

FEDERAL TRADE COMMISSION DECISIONS

FINDINGS, OPINIONS, AND ORDERS
JANUARY 1, 2020, TO JUNE 30, 2020

IN THE MATTER OF

MEDABLE, INC.

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL
TRADE COMMISSION ACT

*Docket No. C-4697; File No. 182 3192
Complaint, January 6, 2020 – Decision, January 6, 2020*

This consent order addresses Medable, Inc.’s alleged false or misleading representations made concerning its participation in the Privacy Shield framework agreed upon by the U.S. and the European Union. The complaint alleges that Respondent violated Section 5 of the Federal Trade Commission Act by falsely representing that it was a certified participant in the EU-U.S. Privacy Shield Framework. The consent order prohibits the company from making misrepresentations about its membership in any privacy or security program sponsored by the government or any other self-regulatory or standard-setting organization, including, but not limited to, the EU-U.S. Privacy Shield framework and the Swiss-U.S. Privacy Shield framework.

Participants

For the *Commission*: *Robin Wetherill*.

For the *Respondents*: *Emily Tabatabai, Orrick*.

COMPLAINT

The Federal Trade Commission (“FTC”), having reason to believe that Medable, Inc., a corporation violated the Federal Trade Commission Act (“FTC Act”), and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Medable, Inc. is a Delaware corporation with its principal office or place of business at 525 University Ave., Suite A70 Palo Alto, CA 94301.
2. Respondent provides technology solutions to business customers operating in pharmaceutical, biotechnology, and research industries.
3. The acts and practices of Respondent as alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act.

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4. Respondent has set forth in its privacy policy, <https://www.medable.com/privacy/>, statements related to its participation in the EU-U.S. Privacy Shield framework agreed upon by the U.S. government and the European Commission.

5. In fact, Respondent has not been certified to participate in the EU-U.S. Privacy Shield framework.

Privacy Shield

6. The EU-U.S. Privacy Shield framework (“Privacy Shield”) was designed by the U.S. Department of Commerce (“Commerce”) and the European Commission to provide a mechanism for U.S. companies to transfer personal data outside of the EU that is consistent with the requirements of the European Union Directive on Data Protection. Enacted in 1995, the Directive sets forth EU requirements for privacy and the protection of personal data. Among other things, it requires EU Member States to implement legislation that prohibits the transfer of personal data outside the EU, with exceptions, unless the European Commission has made a determination that the recipient jurisdiction’s laws ensure the protection of such personal data. This determination is referred to commonly as meeting the EU’s “adequacy” standard.

7. To satisfy the EU adequacy standard for certain commercial transfers, Commerce and the European Commission negotiated the EU-U.S. Privacy Shield framework, which went into effect in July 2016. The EU-U.S. Privacy Shield framework allows companies to transfer personal data lawfully from the EU to the United States. To join the EU-U.S. Privacy Shield framework, a company must self-certify to Commerce that it complies with the Privacy Shield Principles and related requirements that have been deemed to meet the EU’s adequacy standard.

8. Companies under the jurisdiction of the FTC, as well as the U.S. Department of Transportation, are eligible to join the EU-U.S. Privacy Shield framework. A company under the FTC’s jurisdiction that claims it has self-certified to the Privacy Shield Principles, but failed to self-certify to Commerce, may be subject to an enforcement action based on the FTC’s deception authority under Section 5 of the FTC Act.

9. Commerce maintains a public website, <https://www.privacyshield.gov/welcome>, where it posts the names of companies that have self-certified to the EU-U.S. Privacy Shield framework. The listing of companies, <https://www.privacyshield.gov/list>, indicates whether the company’s self-certification is current.

10. Respondent has disseminated or caused to be disseminated privacy policies and statements on the <https://www.medable.com/privacy/> website, including, but not limited to, the following statements:

Information for Persons Outside of the United States

As we are a US headquartered company, your personal information will be transferred to the US for further processing in accordance with the purposes set out above. Accordingly, Medable is EU/US Privacy Shield certified which means that

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we treat your personal information received from the European Economic Area (EEA) in accordance with EU data privacy principles. Please see our Privacy Shield Privacy Policy below for more details. . . .

Privacy Shield Privacy Policy

Medable has certified to the Department of Commerce that it adheres to the Privacy Shield Principles. If there is any conflict between the terms in this privacy policy and the Privacy Shield Principles, the Privacy Shield Principles shall govern. To learn more about the Privacy Shield program, and to view our certification, please visit <https://www.privacyshield.gov/>

11. Although Respondent initiated an application to Commerce for Privacy Shield certification in December 2017, it did not complete the steps necessary to participate in the EU-U.S. Privacy Shield framework and continued to make the statements described in Paragraph 10 in its privacy policy until October 2018.

Count 1-Privacy Misrepresentation

12. As described in Paragraph 10, from December 2017 to October 2018, Respondent represented, directly or indirectly, expressly or by implication, that it was a participant in the EU-U.S Privacy Shield framework.

13. In fact, as described in Paragraph 11, Respondent was never certified to participate in the EU-U.S. Privacy Shield framework. Therefore, the representation set forth in Paragraph 12 is false or misleading.

Violations of Section 5 of the FTC Act

14. The acts and practices of Respondent as alleged in this complaint constitute deceptive acts or practices, in or affecting commerce, in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this sixth day of January 2020, has issued this complaint against Respondent.

By the Commission.

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DECISION

The Federal Trade Commission (“Commission”) initiated an investigation of certain acts and practices of the Respondent named above in the caption. The Commission’s Bureau of Consumer Protection (“BCP”) prepared and furnished to Respondent a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge Respondent with violation of the Federal Trade Commission Act.

Respondent and BCP thereafter executed an Agreement Containing Consent Order (“Consent Agreement”). The Consent Agreement includes: 1) statements by Respondent that it neither admits nor denies any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, it admits the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission’s Rules.

The Commission considered the matter and determined that it had reason to believe that Respondent has violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of thirty (30) days for the receipt and consideration of public comments. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. Respondent Medable, Inc. is a Delaware corporation with its principal office or place of business at 525 University Ave., Suite A70 Palo Alto, CA 94301.
2. The Commission has jurisdiction over the subject matter of this proceeding and over Respondent, and the proceeding is in the public interest.

ORDER**Definitions**

For purposes of this Order, the following definition applies:

- A. “Respondent” means Medable, Inc., a corporation, and its successors and assigns.

Provisions**I. Prohibition against Misrepresentations about
Participation in or Compliance with Privacy Programs**

IT IS ORDERED that Respondent and its officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the advertising, marketing, promotion, offering for sale, or sale of any product or service must not misrepresent in any manner,

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expressly or by implication, the extent to which Respondent is a member of, adheres to, complies with, is certified by, is endorsed by, or otherwise participates in any privacy or security program sponsored by a government or any self-regulatory or standard-setting organization, including but not limited to the EU-U.S. Privacy Shield framework and the Swiss-U.S. Privacy Shield framework.

II. Acknowledgments of the Order

IT IS FURTHER ORDERED that Respondent obtain acknowledgments of receipt of this Order:

- A. Respondent, within ten (10) days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order.
- B. For five (5) years after the issuance date of this Order, Respondent must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for, and all agents and representatives who participate in, conduct related to representing in any manner, expressly or by implication, the extent to which Respondent is a member of, adheres to, complies with, is certified by, is endorsed by, or otherwise participates in any privacy or security program sponsored by a government or any self-regulatory or standard-setting organization, including but not limited to the EU-U.S. Privacy Shield framework and the Swiss-U.S. Privacy Shield framework; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Report and Notices. Delivery must occur within ten (10) days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.
- C. From each individual or entity to which Respondent delivered a copy of this Order, Respondent must obtain, within sixty (60) days, a signed and dated acknowledgment of receipt of this Order.

III. Compliance Report and Notices

IT IS FURTHER ORDERED that Respondent make timely submissions to the Commission:

- A. Sixty (60) days after the issuance date of this Order, Respondent must submit a compliance report, sworn under penalty of perjury, in which Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission, may use to communicate with Respondent; (b) identify all of Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business; (d) describe in detail whether and how Respondent is in compliance with each Provision of this Order; and (e)

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provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

- B. Respondent must submit a compliance notice, sworn under penalty of perjury, within fourteen (14) days of any change in the following: (1) any designated point of contact; or (2) the structure of Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.
- C. Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against Respondent within fourteen (14) days of its filing.
- D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: “I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____” and supplying the date, signatory’s full name, title (if applicable), and signature.
- E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The subject line must begin: In re *Medable, Inc.*, FTC File No. 1823192.

IV. Recordkeeping

IT IS FURTHER ORDERED that Respondent must create certain records for ten (10) years after the issuance date of the Order, and retain each such record for five (5) years. Specifically, Respondent must create and retain the following records:

- A. personnel records showing, for each person providing services in relation to any aspect of this Order, whether as an employee or otherwise, that person’s: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;
- B. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission; and

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- C. a copy of each widely disseminated representation by Respondent making any representation subject to this Order, and all materials that were relied upon in making the representation.

V. Compliance Monitoring

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondent's compliance with this Order:

- A. Within ten (10) days of receipt of a written request from a representative of the Commission, Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.
- B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with Respondent. Respondent must permit representatives of the Commission to interview anyone affiliated with Respondent who has agreed to such an interview. The interviewee may have counsel present.
- C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondent or any individual or entity affiliated with Respondent, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

VI. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate twenty (20) years from the date of its issuance, (which date may be stated at the end of this Order, near the Commission's seal), or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of the Order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. any Provision in this Order that terminates in less than twenty (20) years;
- B. this Order's application to any respondent that is not named as a defendant in such complaint; and
- C. this Order if such complaint is filed after the order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld

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on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an agreement containing a consent order from Medable, Inc. (“Medable” or “Respondent”).

The proposed consent order (“proposed order”) has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement’s proposed order.

This matter concerns alleged false or misleading representations that Medable made concerning its participation in the Privacy Shield framework agreed upon by the

U.S. and the European Union (“EU”). The Privacy Shield framework allows for the lawful transfer of personal data from the EU to participating companies in the U.S. The framework consists of a set of principles and related requirements that have been deemed by the European Commission as providing “adequate” privacy protection. The principles include notice; choice; accountability for onward transfer; security; data integrity and purpose limitation; access; and recourse, enforcement, and liability. The related requirements include, for example, securing an independent recourse mechanism to handle any disputes about how the company handles information about EU citizens.

To participate in the framework, a company must comply with the Privacy Shield principles and self-certify that compliance to the U.S. Department of Commerce (“Commerce”). Commerce reviews companies’ self-certification applications and maintains a public website, <https://www.privacyshield.gov/list>, where it posts the names of companies who have completed the requirements for certification. Companies are required to recertify every year in order to continue benefitting from Privacy Shield.

Medable is a technology development company. It primarily provides services that help pharmaceutical and biotechnology researchers collect and process data about research participants. According to the Commission’s complaint, from approximately December 2017 until October

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2018, Medable published on its website, <http://www.medable.com>, a privacy policy containing statements related to its participation in Privacy Shield.

The Commission's proposed one-count complaint alleges that Respondent violated Section 5(a) of the Federal Trade Commission Act. Specifically, the proposed complaint alleges that Respondent engaged in a deceptive act or practice by falsely representing that it was a certified participant in the EU-U.S. Privacy Shield Framework. Part I of the proposed order prohibits the company from making misrepresentations about its membership in any privacy or security program sponsored by the government or any other self-regulatory or standard-setting organization, including, but not limited to, the EU-U.S. Privacy Shield framework and the Swiss-U.S. Privacy Shield framework.

Parts II through V of the proposed order are reporting and compliance provisions. Part II requires acknowledgement of the order and dissemination of the order now and in the future to persons with responsibilities relating to the subject matter of the order. Part III ensures notification to the FTC of changes in corporate status and mandates that the company submit an initial compliance report to the FTC. Part IV requires the company to create certain documents relating to its compliance with the order for ten years and to retain those documents for a five-year period. Part V mandates that the company make available to the FTC information or subsequent compliance reports, as requested.

Part VI is a provision "sun-setting" the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

Complaint

IN THE MATTER OF

**ILLUMINA, INCORPORATED
AND
PACIFIC BIOSCIENCES OF CALIFORNIA, INCORPORATED (PACBIO)**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT, SECTION 2 OF THE SHERMAN ACT, AND SECTION 7 OF THE CLAYTON ACT

*Docket No. 9387; File No. 191 0035
Complaint, December 17, 2019 – Decision, January 6, 2020*

This case addresses the \$1.2 billion acquisition by Illumina, Incorporated of certain assets of Pacific Biosciences of California, Incorporated (PacBio). The complaint alleges that the acquisition, if consummated, would violate Section 2 of the Sherman Act, Section 7 of the Clayton Act, and Section 5 of the FTC Act by substantially lessening competition in the market for “next-generation sequencing” technology that allows researchers and clinicians quickly, accurately, and efficiently to identify the order of the component blocks—called nucleotides—in a DNA sample. On January 3, 2020, Complaint Counsel and Respondents Illumina, Inc. (“Illumina”) and Pacific Biosciences of California, Inc. (“Pacific Biosciences”) jointly move to dismiss the complaint because Respondents terminated their Agreement and Plan of Merger and Respondent Illumina withdrew its Hart-Scott-Rodino Notification and Report Forms filed for the proposed acquisition. The Commission dismissed the Complaint without prejudice.

Participants

For the *Commission*: Jordan S. Andrew, Michael Barnett, Stephanie C. Bovee, Peter Colwell, Yan Gao, David J. Gonen, Wade Lippard, Jean McNeil, Joseph R. Neely, Brian A. O’Dea, and Stephen W. Rodger.

For the *Respondents*: James J. O’Connell, Covington & Burling LLP; Scott Andrew Sher, Wilson Sonsini Goodrich & Rosati PC.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act (“FTC Act”), and by virtue of the authority vested in it by said Act, the Federal Trade Commission (“FTC” or “Commission”), having reason to believe that Respondents Illumina, Inc. (“Illumina”) and Pacific Biosciences of California, Inc. (“Pacific Biosciences” or “PacBio”), have executed an agreement for the acquisition of PacBio by Illumina (the “Acquisition”), which, if consummated, would violate Section 2 of the Sherman Act, 15 U.S.C. § 2, Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), and Section 11(b) of the Clayton Act, 15 U.S.C. § 21(b), stating its charges as follows: