

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF MICHIGAN**

ACADEMY OF DOCTORS OF  
AUDIOLOGY  
446 E. High St., Suite 10  
Lexington Kentucky 40507

Plaintiff

Case No.

Hon. \_\_\_\_\_, U.S.D.J.

Hon. \_\_\_\_\_, U.S.M.J.

v.

INTERNATIONAL HEARING SOCIETY  
16880 Middlebelt Rd  
Livonia, MI 48154

Defendant

**COMPLAINT FOR  
INJUNCTION AGAINST  
FALSE OR MISLEADING  
ADVERTISING,  
DECEPTIVE TRADE PRACTICES  
AND OTHER CAUSES OF  
ACTION**

Plaintiff Academy of Doctors of Audiology (“ADA”), for its Complaint against Defendant International Hearing Society (“IHS”), states and alleges as follows:

**PARTIES**

1. ADA is a Pennsylvania non-profit corporation with its principal place of business at 446 E. High St., Suite 10, Lexington, Kentucky 40507. ADA is

dedicated to the advancement of audiology practitioner excellence, high ethical standards, professional autonomy and sound business practices in the provision of quality audiology care. ADA has approximately 1,500 members in Michigan and throughout the United States. It brings this action in its organizational capacity to further its objectives and those of its members in connection with the treatment of tinnitus, including those concerning high ethical standards and the protection of the public.

2. IHS is a Michigan non-profit corporation with its principal place of business at 16880 Middlebelt Road Livonia, Michigan 48154. There are approximately 3,000 members of IHS, in Michigan and throughout the United States. A very large proportion of IHS members are Hearing Aid Dealers (as designated in Michigan) and IHS seeks to further their interests. IHS members provide services for the testing, selection and fitting of hearing aids, as well as ongoing follow-up care and counseling. Individuals who have met the standards and requirements established by the current IHS bylaws and Code of Ethics are designated by IHS as Hearing Instrument Specialists®.

### **JURISDICTION AND VENUE**

3. This is an action for false or misleading advertising arising under the laws of the United States, specifically Section 43(a) of the Lanham Act, 15 U.S.C.

§ 1125(a), and related causes of action under the laws of the State of Michigan arising from the intended wrongful issuance by IHS of a “Tinnitus Care Provider Certificate” to persons not legally permitted or professionally competent to provide such care, as described below.

4. This Court has original jurisdiction under the provisions of 15 U.S.C. § 1114, 15 U.S.C. § 1121, 15 U.S.C. § 1125(a), 28 U.S.C. § 1331 and 28 U.S.C. § 1338(a), in that the claims arise under the trademark regulation laws of the United States, 15 U.S.C. § 1051, *et seq.*

5. The Court also has original jurisdiction under 28 U.S.C. §§ 1338(b) with respect to claims arising under the laws of the State of Michigan, in that such claims are joined with the substantial and related claims under the trademark laws of the United States, 15 U.S.C. §§ 1051, *et seq.*

6. Supplemental federal jurisdiction is also invoked under 28 U.S.C. § 1367(a) with respect to all other claims that are so related to the claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.

7. This Court also has jurisdiction over the non-federal claims under 28 U.S.C. § 1332, since there is complete diversity between the parties and the matter in controversy exceeds the sum or value of \$75,000 exclusive of interest and costs.

8. Venue for these claims is proper in this Court under 28 U.S.C. § 1391(b) in that Defendant resides in this judicial district and a substantial part of the events or omissions giving rise to the claim occurred or will occur in this judicial district.

### **ALLEGATIONS**

9. Hearing health care is provided in the United States mainly by three categories of persons, with different levels of training and state-licensed scopes of practice: 1) Medical Doctors, especially otolaryngologists, who specialize in diseases of the ear; 2) Audiologists and 3) Hearing Aid Dealers, as they are called in Michigan (in other states variously called Hearing Instrument Specialists, Hearing Instrument Dispensers, Hearing Instrument Dealers, Hearing Aid Dispensers, or Hearing Aid Specialists, all here referred to as “Dealers” regardless of state-specific title).

10. Medical Doctors are generally required to receive undergraduate and medical school degrees and to complete internship and residency. They have unlimited scopes of practice, including the treatment of tinnitus.

11. Audiologists provide professional clinical services related to the prevention of hearing loss and the audiologic identification, assessment, diagnosis, and treatment of persons with impairment of auditory and vestibular (balance)

function, and to the prevention of impairments associated with them. Their licensed scopes of practice encompass those activities. Audiologists assess and provide audiologic treatment for persons with tinnitus using techniques that include, but are not limited to, biofeedback, masking, hearing aids, education, and counseling. (Source: American Academy of Audiology.)

12. Audiologists entering the profession since 2007 have generally been required for licensure in Michigan and the other States to hold an undergraduate degree and the degree of Doctor of Audiology (Au.D.), usually requiring four years of postgraduate education, including a clinical externship. Prior to the universal Au.D. entry-level requirement, audiologists generally held an undergraduate degree and a two-year Masters degree or a Ph.D. in Hearing Sciences. Some audiologists continue to practice under pre-Au.D. licenses and their associated academic degrees.

13. Dealers in Michigan (like Dealers in the other States through similar statutes) are licensed pursuant to M.C.L. §§ 339.1301 et seq., to engage in the sale or offering for sale at retail of hearing aids. "Hearing aid" means an instrument or device designed for regular and constant use in or proximate to the human ear and represented as aiding or improving defective human hearing. The "Practice of selling or fitting a hearing aid" means the selection, adaptation, and sale of a

hearing aid and includes the testing of hearing by means of an audiometer and other means for the sale of a hearing aid. The practice also includes the making of an impression for an ear mold.

14. In Michigan, as is typical of other States, a Dealer may be licensed if the Dealer is a graduate of an accredited high school or secondary school, has served as a salesperson under a licensed Dealer for two years and passes a written examination. M.C.L. § 339.1305. (In a few States, a two-year post-secondary degree is required, in other States the requirements are even lower than in Michigan.)

15. As described on the website of the American Tinnitus Association (“ATA”):

“Tinnitus is the perception of sound when no actual external noise is present. While it is commonly referred to as “ringing in the ears,” tinnitus can manifest many different perceptions of sound, including buzzing, hissing, whistling, swooshing, and clicking. In some rare cases, tinnitus patients report hearing music. Tinnitus can be both an acute (temporary) condition or a chronic (ongoing) health malady.

Millions of Americans experience tinnitus, often to a debilitating degree, making it one of the most common health conditions in the country.

The U.S. Centers for Disease Control estimates that nearly 15% of the general public — over 50 million Americans — experience some form of tinnitus. Roughly 20 million people struggle with burdensome chronic tinnitus, while 2 million have extreme and debilitating cases.

In general, there are two types of tinnitus:

**Subjective Tinnitus:** Head or ear noises that are perceivable only to the specific patient. Subjective tinnitus is usually traceable to auditory and neurological reactions to hearing loss, but can also be caused by an array of other catalysts. More than 99% of all tinnitus reported tinnitus cases are of the subjective variety.

**Objective Tinnitus:** Head or ear noises that are audible to other people, as well as the patient. These sounds are usually produced by internal functions in the body's circulatory (blood flow) and somatic (musculo-skeletal movement) systems. Objective tinnitus is very rare, representing less than 1% of total tinnitus cases.

There is currently no scientifically-validated cure for most types of tinnitus. There are, however, treatment options that can ease the perceived burden of tinnitus, allowing patients to live more comfortable, productive lives.”

16. Treatment of tinnitus is within the licensed scope of practice of Medical Doctors and Audiologists in Michigan and every other State. Treatment of tinnitus is not within the licensed scope of practice of Dealers in Michigan and the other States, except for North Carolina. N.C.G.S.A. § 93D-1.1.

17. Treatment of tinnitus is complex, currently lacks some areas of research-backed effectiveness data and is evolving. Tinnitus, in some cases, can be a symptom of a more serious medical or surgical condition. There are significant risks to patients in tinnitus treatment. See, *Clinical Practice Guideline: Tinnitus* (American Academy of Otolaryngology, 2014), attached as Exhibit 1. While the Guideline notes that case management and evaluation may be provided by non-physicians such as Audiologists, *Guideline* at S3, it makes reference to Dealers limited only to potentially custom fitting hearing aids, at S20.

18. “Sound Masking Devices” are potentially useful in the treatment of tinnitus. As described by the ATA, “These are devices or applications that provide generic background noise — often white noise, pink noise, nature sounds or other ambient, subtle sounds. The noise generated by sound machines can partially or fully mask a patient’s perception of tinnitus, providing relaxation and temporary respite from the condition.”

19. Hearing aids may also potentially alleviate symptoms of tinnitus. Further, as described by the ATA, “Many hearing aids now come with integrated sound generation technology that delivers white noise or customized sounds to the patient on an ongoing basis. These devices combine the benefits of a hearing aid with those of other sound therapies, and are particularly well suited for tinnitus patients with measurable hearing loss. Also, because of the portable nature of these devices they can provide semi-continuous use and more consistent benefit throughout the day.”

20. Hearing aids are regulated by the United States Food and Drug Administration, 21 CFR Part 874. Sound masking devices incorporated into hearing aids, or “Tinnitus Maskers,” are likewise regulated by the FDA as a Class II Prosthetic Device, 21 CFR § 874.3400. Tinnitus Maskers may only be sold with patient labeling regarding “Hearing health care professional diagnosis, fitting of the device and followup care,” *id.*, (1). A Tinnitus Masker may only be sold on the prescription or order of a practitioner licensed by the applicable State to order such use. 21 CFR § 801.809. Thus, only Medical Doctors and Audiologists may order such use, other than in North Carolina, where Dealers may do so.

21. IHS intends to offer a “Tinnitus Care Provider Certificate” (“the Certificate”), in conjunction with a training program to be offered December 2-3,

2016, in Orlando, Florida (“the Program”). The Program is open to Dealers from every State. See, Program description attached as Exhibit 2. While the description advises participants to check what are permitted practices as to tinnitus care under their state licensure, IHS intends to issue the Certificate to Dealers who meet the experience requirements and successfully complete the training, as shown by passing an examination, regardless of whether they are licensed to provide tinnitus care.

22. As to Dealers licensed by Michigan and every other State except North Carolina, the Certificate will falsely or misleadingly convey to the public that the Dealer holding it is legally permitted to provide tinnitus care. There is a substantial risk that such Dealers will display and advertise the Certificate to the public, resulting in members of the public seeking tinnitus care from them and being provided such care illegally.

23. The Program will not provide Dealers with sufficient knowledge and skill to provide appropriate tinnitus care, given their limited education, training and experience. For that reason, the Certificate will falsely or misleadingly convey to the public that the Dealer holding it is competent to provide tinnitus care. There is a substantial risk that such Dealers will display and advertise the Certificate to the

public, resulting in members of the public seeking tinnitus care from them and receiving inadequate such care.

24. The public will thus be harmed by the issuance of the Certificate to Dealers. The members of ADA will be harmed by the diversion of tinnitus care patients to Dealers holding the Certificate. The organizational purpose of ADA to ensure the provision of ethical and high quality hearing health care to the public will be defeated.

**FIRST CLAIM**  
**(False Advertising - Lanham Act)**

25. ADA re-states the preceding allegations as if fully re-written.

26. The Certificate will falsely or misleadingly communicate that a Dealer holding it, other than a Dealer licensed by the State of North Carolina, is legally permitted to provide tinnitus care.

27. The Certificate will falsely or misleadingly communicate that a Dealer holding it is competent to provide tinnitus care.

28. Unless enjoined, IHS will issue the Certificate to Dealers who are not legally or competently able to provide tinnitus care, but who nevertheless are likely to display and advertise the Certificate to the public to attract business.

29. IHS will thereby, in connection with goods or services, use in interstate commerce words, terms, names, symbols, devices, and combinations

thereof, false or misleading descriptions of fact, and false or misleading representations of fact, which in commercial advertising or promotion, misrepresent the nature, characteristics and qualities of such Dealers' goods, services and commercial activities, in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

30. The false or misleading statements in the Certificate will tend to deceive a substantial proportion of the intended audience.

31. The false or misleading statements in the Certificate are material, in that they will likely influence the deceived consumers' purchasing decisions.

32. ADA and its members will be damaged by the issuance of the Certificate to Dealers and will have no adequate remedy at law.

33. ADA is accordingly entitled to preliminary and permanent injunctive relief against the issuance of the Certificate by IHS to Dealers.

**SECOND CLAIM**  
**(Contributory False Advertising - Lanham Act)**

34. ADA re-states the preceding allegations as if fully re-written.

35. The issuance of the Certificate by IHS will induce the Dealers who receive it, other than Dealers licensed by the State of North Carolina, to advertise falsely that the Dealers holding it are legally permitted to provide tinnitus care.

36. The issuance of the Certificate by IHS will induce the Dealers who receive it to advertise falsely that the Dealers holding it are competent to provide tinnitus care.

37. Unless enjoined, IHS will issue the Certificate to Dealers who are not legally or competently able to provide tinnitus care, but who nevertheless are likely to display and advertise the Certificate to the public to attract business.

38. IHS will thereby, in connection with goods or services, induce the use in interstate commerce of words, terms, names, symbols, devices, and combinations thereof, false or misleading descriptions of fact, and false or misleading representations of fact, which in commercial advertising or promotion, misrepresent the nature, characteristics and qualities of such Dealers' goods, services and commercial activities, in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

39. The false or misleading statements in the Certificate will tend to deceive a substantial proportion of the intended audience.

40. The false or misleading statements in the Certificate are material, in that they will likely influence the deceived consumers' purchasing decisions.

41. ADA and its members will be damaged by the issuance of the Certificate to Dealers and will have no adequate remedy at law.

42. ADA is accordingly entitled to preliminary and permanent injunctive relief against the issuance of the Certificate by IHS to Dealers.

**THIRD CLAIM**  
**(Deceptive Trade Practices under M.C.L. § 445.903(1)(a)-(c))**

43. ADA re-states the preceding allegations as if fully rewritten.

44. The issuance of the Certificate to Dealers will cause a probability of confusion or misunderstanding by members of the public as to the approval or certification of the tinnitus care related goods and services offered by the Dealers.

45. The issuance of the Certificate to Dealers will use deceptive representations in connection with the tinnitus care related goods and services offered by the Dealers.

46. The issuance of the Certificate to Dealers will represent that the tinnitus care related goods and services offered by the Dealers have approval, characteristics and benefits that they do not have and that the Dealers have approval, status, affiliation, or connection that they do not have.

47. The issuance of the Certificate to Dealers will thus be a deceptive, unconscionable or deceptive method, act and practice in trade or commerce, in violation of Michigan law, including M.C.L. 445.901 *et seq.*, and, more particularly, M.C.L. § 445.903(1)(a)-(c).

48. ADA and its members are likely to be damaged by the issuance of the Certificate to Dealers and will have no adequate remedy at law.

49. The general public is likely to be injured by the issuance of the Certificate to Dealers.

50. ADA is accordingly entitled to preliminary and permanent injunctive relief against the issuance of the Certificate by IHS to Dealers.

**FOURTH CLAIM**  
**(Unfair Competition under Michigan Common Law)**

51. ADA re-states the preceding allegations as if fully rewritten.

52. The issuance of the Certificate to Dealers will be unfair competition, in violation of Michigan common law.

53. ADA and its members are likely to be damaged by the issuance of the Certificate to Dealers and will have no adequate remedy at law.

54. The general public is likely to be injured by the issuance of the Certificate to Dealers.

55. ADA is accordingly entitled to preliminary and permanent injunctive relief against the issuance of the Certificate by IHS to Dealers.

**REQUESTS FOR RELIEF**

Wherefore ADA requests the following relief against IHS:

- A. Judgment granting preliminary and permanent injunctions against IHS and all persons affiliated with it with it as set forth in Fed. R. Civ. Proc. 65(d)(2)(A), (B) and (C), prohibiting the issuance by IHS of a “Tinnitus Care Provider Certificate” to Hearing Aid Dealers (persons licensed under M.C.L. §§ 339.1301 et seq. or the comparable statutes of other States);
- B. ADA’s costs, reasonable attorney fees and expenses of litigation; and
- C. Such other and further relief to which ADA may be found to be entitled upon the evidence and law.

Respectfully submitted,

**RODERICK LINTON BELFANCE, LLP**

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