

July 10, 2026

BY EDIS

The Honorable Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street SW
Washington, DC 20436

**Re: Certain Melanoma Predictive and Prognostic Tests and Components
Thereof, Inv. No. 337-TA-___**

Dear Secretary Barton:

Enclosed for filing on behalf of Complainant Castle Biosciences, Inc. (“Castle” or “Complainant”) are documents in support of Castle’s request that the Commission commence an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended. Pursuant to the Commission Rules of Practice and Procedure, a request for confidential treatment of Confidential Exhibit 14C is being transmitted with this filing. In accordance with the Commission’s Rules enclosed are the following:

1. one electronic copy of Castle’s verified Complaint and Statement of Public Interest (Rules 210.8(a)(1)(i) and 210.8(b));
2. one electronic copy of each of the accompanying non-confidential exhibits to the Complaint (Rules 210.4(f) and 210.8(a));
3. one electronic copy of the accompanying confidential exhibit to the Complaint (Rules 201.6(c), 210.4(f) and 210.8(a)); and
4. a letter and certification pursuant to Commission Rules 201.6(b) and 210.5(d) requesting confidential treatment of Confidential Exhibit 14C.

Thank you for your attention to this matter.

Respectfully submitted,

/s/ Andrew K. Beverina

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**Re: Certain Melanoma Predictive and Prognostic Tests and Components
Thereof, Inv. No. 337-TA-___**

Dear Secretary Barton:

I am counsel for Complainant Castle Biosciences, Inc. In accordance with the requirements of 19 C.F.R. §§ 201.6(b) and 210.5 concerning confidential business information, Complainant respectfully requests confidential treatment of the business information contained in Confidential Exhibit 14C (the “Confidential Exhibit”) to the verified Complaint under Section 337 of the Tariff Act of 1930, as amended, filed concurrently herewith.

The information contained in the Confidential Exhibit for which Complainant seeks confidential treatment consists of (a) Complainant’s business operations, and (b) the business operations of Complainant’s investments in its testing and related operations, as that term is defined in the Complainant’s verified Complaint.

The information in the Confidential Exhibits described herein qualifies as confidential information pursuant to 19 C.F.R. § 201.6 because:

1. Substantially identical information is not available to the public;
2. The unauthorized disclosure of the information in the Confidential Exhibits could cause substantial harm to Complainant’s and/or third parties’ competitive positions; and
3. The disclosure of the information in the Confidential Exhibits could impair the Commission’s ability to obtain information necessary to perform its statutory function.

A non-confidential version of the Confidential Exhibit is provided in the public exhibits being filed with the verified Complaint.

Please contact me with any questions regarding this request for confidential treatment of the Confidential Exhibits. Thank you for your attention to this matter.

Respectfully submitted,

/s/ Andrew K. Beverina

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UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of

CERTAIN MELANOMA PREDICTIVE
AND PROGNOSTIC TESTS AND
COMPONENTS THEREOF

Inv. No. 337-TA-_____

COMPLAINANT CASTLE BIOSCIENCES, INC.'S PUBLIC INTEREST STATEMENT

Castle Biosciences, Inc. (“Castle”) respectfully submits this Statement on Public Interest pursuant to 19 C.F.R. § 210.8(b) in connection with the concurrently filed Complaint. The Complaint seeks relief against proposed respondents SkylineDx Holdings B.V., SkylineDx USA, Inc., Qiagen GmbH, and Qiagen LLC (“Proposed Respondents”) based on unfair methods of competition, including false and misleading advertising, in connection with certain melanoma predictive and prognostic tests and related components (the “Accused Products”).

This investigation involves the unfair methods of competition and unfair acts under Section 337(a)(1)(A), including false and misleading advertising actionable under the Lanham Act. As a remedy of Section violation alleged in the Complaint, Castle seeks (1) a limited exclusion order, pursuant to Section 337(d) of the Tariff Act of 1930, as amended, excluding from entry into the United States the Accused Products, and (2) a cease and desist order, pursuant to Section 337(f) of the Tariff Act of 1930, as amended, prohibiting the Proposed Respondents and their affiliates from importing, selling, offering for sale, selling for importation, transferring, distributing, advertising, and marketing the Accused Products that are imported or sold in connection with the unfair acts described in the Complaint.

The requested remedial orders would not have an adverse effect on public health and welfare in the United States, competitive conditions in the United States economy, the production

of like or directly competitive articles in the United States, or US consumers. To the contrary, the requested relief affirmatively serves the public interest by promoting accurate, non-misleading information in the context of cancer diagnostics and provides US consumers with accurate predictive and prognostic testing results that can reduce unnecessary medical intervention. The Commission has long recognized that remedying unfair methods of competition and unfair acts, including false and misleading advertising, serves the public interest. *See Certain Baseband Processor Chips and Chipsets, Transmitter and Receiver (Radio) Chips, Power Control chips, and Products Containing Same, Including Cellular Telephone Handsets*, Inv. No. 337-TA-543, Comm’n Op. at 150 (June 19, 2007) (“We must take into account the strong public interest in enforcing intellectual property rights.”); *Certain Raised Garden Beds and Components Thereof*, Inv. No. 337-TA-1334, Comm’n Op. (April 1, 2024) (issuing LEO for false advertising and trade secret misappropriation). And the exclusion of Proposed Respondents’ Accused Products would not “deprive the public of products necessary for some important health or welfare need.” *Spanston, Inc. v. U.S. Int’l Trade Comm’n*, 629 F.3d 1331, 1360 (Fed. Cir. 2010).

I. How the Accused Products Are Used in the United States

The Accused Products are melanoma predictive and prognostic gene expression profile tests used to inform clinical decision-making, including whether to perform sentinel lymph node biopsy (“SLNB”) in patients diagnosed with cutaneous melanoma.

II. No Public Health, Safety, or Welfare Concerns

The requested remedial orders would not pose any health, safety, or welfare concerns in the United States. To the extent any remedial orders limit the availability of the Accused Products, U.S. clinicians and patients would continue to have full access to Castle’s DecisionDx®-Melanoma and other lawfully marketed melanoma predictive and prognostic tests.

The Accused Products are relatively new to the US market and have not achieved widespread adoption. Their exclusion would therefore cause little, if any, disruption to the availability of melanoma predictive and prognostic testing services. If exclusion of the Accused Products causes any *de minimis* effect on health, safety, or welfare in the United States, DecisionDx®-Melanoma would be available to replace those products as needed to satisfy demand.

Importantly, the requested relief affirmatively promotes public health. Studies show that DecisionDx®-Melanoma is more accurate than Merlin in identifying patients with a <5% risk of SLN positivity. Cancer guidelines suggest consideration of a sentinel lymph node biopsy (“SLNB”) for patients with greater than 5% risk of sentinel lymph node (“SLN”) positivity. Those same guidelines do not recommend SLNB when the patient has less than 5% likelihood of a positive SLN. The Merlin Test low risk result identifies a risk of SLN positivity >5%, up to 7.1%. This means that patients who should be considered for SLNB might not be considered for it based on a low-risk result with poor accuracy for SLN positivity and might be denied medically necessary testing.

Castle’s increased accuracy for prediction of risk of SLN positivity prevents the need for unnecessary procedures, improving US consumer health and safety, and saving consumers and the health system money. Furthermore, studies show that those who use DecisionDx®-Melanoma have better long-term survival rates. Merlin does not have any such data.

III. Identification of Like or Directly Competitive Articles That Could Replace the Accused Products

Castle’s DecisionDx®-Melanoma is a like and directly competitive article to the Accused Products. Both products are melanoma predictive and prognostic gene profile tests designed to inform clinical decision-making, including SLNB decisions. DecisionDx®-Melanoma is

developed, performed, and commercialized in the United States and is widely available to clinicians nationwide. If the requested remedial orders issue, DecisionDx®-Melanoma and other lawfully marketed tests will continue to meet the needs of US clinicians and patients.

IV. Complainant Has the Capacity to Replace Any Excluded Articles Within a Commercially Reasonable Time

Castle has the capacity to replace, within a commercially reasonable period of time, the volume of melanoma predictive and prognostic testing potentially subject to remedial orders in this Investigation. Castle operates clinical laboratory facilities in Phoenix, Arizona and Pittsburgh, Pennsylvania and currently meets nationwide demand for melanoma predictive and prognostic testing. Castle has the infrastructure, personnel, and operational capability to absorb additional testing volume.

The Accused Products rely on components manufactured abroad and were developed by a Netherlands-based company before being commercialized in the United States. Accordingly, issuance of the requested remedial orders would not displace US manufacturing or adversely affect domestic employment.

V. The Requested Remedial Order Would Not Adversely Impact US Consumers

The requested remedial orders would not adversely impact US consumers. Clinicians and patients will continue to have access to widely available, clinically validated melanoma predictive and prognostic tests, including DecisionDx®-Melanoma.

The requested relief benefits US consumers by preventing diagnostic and treatment decisions from being influenced by false or misleading claims. The representations at issue—including claims regarding comparative performance, clinical validity, and purported superiority—directly affect which tests physicians order, which tests healthcare systems adopt, and which tests

payors reimburse. Preventing the use of such misleading claims promotes more reliable, evidence-based decision-making and protects patients.

VI. Conclusion

Castle respectfully submits that the allegations in the Complaint do not present an instance where the public interest issue should be delegated to the presiding ALJ in the Investigation.

Dated: July 10, 2026

Respectfully submitted,

/s/ Andrew K. Beverina

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UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of

CERTAIN MELANOMA PREDICTIVE
AND PROGNOSTIC TESTS AND
COMPONENTS THEREOF

Inv. No. 337-TA-_____

VERIFIED COMPLAINT OF CASTLE BIOSCIENCES, INC. UNDER SECTION 337 OF
THE TARIFF ACT OF 1930, AS AMENDED

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EXHIBIT LIST

Ex.	Description
1	RNeasy FFPE Kit (50) Safety Data Sheet
2	Bailey <i>et al.</i> 31-Gene Expression Profile Testing in Cutaneous Melanoma and Survival Outcomes in a Population-Based Analysis: A SEER Collaboration. <i>JCO Precis Oncol.</i> 2023;7: e2300044. doi: 10.1200/PO.23.00044
3	Whitman <i>et al.</i> Integrating 31-Gene Expression Profiling with Clinicopathologic Features to Optimize Cutaneous Melanoma Sentinel Lymph Node Metastasis Prediction. <i>JCO Precis Oncol.</i> 2021 Sep 13;5:PO.21.00162. doi: 10.1200/PO.21.00162. PMID: 34568719; PMCID: PMC8457832
4	Bellomo, D., <i>et al.</i> (2026), Flawed Benchmarks and Biased Cohorts: Reassessing the Evidence for CP-GEP (Merlin) Versus 31-GEP (DecisionDx®-Melanoma). <i>Int J Dermatol</i> , 65: 12-14. https://doi.org/10.1111/ijd.70000
5	A True Comparison of Merlin vs. DecisionDx
6	Hieken TJ, Egger ME, Angeles CV, et al. Gene Expression Profile–Based Test to Predict Melanoma Sentinel Node Status: The MERLIN_001 Study. <i>JAMA Surg.</i> 2025
7	Merlin – Advanced Generation Melanoma Gene Expression Profiling Test – January 2026 Flyer
8	SkylineDx USA’s publications landing page
9	Merlin – Advanced Generation Melanoma Gene Expression Profiling (GEP) Test) – February 2026 Flyer
10	News Article – New Data from SkylineDx Demonstrates Merlin CP-GEP Test’s Superior Melanoma Risk Stratification
11	Supplement to Hieken TJ, Egger ME, Angeles CV, et al. Gene Expression Profile–Based Test to Predict Melanoma Sentinel Node Status: The MERLIN_001 Study. <i>JAMA Surg.</i> 2025
12	<i>JCO Precis Oncol.</i> 2020;4:319-334. doi: 10.1200/po.19.00206. Epub 2020 Apr 14. PMID: 32405608; PMCID: PMC7220172 (“Bellomo 2020”)
13	U.S. Ordering Information
14C	Confidential Domestic Industry Declaration of Frank Stokes

I. INTRODUCTION

1. Complainant Castle Biosciences, Inc. (“Castle” or “Complainant”) is a U.S.-based developer and provider of molecular tests used by physicians to guide critical cancer care decisions. Through substantial investment in research and development, clinical validation, laboratory infrastructure, and physician education, sales, and marketing, Castle has advanced the use of gene expression profile testing to identify patients who might need treatment for cutaneous melanoma. Castle’s DecisionDx®-Melanoma test is an innovative, first-in-class predictive and prognostic test for melanoma. The test is predictive for sentinel lymph node (“SNL”) positivity and prognostic for risk of recurrence and/or metastasis. “Predictive” and “prognostic” can be used interchangeably as it relates to the melanoma testing that is the focus of this complaint. DecisionDx-Melanoma has both been granted Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) as well as Advanced Diagnostic Laboratory Test (“ADLT”) designation by the Centers for Medicare and Medicaid Services (“CMS”) and is widely used by clinicians across the United States to assess patient risk and inform treatment and surveillance decisions. In fact, in 2025, the National Cancer Institute’s SEER Program estimated the diagnosis (incidence) for melanoma at 104,960 patients. In that year, Castle issued 39,083 DecisionDx-Melanoma test results, indicating that a material percentage of diagnosed patients with melanoma received the test.

2. As the market for melanoma predictive and prognostic testing has expanded, foreign-based providers have begun marketing competing tests to U.S. clinicians and healthcare systems. Castle welcomes legitimate competition. But instead of competing based on accurate scientific evidence and fair comparison, some competitors resort to false and misleading promotional claims concerning the performance, clinical utility, and comparative attributes of an imported melanoma test offered for use in the United States.

3. This complaint is filed under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, to remedy unfair methods of competition and unfair acts—specifically, false advertising and related unfair competition—in the importation into the United States, or sale by the owner, importer, or consignee of their melanoma predictive and prognostic test and components thereof, including the “Merlin Test” (“Accused Products”).

4. The false and misleading statements described herein constitute unfair methods of competition and unfair acts under Section 337(a)(1)(A), including false and misleading advertising actionable under the Lanham Act. These unfair acts have the threat or effect of destroying or substantially injuring an industry in the United States.

5. Castle seeks the assistance of the United States International Trade Commission (“Commission”) to investigate and remedy these violations of Section 337. Castle requests that the Commission institute an investigation and issue a limited exclusion order (“LEO”) to prevent further importation and sale of the Accused Products in connection with the false and misleading advertising and unfair acts described herein. Castle further requests that the Commission issue permanent cease and desist orders (“CDO”) against the Proposed Respondents prohibiting the sale, offer for sale, advertising, marketing, packaging, distribution, maintenance of inventory, or solicitation of any sale of imported Accused Products, whether through direct sales, traditional “brick and mortar” retailers, distributors, the Internet, or other e-commerce platform(s). Complainant also requests that the Commission impose a bond on the Proposed Respondents’ importation of the Accused Products to protect Complainant from further injury during the 60-day Presidential review period.

II. THE PARTIES

A. THE COMPLAINANT

6. Castle is a Delaware corporation founded in 2007, with its principal place of business at 1500 W Parkwood Ave., Suite 400, Friendswood, Texas. Complainant is engaged in the research, development, commercialization, and provision of molecular tests and related services in the United States, including melanoma predictive and prognostic testing. Castle maintains substantial operations, personnel, and laboratory facilities in the United States.

B. THE PROPOSED RESPONDENTS

SkylineDx Holding B.V.

7. Upon information and belief, Respondent SkylineDx Holding B.V. (“SkylineDx BV”) is a company organized under the laws of the Netherlands, with its principal place of business at Lichtenauerlaan 40, 3062 ME Rotterdam, the Netherlands, and is engaged in the importation into the United States or sale as the owner, importer, or consignee of the Accused Products in the United States.

SkylineDx USA, Inc.

8. Respondent SkylineDx USA, Inc. (“SkylineDx USA”) is a Delaware corporation, with its principal place of business at 3030 Bunker Hill Street, Suite 230, San Diego, California 92109. It is described as SkylineDx Holding B.V.’s “laboratory in San Diego, California.” Upon information and belief, SkylineDx USA, Inc. is engaged in the importation into the United States, or sale as the owner, importer, or consignee of the Accused Products in the United States and the marketing, sale, and/or distribution of the Accused Products in the United States and in activities relating to the importation into the United States, or sale by the owner, importer, or consignee of the Accused Products.

Qiagen GmbH

9. Qiagen GmbH is a German corporation with a principal place of business at Qiagen Str. 1, D-40724 Hilden, Germany. Qiagen manufactures the RNeasy FFPE test kit in Germany for importation into the United States for use in SkylineDx's Merlin Test.

Qiagen LLC

10. Qiagen LLC is a California corporation with a principal place of business at 19300 Germantown Rd, Germantown, MD 20874. Upon information and belief, Qiagen LLC is a subsidiary of Qiagen GmbH and is responsible for sales of RNeasy FFPE in the United States.

III. THE PRODUCTS AT ISSUE AND THE ACCUSED PRODUCT

A. The Technology

11. Cutaneous melanoma is an aggressive form of skin cancer, so making timely and accurate assessment of a patient's risk of disease progression is critical for guiding treatment and follow-up care. Melanomas are categorized, or T-staged, on the basis of how deeply the primary tumor has grown into the skin, measured in millimeters (also known as Breslow thickness) and the presence or absence of ulceration.

T category	Definition
T1	≤1 mm
T1a	<0.8 mm thick without ulceration (broken skin)
T1b	<0.8 mm thick with ulceration OR 0.8-1 mm thick with or without ulceration.
T2	>1 mm to 2 mm
T2a	without ulceration
T2b	with ulceration
T3	>2 mm to 4 mm
T3a	without ulceration
T3b	with ulceration
T4	>4mm
T4a	without ulceration
T4b	with ulceration

12. Lymph nodes are part of the lymphatic system which is, in turn, part of the human immune system. Many types of cancer spread through the lymphatic system. If a tumor forms, the sentinel lymph node (“SLN”) is the first lymph node to which the cancer is likely to spread.

13. The generally accepted approach among clinicians is to consider a sentinel lymph node biopsy (“SLNB”) surgical procedure for patients with greater than 5% risk of SLN positivity. Clinicians generally do not recommend SLNB when the patient has less than 5% likelihood of a positive SLN.

14. Physicians traditionally relied upon clinicopathologic factors—such as Breslow thickness, ulceration, mitotic rate, and patient age—to estimate a patient’s risk of SLN involvement. Breslow thickness and ulceration as well as the presence of other adverse clinical or pathologic features, such as uncertainty about the Breslow’s thickness, a mitotic index $\geq 2/\text{mm}^2$ (particularly in the setting of young age), lymphovascular invasion or a combination of these and/or other histopathologic and clinical factors have been traditionally used to estimate risk of SLN positivity. All told, these factors are commonly known as clinicopathologic factors. While clinicopathologic factors provide useful information, they do not fully capture the underlying biological behavior of an individual patient’s tumor and can leave meaningful uncertainty in risk assessment and management decisions. For example, 88% of patients that undergo the SLNB surgical procedure on the basis of clinicopathologic information alone receive a negative result, indicating an opportunity to forgo the surgery in more patients that are unlikely to benefit from the procedure.

15. To address this gap, molecular gene expression profile (“GEP”) tests have been developed to provide additional predictive and prognostic information by analyzing a patient’s tumor biology at the molecular level. These tests are designed to complement the traditional

clinicopathologic factors described above. By evaluating patterns of gene expression within a tumor, GEP assays stratify patients into clinically relevant risk categories that help inform physician decisions regarding SLN biopsy, surveillance¹ intensity, imaging approach, and discussions about potential adjuvant therapy.

16. Melanoma GEP tests are typically performed on formalin-fixed, paraffin-embedded (“FFPE”) tumor tissue obtained from a patient’s primary melanoma through biopsy or surgical excision. Laboratory testing involves extracting RNA from the tumor sample, measuring the expression levels of a defined set of genes, and applying a validated algorithm to generate a risk classification. The results are then reported to the ordering clinician and are used alongside traditional clinicopathologic factors to support clinical decision-making.

17. Melanoma GEP tests may go further and integrate clinicopathologic factors into the generation of the risk classification. The ordering clinician still uses the results of these “CP-GEP” tests alongside traditional clinicopathologic factors to support clinical decision-making.

18. Pursuant to Commission Rules 210.10(b)(1) and 210.12(a)(12), the Accused Products may be plainly described as melanoma predictive and prognostic CP-GEP tests and related components used in connection with such tests.

B. Castle’s DecisionDx®-Melanoma

19. Complainant Castle is engaged in domestic research, development, commercialization, and sales and marketing of molecular tests that provide clinically actionable information to physicians treating patients with serious diseases, including cancer. One of Castle’s core products is DecisionDx®-Melanoma, a proprietary test used in the management of patients diagnosed with cutaneous melanoma, which has been available in the US since 2013.

¹ Surveillance for patients with a history of cancer involves observing the patient’s condition to detect recurrence or new cancers while still treatable.

20. DecisionDx®-Melanoma was granted Breakthrough Device designation from the U.S. Food and Drug Administration in 2025. The FDA grants Breakthrough Device designation to select qualifying devices that may offer improved treatment or diagnosis of life-threatening or irreversibly debilitating diseases when compared to currently available alternatives.

21. DecisionDx®-Melanoma was also granted ADLT status by the Centers for Medicare & Medicaid Services (“CMS”). CMS grants ADLT status to clinical diagnostic laboratory tests that, among other things, yield a result that predicts the probability of a specific individual patient developing a certain condition or conditions, or responding to a particular therapy or therapies; and provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests.

22. DecisionDx®-Melanoma is a clinically validated CP-GEP test that analyzes the expression levels of a defined set of genes from a patient’s FFPE primary melanoma tumor tissue. It assesses 31 genes (3 control and 28 discriminant genes), creating a 31-gene expression profile (“31-GEP”). The 31-GEP score is then integrated with a patient’s clinicopathologic factors as a CP-GEP to provide an individualized risk of the likelihood of SLN positivity and recurrence and/or metastasis. DecisionDx®-Melanoma can accurately identify patients with <5% risk of SLN positivity. A prospective, multi-center clinical trial has found that patients with a <5% predicted risk of SLN positivity by DecisionDx®-Melanoma had an actual SLN positivity rate of just 2.6%, confirming the clinically actionable performance of DecisionDx®-Melanoma.

23. By evaluating tumor biology at the molecular level, DecisionDx®-Melanoma generates actionable results in a single, comprehensive report that informs personalized patient management decisions. These results assist clinicians in tailoring SLNB surgical procedure

considerations, surveillance strategies, imaging decisions, and discussions regarding potential adjuvant therapy based on an individual patient's risk profile.

24. DecisionDx®-Melanoma is the only melanoma predictive and prognostic test associated with improved survival rate based on a large population-based study conducted in collaboration with the National Cancer Institute, the federal government's principal agency for cancer research and training. *See Bailey et al. 31-Gene Expression Profile Testing in Cutaneous Melanoma and Survival Outcomes in a Population-Based Analysis: A SEER Collaboration. JCO Precis Oncol.* 2023;7: e2300044. doi: 10.1200/PO.23.00044 ("Bailey"). **Exhibit 2.** The success of DecisionDx®-Melanoma lies in its ability to support more personalized and evidence-based melanoma care. Identifying patients at higher risk of recurrence or metastasis enables closer surveillance and earlier intervention, and identifying lower-risk patients can help avoid unnecessary procedures, testing, and associated costs and morbidity.

25. Castle has made substantial investments in research, clinical validation, laboratory infrastructure, and commercialization of DecisionDx®-Melanoma. The tests are performed in a College of American Pathologists ("CAP") accredited, Clinical Laboratory Improvement Amendments of 1988 ("CLIA")-certified clinical laboratory using standardized and quality-controlled processes for tissue handling, gene expression analysis, and reporting. The clinical laboratory and DecisionDx-Melanoma test are also NYS-DoH approved (New York State Department of Health), which is recognized as the most stringent approval process. As noted above, DecisionDx-Melanoma has been reviewed by CMS and granted ADLT status. The FDA has also reviewed DecisionDx-Melanoma and granted it Breakthrough Device designation status. Through these efforts, DecisionDx®-Melanoma has become a widely used predictive and

prognostic tool in the United States and an important component of the melanoma diagnostic marketplace.

C. The Accused Products: SkylineDx's Merlin Test

26. The Accused Products described below are marketed for the same clinical purpose as DecisionDx®-Melanoma—namely, to provide gene-expression-based predictive and prognostic information for patients with cutaneous melanoma and to inform physician decision-making regarding surveillance, sentinel lymph node biopsy, and related management decisions. As such, the Accused Products compete directly with DecisionDx®-Melanoma for use by U.S. clinicians, healthcare systems, and payors.

27. SkylineDx sells Merlin, a test to assist in SLNB decisions. Merlin does not use any of the 31 genes contained in Castle's DecisionDx®-Melanoma test.

28. Instead, Merlin uses 10 genes (2 control and 8 discriminant genes) extracted from a patient's FFPE primary melanoma tissue and combines the relative expression levels of the 8 discriminant gene expression profiles with one clinical factor (age) and one pathologic factor (Breslow thickness) in an algorithm. The algorithm reports a binary result of "Low Risk" or "High Risk" of nodal metastasis and of 5-10 year survival outcome.

29. When a third party, or healthcare provider, orders the Merlin Test, SkylineDx uses Qiagen RNeasy FFPE to extract and analyze RNA in its San Diego facility.

30. The Accused Products unfairly compete with Complainant's melanoma predictive and prognostic test and components thereof through false and misleading advertising. Complainant's identification of specific models or types of products is not intended to limit the scope of the investigation or requested relief, which should extend to all present and future accused products made by or on behalf of each Respondent, regardless of format, model, or branding.

IV. THE ASSERTED LANHAM ACT VIOLATIONS

31. Upon information and belief, each of the Proposed Respondents has worked in concert to falsely advertise its product, violating Section 337 and the Lanham Act, as described in more detail below.

32. SkylineDx's Vice President of Marketing, Glenn Kutchera, and its Sales and Marketing Manager, Emad Nour, are based at SkylineDx BV in Netherlands.

33. Proposed Respondents have made and disseminated false and misleading statements in commercial advertising and promotion concerning the Accused Products, including the Merlin test. These statements have been directed to clinicians, healthcare systems, and payors in the United States and are material to purchasing, use, and reimbursement decisions.

34. Proposed Respondents' false and misleading statements have deceived and/or have the tendency and capacity to deceive a substantial segment of the intended audience and are material to purchasing and usage decisions.

35. The statements are likely to deceive a substantial segment of the intended audience.

36. Proposed Respondents caused its false and misleading statements to be placed in interstate commerce and cause confusion or mistake regarding the quality and characteristics of Complainant's products and those of Proposed Respondents.

37. Castle has been or is likely to be injured as a result of Proposed Respondents' false and misleading statements.

38. Proposed Respondents' false and misleading statements on its websites and promotional materials, discussed below, used to sell the Accused Products constitute false and deceptive advertising under Section 43(a) of the Lanham Act and violate section 337.

A. Violations of Section 337(a)(1)(A): False Comparative Claims under Section 43(a) of the Lanham Act—False Statements Based on the 2021 Article

39. A 2021 journal article studied Castle’s 31-GEP test with a neural network algorithm that integrated additional clinicopathologic factors and concluded that among all factors studied, the 31-GEP test had the largest likelihood of predicting SLN positivity. The resulting integrated 31-GEP (“i31-GEP”) was validated in an independent patient cohort of 1,674 patients from 30 contributing centers. See Whitman *et al.* Integrating 31-Gene Expression Profiling with Clinicopathologic Features to Optimize Cutaneous Melanoma Sentinel Lymph Node Metastasis Prediction. *JCO Precis Oncol.* 2021 Sep 13;5:PO.21.00162. doi: 10.1200/PO.21.00162. PMID: 34568719; PMCID: PMC8457832 (“Whitman”). **Exhibit 3.**

40. Whitman reported results from the study with DecisionDx®-Melanoma and concluded that it “could reduce the number of SLNBs performed by identifying patients with likelihood under the 5% threshold for performance of SLNB and improve the yield of positive SLNBs by identifying patients more likely to have a positive SLNB.”

41. To discredit the Whitman study, SkylineDx commissioned a study to “rebut” Whitman, *et. al.*. A Viewpoint (a type of manuscript with a critical analysis) was published: Bellomo, D., *et al.* (2026), Flawed Benchmarks and Biased Cohorts: Reassessing the Evidence for CP-GEP (Merlin) Versus 31-GEP (DecisionDx®-Melanoma). *Int J Dermatol*, 65: 12-14. <https://doi.org/10.1111/ijd.70000> (“Bellomo”). **Exhibit 4.**

42. Notably, three of the six authors—Domenico Bellomo, Christian Gross, and Jvalini Dwarkasing—are employees of SkylineDx BV and two others received research funding from or provided consulting services to SkylineDx.

43. Bellomo, *et. al.* attacked the Whitman study, claiming the analysis was misleading because it included patients who did not undergo SLNB and were clinically node negative (*i.e.*,

did not have visible/physical signs of cancer spread). Bellomo, *et. al.* decided to remove these patients along with patients who had T4 melanoma from the analysis, but did not use publicly available data (*e.g.*, published distributions of test results or published specificity of the test) and apply those distributions to Whitman. Instead, Bellomo, *et. al.* made a series of assumptions to arrive at a predetermined conclusion. Bellomo assumed that all patients that did not have an SLNB and did not have a positive node would have received a low risk i31-SLNB result, and that all patients that were T4 or had a positive node without SLNB would have received a high risk i31-SLNB. But there is no data supporting these assumptions. What is more, readily available data directly refutes these assumptions. The unfounded assumptions enabled the authors to remove 522 patients from the analysis (106 T4 melanomas and 416 patients that did not undergo SLNB). In removing these patients and assuming incorrectly what their test results from DecisionDx®-Melanoma would have been, the authors significantly skewed the test results and performance analysis attributed to the remaining patients and analysis and thus fabricated test performance. See Reassessment of Published Comparative Performance Model for 31-GEP and CP-GEP in Sentinel Lymph Node Biopsy Prediction in Cutaneous Melanoma. *J of Skin.* 2026;10(1):2819-2825. doi:[10.25251/3sq6eq75](https://doi.org/10.25251/3sq6eq75). The Proposed Respondents then used this fabricated test performance to make statements to customers and potential customers.

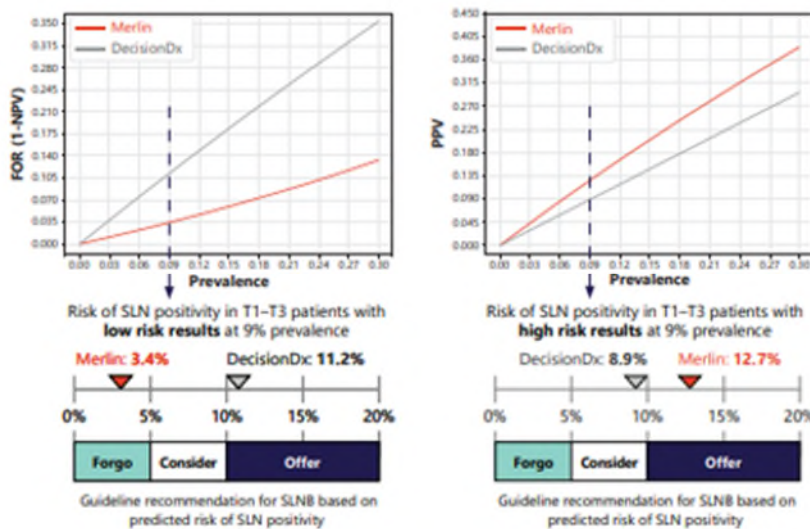
44. As shown in **Exhibit 5**, the Proposed Respondents circulated promotional materials based on Bellomo, *et. al.* These materials include presentation slides circulated to customers and potential customers in the United States, directly comparing Complainant's DecisionDx®-Melanoma test with Proposed Respondents' Merlin test and claiming that the Merlin test "outperforms" DecisionDx®-Melanoma based on purportedly comparable cohorts. A screenshot of this slide, which relies on Bellomo, *et. al.*, is shown below:

Merlin outperforms DecisionDx based on comparable, harmonized cohorts that included T1-T3 patients (excluded T4 and SLNB-naïve patients).⁵

The analysis focused on the largest, most representative study from each group: MERLIN_001 for CP-GEP (prospective, blinded; n = 1761)³ and the Whitman study for 31-GEP (retrospective; n = 1674).⁶

Merlin vs. DecisionDx

FOR and PPV across varying SLN positivity prevalence rates⁵



Conclusions:

- Merlin consistently outperforms DecisionDx on NPV and PPV across all prevalence levels.
- Merlin results correlate with definitive risk levels that align with guideline recommendations to either forgo or offer SLNB.
- DecisionDx low risk results correlate with a higher risk of SLN positivity than its high risk results (11.2% vs. 8.9%).

Exhibit 5.

45. Proposed Respondents' comparative claims are based on knowingly fabricated, unreliable, estimated, or otherwise flawed data and therefore misrepresent the performance of the Merlin test relative to the DecisionDx®-Melanoma test. By positioning the cohort with modeled data on the basis of flawed, unreliable assumptions as comparable to actual performance data and presenting these comparisons as accurate, data-driven, head-to-head results, Proposed Respondents have made literally false statements and/or misleading descriptions of fact in commercial advertising and promotion.

46. Comparative product claims relying on a comparison of actual test performance with a modeled test performance that is contrary to what the data shows, unsupported assumptions, or unreliable inputs are false and misleading when presented as valid head-to-head evidence (i.e.,

actual test performance in real-world cohorts or in the same cohort). Such statements are material because clinicians, healthcare systems, and payors rely on comparative performance representations when deciding which tests to adopt, order, and reimburse.

B. Violations of Section 337(a)(1)(A): False Comparative Claims under Section 43(a) of the Lanham Act—False Statements Based on the 2025 JAMA Study

47. A 2025 journal article outlined the results of SkylineDx’s MERLIN_001 study evaluating Merlin’s ability to identify patients who could safely forgo an SLNB. *See* Hieken TJ, Egger ME, Angeles CV, et al. Gene Expression Profile–Based Test to Predict Melanoma Sentinel Node Status: The MERLIN_001 Study. *JAMA Surg.* 2025. **Exhibit 6.** The study’s primary endpoint was validating if the low-risk result of the Merlin test would identify patients with an SLN positivity rate of <5%. The study failed to meet this primary endpoint in that the “low risk” group had an actual SLN positivity rate of 7.1%, exceeding the generally accepted 5% threshold for safely foregoing SLNB. As noted in the publication, “[Low-risk results in patients with stage IB melanoma] 6.5% of sentinel node metastasis, however, means that the test would not exclude a guideline-based recommendation for surgical referral for discussion and consideration of SLNB (ie., <5% risk). Hence, the primary objective of our trial was not met.”

48. For years, clinicians have avoided an SLNB if the likelihood of a positive SLN was <5%, considered SLNB if between 5-10% and recommended SLNB if >10%. In fact, the MERLIN_001 study authors themselves state: “A low-risk CP-GEP test result places an individual in the 5% to 10% risk group to discuss and consider sentinel node biopsy.” Thus, the results of the MERLIN_001 study did not identify patients who are likely to have an SLN positivity rate of <5%. Because the primary endpoint failed, all subsequent analyses presented in the paper are exploratory only, meaning they are observations but not validated or proven in this study. The authors acknowledged that a new study would be required to confirm those findings. Additionally, the

study notes that “The study was not powered for subset analyses; hence, these were considered exploratory.” Finally, multivariate analyses were not conducted to demonstrate independence from standard clinicopathologic factors.

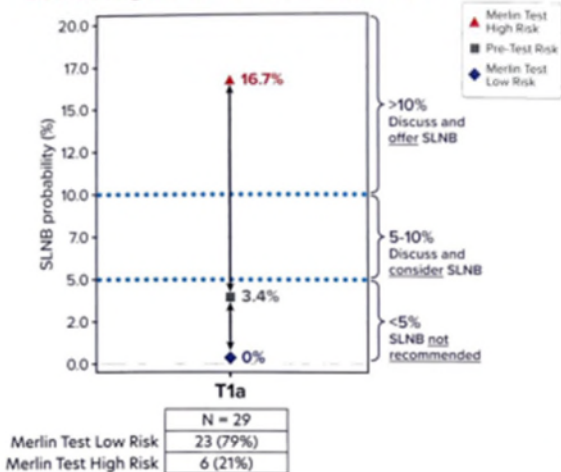
49. The Study concluded “CP-GEP testing merits further evaluation as a way to refine the selection of clinically high-risk T1a patients for SLNB, **but the limited number of patients with T1a melanoma in this study preclude definitive recommendations.**” Exhibit 6 at E6 (emphasis added).

50. Despite the failed primary endpoint of the study, the failure to validate secondary endpoints in an independent study and the study’s qualification that there were not enough patients for definitive recommendations in patients with T1a melanoma, SkylineDx circulated promotional materials, including presentation slides circulated to customers and potential customers in the United States, stating that the study showed Merlin “Allows for Actionable and Personalized SLNB Decision Making & Melanoma Management” and “Accurately Stratifies Your T1a Patients as Low or High Risk for SLN Metastasis”. SkylineDx’s promotional materials also show other subset analyses, such as T1b and T2a subsets, without disclosing that these were exploratory analyses which require an additional study to validate these findings.

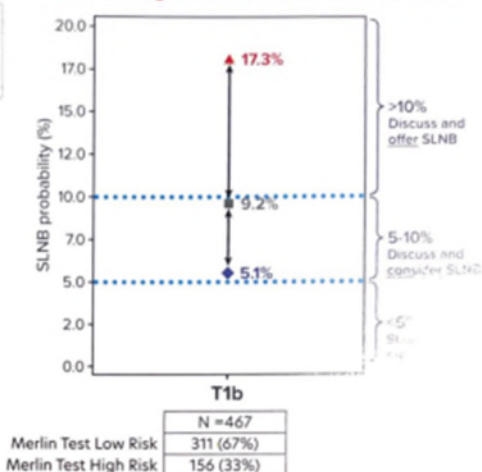
The Merlin CP-GEP Test Allows for Actionable and Personalized SLNB Decision Making & Melanoma Management

Pre- and post-test probabilities for SLNB positivity with the Merlin Test

Accurately Stratify Your T1a Patients as Low or High Risk for SLN Metastases



Accurately Stratify Your T1b Patients as Low or High Risk for SLN Metastases



Accurately Stratify Your T2a Patients as Low or High Risk for SLN Metastases

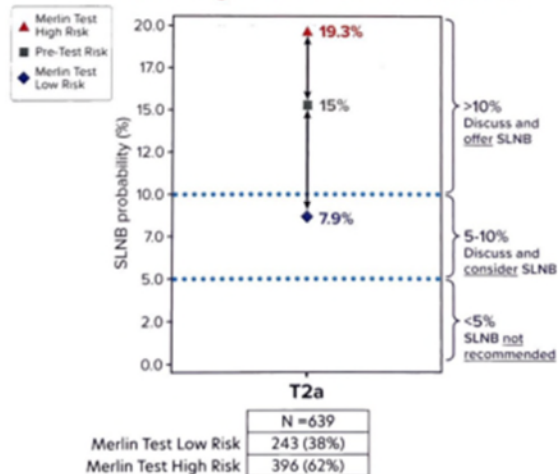


Exhibit 7.

51. Claims based on a failed study, contrary to the study's explicit warning that there is not enough data for definitive recommendations and contrary to the study's explicit statement that

all subset analyses are exploratory only are false and misleading. Such statements are material because clinicians, healthcare systems, and payors rely on comparative performance representations when deciding which tests to adopt, order, and reimburse.

C. Violations of Section 337(a)(1)(A): False and Misleading Claims Regarding Actionable and Personalized Decision-Making under Section 43(a) of the Lanham Act—False Statements Based on the 2025 JAMA Study

52. Proposed Respondents have further represented that the Merlin test enables actionable and personalized clinical decision-making in melanoma management, including SLN biopsy decisions. **Exhibit 8.**

53. Certain studies cited to support these claims include limited patient populations (only 29 T1a patients were included in study) or contain express limitations acknowledged by their authors (not enough patients to make a meaningful conclusion), such that the data do not support the breadth of the promotional claims being made. Statements suggesting that the test enables actionable or personalized decisions beyond what the supporting evidence demonstrates are false and misleading.

54. Claims that a test provides “personalized” results or uniquely actionable information are material to clinicians and payors because they directly relate to patient management and the perceived value of the test.

55. The above-described acts constitute false and misleading advertising and unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

56. The Proposed Respondents’ use of this advertising misrepresents the nature, characteristics, qualities of their or Castle’s goods and services.

D. Violations of Section 337(a)(1)(A): False and Misleading Claims of Scientific Uniqueness under Section 43(a) of the Lanham Act

57. Proposed Respondents have also represented that “Merlin is the only GEP test where all included genes are functionally linked to melanoma & metastatic pathways.”

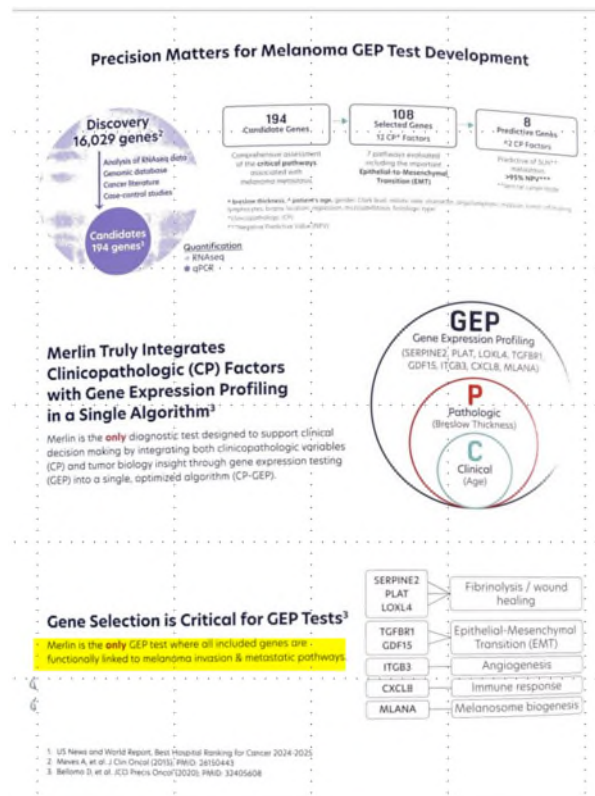


Exhibit 9 (highlighting added).

58. This claim of exclusivity is literally false or misleading.

59. Complainant’s DecisionDx®-Melanoma is a CP-GEP test where all included genes are functionally linked to melanoma and metastatic pathways.

60. Statements asserting that Merlin is uniquely linked to melanoma biology, or is the only test with such characteristics, is literally false or misleadingly represents the capabilities and design of Complainant’s DecisionDx®-Melanoma test.

61. Claims of exclusivity or uniqueness are material because they are likely to influence physicians’ and payors’ perceptions of a test’s scientific validity and comparative value.

62. The Proposed Respondents' use of this advertising misrepresents the nature, characteristics, qualities of their or Castle's goods and services.

E. Violations of Section 337(a)(1)(A): False and Misleading Claims of Clinical Utility and Superiority under Section 43(a) of the Lanham Act

63. Proposed Respondents have issued press releases and promotional materials asserting that the Merlin test "consistently delivered higher clinical utility" than competing tests, including DecisionDx®-Melanoma. **Exhibit 10.**

64. Certain studies cited in support of these claims did not use the tests to guide actual clinical decision-making and therefore do not establish "clinical utility" as represented. Statements characterizing such studies as demonstrating superior clinical utility or real-world decision-making impact are false and misleading.

65. Proposed Respondents have also characterized studies supporting DecisionDx®-Melanoma as "methodologically flawed" or based on "selectively chosen benchmarks." These criticisms rely on definitions and standards that depart from accepted scientific practice and mischaracterize the underlying studies, and so they are false and misleading.

66. Proposed Respondents have also claimed that Merlin tests are "stronger" and "superior" when compared to 31-GEP/i31-SLNB. Complainant offers testing that is stronger than the Merlin test.

67. These statements misrepresent the quality and characteristics of Proposed Respondent's product and are literally false and misleading.

68. Comparative superiority claims are material where, as here, physicians and healthcare systems rely on such claims when determining which test to adopt for clinical use.

69. The Proposed Respondents' use of this advertising misrepresents the nature, characteristics, qualities of their or Castle's goods and services.

F. Violations of Section 337(a)(1)(A): False and Misleading Claims Regarding Physician Liability for Using DecisionDx®-Melanoma

70. SkylineDx employs sales representatives, who are agents of SkylineDx. These sales representatives visit physicians and attempt to induce the physicians to buy the Merlin Test.

71. Upon information and belief, sales representatives are financially rewarded for sales of the Merlin Test.

72. On multiple occasions, SkylineDx sales representatives have told physicians that if the physician uses DecisionDx®-Melanoma instead of the Merlin Test they could be sued (presumably for malpractice).

73. For example, in April 2026, a SkylineDx employee told a physician that they could be sued if they chose to use DecisionDx®-Melanoma. In reality, physicians will not be sued for malpractice (or any other reason) based on the use of DecisionDx®-Melanoma.

74. Upon information and belief, a SkylineDx sales representative warned clinicians that if they order a test other than Merlin they run the risk of being sued.

75. Upon information and belief, these false and misleading statements are based on the fact that the National Comprehensive Cancer Network (“NCCN”) revised its guidelines to state that CP-GEP testing “may be used in select patients with T1b +/- T2a melanoma to support shared decision-making, when a patient or provider would decide against SLNB if the true risk was <10%”. The NCCN is a nonprofit consortium of cancer centers that publishes guidelines for cancer screening, detection, and treatment. It states expressly that its guidelines “are a statement of evidence and consensus of the authors[,]” and that “[a]ny clinician seeking to apply ... the NCCN Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient’s care or treatment.”

76. SkylineDx's statements are false. First, DecisionDx®-Melanoma is a type of CP-GEP test and so is within this guideline language. Second, clinicians across the country have generally accepted the ordering of DecisionDx®-Melanoma as within the standard of care for treatment of melanoma. The Medicare program reimburses Castle for DecisionDx-Melanoma because it is reasonable and medically necessary for beneficiaries. CMS granted ADLT status to DecisionDx®-Melanoma because it provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests. And FDA designated DecisionDx®-Melanoma a Breakthrough Device because it may offer improved treatment or diagnosis of life-threatening or irreversibly debilitating diseases when compared to currently available alternatives. SkylineDx has not identified and Castle knows of no clinician in the United States being sued based on the ordering of DecisionDx®-Melanoma since the inception of the test in 2013. SkylineDx's assertions that clinicians ordering DecisionDx®-Melanoma run the risk of being sued or could be sued for malpractice notwithstanding DecisionDx®-Melanoma's widespread clinical acceptance, FDA and CMS designations, and long history of Medicare reimbursement are sheer fantasy.

77. These statements are material to physician purchasing decisions. SkylineDx's sales representatives are making these statements to induce physicians to purchase the Merlin Test and not purchase DecisionDx®-Melanoma.

78. The above-described acts constitute false and misleading advertising and unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

79. The Proposed Respondents' and/or its agents' use of this advertising misrepresents the nature, characteristics, qualities of their or Castle's goods and services.

V. SPECIFIC INSTANCES OF UNLAWFUL IMPORTATION

80. Proposed Respondents import into the United States, and/or sell as owner, importer or consignee melanoma prognostic testing devices or components thereof.

Qiagen GmbH

81. A recent article in JAMA Surgery studied Merlin_001. See Hieken TJ, Egger ME, Angeles CV, et al. Gene Expression Profile–Based Test to Predict Melanoma Sentinel Node Status: The MERLIN_001 Study. *JAMA Surg.* 2025, **Exhibit 6**. Supplement 1 to that article is “Trial Protocol.” **Exhibit 11**. The Trial Protocol states that RNA was extracted using Qiagen RNeasy FFPE Kit and the RNA samples were sent to SkylineDx USA for testing. *Id.* at 10, 17.

82. Qiagen’s Safety Data Sheet for RNeasy FFPE Kit lists “QIAGEN GmbH” in Hilden Germany as the manufacturer or supplier of the test. **Exhibit 1**.

SAFETY DATA SHEET		
according to the OSHA Hazard Communication Standard		
		
RNeasy FFPE Kit (50)		
Version 2.0	Revision Date: 09/28/2025	Date of last issue: 09/04/2021 Date of first issue: 09/04/2021
SECTION 1. IDENTIFICATION		
Product name	: Water	
Manufacturer or supplier's details		
Company	: QIAGEN GmbH QIAGEN Str. 1 D-40724 Hilden	

83. The (1) use of RNeasy FFPE, manufactured in Germany, by the authors of the paper, and (2) the fact the RNeasy FFPE Kit was sent to SkylineDx USA, shows importation into the United States by Qiagen

84. In addition to the 2025 article, the initial CP-GEP paper (for what became Merlin) was published in 2020 with several authors who worked for or received financial benefits from SkylineDx. That paper is Bellomo, et al. Model Combining Tumor Molecular and

Clinicopathologic Risk Factors Predicts Sentinel Lymph Node Metastasis in Primary Cutaneous Melanoma. *JCO Precis Oncol.* 2020;4:319-334. doi: 10.1200/po.19.00206. Epub 2020 Apr 14. PMID: 32405608; PMCID: PMC7220172 (“Bellomo 2020”). Bellomo 2020 states that “RNA purification was from formalin-fixed paraffin-embedded tissue (QIAGEN, Hilden, Germany).” **Exhibit 12** at 329. This reference shows that SkylineDx was using imported Qiagen kits as early as 2020.

Qiagen LLC

85. Qiagen LLC handles orders of Qiagen goods for the United States. **Exhibit 13.** Upon information and belief Qiagen LLC acts in concert with Qiagen GmbH in the importation into or sale within the United States of RNeasy FFPE.

SkylineDx USA

86. SkylineDx USA is the consignee of the Qiagen RNeasy FFPE Kits imported into the United States. Upon information and belief SkylineDx USA is the ultimate consignee of the Qiagen RNeasy FFPE kits imported into the United States for use in Merlin tests.

87. The RNeasy FFPE kit is part of the Merlin Test that is sold in the United States for melanoma prognostic testing. See **Exhibits 6 and 11.**

SkylineDx BV

88. Upon information and belief, SkylineDx BV acts in concert with SkylineDx USA to have RNeasy FFPE imported or sold after importation as part of the Merlin Test.

VI. RELATED LITIGATION

89. Concurrently with this ITC complaint, Castle is filing a district court lawsuit against SkylineDx USA, Inc. in the Southern District of California alleging Lanham Act and state law unfair advertising violations in the advertisement and sale of SkylineDx’s Merlin diagnostic test.

VII. THE DOMESTIC INDUSTRY

90. A domestic industry exists in the United States as defined in Section 337(a)(1)(A) with respect to DecisionDx®-Melanoma as set forth in the Confidential Declaration of Frank Stokes, Confidential **Exhibit 14C**.

A. An Industry Exists in the United States

91. Castle has developed, commercialized, and continues to support a substantial U.S. industry relating to molecular testing, including its DecisionDx®-Melanoma test.

92. Castle has, and continues to make, significant investments in plant and equipment, labor and capital, and research and development and engineering in the United States.

93. Complainant operates clinical laboratory facilities in Phoenix, Arizona and Pittsburgh, Pennsylvania. These facilities perform testing for U.S. patients and support Complainant's nationwide commercial operations relating to melanoma prognostic testing and other molecular diagnostic services. These domestic laboratory investments enable Complainant to provide testing services across the United States and to meet the needs of physicians and patients in all 50 states.

94. Each of Complainant's laboratory facilities is certified under CLIA, accredited by CAP, and approved to perform testing for patients in the State of New York. Complainant maintains these certifications and accreditations to ensure compliance with federal and state regulatory requirements and to support the delivery of high-quality diagnostic testing services. DecisionDx®-Melanoma has also been reviewed by CMS and granted Advanced Diagnostic Laboratory Test (ADLT) status. The FDA has also reviewed DecisionDx®-Melanoma and granted it Breakthrough Device designation status.

95. Complainant's facilities are licensed or authorized, as required, to provide testing services in states that impose additional regulatory requirements, including California,

Pennsylvania, Rhode Island, Maryland, and New York. These regulatory approvals reflect substantial investment in U.S. infrastructure, personnel, compliance, and quality systems.

96. In addition to its laboratory operations, Complainant employs personnel throughout the United States in research and development, clinical validation, regulatory affairs, sales and marketing, reimbursement, and physician education relating to DecisionDx®-Melanoma and related tests. Complainant also invests in clinical studies, data generation, and physician outreach programs within the United States.

B. Injury or Threat of Substantial Injury to a U.S. Industry under Section 337(a)(1)(A)

97. Through these activities and investments, Complainant has developed and maintains a substantial U.S. industry dedicated to melanoma predictive and prognostic testing. This domestic industry depends on fair competition and truthful marketing in the U.S. marketplace and is directly affected by the unfair acts described in this Complaint.

98. Proposed Respondents' false and misleading statements, described above, have threatened and continues to threaten further substantial injury to the domestic industry. These false and misleading statements have the threat or effect of substantial injury to the domestic industry. See Confidential Exhibit of Frank Stokes, Confidential **Exhibit 14C**.

99. The Merlin test directly competes with DecisionDx®-Melanoma as seen by the advertisements and promotional material in this Complaint and attached as exhibits. Proposed Respondents' false and misleading statements concern matters that are material to purchasing and usage decisions, including comparative performance, clinical validity, clinical utility, and the purported uniqueness or superiority of the Accused Products. Such claims influence which test a physician orders, which test a healthcare system adopts, and which test a payor agrees to reimburse.

100. As a result of these unfair acts, Complainant has suffered and continues to suffer injuries in the United States. These injuries include loss of sales, loss of business opportunities, harm to relationships with clinicians and healthcare systems, loss of market share and market value, negative impact on employee equity, and damage to Complainant's reputation and goodwill.

101. For example, SkylineDx's false and misleading advertising has caused, and is likely to continue to cause, decreased sales of DecisionDx®-Melanoma.

102. SkylineDx's false and misleading advertising has caused and is likely to continue to cause Castle's share price to drop. This, in turn, has made it harder and more expensive to raise capital and resulted in a significant market value loss for Castle.

103. Unless the Commission grants relief, Proposed Respondents' ongoing advertising and promotional activities will continue to mislead U.S. customers and further injure Complainant's domestic industry, restrain trade and commerce in the United States, and distort competition in the U.S. market for melanoma prognostic testing.

VIII. CLASSIFICATION OF THE ACCUSED PRODUCTS UNDER THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES

104. The Accused Products may be classified under the following HTSUS headings/subheadings: 3822.19.0080, identified for illustrative purposes and not to limit the scope of requested relief.

IX. REQUESTED RELIEF

105. By reason of the foregoing, Complainant respectfully requests that the Commission:

- a. Institute an investigation pursuant to Section 337 into violations based on unfair methods of competition and unfair acts, including false and misleading advertising,

in the importation into the United States, or sale by the owner, importer, or consignee of the Accused Products;

- b. Schedule and conduct a hearing pursuant to Section 337(c) and determine that Proposed Respondents have violated Section 337;
- c. Issue a permanent limited exclusion order under Section 337(d) barring entry into the United States of Accused Products imported into the United States, or sale by the owner, importer, or consignee, on behalf of the Proposed Respondents and their affiliates, subsidiaries, related companies, successors, assigns, and agents;
- d. Issue permanent cease and desist orders under Section 337(f) directing Proposed Respondents and related entities to cease importing, selling, offering for sale, marketing, distributing, transferring (except for exportation), advertising, soliciting U.S. agents or distributors, and aiding or abetting others in the same, for the Accused Products associated with the unfair acts;
- e. Impose a bond pursuant to 19 U.S.C. § 1337(e) and (j) during the 60-day Presidential review period to prevent further injury; and
- f. Grant such other and further relief as the Commission deems just and proper.

Date: July 10, 2026

Respectfully submitted,

/s/ Andrew K. Beverina

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Andrew K. Beverina
April M. Meeks
Thomas J. Caufield
Nikita R. Kulkarni
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VERIFICATION

I, Frank Stokes, declare, in accordance with 19 C.F.R. 21C.4 and 210.12(a), under penalty of perjury under the laws of the United States of America, that the following statements are true:

1. I am the Chief Financial Officer for Castle Biosciences, Inc. ("Castle"). I am duly authorized by Castle to verify the foregoing Verified Complaint of Castle Biosciences, Inc. Under Section 337 of the Tariff Act of 1930, as Amended.

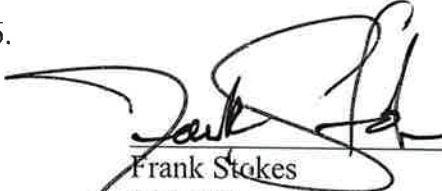
2. I have read the foregoing complaint.

3. The Complaint is not being filed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

4. To the best of my knowledge, information and belief, formed after reasonable inquiry, the claims and contentions contained in the foregoing complaint are warranted by existing law or by good faith, non-frivolous argument for the extension, modification, or reversal of existing law or establishment of new law.

5. To the best of my knowledge, information and belief, formed after reasonable inquiry, the allegations and factual contentions contained in the foregoing complaint are well-founded in fact or, if specifically identified, are likely to have evidentiary support after a reasonable opportunity to conduct further investigation or discovery.

Executed this 9th day of June, 2026.



Frank Stokes
Chief Financial Officer
Castle Biosciences, Inc.