board of Directors as well as its "chief science officer" and "radiation safety officer." Dr. DeWerd has been very active in the affairs of the AAPM over the course of many years, particularly those of the CLA.

12. The director of the MDA ADCL since 2006 is Geoffrey Ibbott, Ph.D., a former President and Chairman of the AAPM Board of Directors. Dr. Ibbott, too, has been very active in the affairs of the CLA over the course of many years.

13. The director of K&S ADCL is Thomas W. Slowey. He, too, has been very active in the CLA.

14. All three laboratory directors were, at all relevant times, non-voting members of the CLA.

15. The CLA has developed guidelines for ADCL accreditation,[3] and all three laboratory directors have been involved in the process. The most recent version of the accreditation criteria is dated July 2006. Generally,

> A calibration laboratory retains its accreditation at the discretion of the AAPM. The AAPM will normally have no reason to consider revocations as long as the performance on efficiency tests are [sic] satisfactory, the procedures of the laboratory are in accordance with approved protocols, and its personnel or performance are [sic] not significantly changed.

(Pf. Ex. 33). However, the Criteria also includes conflict of interest provisions, and Mr. Slowey is

[3] The guidelines governing ACDLS have been updated and revised over the years and are are currently known as the "Criteria for Accreditation of Dosimetry Calibration Laboratories," or the "Criteria."

a principal architect of what is know known as Section 1.B.2 which provides, in pertinent part:

. **GENERAL REQUIREMENTS FOR ACCREDITATION**

* * *

2. Free of conflict of interest

> The applicant institution must be free of any conflict of interest with regard to its ownership and/or business and its responsibility to provide unbiased calibration results, technical advice, and assistance to the AAPM membership. The applicant must comply with the requirements of paragraphs 4.1.4 and 4.1.5 later in this document.
>
> The AAPM accreditation is a voluntary activity of the association conducted for the benefit of the AAPM membership and to promote the application of physics to medicine and biology under ARTICLE 3 of its Charter. Its primary objective is to establish and maintain the highest quality secondary standard dosimetry system in the US. It is not established for the benefit of commercial organizations engaged in the manufacture, marketing, distribution or sale of dosimetry instrumentation, since this would represent a conflict of interest under the ADCL's role as a technical advisor and since there are other agencies, such as the National Voluntary Laboratory Accreditation Program (NVLAP) and the American Association for Laboratory Accreditation (A2LA), which currently provide accreditation programs to serve commercial interests.

(Def. Ex. 38).[4]

16. Section 1.B.2 has been understood for years by most members of the CLA-X to mean that the AAPM would not grant ADCL accreditation to a manufacturer of dosimetry equipment.

17. The independence of the accreditation body in the United States may be somewhat unique. For example, it not uncommon for a dosimetry equipment manufacturer to own a calibration laboratory, and, in Germany,[5] such laboratories also act as secondary standards laboratories in much

[4] The provisions about labs being free of any conflict of interest with regard to ownership and/or business interests, and about the AAPM not being for the benefit of enterprises engaged in the manufacture, marketing, distribution of dosimetry instruments appeared in earlier incarnations of the Criteria and, indeed, the 1999 version contains virtually identical language.

[5] The majority of the European dosimetry equipment manufacturers are located in Germany.

the same fashion as an ADCL. Even so, the German secondary standards dosimetry calibration laboratory network is not overseen by a non-profit society like the AAPM, but rather is overseen by paid personnel specifically assigned to that duty, or by governmental personnel.

18. Which model better serves the medical physicist is open to debate, but the AAPM model may garner more confidence because there is a lesser chance that the calibrations (and their interpretations) are influenced by the manufacturer that makes the instruments being tested. Moreover, without the potential influence of the manufacturers, there may be more open communications between ADCLs that may otherwise be reluctant to share information with a lab that is connected to a manufacturer. Still, the potential for conflicts of interest may be somewhat minimized through the promulgation and enforcement of appropriate standards of conduct that separate the management of the laboratory from the manufacturer.

19. The AAPM's conflict of interest provision arose in 1999, when Inovision Radiation, a manufacturer of dosimetry equipment, expressed interest in joining the ADCL network. Inovision contested the conflict of interest provision and lobbied the ADCL subcommittee and then-committee chair, Dr. Geoffrey Ibbott, in an attempt to persuade the committee that the ADCL Criteria should not exclude manufacturers of dosimetry equipment.

20. An outspoken critic of Inovision becoming an ADCL was K&S's Mr. Slowey,[6] and he made his feelings known in a series of memorandums, emails and letters to the subcommittee as a whole, to some of its members, and to its chair, Dr. Ibbott. Just by way of examples: (1) On September 27, 1999, Mr. Slowey sent an email to the subcommittee in which he stated, "If we allow

[6] Drs. DeWerd and Ibbott also opposed the idea of a dosimetry instrument manufacturer becoming an ADCL.

one manufacturer to breach our criteria which specifically excludes them due to the conflict of interest issue, all the manufacturers will want and demand accreditation because it is cheaper than NVLAP because it is a voluntary activity of the Society"; (2) In a memorandum to the subcommittee and the Diagnostic Imaging Committee some two weeks later, Dr Slowey wrote, "Inovision's request for accreditation should be rejected on the basis of the conflict of interest issue identified in our Criteria. The issue of freedom from a conflict of interest is clearly stated. Dosimetry instrument manufacturers are identified as having a conflict of interest with the requirement that the ADCLs provide unbiased and impartial technical advice and assistance to the AAPM membership"; and (3) In a November 23, 1999 email to Dr. Ibbott, Mr. Slowey wrote, "I think it important to be firm on the conflict of interest with regard to unbiased advice. . . . . Is a dosimetry manufacturer biased? Absolutely! Can the calibration lab personnel escape the bias if it's [sic] existence depends on it's [sic] companies [sic] sale of instruments? No! Is there a perception on the part of the AAPM membership that the advice would be biased? Absolutely!"

(Def. Exs. 9, 14 & 15).

21. In an undated letter sent some time prior to the July 2000 annual AAPM meeting, Dr. Ibbott wrote Inovision a letter, informing it of the AAPM's concern about a potential conflict of interest, and the AAPM's reluctance to consider commercial laboratories for ADCL accreditation. Ultimately, Inovision never formally submitted an application for accreditation.

22. In early 2008, Mr. Slowey and Dr. Christian Pychlau, the majority owner of PTW-Freiburg Physikalisch-Technische Werkstaetten Dr Pychlau GmbH ("PTW-Freiburg") began discussing PTW-Freiburg's possible purchase of K&S. PTW-Freiburg is a competitor of Standard Imaging, and has a subsidiary in New York involved in customer service and sales of its dosimetry

equipment in North America.

23. After a site visit and reflecting on the matter, Dr. Pychlau sent Mr. Slowey an email dated April 14, 2008, indicating that PTW-Freiburg was "stepping back from [its] acquisition plans" over concerns about the equipment and "uncertainties," including the possibility of the other "ADCLs frowning at a laboratory owned by a major supplier[.]" (Def. Ex. 1). In response, Mr. Slowey recognized the concern about a conflict of interest, but wrote that K&S had an "established reputation that will not change with ownership," that he did "not believe that the AAPM will have any problems with your ownership as long as there is a separation of management," and that "there is no language in the AAPM Criteria or Quality Manual that would limit the ownership of an ADCL." (Id.). Dr. Pychlau replied that his company had contacted the AAPM to inquire about the conditions for an ADCL, that AAPM's response made PTW-Freiburg "nervous," and requested that K&S secure a "statement from the APPM responsible" because that "would be somewhat reassuring." Similar e-mail exchanges followed, but, ultimately, PTW-Freiburg decided to go forward with the acquisition.

24. In August of 2008, the parties entered into a tentative agreement. A condition precedent to the agreement was that the K&S laboratory would maintain its accreditation. Indeed, the August 28, 2009, Letter Agreement between the parties provided:

> 2. Third-Party and Governmental Approvals. All third-party and governmental consents and approvals must be obtained. . . . Without limiting the above, the approval of the accreditation authorities AAPM, A2LA and HPS for ownership transfer of the calibration laboratory must be obtained prior to closing.

(Pf. Ex. 70).

25. Mr. Slowey immediately set about to seek assurances from the AAPM that PTW-Freiburg's ownership would not result in revocation of K&S's accreditation. The day after entry

into the tentative agreement, he called and wrote Jan Seuntjens, Ph.D., the then Chair of the CLA. In a letter which confirmed the phone call, Mr. Slowey informed Dr. Seuntjens that PTW-Freiburg and K&S had reached an agreement, that he had informed PTW-Freiburg about the need to maintain separation between the laboratory management and the parent companies as required by Sections 4.1.4 and 4.1.5 of the Criteria,[7] and that K&S would answer only to the highest level of management at PTW-Freiburg. Mr. Slowey closed by requesting Dr. Seuntjens "as Chair of the CLA to indicate your recommendations regarding any needed changes in policies and procedures that would be needed to satisfy the APPM Criteria and maintain the APPM accredited status of K&S." (Def. Ex. 26).

26. By letter dated August 29, 2008, Dr. Seuntjens responded, stating that he had discussed the matter with his co-Chair, Malcolm McEwen, Ph.D., and that the letter contained their combined thoughts. The letter quoted Section 1.B.2 of the Criteria, and highlighted a "number of potential concerns regarding the change of status of the laboratory." The letter then sought clarification on a number of points, including the level of ownership to be transferred, the management structure and links to PTW-Freiburg, whether PTW-Freiburg equipment would automatically include K&S calibration, and whether K&S would continue to calibrate devices manufactured by others. The letter asked that K&S "submit a more substantial document to the CLA management," addressing

[7] Both of these sections are referenced in Section 1.b.2, the Conflict of Interest provision. Section 4.1.4 provides that "if the laboratory is part of a larger organization, the responsibilities of key personnel shall be defined in order to identify potential conflicts of interest," and, in an accompanying note, states that "if the laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests such as production, commercial, marketing of financial do not adversely influence the laboratory's compliance with the requirements of this standard." Section 4.1.5, in turn, sets out requirements for laboratories, including that they "[h]ave arrangements to ensure that [their] personnel are free from any commercial, financial and other pressures that might affect the quality of their work."

the concerns, and indicated that he could reply with an "official letter regarding accreditation status" once the issues "sensitive issues" had been addressed. (Def. Ex. 27).

27. In a letter signed by both Mr. Slowey and Dr. Pychlau dated September 9, 2008, K&S sought to address the concerns raised, and noted that it had been providing unbiased calibration results for 26 years, that the transfer of ownership would not affect that record, that the ownership of K&S would be disclosed, that its staff would remain the same, that it planned to retain its name and would offer calibration services for all dosimetry instrument manufacturers, and that it would have "an organizational structure, policies and procedures that minimize any adverse influence from manufacturing activities and comply with section 4.1.4 and 4.1.5 of the Criteria." (Def. Ex. 3).

28. By e-mail dated September 10, 2008, Dr. Seuntjens thanked Mr. Slowey for his "prompt reply letter which adequately addressed our concerns." He then went on to write:

> We believe at this moment that there is no particular urgency about the new structure until the acquisition by PTW is complete. The accreditation status will stay the same as long as the conflict of interest issue is addressed satisfactorily, continued accreditation until the surveillance visit can be maintained. We would plan to organize a surveillance visit at an agreed date in April of next year sometime after the acquisition by PTW has been completed.

(Def. Ex. 28).

29. In an email to Drs. Seuntjens and McEwen dated November 20, 2008, Mr. Slowey provided a draft of K&S's "Conflict of Interest Protocol." Among other things, the draft included the following:.

> **Organization**
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> K&S is organized as a separate, stand-alone corporation under the direction of a Board of Directors, composed of representatives of its owner and the officers and directors of the Laboratory, and having officers and technical personnel who manage the day-today operation of the Laboratory. While K&S is a wholly-owned subsidiary of a larger company, K&S is not part of the business of its owner as an independent

> business. K&S provide [sic] services to its owner in the same manner that it provides its services to other organizations. This structure is intended to allow K&S to operate as a third-party independent laboratory that is insulated by its Board of Directors from the business interests of its owner.
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> **Personnel Procedures**
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> 1. All Laboratory employees are required to sign a Confidentiality and Non-Disclosure Agreement.
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> * * *
>
> 5. Laboratory staff are required to report to management any actions or activities that may be an actual or perceived conflict of interest.
>
> 6. No activities may be undertaken by the Laboratory or its staff that could cast doubt upon the Laboratory's integrity or independence of judgment.

(Id. at pp. 2 & 3.).

30. Through the fall of 2008, Mr. Slowey and Drs. Seuntjens and McEwen continued to exchange letters and emails discussing potential conflict of interest policies and possible protocols. The discussions at this time were confidential and between these principals.

31. During this period, both Dr. Seuntjens and Dr. McEwen were of the view that the Accreditation Criteria, and specifically section 1.B.2 did not prohibit an ADCL's ownership by a manufacturer of dosimetry equipment, and that the "Conflict of Interest Protocol" that K&S and PTW-Freiburg had proposed were sufficient to manage the potential conflict of interest. It was understood by all concerned, however, that two additional steps remained: (1) Drs. Seuntjens and McEwen would conduct a "surveillance visit" of the K&S laboratory that would be largely focused on an assessment of the actual handling of the conflict of interest situation, and (2) the voting membership of the CLA, *i.e.*, the CLA-X would have to approve K&S's re-accreditation under its new ownership at the annual meeting of the AAPM in July 2009.

32. On January 16, 2009, having obtained what they considered to be satisfactory assurances of K&S's continuing accreditation under the circumstances, Mr. Slowey and Dr. Pychlau closed the purchase effective January 1, 2009. Still, they had not sought, nor received, official confirmation that K&S would remain accredited.

33. Less than three weeks after the sale was publicly announced, Larry G. Bryson, Associate Director of K&S, sent an e-mail dated February 15, 2009, to Dr. Pychlau, Mr. Slowey, and Edmund Schüele, Managing Director of PTW-Freiburg. In that e-mail, Mr. Bryson discussed Standard Imaging's Supermax and its warmup time. It was inappropriate for K&S as an ADCL to send this type of communication to to Mr. Schüele who is strictly involved in PTW's manufacturing and sales. The communication also violated K &S's own Conflict of Interest Protocol.

34. The public announcement of the acquisition on January 26, 2009, triggered a swift reaction from Standard Imaging (PTW-Freiburg's creditor), and from the UW ADCL.[8] On February 4, 2009, Ray Riddle, Standard Imaging's "Chief Regulatory Officer and Co-founder" emailed Dr. DeWerd seeking the contact information for Drs. Seuntjens and McEwen so that so that he could "write a letter against the PTW acquisition of K&S," and, shortly thereafter, sent Dr. DeWerd a "quick rough draft" of the letter. That same day, Dr. DeWerd sent Dr. Seuntjens an e-mail objecting to K&S' new ownership based upon section 1.B.2 of the Criteria. That email was forwarded by Dr. Seuntjens to Dr. McEwen the next day.

35. On February 9, 2009, Standard Imaging sent the final version of Mr. Riddle's letter to Drs. Seuntjens and McEwen. The letter concluded by stating that "Standard Imaging will take the

[8] There is a close relationship between Standard Imaging and UW ADCL, not only because of the geographical proximity, but also because Dr. DeWerd, the Director of the UW ADCL was one of the three founders of Standard Imaging, sits on its Board of Directors, and has owned one-third of the company since its formation in 1989.

actions deemed appropriate to prevent any manufacturer from operating an accredited dosimetry calibration laboratory in the U.S."[9]

36. On February 13, 2009, Dr. Paul DeLuca, the then-Chairman of the Advisory Committee of the UW ADCL and an active member of the AAPM, sent a letter to Drs. Seuntjens and McEwen. That letter, which was drafted with imput from Dr. DeWerd, stated, among other things, that the AAPM was "opening itself to possible litigation from other dosimetry equipment manufacturers to whom the conflict of interest is obvious."

37. The letters from Standard Imaging and the UW ADCL prompted Dr. Seuntjens to convene an *ad hoc* telephonic meeting with a majority of CLA-X members on February 29, 2009. Prior to that meeting, Dr. Seuntjens circulated an email containing a proposed agenda for the meeting and attaching seven documents, including the Standard Imaging and UW letters, copies of correspondence between Dr. Seuntjens and Mr. Slowey from the Fall of 2008, and K&S' conflict of interest policy.[10]

38. The minutes from the meeting indicate that the "Agenda" was "Discussion of K&S – PTW-Issue" and go on to state:

> 1. JS gave overview of K&S situation. Majority of members believe there is a conflict of interest. M Mc and JS point to inconsistency in the criteria about this.
>
> 2. Sialful Hug recommended that AAPM lawyers should be involved and that site visit go ahead quickly.

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[9] In response to that letter, Maryellen Giger, President of the AAPM, sent a letter to Standard Imaging dated April 15, 2009, stating that any future action should be directed to her, or to PTW-Freiburg.

[10] One of the recipients of the e-mail was Dr. David Followill, who is affiliated with M.D. Anderson as a result of his position with the Radiologic Physics Center. This Center is not a part of the M.D. Anderson ADCL.

> 3. Committee was in agreement on this. Action: JS to contact AAPM (TPC)[11] to ask for support.

(Pf. Ex. 13).[12]

39. On March 4, 2009, Dr. Seuntjens sent an e-mail to Ellen Yorke, Ph.D., the Chair of the TPC, of which the CLA was a subcommittee. The email noted "a somewhat worrisome matter," explained that K&S was acquired by PTW-Freiburg, and went on to discuss the letter received from Standard Imaging:

> . . . Standard Imaging is an ionization chamber manufacturer which has a friendly relationship with U. Wisconsin ADCL but they do not own the U. Wisconsin lab. The letter is quite aggressive and implies legal actions in response to any situation that would imply that a manufacturer would own a cal lab such as in the case of K7S. I also received a letter from Paul Deluca, the chair of the oversight committed of the U. Wisc. Lab criticizing the PTW ownership of K&S and asking action from CLA.
>
> We had a telephone conference with the CLA member, the lab directors excluded. We are concerned about this and have questions about which legal protection we have from the AAPM. We feel between a rock and a hard place. On the one hand, lifting the accreditation status would lead to a shortage of calibration capacity by the ADCLs left and would for certain lead to legal actions by K&S based on the fact that they follow 17025 procedures. On the other hand it seems that some action from Standard Imaging will occur although it is not clear how they would challenge this since K&S operates by ISO 17025 rules.
>
> Malcolm McEwen and myself plan to visit K&S to review their quality procedures and to specifically look at conflict of interest issues with respect to PTW. . . .

(Pf. Ex. 12).

40. On March 16, 2009, Mr. Riddle emailed a copy of the Standard Imaging letter to Thomas

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[11] "TPC" is an acronym for the Therapy Physics Committee.

[12] Days after the meeting, Drs. Deluca, DeWerd and others at UW exchanged emails concerning the lack of response to Dr. DeLuca's letter of February 13, 2009.

R. ("Rock") Mackie, Ph.D., the then-Chair of the AAPM's "Science Council"[13] and a member of the UW ADCL Advisory Council. Dr. Mackie responded: "Good letter. Paul's was also. I think this might work." Dr. Mackie then forwarded Mr. Riddle's email to Dr. DeLuca (with a copy to Dr. DeWerd), commenting that "Standard Imaging did not address how we protect Larry [DeWerd's] potential conflict of interest but I assume that you did so in your letter to Jan Seuntjens [sic]." (Pf. Exs. 44 & 80).

41. In early April 2009, Gerald White, then-Chairman of the AAPM's Board of Directors, distributed an email to the Executive Committee of the AAPM Board of Directors ("EXCOM") and Ms. Angela Keyser, the Executive Director of the AAPM and an *ex officio* member of EXCOM. Attached was an e-mail received from Dr. Seuntjens similar to the one he had sent Dr. Yorke on March 4, 2009. Mr. White concluded his email by stating that he suspected the issue would "eventually need to go the BOD [Board of Directors]," and that "[t]here is no shortage of potential conflicts of interest among the parties," referring, in part, to the UW ADCL/Standard Imaging/DeWerd relationships, as well as the K&S/PTW-Freiburg relationship.

42. On April 2, 2009, Dr. Michael Herman (the then-President-Elect of the AAPM) replied to Mr. White's email and offered a point-by-point response to the Standard Imaging letter, rebutting many of the concerns raised by Standard Imaging, and opining that most of the perceived conflicts could be managed. Still, Dr. Herman stated that EXCOM needed "to weigh the issue, get input from experienced previous CLA chairs, have AAPM legal review our position and prepare a summary for the BOD to address." (Pf. Ex. 100).

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[13] While the Science Council has broad ranging responsibilities on matters of concern to the AAPM, there is no evidence before the Court that the Science Council is involved in the accreditation process.

43. Dr. Seuntjens submitted a CLA sub-committee report to the TPC at its April 2, 2009, meeting in Houston, Texas. The report noted that K&S had been acquired by PTW-Freiburg, and that CLA management had received "[l]etters of protest" from the University of Wisconsin "board" and from an unnamed "competing ion chamber manufacturer." Dr. Seuntjens concluded his report by stating that K&S would be undergoing a surveillance visit and that the "conflict of interest matter will be assessed." (Pf. Ex. 14).

44. Shortly thereafter, Dr. Followill (Dr. Ibbott's colleague at M.D. Anderson) provided Dr. Ibbott with an account of this closed door meeting,[14] On April 9, 2009, Dr. Ibbott sent an email to Dr. DeWerd conveying Dr. Followill's account of the meeting and indicating that Dr. Seuntjens had expressed his view that the conflict of interest provisions in the "accreditation guidelines" did not prohibit PTW-Freiburg's ownership of K&S. Dr. DeWerd, in turn, passed along Dr. Ibbott's email to Dr. DeLuca, complaining that "it seems that Jan is blowing off the whole thing," and suggesting that Dr. DeLuca send a letter to AAPM Executive Director Angela Keyser. Dr. DeLuca responded with the observation that Dr. Seuntjens "will try and set up a situation to 'manage' the so-called conflict," and that he (Dr. DeLuca) would write a follow-up letter "[i]f we haven't heard anything in a month[.]" (Pf. Ex. 41).

44. On April 21, 2009, Drs. Seuntjens and McEwen, the CLA Co-Chairs, conducted the planned "surveillance visit" at K&S, primarily to assess the implementation of K&S's conflict-of-interest policies and procedures. Drs. Seuntjens and McEwen did not tell K&S that its acquisition had been met with strong protest, particularly from Standard Imaging and UW, or

[14] Dr. Ibbott had been excluded because he was a director of an ACDL that competed with K&S. He opposed K&S being accredited after the acquisition, and believed that the Criteria prohibited ownership of an ACDL by a dosimetry equipment manufacturer.

anything about the telephone meeting of the CLA-X, or the report provided to the TPC in Houston.

45. In an April 29, 2009, email responding to concerns expressed by John Micka (the Technical Director of the UW ADCL) about the separation between manufacturers and labs and the sharing of information, Dr. McEwen acknowledged that "[a] lot of language from various people seems to imply that such professionalism will immediately disappear at K&S with confidential information freely shared or withheld for economic advantage." Nevertheless, he defended his view[15] that K&S's ownership by a manufacturer of dosimetry equipment was manageable, just as the UW ADCL/Standard Imaging "link" was being "managed correctly." Micka replied on April 30, 2009, stating, "I'm sorry Malcolm, I can't even begin to respond to this. We apparently live in two different worlds; I can't decide whether I'm sick, angry, disappointed or insulted. It is obvious there is nothing for me to add as your position is very clear, and my opinion is irrelevant." (Pf. Ex. 132).

46. Two weeks after the surveillance visit, Dr. Pychlau received email correspondence from Drs. Seuntjens and McEwen, expressing a "major concern" about a flyer distributed by PTW-NY that advertised K&S calibrations in conjunction with sales of PTW dosimetry equipment. These flyers were brought to the attention of Dr. Seuntjens by Mr. Micka and that, together with the timing, is interesting. Nevertheless, K&S recognized months before that utilizing the ADCL designation could cause problems in light of the fact that ADCL was an AAPM trademark, and K&S was under scrutiny in light of PTW's acquisition. Dr. Pychlau apologized, and forwarded documents that

[15] At trial Dr. McEwen testified that his position on the issue evolved over time and was influenced by discussions with other CLA-X member during their teleconferences leading up to the July 29, 2009 vote which resulted in a vote recommending that K&S not be re-accredited.

showed that Standard Imaging, too, disclosed a relationship with an ADCL.[16]

47. On June 9, 2009, Drs. Seuntjens and McEwen received a legal opinion from counsel for AAPM that set forth counsel's opinion on the conflict of interest Criteria. Both Dr. Seuntjens and Dr. McEwen understood this to be "a very definitive legal opinion" that was contrary to their then- (and long-) held belief that the Criteria did not prohibit laboratory ownership by a manufacturer. They questioned the basis for the opinion with Dr. Seuntjens emailing Dr. McEwen: "On the one hand, we have never really applied the criteria to the letter. It has always been in a spirit of collaboration that we went through the site visits. This time no different [sic]. I bet if we invited lawyer[']s opinions on the criteria, multiple lab shutdowns would have occurred in the past. So what is different now? The loud voice of the Uwisc [sic]?" (Pf. Ex. 23).

48. In the final "Report on Surveillance Visit" dated June 12, 2009, Co-Chairs Seuntjens and McEwen recommended K&S's re-accreditation. This report reassured K&S that there were not serious issued presented by the change of ownership, as they were not privy to the protest letters or the conference or discussions that had been held among members of the CLA-X. By this point, however, Dr. McEwen had already decided that the Criteria actually prohibited re-accreditation, and Dr. Seuntjens, too, changed his mind at some point after the surveillance visit and receipt of counsel's opinion, and a roundtable meeting on July 25, 2009, at the AAPM annual meeting in

[16] A Standard Imaging brochure stated: "Send your Standard Imagins Electometers, Well Chambers and Extradin Ion Chambers directly to Standard Imaging for Calibrations. We will perform diagonistc tests and clean them before hand carrying them to the University of Wisconsin ADCL for calibration which is located only a few miles from our facility." (Pf. Ex. 17). In a May 6, 2009, email to Dr. Followill at M.D. Anderson (Pf. Ex. 18), Dr. Seuntjens himself observed that "[w]ith regards to the [PTW] flyer, there are numerous examples on the Standard Imaging website that couple ADCL calibrations at UW in the context of package deals and it never triggered outbursts in the past since we know that the UW has professional people on the ground that will provide objective and professional advice." In early June 2009, and undoubtedly as a result of the admonition PTW-Freiburg received, Standard Imaging decided that future promotional material would not refer to the UW ADCL by name.

Anaheim, California.

49. The July 25, 2009 roundtable discussion was placed on the calendar by Dr. Seuntjens to discuss the "current handling of conflict of interest procedures in the Accreditation Criteria." (Pf. Ex. 24). Present at the roundtable were the three lab directors (Drs. DeWerd and Ibbott, and Mr. Slowey), Drs. Seuntjens and McEwen, Ms. Keyser, Mr. White, and Mr. Stephen Seltzer (the then-current representative of the NIST on the CLA-X[17]). With this makeup, there were three of the nine members of the CLA-X at the meeting.

50. The roundtable discussions were contentious, and perhaps one of the most heated AAPM meetings ever. With the exception of Mr. Slowey (who sat at the far end of the table away from Drs. Ibbott and DeWerd who were sitting together), and Mr. White who attempted to act as a moderator,[18] those in attendance opposed PTW-Freiburg's ownership of K&S, and believed that K&S could not maintain its accreditations in light of that ownership. Drs. DeWerd and Ibbott were the most strongly opposed to the notion of K&S being owned by a manufacturer of dosimetry equipment. According to Mr. Slowey, this was the first notice he had of the strong opposition to K&S' continued accreditation under PTW-Freiburg's ownership.

51. The CLA-X met later that day and, by a vote of 8 to 1, "declined" the motion to re-accredit which had been based upon the Report of Surveillance Visit that had recommended re-accreditation of K&S as an ADCL for a period of two years. Mr. Slowey was informed of that decision by letter from Dr. Seuntjens dated July 27, 2009, and that the decision would be forwarded

[17] Because of the close relationship between the AAPM and NIST, NIST has always had a representative on the CLA-X.

[18] According to Mr. White's contemporaneous notes which he read into the record a trial, there was "bad karma" in the air, and there "[s]eems to be a bit of a relationship between University of Wisconsin and M.D. Anderson. General GOB, good ole boy feeling. Slowey, odd man out." (Tr. Trans. at 541).

to the Board of Directors for consideration.

52. On October 20, 2009, K&S appealed the decision to the TPC. A four member "Task Group" of that committee held a telephone conference on the appeal on November 12, 2009, and unanimously upheld the decision of the CLA-X to deny K&S re-accreditation. A summary of that meeting states:

> The key sections of the AAPM Criteria Documentation that led to this decision are Sections B.1 regarding quality of the ADCL system, Section B.2 stating "The applicant institution must be free of any conflict of interest with regard to its ownership and/or business and its responsibility to provide unbiased calibration results, technical advice, and assistance to the AAPM membership. While Section B.4.1.4 provides guidance with respect to management of the conflict, it is deemed that Sections B.1 and B.2 regarding quality of the ADCL system explicitly prevent management in the case of a manufacturer owning a calibration laboratory.

(Pf. Ex. 30).

53. The EXCOM was scheduled to meet in Chicago on Friday, November 27, 2009, during the annual meeting of the Board of Directors, and the parties in this litigation agree that the decision denying re-accreditation would have been confirmed, and K&S' accreditation would have been revoked. However, K&S filed suit in this Court on November 18, 2009, and an Agreed Order has been entered maintaining the status quo *pendente lite*. K&S has continued to operate its laboratory without any apparent problems or harm to the radiation therapy community.

54. It is possible that a reduction of ADCLs from three to two may, to some extent and for some unknown period, negatively affect the relevant market (*i.e.*, the market for accredited dosimetry laboratories in the United States) because the "sellers" in the market – the ADCLS are few in number to begin with, and that has been so for decades. This possible negative effect is conceivably heightened by the fact that there is an impediment to entry into the market, to wit, AAPM accreditation.

55. Certain economic models suggest that when the number of sellers in a finite market diminishes, there is less competition which results in increased prices – at least when there are less than a handful of sellers. According to K&S's expert John J. Siegfried, Ph.D., a retired economics professor at Vanderbilt University, studies show that markets with more than five sellers generally do not notice a rise in prices when one seller leaves, and that remains true when the number of sellers is five and thereafter reduced to four, or the number of sellers is reduced from four to three.[19] However, when the number of sellers in a market is three and that number is reduced to two, it is expected that prices will rise, perhaps by a significant amount. This may be due to the fact that the players left are more cognizant about what their competitors are charging and better able to reach an accord about pricing.[20]

56. Based upon such models, Dr. Siegfried expects that K&S's departure would necessarily result in an increase in cost that will ultimately be passed on to the consumer, particularly since the demand is inelastic because dosimetry equipment utilized in the radiation therapy field must be periodically calibrated by an ADCL. He also predicts that the unequal size of the remaining providers will necessarily lead to the UW ADCL becoming a dominant player in the market.

57. Moreover, Dr. Siegfried is of the opinion that the impediment to entry in the form of accreditation will discourage potential competitors. As indicated, AAPM accreditation is the only feasible accreditation for those wanting to enter the radiation therapy dosimetry calibration field, and this can be a time consuming and costly endeavor. Even assuming K&S could be sold to

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[19] Dr. Siegfried observed that, somewhat surprisingly, the models suggest that a reduction in the number of sellers from four to three may actually result in a more competitive industry.

[20] According to Dr. Siegfried, with fewer sellers, deviations from a pricing agreement are easier to detect, and, therefore, the participants are less likely to deviate out of fear of being caught.

another, non-manufacturing concern, Dr. Siegfried believes this would take time during which the remaining ADCLs will take K&S's customers, leaving it to fight for their return upon re-entry into the market.[21] 58. The use of standardized economic models and the conclusions that flow therefrom may not be entirely *apropos* under the facts of this case. While Dr. Siegfried predicts that prices will increase with K&S's departure, this is hardly a certainty because of the nature of the remaining two laboratories. According to the testimony at trial, the UW ADCL is not allowed to undercut other ADCLs and so it sets its prices by how much other firms charge for calibration.[22] MD ADCL's charge for calibrations is based upon the laboratory's expenses and it is not expected to make a profit or generate any revenue beyond its expenses.

59. Nor is it clear that PTW-Freiburg's present ownership of K&S will be the death-knell of K&S as an ADCL. K&S can be resold, and at least one institution, Vanderbilt University Medical Center, expressed some interest at one point in its purchase. Moreover, even if K&S were to depart permanently, this does not mean that there would not be other entities willing to step into the void, particularly other medical institutions.

60. While the requirement for AAPM accreditation is an impediment to entry into the market, this impediment cannot be viewed simply as being purely anti-competitive, and, indeed, the AAPM seal of approval may have pro-competitive effects by increasing information and reducing consumer confusion. The relationship between consistent dosing in radiation therapy and patient outcomes cannot be denied and, consequently, rigid standards for calibrating equipment is important to patient welfare. This goal is undeniably served by the accreditation process at issue here because

[21] During this period, K&S would likely also lose valuable employees, making it an even less attractive purchase.

[22] The UW ADCL has had one price increase in the past ten years.

the quality of the services that the laboratories provide is difficult (if not impossible) for consumers to verify, and so they must rely upon AAPM accreditation to insure that the laboratories are performing as expected. Obviously, the value of an AAPM accreditation hinges upon that body being able to refuse to accredit laboratories that do not meet the standards that have been developed.

II. CONCLUSIONS OF LAW

1. The Sherman Act provides, in part, that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal." 15 U.S.C. § 1. Although it "literally prohibits every agreement 'in restraint of trade,'" Arizona v. Maricopa County Med. Soc'y, 457 U.S. 332, 342 (1982), the Supreme Court "has long recognized that Congress intended to outlaw only unreasonable restraints." State Oil Co. v. Khan, 522 U.S. 3, 10 (1997).

2. Whether a restraint qualifies as unreasonable and therefore conflicts with the statute is normally evaluated under the "rule of reason." Id. Applying this approach, "the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." Id.

3. Although the rule of reason is the default approach when considering restraints of trade alleged to violate the Sherman Act, some "'[a]greements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use.'" Found. for Interior Design Educ. Research v. Savannah Coll. of Arts & Design, 244 F.3d 521, 529 (6th Cir.2001) (quoting Northern Pac. Ry. Co. v. United States,

356 U.S. 1, 5 (1958)). Such practices or agreements, in short, are illegal *per se*. "Restraints that would fall under this category are illegal as a matter of law for reasons of efficiency; in essence, it is simply not worth the effort or resources of a Rule of Reason analysis when 'the Court [can] predict with confidence that the Rule of Reason will condemn [a restraint].'" Agnew v. NCAA, 683 F.3d 328, 336 (7th Cir. 2012) (quoting, Atl. Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 342 (1990)). "Examples of agreements that have been held unlawful pursuant to the *per se* rule include horizontal price fixing, output limitations, market allocation, and group boycotts." In re K-Dur Antitrust Litig., 686 F.3d 197, 209 (3rd Cir. 2012) (collecting cases).

4. In between the rule of reason and *per se* approaches is the "quick-look" approach (or "truncated rule of reason" analysis). This analysis "is used where the *per se* framework is inappropriate, but where 'no elaborate industry analysis is required to demonstrate the anticompetitive character of . . . an agreement,' and proof of market power is not required." Agnew, 683 F.3d at 336 (citation omitted). "Put another way, the quick-look approach can be used when 'an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets,' . . . but there are nonetheless reasons to examine potential procompetitive justifications." Id. (internal citation omitted). Thus, "if an arrangement 'might plausibly be thought to have a net procompetitive effect, or possibly no effect at all on competition,' then a 'quick look' form of analysis is inappropriate." Cal. *ex rel.* Harris v. Safeway, Inc., 651 F.3d 1118, 1134 (9th Cir. 2011) (quoting, Cal. Dental Ass'n v. F.T.C., 526 U.S. 756, 771 (1999)).

5. "There is an automatic presumption in favor of the rule of reason standard," Care Heating & Cooling v. Amer. Std. Inc., 427 F.3d 1008, 1012 (6th Cir. 2005), and that presumption is

applicable here given the AAPM's role as the accrediting body for ADCLs. See, Interior Design, 244 F.3d at 530 (applying rule of reason approach in anti-trust claim against college accrediting body); Massachusetts Sch. of Law v. Am. Bar Assoc., 107 F.3d 1026, 1033 (3rd Cir. 1997) (rule of reason rather than *per se* approach was appropriate for discovery in law school's antitrust action against ABA relating to its accreditation standards).

6. "The rule-of-reason test requires the court to analyze the actual effect on competition in a relevant market to determine whether the conduct unreasonably restrains trade," Total Benefits Planning Agency, Inc. v. Anthem Blue Cross & Blue Shield, 552 F.3d 430, 436 (6th Cir. 2008), because the very "essence of the Section 1 rule of reason analysis is whether the challenged agreement is one that promotes competition or one that suppresses competition." White & White, Inc. v. Am. Hosp. Supply Corp., 723 F.2d 495, 505 (6th Cir. 1983) (citation omitted). "This query must be resolved by distinguishing between conduct that injures competition and that which may injure competitors." Id. Thus, it is necessary for a court "to examine both the history of the restraint, and the restraint's effect on competition." Care Heating, 427 F.3d at 1012.

7. "In order to establish a prima facie case under the rule of reason, the plaintiff must prove (1) that the defendants contracted, combined, or conspired; (2) that the scheme produced anticompetitive effects; (3) that the restraint affected relevant product and geographic markets; (4) that the object of the scheme and the conduct resulting from it was illegal; and (5) that the scheme was a proximate cause of the plaintiff's antitrust injury." Expert Masonry, Inc. v. Boone County, 330 F.3d 336, 342 (6th Cir. 2006) (citation omitted). "If the plaintiff satisfies this prima facie test, the burden shifts to the defendant to 'come forward with evidence of the restraint's procompetitive effects to establish that the alleged conduct justifies the otherwise anticompetitive injuries;' if the

defendant successfully makes this showing, the plaintiff 'then must show that any legitimate objectives can be achieved in a substantially less restrictive manner.'" Id. (citations omitted).

8. K&S has not established a *prima facie* case under the rule of reason. It has not shown a conspiracy whose object was illegal, nor has it shown that the AAPM, as an alleged participant in the conspiracy, engaged in conduct that was illegal.

9. A conspiracy may be established through direct or indirect (circumstantial) evidence. See, Monsanto Co. v. Spray-Rite Serv. Corp., 104 S. Ct. 1464, 1471 (1984); Wallace v. Bank of Bartlett, 55 F.3d 1166, 1168 (6th Cir. 1995); Riverview Invest. Inc. v. Ottawa Comm. Corp., 899 F.2d 474, 482 (6th Cir. 1990).) "Direct evidence of a conspiracy is 'evidence that is explicit and requires no inferences to establish the proposition or conclusion being asserted.'" Burtch v. Milberg Factors, Inc., 662 F.3d 212, 226 (3rd Cir. 2011). Direct evidence of a conspiracy is generally shown by such things as an explicit "admission by an employee of one of the conspirators, that officials of the defendants had met and agreed explicitly on the terms of a conspiracy," In re Text Messaging Antitrust Litig., 630 F.3d 622, 628 (7th Cir. 2010), or by "a memorandum produced by a defendant conspirator detailing the discussions from a meeting of a group of alleged conspirators," or by "a direct threat to the plaintiff from a competitor." TruePosition, Inc. v. LM Ericsson Tele. Co., 844 F. Supp.2d 571, 593 (E.D. Pa. 2012) (collecting cases).

10. Because the proverbial smoking gun is difficult to come by, "'[c]onspiracies are rarely evidenced by explicit agreements,'" Anderson News, LLC v. Am. Media, Inc., 680 F.3d 162, 183 (2nd Cir. 2012) (citation omitted), but, instead, "are often tacit or unwritten in an effort to escape detection, thus necessitating resort to circumstantial evidence to suggest that an agreement took place." Robertson v. Sea Pines Real Estate Co., 679 F.3d 278, 289-90 (4th Cir. 2012).

11. K&S has shown not an explicit agreement to restrain trade in this case, but instead relies upon inferences to establish an agreement between the AAPM, the UW ADCL, the MDA ADCL, and Standard Imaging to oust K&S from the market to the benefit of the remaining players.

12. In assessing circumstantial evidence of an alleged conspiracy in violation of Section 1, the Supreme Court has adopted what some courts have characterized as a "fairly stringent"[23] standard of review:

> [A]ntitrust law limits the range of permissible inferences from ambiguous evidence in a § 1 case. Thus, in Monsanto Co., [supra], we held that conduct as consistent with permissible competition as with illegal conspiracy does not, standing alone, support an inference of antitrust conspiracy. . . . [A] plaintiff seeking damages for a violation of § 1 must present evidence 'that tends to exclude the possibility' that the alleged conspirators acted independently. . . . [The plaintiff], in other words, must show that the inference of conspiracy is reasonable in light of the competing inferences of independent action or collusive action that could not have harmed [the plaintiff]."

Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 106 S. Ct. 1348, 1356–57 (1986) (internal citations omitted). "[M]istaken inferences" in assessing the evidence of a claimed antitrust conspiracy "are especially costly, because they chill the very conduct the antitrust laws are designed to protect." Id. at 1360.

13. Certain types of circumstantial evidence tend to demonstrate the existence of an agreement, including (1) a motive for defendant to enter into the agreement, (2) action which is contrary to the defendant's interest, and (3) facts suggesting a traditional conspiracy, such as proof that the defendants got together and exchanged assurances of common action or otherwise adopted a common plan. Burtch v. Milberg Factors, Inc., 662 F.3d 212, 227 (3rd Cir. 2011); see also, Re/Max Intern. Inc. v. Realty One, Inc., 173 F.3d 955, 1009 (6th Cir. 1999) ("circumstantial evidence must

[23] See, Cason-Merenda v. Detroit Medical Center, 862 F. Supp.2d 603, 625 (E.D. Mich. 2012).

tend to exclude the possibility of independent conduct in order that an antitrust claim survive summary judgment" with the "important factors" being "(1) whether the defendants' actions, if taken independently, would be contrary to their economic self-interest; (2) whether the defendants have been uniform in their actions; (3) whether the defendants have exchanged or have had the opportunity to exchange information relative to the alleged conspiracy; and (4) whether the defendants have a common motive to conspire"); Champagne Metals v. Ken-Mac Metals, Inc. 458 F.3d 1073, 1085 (10th Cir. 2006) ("range of inferences that can be drawn from circumstantial evidence varies with the strength of the proffered economic theory-the more economically rational a conspiracy is in a given situation, the broader the range of inferences that can be drawn from the evidence").

14. K&S asserts that "the AAPM acted in concert with the UW and MDA ADCLs (along with Standard Imaging) to eliminate K&S from the national market for accredited dosimetry calibration services." (Docket No. 165 at 37). They also argue that "the AAPM through Drs. Sentjens and McEwen and the members of the CLA-X), the UW ADCL, the MDA ADCL, and Standard Imaging all joined in the agreement to disaccredit K&S." (Docket No. 169 at 6).

15. Drs. Seuntjen's and McEwen's inclusion (and perhaps key role) in the alleged conspiracy is questionable because, for the longest time, they shared K&S's opinion that the ownership of an ADCL by a manufacturer was not prohibited by the Criteria. Under Plaintiff's theory of the evidence, these two capitulated, perhaps hearing the "loud voice" of the University of Wisconsin. While that may be one inference from the evidence, another inference that can be drawn, and the inference the Court finds more probable, is that Drs. Seuntjen's and McEwen's opinions changed after hearing from other APPM associates and legal counsel for the AAPM,

particularly since there is nothing that suggests either would benefit from K&S's departure or the UW ADCL's expected assumption of the alpha dog role in the accredited dosimetry laboratory field. See, Sancap Abrasives Corp. v. Swiss Indus. Abrasives, 19 Fed. App'x 181, 187 (6th Cir. 2001) ("circumstantial evidence alone cannot support a finding of conspiracy when the evidence is equally consistent with independent conduct," because, "[i]n such a case, the evidence of conspiracy would not preponderate").

16. The Court recognizes other facts relied upon by K&S from which it might be inferred that some sort of agreement was reached by the AAPM and its alleged co-conspirators to deny K&S re-accreditation. Those inferences, however, are not sufficiently persuasive to show that AAPM was a part of an agreement or conspiracy.

17. When the PTW-Freiburg/K&S acquisition was announced, the AAPM received protests from K&S's competitor the UW ADCL and from PTW-Freiburg's competitor Standard Imaging, but these protests alone are not indicative of collusion. See, Monsanto, 465 U.S. at 763 ("Permitting an agreement to be inferred merely from the existence of complaints, or even from the fact that termination came about 'in response to' complaints, could deter or penalize perfectly legitimate conduct" and "[t]hus, something more than evidence of complaints is needed."). The most the Court sees from this effort is lobbying, just as Mr. Slowey lobbied the AAPM against Inovision becoming accredited, and just as he lobbied the AAPM after the PTW-Freiburg acquisition, expressing what can only be characterized his newly-formed view that a manufacturer can, in fact, own an ADCL without running afoul of the Criteria.

18. Of course, the objections voiced by the UW ADCL, Standard Imaging, and (to a lesser extent) the MDA ADCL were not limited to letters of protest, and the lobbying clearly continued

at CLA conferences and meetings. But "'mere contacts and communications, or the mere opportunity to conspire, among antitrust defendants is insufficient evidence [of] an anticompetitive conspiracy,'" American Chiropractic Ass'n v. Trigon Healthcare, Inc. 367 F.3d 212, 227 (4th Cir. 2004), and the Court finds no probative evidence to conclude that the AAPM acted in concert, or agreed with others, to remove K&S from the ADCL field.

19. K&S relies upon the existence of numerous relationships as suggesting an agreement. Clearly there is a close connection between the UW ADCL and Standard Imaging given Dr. DeWerd's directorship of the former, and his part ownership of the latter. There is also a connection between Drs. DeWerd and DeLuca because of their affiliation with UW. Further there is a connection between Drs. DeWerd and Ibbott of the MDA ADCL, if for no other reason than they were fellow lab directors whose laboratories might benefit somehow if K&S were to be de-accredited. And there was a connection between Drs. Followill and Ibbott, and DeLuca and DeWerd because Dr. Followill shared with Dr. DeLuca what he had learned at the April 7, 2009, closed door meeting in Houston, and that information was then passed on to others by Dr. Deluca.

20. The Drs. DeWerd/Ibbott relationship was clearly on display at the July 29, 2009, roundtable discussion where the internecine dispute was laid bare. While the AAPM insists that those two were only expressing their individual opinions, it is not a stretch to say that their opinions were not entirely altruistic given their roles as directors of competing labs. But only three members of nine members of the CLA-X were present at the roundtable discussion, and there is no proof that the other members agreed or acquiesced in the decision to deny re-accreditation in order to stifle competition, as opposed to denying re-accreditation because of the new ownership and resulting conflict of interest problems. Nor is there any proof that the four members of the TPC Task Force

were influenced to deny accreditation for the benefit of the remaining two laboratories.

21. The idea that the AAPM would conspire with ADCL laboratories and/or a manufacturer (Standard Imaging) to oust a competitor makes little, if any, sense. AAPM members are individual medical physicists who collaborate on professional education, scientific journals, and the oversight of dosimetry laboratories. This oversight of dosimetry labs is a service that provides the AAPM with no financial rewards, and the AAPM has no role in setting the prices that are charged by the ADCLs.

22. It is simply illogical for AAPM members to have conspired to achieve what K&S insists will be a virtual certainty upon its departure – a delay in calibrations and a rise in prices for those calibrations – because AAPM's members need to have their dosimetry equipment calibrated, and AAPM's stated goals under the Criteria are to provide "high quality secondary calibrations" for its members, and to "minimize the cost to membership," (Def. Ex. 38).

23. There has also been no showing that the AAPM (or even the remaining ADCLs) have a commercial motive to eliminate K&S as a competitor. The only ADCL capable of making a commercial profit is K&S, as neither the MD ADCL nor the UW ADCL operate for profit, and K&S has not shown that the AAPM manifested a desire to insulate the UW ADCL and/or the MDA ADCL from K&S's competition. Even if the remaining ADCLs might like to see K&S's departure, Plaintiff has not presented evidence that the AAPM shares any such desire.

24. Given the nature of the remaining ADCLs (and even assuming that another calibration laboratory would not take K&S's place), it is not self-evident that the standard economic models which suggest that there will necessarily be a rise in prices upon the exit of one player in a three-player market are appropriate. Regardless, what is clear from the evidence is that, if K&S loses its

accreditation, it will suffer economic consequences, and may even go out of business or, as K&S puts it, suffer the "corporate death penalty." However, "[a]ntitrust 'plaintiffs must prove antitrust injury, which is to say injury of the type the antitrust law were intended to prevent and that flow from that which makes defendants' acts unlawful'" B & H Med., LLC v. ABP Admin., Inc., 526 F.3d 257, 265 (quoting, Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1997)). This is because "'[t]he antitrust laws . . . were enacted for 'the protection of competition not competitors,'" Brunswick, 429 U.S. at 488 (citation omitted), and hence where the only harm is to plaintiff as a competitor and not to marketplace competition, an antitrust claim is not stated. B & H. Med., 526 F.3d at 265; see, Indeck Energy Serv. V. Consumers Energy, 250 F.3d 972, 977 (6th Cir. 2000) (italics in original) (dismissal appropriate where record showed "no indication that *competition* was harmed by any act of the defendant).

25. Far from suggesting a conspiracy to restrain trade, the AAPM's decision (through the CLA-X and the TPC) is consistent with previous concerns about the potential conflicts of interest posed by a manufacturer's ownership of a dosimetry calibration lab, and the AAPM's reaction thereto. Victoreen's ownership by a laboratory raised problems and concerns, and this relationship served as the basis for the development of the conflict of interest provision in the Criteria. Further, in 1999 when Inovision expressed an interest in becoming an ADCL, it, too, met with opposition, including forceful opposition by Mr. Slowey. Ultimately, Inovision never filed a formal application and the AAPM did not have to make a final determination, but Inovision was informed of the AAPM's reluctance to consider "commercial, proprietary laboratories for ADCL Accreditation," not because of a desire to restrain competition, but "to maintain the highest quality and most objective secondary standard dosimetry system[.]" (Def. Ex. 56). To be sure, this statement of

reasons is self-serving, but it does show a consistency in viewpoint, a point of view shared by Mr. Slowey, at least until his firm was acquired by PTW-Freiburg.

26. The Court recognizes K&S's argument that the Inovision matter occurred before the implementation of Sections 4.1.4 and 4.1.5 which deals with management of conflicts of interest where the laboratory is a part of a "larger organization." However, and leaving aside whether the "larger organization" language might be a reference to public institutions (like the MDA ADCL being a part of the University of Texas), it is clear that a laboratory "must be free of any conflict of interest with regard to its ownership and/or business," and those charged with enforcing that requirement could, without being a part of a conspiracy in restraint of trade, understand this to be a prohibition against a manufacturer owning an ADCL.

27. The Court also acknowledges Plaintiff's argument that the Inovision matter came up in the context of a lab seeking accreditation, whereas K&S was seeking re-accreditation. While it is true that "[t]he AAPM will normally have no reason to consider revocations as long as the performance [is] satisfactory, the procedures of the laboratory are in accordance with approved protocols, and [the] personnel or performance are not significantly changed," it is also true that an ADCL "retains its accreditation at the discretion of the AAPM." Moreover, the accreditation/re-accreditation issue as between Inovision and K&S may actually be a distinction without a difference because § 4.3.8 of APPM's Quality Manual for Laboratory Accreditation provides that "a change in ownership of the laboratory shall require re-approval of the accreditation to the new owner." (Pf. Ex. 51).

28. The Court finds both historical precedence and support in the Criteria for AAPM's decision regarding K&S. The Court further finds no evidence of a deliberate intention to distort the

Criteria or deviate from that which has been long-understood and enforced: ADCLs cannot be owned by manufacturers of dosimetry equipment.

29. Even if K&S established a *prima facie* case, and the Court finds that it did not, the AAPM has presented evidence justifying its conduct in refusing to allow manufacturer ownership of ADCLs. The Court also finds that K&S has not shown this legitimate objective can be achieved in a substantially less restrictive manner.

30. "[A]ccreditation serves an important public purpose and can enhance competition." Interior Design, 244 F.3d at 530, and so it does in this case. AAPM's seal of approval on calibration laboratories reduces informational asymmetries and consumer confusion in a field where precision is of paramount concern. The function and purpose of the ADCL network is to provide high quality, unbiased calibration for the benefit of AAPM's members. Consequently, those in the radiation therapy community rely on ADCLs to insure proper calibration of equipment that is ultimately used in the treatment of cancer patients.

31. The ownership of ADCLs by manufacturers of dosimetry equipment presents legitimate concerns. Such ownership is fodder for bias because the ADCL is called upon to calibrate the very equipment that its owner manufacturers. And, even if those calibrations are accurate, the possible taint and prospect of undue influence lingers. Moreover, and as Mr. Slowey himself observed in challenging Inovision's desire to have its lab accredited, ADCL accreditation is a voluntary activity of the AAPM, done for the benefit of its membership, not the dosimetry manufacturers. Further, the collegiality among laboratories will likely be lessened, and the sharing of information less frank where one of the laboratories is owned by a manufacturer.

32. The Court is not persuaded by K&S's argument or its expert testimony that any conflicts

of interest which arise where a manufacturer owns an ADCL can be effectively managed. Within weeks of the acquisition, PTW-Freiburg/K&S violated their own Conflict of Interest Protocol when the laboratory advised the manufacturing arm about its view of a competitor's equipment. While K&S characterizes this as a mistake, there is no assurance that such mistakes will not be repeated, nor is it clear that any real and effective oversight by the AAPM is possible. As the AAPM posits, how will it effectively know that there are no further improper communications between the ADCL and the manufacturer?; will it be required to review the communications between K&S and PTW-Freiburg?; should someone be on scene at K&S to insure that the policies are being followed?; and/or are weekly audits necessary? These queries only underscore the problems of policing an ADCL that is owned by a manufacturer. The simplest and most effective way to insure that there are no conflicts of interest is simply to ban manufacturers for owning ADCLs.

33. Contrary to K&S's assertion, Dr. DeWerd's relationship with Standard Imaging and the UW ADCL is not the same as the relationship between K&S and PTW-Freiburg, although it admittedly raises some concerns that the AAPM may want to address. The AAPM accredits laboratories, not individuals, and the Criteria can properly be read as prohibiting a manufacturer of dosimetry equipment from owning an ADCL. Dr. DeWerd does not own the UW ADCL, nor does Standard Imaging – the UW ADCL is owned by the University of Wisconsin. Moreover, there has been no proof presented that Dr. DeWerd has violated any conflict of interest policies, that the UW ADCL's calibrations have been compromised by Dr. DeWerd's dual relationship, or that Mr. Slowey, a competing lab director, voiced concerns about the relationship until K&S was sold to PTW-Freiburg.

34. K&S has failed to show by a preponderance of the evidence that the AAPM conspired

with others to restrain trade in declining to re-accredit K&S as an ADCL. Consequently, the AAPM is entitled to judgment in its favor on K&S's antitrust claim under the Sherman Act.

An appropriate Order will be entered.

Kevin H. Sharp

KEVIN H. SHARP
UNITED STATES DISTRICT JUDGE