

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ROCHE DIABETES CARE, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
TRIVIDIA HEALTH, INC.,	)	
	)	<b>DEMAND FOR JURY TRIAL</b>
Defendant.	)	
	)	
	)	

**COMPLAINT**

Roche Diabetes Care, Inc. (“Roche”), by and through its attorneys, hereby alleges for its Complaint against Trividia Health, Inc. (“Trividia”) as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement arising under the United States Patent Act, 35 U.S.C. §§ 1 *et seq.*, including 35 U.S.C. § 271.
2. Roche brings this action to seek relief for Trividia’s infringement of Roche’s rights arising under the patent laws of the United States 35 U.S.C. §§ 1, *et. seq.*, from U.S. Patent No. 7,727,467 (the “’467 patent”) and No. 7,892,849 (the “’849 patent”).

**THE PARTIES**

3. Roche Diabetes Care, Inc. is and was a corporation organized and existing under the laws of Delaware, with its principal place of business at 9115 Hague Road, Indianapolis, Indiana 46256. Roche Diabetes Care, Inc. is and was the owner by assignment of the ’467 and ’849 patents.
4. Upon information and belief, Trividia is and was a corporation organized and existing under the laws of Delaware, with its principal place of business at 2400 N.W. 55th Court,

Ft. Lauderdale, Florida 33309. Upon information and belief, Trividia was formerly known as Nipro Diagnostics, and has been a subsidiary of Sinocare Inc. since at least 2016.

### **JURISDICTION AND VENUE**

5. Roche brings this action for patent infringement by Trividia arising under the patent laws of the United States, Title 35 of the United States Code. Accordingly, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Trividia because, *inter alia*, Trividia is and was incorporated in Delaware and resides in this District. This Court also has personal jurisdiction over Trividia because it has committed, aided, abetted, induced, contributed to, and/or participated in the commission of tortious acts of patent infringement that led to foreseeable harm and injury to Roche in Delaware. Trividia's contacts with Delaware are substantial, and include its incorporation in Delaware and its conduct of business in Delaware. For example, Trividia has made, used, sold, offered for sale, and/or imported infringing products (*see infra* ¶¶ 13-56) and placed infringing products in the stream of interstate commerce with the intent and expectation that such infringing products would be used, distributed, sold, and/or offered for sale in Delaware—indeed, they have been—causing harm to Roche as a Delaware-incorporated entity. Notwithstanding the foregoing, to the extent Trividia disputes that it is incorporated under Delaware law, personal jurisdiction also exists over Trividia under Delaware's long-arm statute because it “[t]ransacts any business or performs any character of work or service in the State” (10 Del. C. § 3104(c)(1)), “[c]ontracts to supply services or things in this State” (*id.* § 3104(c)(2)), and “[c]auses tortious injury in the State by an act or omission in this State” (*id.* § 3104(c)(3)).

7. Venue is proper in this District under 28 U.S.C. § 1400(b) because Trividia is and was a Delaware corporation that, upon information and belief, conducts and did conduct business

in Delaware. Delaware is also the most convenient forum, and litigating this action in Delaware is in the interests of justice, under 28 U.S.C. § 1404(a).

### **FACTUAL ALLEGATIONS**

#### **I. ROCHE'S PATENTED BLOOD GLUCOSE TEST STRIP TECHNOLOGY**

8. Roche has been a pioneer in innovative diabetes technologies and services for more than 50 years. In 1983, Roche introduced the world's first self-monitoring blood glucose meter, revolutionizing care by enabling people with diabetes to measure blood glucose levels by themselves—at home, in the office, or wherever they are—and then make their own therapy decisions informed by those measurements. For the first time, diabetes patients could conveniently collect blood samples themselves using special test strips, which, when inserted into an electronic meter, would inform them of their blood glucose levels. Over the next several decades, Roche continued to innovate and develop blood glucose self-testing technology and test strips used by millions of diabetes patients. In addition, Roche developed ways to improve the speed and efficiency in manufacturing such test strips. Two of Roche's key inventions in this regard are patented in the '467 and '849 patents.

9. The '467 patent, entitled "Reagent Stripe for Test Strip," was duly and legally issued on June 1, 2010, to inventors David W. Burke, Michael Marquant, Udo Zapf, Michael Fritz, Dan Mosoiu, and Chris Wilsey. A true and correct copy of the '467 patent is attached as **Exhibit 1**.

10. The '849 patent, entitled "Reagent Stripe for Test Strip," was duly and legally issued on February 22, 2011, to inventors David W. Burke, Michael Marquant, Udo Zapf, Michael Fritz, Dan Mosoiu, and Chris Wilsey. A true and correct copy of the '849 patent is attached as **Exhibit 2**.

11. The test strip of the '467 patent, for example, comprises a base substrate having a working electrode and a counter electrode formed thereon and having two opposite side edges and an end edge; a spacing layer overlying the base substrate and having a void that at least partially defines a sample-receiving chamber; a covering layer overlying the spacing layer; and a reagent layer disposed in the sample-receiving chamber and covering a portion of the base substrate and at least one of the electrodes, the reagent layer extending under the spacing layer to the two side edges of the base substrate and being sandwiched between the spacing layer and the base substrate. **Exhibit 1** ('467 patent), claim 1. Further, for example, the '849 patent claims a method of manufacturing a test strip having first and second sides, a sample-receiving end and a meter insertion end, and a central longitudinal axis extending between the two ends, the method comprising: (a) providing a web of base substrate material having first and second web edges; (b) forming an electrode set on the web comprising a working electrode and a counter electrode; (c) applying a stripe of reagent material to the web and covering at least one electrode of the electrode set with the stripe, the stripe being oriented substantially parallel to the first web edge; and (d) laminating a web of spacing material on top of the base substrate material and providing a cavity in the spacing material such that the electrode set is received within the cavity and the cavity at least partially defines a sample receiving chamber; (e) aligning and then laminating a web of covering layer material over the web of base substrate and spacing material; and (f) cutting a test strip from the laminated web produced from steps (a)-(e), the cutting defining the first and second sides of the test strip, wherein the test strip comprises a reagent layer extending to the first and second sides of the test strip under the spacing layer. **Exhibit 2** ('849 patent), claim 1.

12. Roche owns all rights, title, and interest in the '467 and '849 patents.

## II. TRIVIDIA'S INFRINGEMENT

13. Trividia makes, sells, offers for sale, uses, imports, and supplies infringing products, including at least TRUE METRIX® Test Strips and TRUE METRIX® PRO Test Strips (the “Infringing Products”):<sup>1</sup>

### TRUE METRIX® Test Strips

Advanced technologies – the meter, a complex algorithm, chemistry and electrodes on the test strip – work together as part of the TRUE METRIX® system to produce accurate results.



### Features

TRIPLE SENSE TECHNOLOGY® automatically detects, analyzes and corrects variables<sup>1</sup> in each blood sample to ensure proven accuracy and confidence in results.

### TRUE METRIX® PRO Test Strips

Advanced technologies – the meter, a complex algorithm, chemistry and electrodes on the test strip – work together as part of the TRUE METRIX® PRO system to produce accurate results.



For use only with TRUE METRIX PRO Meter

### Features

TRIPLE SENSE TECHNOLOGY® automatically detects, analyzes and corrects variables<sup>1</sup> in each blood sample to ensure proven accuracy and confidence in results.

<sup>1</sup> See <https://www.trividiahealth.com/products/blood-glucose-meters-test-strips/true-metrix/#true-metrix-test-strips> (**Exhibit 3**); <https://www.trividiahealth.com/products/blood-glucose-meters-test-strips/true-metrix-pro/#true-metrix-test-strips> (**Exhibit 4**).

14. The Infringing Products further include (1) any products or components that were imported, made, used, sold, and/or offered for sale by or on behalf of Trividia in connection with and/or as part of the TRUE METRIX® Test Strips and TRUE METRIX® PRO Test Strips, and (2) any other of Trividia's products that embody like functionality and structure of the TRUE METRIX® Test Strips and TRUE METRIX® PRO Test Strips, including without limitation, the test strips intended for use and/or sold with the TRUE METRIX® Self Monitoring Blood Glucose System, TRUE METRIX® AIR Self Monitoring Blood Glucose System, TRUE METRIX GO® Self Monitoring Blood Glucose System, and TRUE METRIX® PRO Professional Monitoring Blood Glucose Meter.

15. Trividia's infringing manufacturing method includes the method that Trividia performs to manufacture each of the Infringing Products in the United States (the "Infringing Method").

16. By selling, manufacturing, using, offering for sale in the United States and/or importing into the United States the Infringing Products, Trividia has infringed and continues to infringe the '467 and '849 patents and has benefited from doing so.

17. On information and belief, Trividia knew of and/or was willfully blind to the '467 and '849 patents, and Trividia's infringements of the '467 and '849 patents were knowing and willful or willfully blind. *First*, on information and belief, Trividia has hired Roche employees, including employees that have worked on Roche's blood glucose meter and/or test strip products, who have knowledge of Roche's patents on blood glucose meter technology and test strip technology. *See, e.g.*, U.S. Patent No. 8,574,424 (Trividia blood glucose meter and test strip patent listing former Roche employee among inventors, and citing Roche patents); U.S. Patent No. 8,529,741 (same). On information and belief, Trividia identified, monitored, investigated, and

assessed Roche's patent portfolio and Roche's marked blood glucose meter and test strip patents, and that portfolio includes the '467 and '849 patents. *See, e.g.*, U.S. Patent No. 8,574,424 (Trividia patent citing Roche's U.S. Patent No. 5,997,817, entitled "Electrochemical biosensor test strip," which shares a named inventor with the '467 and '849 patents); U.S. Patent No. 8,394,328 (Trividia patent citing numerous Roche patents directed to *inter alia* test strip containers, and measuring substance concentrations using test strips); WO 2007/022215 A3 (search report for patent application filed by Home Diagnostics, Inc.—Trividia's predecessor—citing US 2005/016844 A1, the patent application publication that would issue as the '467 patent). Additionally, upon information and belief, Roche is among the top three companies whose patents are cited by Trividia's patents.

18. *Second*, on information and belief, Trividia is a sophisticated company in the diabetes management market. On information and belief, it is common practice for companies in the diabetes management market—such as Trividia—to monitor, investigate, and assess competitor products and competitor patents for risk assessment purposes, including, on information and belief, patents marked on Roche products, such as Roche's Accu-Chek blood glucose meter and test strip products and the patents marked thereon. For example, Trividia's predecessor, Home Diagnostics, Inc., publicly stated that it performed investigations of the intellectual property of third parties.<sup>2</sup>

19. Further, the '467 and '849 patents are well-known in the industry and have been cited by dozens of patents and patent applications. Additionally, prior to this complaint and during the damages period under 35 U.S.C. § 286, Roche properly marked and marks its blood glucose

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<sup>2</sup> *See* Home Diagnostics Form 10-K (2007) at 20, *available at* <https://www.sec.gov/Archives/edgar/data/884909/000095014408001992/g12278e10vk.htm>.

test strip products that practice the '467 and '849 patents—including combination products that include practicing test strips—with the word “patent” or the abbreviation “pat.” and an address of a posting on the Internet that associated those patented articles with the '467 and '849 patents, in compliance with 35 U.S.C. § 287. Trividia’s TRUE METRIX® Test Strips and TRUE METRIX® PRO Test Strips are in direct competition with Roche’s Accu-Chek test strip and combination products marked with the '467 and '849 patents and therefore, on information and belief, Trividia considered Roche’s Accu-Chek® test strip and combination products to be in competition with its TRUE METRIX® Test Strips and TRUE METRIX® PRO Test Strips. For example, Roche previously sued Trividia’s predecessor, Home Diagnostics, Inc., for patent infringement in the Southern District of Indiana. Thus, on information and belief, Trividia monitored, investigated, and assessed at least the patents marked on Roche’s Accu-Chek® test strip and combination products, and therefore knew or should have known that its TRUE METRIX® Test Strips and TRUE METRIX® PRO Test Strips were infringing at least the '467 and '849 patents, or else Trividia deliberately avoided evaluating its products and was willfully blind to its infringement of the '467 and '849 patents and acted despite an objectively high likelihood that its products infringed the '467 and '849 patents.

20. *Third*, on April 28, 2023, Roche sent Trividia a letter identifying the '467 patent “in connection with [Trividia’s] True Metrix® line of products.” The letter was sent to Jonathan Chapman, CEO of Trividia, with copies to Jason Mondek, Senior Vice President of Trividia and Pennie Goldman, Corporate Counsel for Trividia. The letter identified and attached a copy of the '467 patent. The letter provided Trividia with actual notice of the '467 patent at least by April 28, 2023. On information and belief, Trividia then analyzed the '467 patent and its family members, including the related '849 patent, and came to the conclusion that it infringed the '467 and '849



patents, as set forth in paragraphs 24 to 56 below. Thus, on information and belief, at least as of April 28, 2023, Trividia had actual knowledge of the '467 and '849 patents, and had actual knowledge of its infringement of those patents or was willfully blind to its infringement of those patents.

21. Further, on June 27, 2023, Roche gave a presentation to Trividia. During that presentation, Roche again identified the '467 patent. That presentation also identified, *inter alia*, “Method of Manufacture Family Members” including the '849 patent. The presentation provided Trividia with actual notice of the '467 patent and '849 patent no later than June 27, 2023. During the presentation, Roche’s representatives explained how and why Trividia’s “TrueMetrix Test Strip” met each limitation of claim 1 of the '467 patent, including by annotating images of Trividia’s “TrueMetrix Test Strip” product to explain how the product met each limitation. After the presentation, Roche sent a copy of the PowerPoint to Trividia.

22. By virtue of the fact that Roche included the '849 patent in the presentation, Trividia understood that Roche was also alleging that Trividia’s “TrueMetrix Test Strip” was made using a process that practices the '849 patent. Roche also explained during the presentation why and how Trividia’s manufacturing process infringed the '849 patent. Upon information and belief, Trividia subsequently evaluated (or, at minimum, should have evaluated) the '849 patent—a family member of the '467 patent that was identified in the presentation—to determine whether it infringes the '849 patent’s claims and thereby gained further knowledge of its infringement of the '849 patent, as set forth in paragraphs 42 to 56 below, or else Trividia deliberately avoided evaluating its manufacturing methods and was willfully blind to its infringement of the '849 patent and acted despite an objectively high likelihood that its products infringed the '849 patent. Thus, by no later than June 27, 2023, Trividia had actual knowledge of the '467 patent and the '849

patent, and actual knowledge of its infringement of those patents or was willfully blind to its infringement.

23. Nevertheless, Trividia has not licensed the '467 and '849 patents and has continued its willful and deliberate infringement of the '467 and '849 patents, including by continuing to make, use, import, promote, market, sell, and offer to sell the TRUE METRIX® Test Strips and TRUE METRIX® PRO Test Strips with knowledge of their infringement.

**COUNT 1**  
**(INFRINGEMENT OF THE '467 PATENT)**

24. Roche incorporates each of the above paragraphs as though fully set forth herein.

25. On information and belief, Trividia directly or through the actions of its employees, agents, distributors, divisions, affiliates, and/or subsidiaries, has infringed one or more of the claims of the '467 patent, including at least claim 1, directly, indirectly, literally and/or by equivalents under 35 U.S.C. §§ 1 *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), supplying, distributing, selling, offering for sale the Infringing Products in the United States and/or importing the Infringing Products within the United States, and/or inducing or contributing to such acts, without authority.

26. For example, Trividia infringes each element of at least claim 1 the '467 patent, which states:

Claim 1. A test strip, comprising:

a base substrate having a working electrode and a counter electrode formed thereon and having two opposite side edges and an end edge;

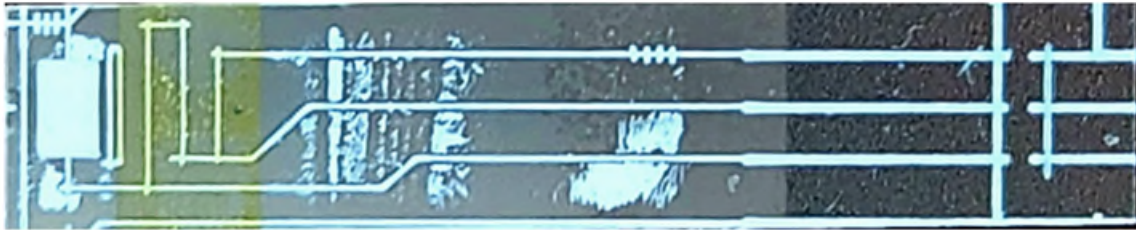
a spacing layer overlying the base substrate and having a void that at least partially defines a sample-receiving chamber;

a covering layer overlying the spacing layer; and

a reagent layer disposed in the sample-receiving chamber and covering a portion of the base substrate and at least one of the electrodes, the reagent layer extending under the spacing layer to the two side edges of the base substrate and being sandwiched between the spacing layer and the base substrate.

27. Each Infringing Product is a test strip, intended for use with a blood glucose meter to quantitatively measure whole blood glucose in blood taken from the fingertip.

28. Each Infringing Product is a test strip comprising multiple layers, where the bottom is a base substrate as claimed. For example, the following image shows a TRUE METRIX test strip with all but the base substrate removed:

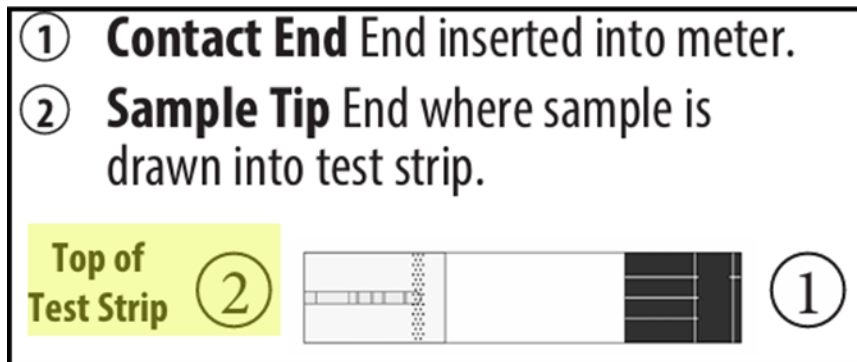


29. As shown above, the base substrate of each Infringing Product has a working electrode and a counter electrode formed on the base substrate. According to Trividia's product documentation, the strip "is a plastic strip containing chemicals and electrodes."<sup>3</sup> When blood is drawn into the sample tip of the test strip, glucose in the blood sample reacts with the chemicals and produces an electrical current.

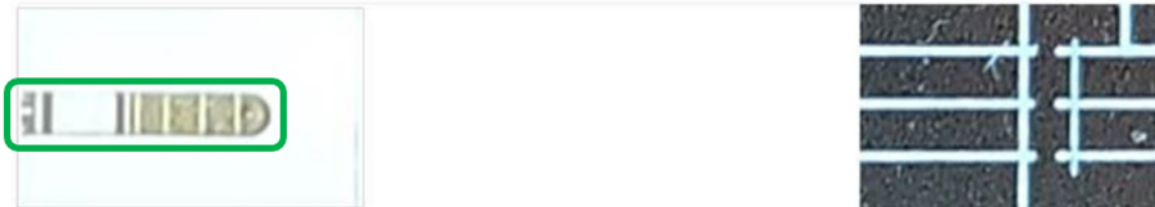
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<sup>3</sup> [https://www.trividiahealth.com/wp-content/uploads/2021/04/TRUE\\_METRIX\\_InstructionsForUse\\_RF3TVH03r53.pdf](https://www.trividiahealth.com/wp-content/uploads/2021/04/TRUE_METRIX_InstructionsForUse_RF3TVH03r53.pdf) (**Exhibit 5**).

30. As shown above, the base substrate of each Infringing Product has two opposite side edges and an end edge as claimed. Trividia documents also refer to the “top of test strip” or “sample tip end”:<sup>4</sup>



31. Each Infringing Product has a spacing layer overlying the base substrate. For example, the following image shows the spacing layer of the TRUE METRIX test strip positioned on top of the base substrate.

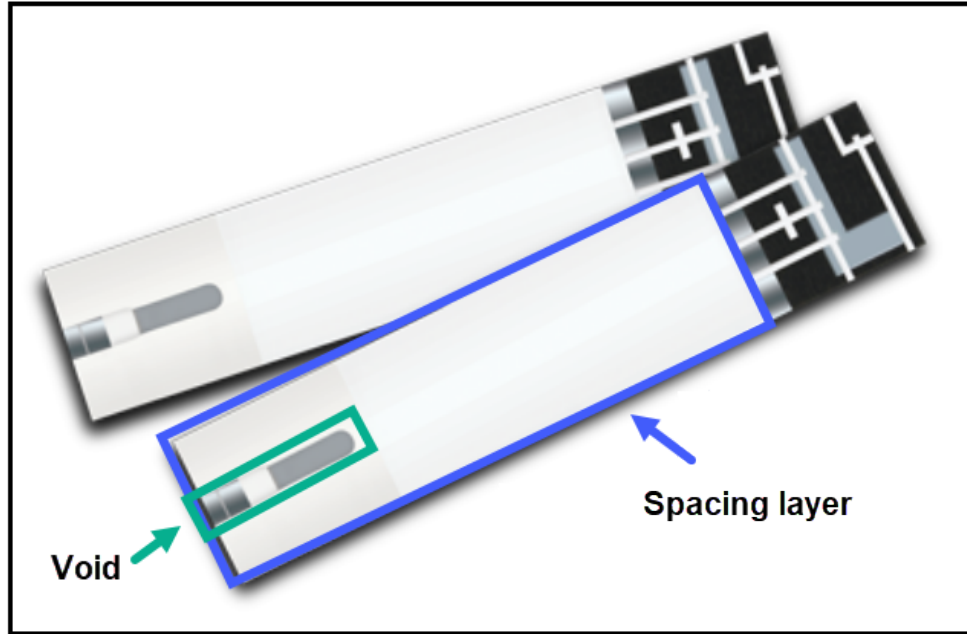


32. As shown above and circled in green, the spacing layer of each Infringing Product has a void that at least partially defines a sample-receiving chamber.

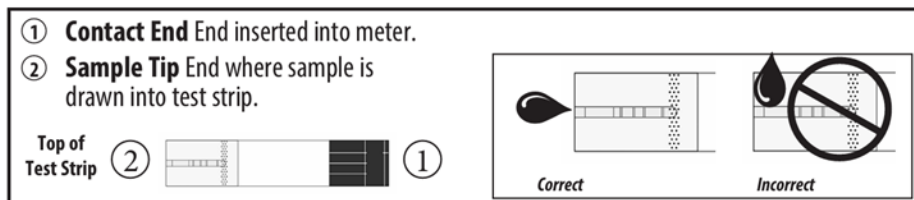
33. Trividia documents further show a spacing layer (in blue) and void (in green):<sup>5</sup>

<sup>4</sup> [https://www.trividiahealth.com/wp-content/uploads/2021/04/TRUE\\_METRIX\\_InstructionsForUse\\_RF3TVH03r53.pdf](https://www.trividiahealth.com/wp-content/uploads/2021/04/TRUE_METRIX_InstructionsForUse_RF3TVH03r53.pdf) (**Exhibit 5**); <https://www.trividiahealth.com/wp-content/uploads/2022/11/TMX-PRO-IFU-R3TVHP03.pdf> (**Exhibit 6**).

<sup>5</sup> <https://www.trividiahealth.com/products/blood-glucose-meters-test-strips/true-metrix/#true-metrix-test-strips> (**Exhibit 3**); <https://www.trividiahealth.com/products/blood-glucose-meters-test-strips/true-metrix-pro/> (**Exhibit 4**).



34. The void in the spacing layer at least partially defines a sample-receiving chamber as shown below.<sup>6</sup>



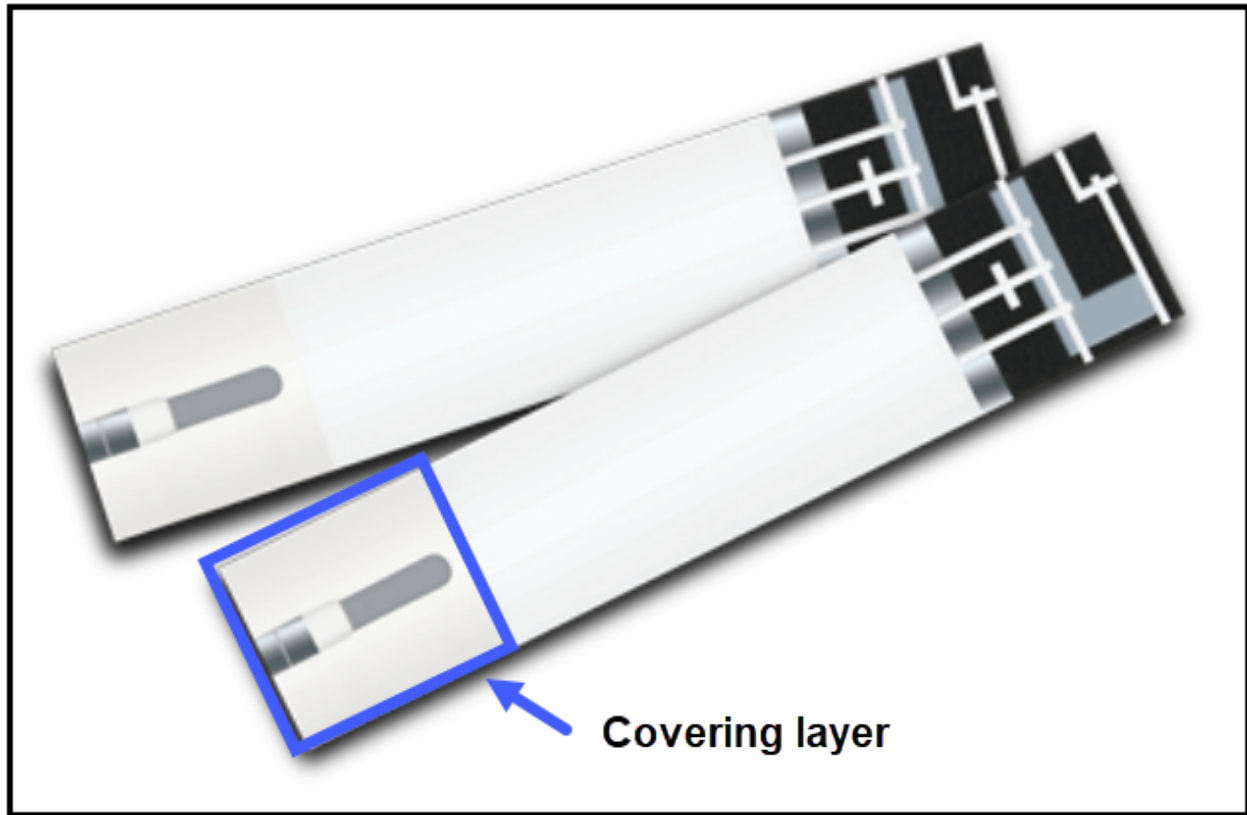
<sup>6</sup> [https://www.trividiahealth.com/wp-content/uploads/2021/04/TRUE\\_METRIX\\_InstructionsForUse\\_RF3TVH03r53.pdf](https://www.trividiahealth.com/wp-content/uploads/2021/04/TRUE_METRIX_InstructionsForUse_RF3TVH03r53.pdf) (**Exhibit 5**); <https://www.trividiahealth.com/wp-content/uploads/2022/11/TMX-PRO-IFU-R3TVHP03.pdf> (**Exhibit 6**); [https://youtu.be/eOjCUI6OxIM?si=AsNCVfyfYR2xs\\_P6&t=117](https://youtu.be/eOjCUI6OxIM?si=AsNCVfyfYR2xs_P6&t=117).



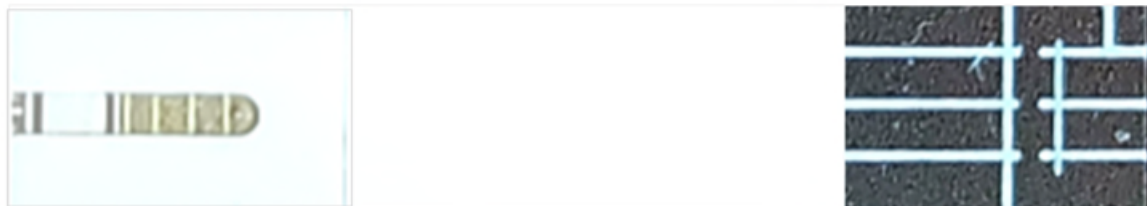
35. Each Infringing Product has a covering layer overlying the spacing layer as claimed. For example, Trividia documents show a covering layer (annotated in blue) overlying the spacing layer as shown below:<sup>7</sup>

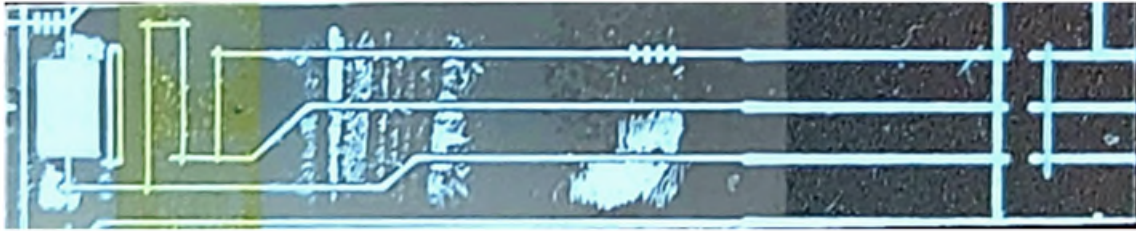
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<sup>7</sup> <https://www.trividiahealth.com/products/blood-glucose-meters-test-strips/true-metrix/> (**Exhibit 3**); <https://www.trividiahealth.com/products/blood-glucose-meters-test-strips/true-metrix-pro/> (**Exhibit 4**).



36. Each Infringing Product has a reagent layer disposed in the sample-receiving chamber and covering a portion of the base substrate and at least one of the electrodes as claimed. Below is an exemplary picture of a TRUE METRIX test strip with the spacing layer/covering layer and without the spacing layer/covering layer:





37. As shown above, the reagent layer (yellow) extends to the two side edges of the base substrate. The reagent layer also covers a portion of the base substrate and at least one of the electrodes. The reagent layer is sandwiched between the spacing layer and the base substrate. The reagent layer is disposed in the sample-receiving chamber.

38. On information and belief, Trividia has also induced infringement of the '467 patent under § 271(b) by providing customers (including white label resellers) with the Infringing Products and encouraging its customers to sell the Infringing Products in the United States. Trividia has also induced infringement by directing end users to purchase and use the Infringing Products, providing technical support for the Infringing Products. *See, e.g., Exhibit 5*, TRUE METRIX® Self-Monitoring Test Strips Instructions for Use (providing instructions for using the TRUE METRIX® Self-Monitoring Test Strips); *Exhibit 6*, TRUE METRIX® PRO Test Strips Instructions for Use (providing instructions for using the TRUE METRIX® PRO Test Strips).

39. As alleged above in paragraphs 17-21, Trividia both had knowledge of the '467 patent and understood that the Infringing Products infringed the '467 patent. Moreover, the Infringing Products include the same structure and characteristics as the claimed inventions of the '467 patent, as alleged above. *See, e.g., supra ¶¶ 20-21, 25-37*. At a minimum, Trividia acted with willful blindness of infringement of the '467 patent. Thus, by selling, distributing, and/or



marketing the Infringing Products to customers, Trividia specifically intended for and induced its customers (including white label resellers) to infringe the '467 patent.

40. For the reasons alleged above in paragraphs 14-21, Trividia's infringement was willful and deliberate because, on information and belief, Trividia knew of and/or was willfully blind to the '467 patent and knew or should have known of its infringement but acted despite an objectively high likelihood that such acts would infringe the '467 patent.

41. Roche has sustained damages as a direct and proximate result of Trividia's infringement of the '467 patent. Roche is entitled to recover damages for Trividia's infringement under 35 U.S.C. § 284, including damages for convoyed sales. Roche has further complied with the marking requirement of 35 U.S.C. § 287. The amount of damages will be proven at trial.

**COUNT 2**  
**(INFRINGEMENT OF THE '849 PATENT)**

42. Roche incorporates each of the above paragraphs as though fully set forth herein.

43. On information and belief, Trividia directly or through the actions of its employees, agents, distributors, divisions, affiliates, and/or subsidiaries, has infringed one or more of the claims of the '849 patent, including at least claim 1, directly, indirectly, literally and/or by equivalents under 35 U.S.C. §§ 1 *et seq.*, including, but not limited to § 271 by, among other things, using (including during research and development activities and product testing) the Infringing Method without authority.

44. For example, Trividia infringes each element of at least claim 1 the '849 patent, which states:

Claim 1. A method of manufacturing a test strip having first and second sides, a sample-receiving end and a meter insertion end, and a central longitudinal axis extending between the two ends, the method comprising:

- (a) providing a web of base substrate material having first and second web edges;
- (b) forming an electrode set on the web comprising a working electrode and a counter electrode;
- (c) applying a stripe of reagent material to the web and covering at least one electrode of the electrode set with the stripe, the stripe being oriented substantially parallel to the first web edge; and
- (d) laminating a web of spacing material on top of the base substrate material and providing a cavity in the spacing material such that the electrode set is received within the cavity and the cavity at least partially defines a sample receiving chamber;
- (e) aligning and then laminating a web of covering layer material over the web of base substrate and spacing material; and
- (f) cutting a test strip from the laminated web produced from steps (a)-(e), the cutting defining the first and second sides of the test strip, wherein the test strip comprises a reagent layer extending to the first and second sides of the test strip under the spacing layer.

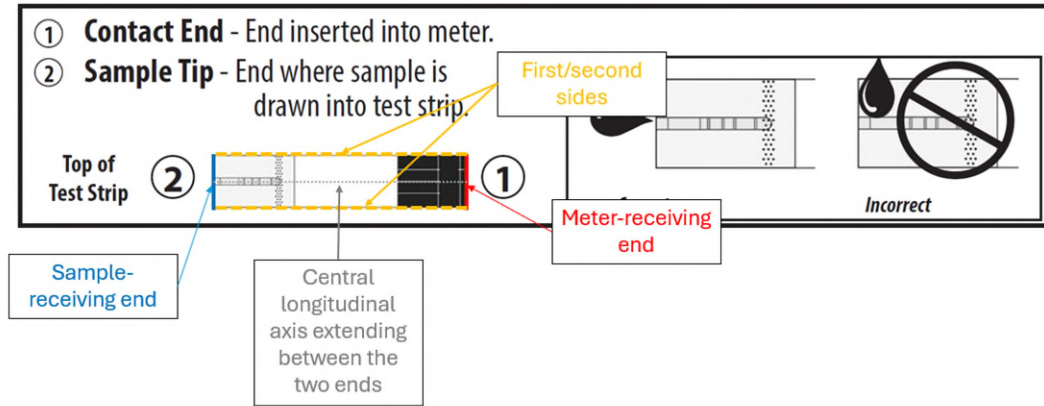
45. Trividia performs a method of manufacturing a test strip in the United States to produce the Infringing Products. For example, Trividia (then Nipro Diagnostics) described its manufacturing of TRUE METRIX and TRUE METRIX PRO test strips in the United States.<sup>8</sup>

46. Test strips produced by the Infringing Method have first and second sides, a sample-receiving end and a meter insertion end, and a central longitudinal axis extending between the two ends. For example, Trividia documents show how test strips produced by the Infringing Method has each of these elements, as shown by the annotated figure below:<sup>9</sup>

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<sup>8</sup> See <https://www.businesswire.com/news/home/20140824005009/en/Nipro-Diagnostics-Inc.-Announces-FDA-Clearance-of-its-Newest-Blood-Glucose-Monitoring-Systems-TRUE-METRIX-and-TRUE-METRIX-PRO-and-Expansion-of-Manufacturing-in-the-USA> (**Exhibit 7**).

<sup>9</sup> [https://www.trividiahealth.com/wp-content/uploads/2021/04/TRUE\\_METRIX\\_InstructionsForUse\\_RF3TVH03r53.pdf](https://www.trividiahealth.com/wp-content/uploads/2021/04/TRUE_METRIX_InstructionsForUse_RF3TVH03r53.pdf) (**Exhibit 5**); <https://www.trividiahealth.com/wp-content/uploads/2022/11/TMX-PRO-IFU-R3TVHP03.pdf> (**Exhibit 6**).



47. On information and belief, certain steps of the Infringing Method are the same or are materially the same as the steps shown and described in a demonstration video produced by Liberty Medical (the “Liberty Demonstration”).<sup>10</sup> On information and belief, the Liberty Demonstration shows the manufacturing process to produce certain test strips of Nipro Diagnostics (now Trividia). For example, as shown in the screen capture below, an employee shown in the video is wearing a shirt with the “Nipro” logo. Further, Nipro Diagnostics manufactured test strips for distribution by Liberty Medical.<sup>11</sup>

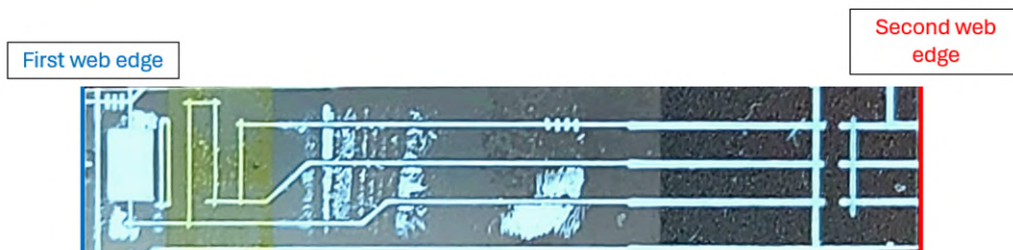
<sup>10</sup> <https://www.youtube.com/watch?v=72IgXDMOE60>.

<sup>11</sup> <https://www.sec.gov/Archives/edgar/data/884909/000095012310011266/c56181exv99waw5wb.htm>; <https://www.cnbc.com/2012/10/10/nipro-diagnostics-introduces-extensive-new-line-of-ancillary-products-for-the-diabetes-category.html>.



48. On information and belief, certain steps shown in the Liberty Demonstration are the same or materially the same as steps present in the Infringing Method, as explained for each claim element below.

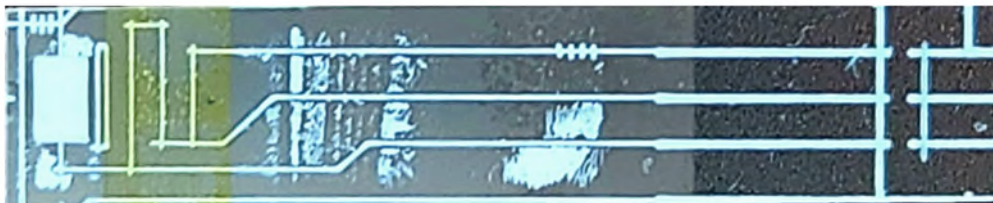
49. The Infringing Method includes the step of providing a web of base substrate material having a first and second web edges as claimed. For example, test strips produced by the Infringing Method have a base substrate material having first and second web edges. The following annotated image shows a TRUE METRIX test strip with all but the base substrate removed:



*See also supra* ¶¶ 27-30. On information and belief, during manufacturing, the test base substrate material is provided in the form of a web, as in the Liberty Demonstration. In that video, the

narrator explains: “The strip manufacturing process uses multiple layers of materials. *Our base material* is constructed using 24 karat gold that has been *applied to a rigid plastic* backing.”<sup>12</sup>

50. Next, the Infringing Method forms an electrode set on the web comprising a working electrode and a counter electrode as claimed. Test strips produced by the Infringing Method have an electrode set on the base substrate material comprising a working electrode and counter electrode. For example, the TRUE METRIX test strip produced by the Infringing Method has an electrode set formed on the base substrate material comprising a working electrode and a counter electrode:



*See also supra* ¶¶ 28-29. On information and belief, during manufacturing, an electrode set is formed on the web of base substrate material. For example, the Liberty Demonstration describes that an electrode set is formed on the web of base substrate material. The narrator explains that “[T]wo of the electrodes ensure an adequate blood sample. The other two measure the glucose reaction.”<sup>13</sup> Nipro Diagnostics (now Trividia) also issued a press release describing how electrodes are formed on the test strips: “The high-speed, high-accuracy manufacturing line will

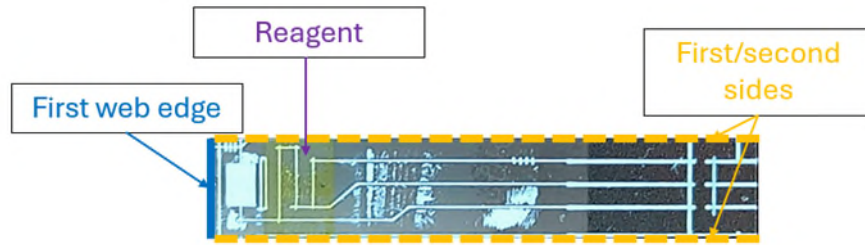
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<sup>12</sup> <https://youtu.be/72IgXDMOE60?si=pyeUOuMKOwDtdV6v&t=91>.

<sup>13</sup> <https://youtu.be/72IgXDMOE60?si=-bJm1S9z9B0pKUvM&t=97>.

employ the latest innovative technologies *including precision lasers that ablate electrodes on the test strips...*<sup>14</sup>

51. Next, the Infringing Method applies a stripe of reagent material to the web and covering at least one electrode of the electrode set with the stripe, the stripe being oriented substantially parallel to the first web edge as claimed. Test strips produced by the Infringing Method have a stripe of reagent material to the web and covering at least one electrode of the electrode set with the stripe, the stripe being oriented substantially parallel to the first web edge as claimed, as shown, for example, by the following annotated image of a TRUE METRIX test strip:

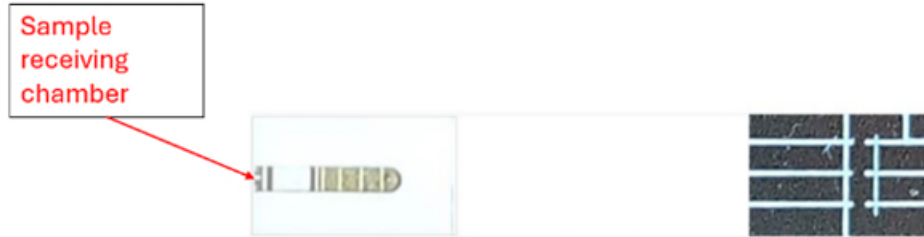


See also *supra* ¶¶ 28-29. Based on the image above, and on information and belief, the Infringing Method applies the reagent layer as a stripe in parallel with the first web edge.

52. Next, the Infringing Method laminates a web of spacing material on top of the base substrate material that provides a cavity in the spacing material such that the electrode set is received within the cavity and the cavity at least partially defines a sample receiving chamber as claimed. Test strips produced by the Infringing Method have spacing material laminated on top of the base substrate material that provides a cavity in the spacing material such that the electrode set is received within the cavity and the cavity at least partially defines a sample receiving chamber.

<sup>14</sup> <https://www.businesswire.com/news/home/20140824005009/en/Nipro-Diagnostics-Inc.-Announces-FDA-Clearance-of-its-Newest-Blood-Glucose-Monitoring-Systems-TRUE-METRIX-and-TRUE-METRIX-PRO-and-Expansion-of-Manufacturing-in-the-USA> (**Exhibit 7**).

For example, the following annotated image shows a TRUE METRIX test strip shows these elements:



*See also supra* ¶¶ 31-34. On information and belief, during manufacturing, a web of spacing material is laminated on top of the base substrate material, as shown in the Liberty Demonstration Video.<sup>15</sup> The narrator in the Liberty Demonstration Video explains that “[t]hen, we add material to protect the electrodes and create a space where chemistry is applied and blood is connected.”<sup>16</sup>

53. Next, the Infringing Method aligns and then laminates a web of covering layer material over the web of base substrate and spacing material as claimed. Test strips produced by the Infringing Method have a covering layer material over the base substrate and spacing material as claimed. *See* paragraph 31, which is incorporated by reference. On information and belief, during manufacturing, a web of covering layer material is aligned and then laminated over the web of base substrate and spacing material, as shown by the Liberty Demonstration.<sup>17</sup> The narrator in the Liberty Demonstration video explains that “a final layer protects the chemistry and helps draw the blood into the test strip.”<sup>18</sup>

<sup>15</sup> <https://youtu.be/72IgXDMOE60?si=HC0dMUbGKz6KYYcQG&t=135>.

<sup>16</sup> [https://youtu.be/72IgXDMOE60?si=JvQEjgHbMC\\_v5f9K&t=129](https://youtu.be/72IgXDMOE60?si=JvQEjgHbMC_v5f9K&t=129).

<sup>17</sup> <https://youtu.be/72IgXDMOE60?si=2VhDlgnM56qb3ab8&t=84>.

<sup>18</sup> <https://youtu.be/72IgXDMOE60?si=cBLKGGxLsQ5v4TJn&t=137>.

54. Next, the Infringing Method cuts a test strip from the laminated web produced from steps (a)-(e), the cutting defining the first and second sides of the test strip, wherein the test strip comprises a reagent layer extending to the first and second sides of the test strip under the spacing layer. Test strips produced by the Infringing Method have a reagent layer extending from the first to second side of the test strip under the spacing layer, as shown, for example, by the following annotated image of a TRUE METRIX test strip:



*See also supra* ¶¶ 28-29. On information and belief, the Infringing Method cuts a test strip from the laminated web produced from the foregoing steps (a)-(e), the cutting defining the first and second sides of the test strip, wherein the test strip comprises a reagent layer extending to the first and second sides of the test strip under the spacing layer. For example, in the Liberty Demonstration Video, the narrator explains that “the strips are cut with high speed rotary blades into individual strips and inserted into test strip vials.”<sup>19</sup> The Liberty Demonstration Video further shows that the cutting defines a first and second side of each test strip. *Id.*

55. As alleged above at paragraphs 17-23, Trividia both had knowledge of the ’849 patent and understood that the Infringing Method infringed the ’849 patent. Trividia’s infringement was willful and deliberate because, on information and belief, Trividia knew of

<sup>19</sup> <https://youtu.be/72IgXDMOE60?si=IjkeFNK4rJUzefCM&t=155>.



and/or was willfully blind to the '849 patent and knew or should have known of its infringement but acted despite an objectively high likelihood that such acts would infringe the '849 patent.

56. Roche has sustained damages as a direct and proximate result of Trividia's infringement of the '849 patent. Roche is entitled to recover damages for Trividia's infringement under 35 U.S.C. § 284, including damages for convoyed sales. The amount of damages will be proven at trial.

#### **DEMAND FOR JURY TRIAL**

57. Pursuant to Federal Rule of Civil Procedure 38(b), Roche hereby demands a trial by jury on all issues so triable.

#### **PRAYER FOR RELIEF**

WHEREFORE, Roche prays for relief, declaration and judgment that:

- A. Trividia has infringed the '467 and '849 patents under at least 35 U.S.C. § 271, including at least § 271 (a), (b), (c), (f), and (g);
- B. Roche is entitled to an award of damages pursuant to 35 U.S.C. § 284, including pre-judgment and post-judgment interest;
- C. Trividia's infringement of the '467 and '849 patents was willful and Roche is entitled to enhanced damages up to and including trebling of the damages awarded to it;
- D. Roche is entitled to costs and reasonable expenses to the fullest extent permitted by law;
- E. Roche is entitled to an injunction against Trividia, all persons acting in concert or participation with Trividia, all parent and subsidiary corporations and affiliates, and

their assigns and successors in interest from continuing acts of infringement of the '467 and '849 patents;

F. This case is exceptional pursuant to 35 U.S.C. § 285, and Roche is entitled to an award of attorneys' fees; and

G. Roche is entitled to other and further relief as the Court may deem just and proper.

DATED: June 4, 2024

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