

Analysis of Proposed Consent Order to Aid Public Comment
In the Matter of Ortho-Clinical Diagnostics, Inc.
File No. 1923050

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

The proposed consent order (“proposed order”) has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty 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 Ortho 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. 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.

Ortho markets and sells medical devices and in vitro diagnostics services to the global clinical laboratory and immunohematology communities. It collects personal data from its suppliers and capital customers around the world, including from EU citizens. According to the Commission’s complaint, from approximately September 2017 until March 2019, Ortho published on its website https://www.orthoclinicaldiagnostics.com/en_us/home/privacy-policy a privacy policy containing statements related to its participation in Privacy Shield.

The Commission’s proposed three-count complaint alleges that Respondent violated Section 5(a) of the Federal Trade Commission Act. Specifically, the first count in 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. The second count alleges that Ortho did not verify the truth of the Privacy Shield assurances in its privacy policy, either through a self-assessment or a third party compliance review, so its representation that it “complied with” the Privacy Shield principles was false. Finally, the third count alleges that Ortho failed to annually affirm to Commerce that Ortho will continue to apply the Privacy Shield Principles to personal data it

received while it was part of the framework after it withdraws from Privacy Shield.

Part I of the proposed order prohibits the Respondent 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. Part II also specifically requires the Respondent to comply with the Privacy Shield requirement to continue to protect personal information received while in the framework.

Parts III through VI of the proposed order are reporting and compliance provisions. Part III 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 IV ensures notification to the FTC of changes in corporate status and mandates that the Respondent submit an initial compliance report to the FTC. Part V requires the Respondent 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 VI mandates that the Respondent make available to the FTC information or subsequent compliance reports, as requested.

Part VII is a provision “sun-setting” the order after twenty 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.