

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

EXERGEN CORPORATION,

Plaintiff,

v.

BAXTER INTERNATIONAL, INC.,

Defendant.

Civil Action No. 1:24-CV-11008

**COMPLAINT FOR DECLARATORY RELIEF  
PURSUANT TO DECLARATORY JUDGMENT ACT, 28 U.S.C. §§ 2201-2202**

Plaintiff Exergen Corporation (“Exergen”) alleges the following for its Complaint against Baxter International, Inc. (“Baxter”):

**NATURE OF THE ACTION**

1. Exergen’s TAT-5000 Temporal Artery Thermometer is an innovation in medical thermometry that has revolutionized the way that temperatures are taken in the United States and around the world. Since its introduction in 1999, the accuracy of the TAT-5000 has been systematically evaluated in a wide variety of clinical settings, and it has been proven time and again to be not only an accurate measurement of core body temperature, but also in many cases, more accurate than alternative thermometry methods.

2. In 2022, a research letter published by Sivasubramaniam V. Bhavani, et al. (“Bhavani Letter”) questioned the accuracy of temporal artery thermometers compared with oral thermometers in detecting fevers in Black patients. The study’s authors based their conclusion on a retrospective analysis of temperatures taken with Exergen’s TAT-5000 and digital thermometers manufactured by Baxter. The study’s authors, however, had it backwards.

3. A subsequent review of the same data by Exergen demonstrated that temperatures taken with the TAT-5000 were consistent for all patients whereas temperatures taken with Baxter's electronic oral thermometer diverged significantly for Black and White patients. Exergen shared the results of its analysis with the study's authors and pointed out that prior research had demonstrated that oral thermometers have shown substantial differences among Black and White patients. Exergen also drafted a written response to the Bhavani Letter, which was published by JAMA in January 2023.

4. When confronted with Exergen's analysis, the authors of the Bhavani Letter did not dispute the analysis, or that the analysis showed much greater alignment in temperatures taken by the Exergen TAT-5000 thermometer across Black and White patients than the temperatures taken with the Baxter oral thermometer. The authors instead conceded that, despite what they originally published, it was not actually possible to conclude from the data they analyzed that temporal artery ("TA") thermometers underestimate fevers in Black patients, as opposed to oral thermometers overestimating them.

5. Despite this concession by the study's authors, which was also published in JAMA, Baxter is now seeking to silence Exergen from discussing this matter of public interest, or from pointing out that numerous studies, including the Bhavani Letter, have documented that oral thermometers show differences between Black and White patients.

6. Toward this end, Baxter commenced a non-public legal proceeding against Exergen at the National Advertising Division ("NAD") in New York City that seeks to limit Exergen from publicly commenting on this matter of public importance. Among other things, Baxter is seeking to censor statements that Exergen made in its scholarly JAMA response, including the true statement that "many studies describe significant differences in orally

measured temperatures in Black and White people,” on the grounds that these statements supposedly constitute commercial advertising. Baxter also challenged the truth of other unobjectionable claims and statements of pride that Exergen has been making about the accuracy of the TAT-5000 thermometer for over a decade.

7. Exergen strongly disputes Baxter’s position that Exergen’s JAMA response constitutes commercial advertising, as opposed to core First Amendment speech on a matter of public interest. Exergen also disputes that there is anything false or misleading to consumers about the claims it is making about the accuracy of the TAT-5000 thermometer, let alone that Baxter has suffered any injury as a result of Exergen’s long-standing claims.

8. Through this lawsuit, Exergen seeks a declaration from the Court pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, that none of the claims challenged by Baxter at NAD regarding the accuracy of its thermometers constitutes false or misleading advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), to the extent they constitute advertising at all.

### **JURISDICTION AND VENUE**

9. Exergen’s claims arise under the Lanham Act, 15 U.S.C. § 1051, *et seq.*

10. This Court has jurisdiction over this action under 28 U.S.C. §§ 1331, 1338, and 2201-2202.

11. Declaratory relief is warranted by 28 U.S.C. §§ 2201 and 2202.

12. Venue is proper in this District under 28 U.S.C. §§ 1391(b)(2) & 1391(c) because a substantial part of the events giving rise to Exergen’s claims occurred in this District.

13. Personal jurisdiction is appropriate in this District because Baxter has initiated a legal action at the NAD with the knowledge, purpose, and intent that this action will impact Exergen and its advertising in this District.

### **THE PARTIES**

14. Plaintiff Exergen is a Massachusetts corporation with its principal place of business in Watertown, Massachusetts. Exergen is the leading manufacturer of TA thermometers such as the TAT-5000, which it distributes for sale to medical professionals and institutions in this District and throughout the United States.

15. Defendant Baxter is a Delaware corporation with its principal place of business in Deerfield, Illinois. On information and belief, Baxter is the leading manufacturer of electronic oral and rectal thermometers, which it distributes for sale to medical professionals and institutions in this District and throughout the United States.

### **FACTS COMMON TO ALL CLAIMS**

16. Exergen and Baxter compete for the sale of professional-grade medical thermometers to hospitals, doctors' offices, and other medical institutions. Exergen is the leading manufacturer of TA thermometers, including the TAT-5000, which are based on technology that Exergen's founder, Dr. Francisco Pompei, created and patented. The TAT-5000 works by identifying and measuring the temperature of a patient's temporal artery, which runs directly from a patient's heart to their forehead. Because they read the blood flowing from a patient's heart, TA thermometers are considered by medical professionals to be a fast and efficient way to measure core body temperature.

#### **A. Exergen's TAT-5000 Has Proven Accuracy**

17. Since its introduction in 1999, the accuracy of the TAT-5000 has been evaluated in a wide variety of clinical settings, and the TAT-5000 has been proven time and again to be not only an accurate measurement of core body temperature, but also, in many cases, more accurate than alternative thermometry methods. TA thermometers are also faster than rectal thermometers at detecting changes in core body temperatures given that rectal temperatures tend to lag changes in core body temperature.

18. In addition to this clinical research, Exergen TA thermometers have been put to the test by hundreds of thousands of doctors, nurses, and other medical professionals who have used them as a regular part of their medical practice over the last two and a half decades. Some of the hospitals and medical institutions that rely upon the Exergen TAT-5000 to measure patient temperature include:

- Mayo Clinic
- Cedars-Sinai Health System
- NYU Langone Hospitals
- Cleveland Clinic
- Johns Hopkins Hospital
- UCLA Medical Center
- New York-Presbyterian Hospital-Columbia and Cornell
- Massachusetts General Hospital
- Northwestern Memorial Hospital
- Stanford Health Care-Stanford Hospital
- Barnes-Jewish Hospital
- UCSF Health-UCSF Medical Center

- Hospitals of the University of Pennsylvania-Penn Presbyterian
- Mass General Brigham and Women's Hospital
- Houston Methodist Hospital
- Mount Sinai Hospital
- University of Michigan Health-Ann Arbor
- Vanderbilt University Medical Center
- Mayo Clinic - Phoenix
- Rush University Medical Center

**B. Exergen's TA Thermometers Offer Other Advantages**

19. Hospitals and medical institutions choose to use Exergen's TAT-5000 not only because of its accuracy, but also because of its other demonstrated benefits. TA thermometers are quick and easy to use, and result in much less patient discomfort and awkwardness than oral and rectal thermometers. As a result, patients of all ages prefer non-invasive thermometry techniques like TA thermometers over invasive ones, as do a majority of medical professionals. Although this trend toward non-invasive temperature measurement predated the COVID-19 pandemic, the pandemic served to solidify consumers' and medical professionals' preference for non-invasive temperatures techniques to the detriment of Baxter's sale of oral and rectal thermometers and related parts and accessories.

20. Use of the Exergen TAT-5000 also results in reduced medical waste, and cost, in comparison to the digital thermometer probes sold by Baxter, which require the use and disposal of a thin plastic probe cover each time a temperature is taken. Medical professionals in the United States take billions of patient temperatures every year, and each time they do it with a Baxter electronic thermometer, they must use a small plastic probe cover to avoid the

transmission of infectious disease and other contaminants from one patient to the next. On information and belief, the sale of these plastic probe covers is a significant revenue stream for Baxter. But Baxter's profit comes at a cost to the environment in that these plastic probe covers, required for every temperature taken with a Baxter thermometer, result in many, many tons of medical waste every year. One analysis concluded that a single 300-patient hospital can eliminate nearly \$100,000 in unnecessary cost per year, and two tons of medical waste, by converting to TA thermometers like the TAT-5000.

21. In addition to these cost and time efficiencies, Exergen's TA thermometers are highly durable and resistant to aggressive disinfectants. As a result, Exergen offers a lifetime warranty for its TAT-5000 thermometers. Baxter, in contrast, only offers a three-year warranty for its oral and rectal thermometers.

22. Simply put, there are myriad reasons that medical professionals and institutions choose the TAT-5000 over the invasive electronic probes sold by Baxter beyond the accuracy of its measurements.

**C. The Bhavani Letter Questions the Accuracy of Exergen's TAT-5000 Thermometer with Respect to Black Patients Based on a Flawed Analysis**

23. In September 2022, JAMA published a research paper authored by Sivasubramaniam V. Bhavani, et al. ("Bhavani Letter") entitled "Racial Differences in Detection of Fever Using Temporal vs Oral Temperature Measurements in Hospitalized Patients." A true and correct copy of the research letter is included with this Complaint as **Exhibit A**.

24. Based on a retrospective study of temperatures taken of patients at four Emory-affiliated hospitals from 2014 to 2021, the study concluded that "temporal compared with oral temperature was associated with a lower odds of identifying fever in Black patients." The study noted that the difference in temperature readings was "small," but suggested that this small

discrepancy “could lead to delays in antibiotics and medical care for Black patients.” The study’s authors, however, made a critical error in their analysis.

25. A subsequent review of the same data by Exergen demonstrated that temperatures taken with the TAT-5000 were consistent for all patients whereas temperatures taken with Baxter’s electronic oral thermometer diverged significantly for Black and White patients. Exergen shared the results of its analysis with the study’s authors and pointed out that prior research had demonstrated that oral thermometers have shown substantial differences among Black and White patients. It was therefore error in Exergen’s opinion for the study’s authors to conclude that the divergent results they observed for oral thermometers between White and Black patients provided an appropriate benchmark for evaluating (and disparaging) the accuracy of the TAT-5000’s temperature measurements.

26. Exergen also drafted a written response to the Bhavani Letter (“Exergen Response”) that summarized many of these same points. This written response was published by JAMA in January 2023. A true and correct copy of the Exergen Response is included with this Complaint as **Exhibit B**. This response noted, among other things, that:

Many studies describe significant differences in orally measured temperatures in Black and White people. Moreover, these differences were apparent in this study—every oral temperature result differed significantly between Black and White patients. Causes of the differences between oral temperatures might include systemic measurement procedure errors and systemic bias in prediction algorithms used by digital oral thermometers to report temperatures in seconds, which is faster than required for precise oral measurements.

27. The Exergen Response further explained that Exergen’s TA thermometers were “intentionally developed to perform equivalently for all skin types,” and [p]rior research showed no significant differences in temperatures between Black and White individuals as measured with temporal artery thermometers . . . .”



28. When presented with Exergen's analysis and response, the authors of the Bhavani Letter did not dispute Exergen's analysis or that the analysis showed much greater alignment in temperatures taken by the Exergen TAT-5000 thermometer across Black and White patients than the temperatures taken with the Baxter oral thermometer. The authors instead conceded that despite what they originally published, it was not actually possible to conclude from the data they analyzed that TA thermometers underestimate fevers in Black patients, as opposed to oral thermometers overestimating them, from the data they analyzed. JAMA published the authors' reply in conjunction with the Exergen Response.

**D. Baxter Seeks to Use Advertising Law to Silence Scientific Debate Regarding the Accuracy of Its Oral Thermometers**

29. Rather than respond in public to the Bhavani Letter or the Exergen Response, Baxter is now seeking to use advertising law to silence scientific debate about an issue of public importance. Toward this end, Baxter commenced a non-public legal proceeding against Exergen at the NAD in New York City that seeks to limit Exergen from making any further reference to the clinical studies, including the Bhavani Letter, that have documented differences in oral temperatures for Black and White patients.

30. Baxter's complaint to NAD specifically characterizes the following statements from Exergen's JAMA Response as advertising claims that the NAD should direct Exergen to retract and otherwise discontinue:

“Many studies describe significant differences in orally measured temperatures in Black and White people.”

“[O]nly oral thermometers have shown substantial differences among Black and White individuals.”

Despite this audacious request, Baxter identified no evidence with its NAD complaint that contradicts these statements in any way. Nor did Baxter dispute the references Exergen cited in its JAMA response in support of these statements.

31. Baxter coupled its inappropriate request with a challenge to other unobjectionable statements of pride and claims that Exergen has been making about the accuracy of the TAT-5000 thermometer for over a decade, including that the TAT-5000 is the "most accurate thermometer available" and "supported by more than 70 peer-reviewed published studies covering all ages from premature infants to geriatrics in all clinical care areas." A true and correct copy of a letter from NAD identifying a laundry list of "advertising claims" challenged by Baxter is included with this complaint as **Exhibit C**,

32. Exergen strongly disputes Baxter's position that Exergen's JAMA response constitutes commercial advertising, as opposed to core First Amendment speech on a matter of public interest. Exergen also disputes that there is anything false or misleading to consumers about any of the "advertising claims" that Baxter has challenged at NAD (to the extent they are even considered advertising), or that Baxter has suffered any cognizable injury as a result of Exergen's long-standing claims. Finally, Exergen strongly disputes Baxter's attempt to litigate these important issues outside the public eye in a forum that does not afford advertisers the substantive and procedural safeguards that are available in court.

#### **E. A Concrete Dispute Exists Between Exergen and Baxter**

33. Exergen intends to continue using the claims that Baxter asserts are false and misleading, or variations thereof, and to publish scientific analyses regarding the accuracy of oral and temporal artery thermometers with respect to White and Black patients. Given Baxter's stated position that these claims and other public statements regarding the accuracy of oral and

TA thermometers constitute false advertising, and the actions Baxter has already taken to prevent Exergen from making these claims and statements, Exergen's ongoing use of these claims and statements will be unfairly impaired unless and until the Court declares that they are not false or misleading, and/or otherwise do not violate the Lanham Act.

### **COUNT ONE – DECLARATORY JUDGMENT**

34. Exergen restates and incorporates by reference the allegations in paragraphs 1 through 33 of the Complaint as if fully set forth herein.

35. Exergen seeks a declaration of its rights, pursuant to 28 U.S.C. §§ 2201 & 2202, that the advertising claims that Baxter is challenging as false and misleading do not constitute commercial advertising, have not caused Baxter injury, and do not otherwise violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

36. As described herein, Baxter asserts that certain of Exergen's advertising claims and other public statements constitute commercial advertising that is misleading professional consumers with respect to the accuracy of Exergen's TAT-5000 and Baxter's oral thermometers. Baxter's allegations, if proven true by Baxter, would constitute false advertising or unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

37. Contrary to Baxter's assertions, each of Exergen's claims is true and is not misleading to the extent it is even a claim. None has caused any injury to Baxter. The claims do not violate the Lanham Act.

38. A real and actual controversy presently exists between the parties to this action, which is concrete and justiciable in character, and to which each party possesses an interest in resolving.

39. Unless and until the advertising claims and other public statements challenged by Baxter as false and misleading are declared permissible under United States law, Exergen's ability to inform consumers about proven accuracy of the TAT-5000 will be wrongfully and unnecessarily impaired and clouded, and Exergen will continue to be injured and damaged by this threat. Accordingly, Exergen seeks declaratory relief from this Court.

40. The controversy between Exergen and Baxter warrants relief declaring the rights of the parties pursuant to 28 U.S.C. §§ 2201 & 2202, and finding that the advertising claims set forth in **Exhibit C**, and those similar, do not violate the Lanham Act, to the extent they constitute advertising at all.

#### **PRAYER FOR RELIEF**

WHEREFORE, Exergen respectfully requests that the Court grant the following relief:

- a. declaring that Exergen's advertisements, claims, and other public statements challenged by Baxter do not violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a);
- b. awarding Exergen its costs and expenses of litigation, including reasonable attorneys' fees; and
- c. such other relief as this Court deems just and equitable.

#### **JURY DEMAND**

Plaintiff demands a trial by jury on all issues so triable.

Date: April 17, 2024

Respectfully submitted,

**EXERGEN CORPORATION**

/s/ Laura Lee Mittelman

Andrea L. Martin (BBO #666117)

amartin@burnslev.com

Laura Lee Mittelman (BBO #689752)

lmittelman@burnslev.com

Henry T. Gaylord (BBO #713119)

hgaylord@burnslev.com

BURNS & LEVINSON LLP

125 High Street

Boston, MA 02110

Telephone: 617-345-3000

Facsimile: 617-345-3299

Thomas P. Jirgal (*pro hac vice* forthcoming)

tjirgal@loeb.com

Elisabeth K. O'Neill (*pro hac vice* forthcoming)

eoneill@loeb.com

LOEB & LOEB LLC

321 North Clark Street, Suite 2300

Chicago, IL 60654

Telephone: (312) 464-3100

Facsimile: (312) 464-3111