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[Your Name]

[Your Title]

[Your Company]

[Street Address, City, State ZIP]

May 14, 2026

[Opposing Counsel Name]

[Firm Name]

[Address]

Re: U.S. Patent No. 12171916 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 12171916 (the "12171916 Patent"). After preliminary review, we have substantial concerns about the validity, enforceability, and scope of the asserted claims, summarized below. We reserve all rights and defenses.

1. Subject Patent — Summary

Summary of U.S. Patent 12,171,916

A thorough review of U.S. Patent 12,171,916 has been conducted. As of April 26, 2026, no records of this patent were found in the 2026 dockets of the U.S. Court of Appeals for the Federal Circuit (CAFC).

Title: System and method for collecting plasma

Assignee: Haemonetics Corp

Inventors: Michael Ragusa

Filing Date: March 18, 2021

Issue Date: December 24, 2024

Abstract:

The patent describes a method for collecting plasma from a donor. The method involves determining the donor's weight and hematocrit, and then using a venous-access device to withdraw blood. Anticoagulant is introduced into the withdrawn blood, which is then separated into a plasma...

2. Validity Concerns under 35 U.S.C. § 102 — Prior Art

We have identified prior-art references that, in our preliminary view, anticipate one or more asserted claims of the 12171916 Patent:

Analysis of Prior Art for U.S. Patent 12,171,916

Based on the 205 citations listed for U.S. Patent 12,171,916, the following references are identified as most relevant to the patent's claims concerning a system and method for collecting plasma by determining a target volume based on donor parameters like weight and hematocrit. The analysis focuses on potential anticipation under 35 U.S.C. § 102, which requires a single prior art reference to disclose every element of a claimed invention.

1. U.S. Patent 4,086,924: Plasmapheresis apparatus

- Full Citation: US4086924A
- Publication Date: May 2, 1978
- Filing Date: October 6, 1976
- Assignee: Haemonetics Corporation
- Description: This patent discloses an early automated plasmapheresis apparatus that processes whole blood from a donor in cycles. It separates plasma and returns red blood cells. The system uses a centrifuge and includes controls for managing the draw and return cycles. While it describes a system for separating blood components, it does not explicitly teach calculating a target plasma volume based on a donor's specific...

3. Obviousness under 35 U.S.C. § 103

Independent of § 102, we believe the asserted claims are obvious in view of combinations of prior art that a person having ordinary skill in the art would have been motivated to combine:

As a technical patent analyst, I have analyzed the obviousness of U.S. Patent 12,171,916 ("the '916 patent") under 35 U.S.C. § 103, based on the provided prior art references. The following analysis outlines potential combinations of these references that would render the independent claims of the '916 patent obvious to a person having ordinary skill in the art (PHOSITA) as of the priority date of May 30, 2017.

Summary of Key Claim Elements

The independent claims (1, 7, 10, and 14) of the '916 patent are directed to a plasma collection system and method. The core features can be summarized as:

1. Using Donor Parameters: Determining a target collection volume for plasma based on the donor's weight and hematocrit.
2. Pre-Procedure Calculation: Calculating this target volume before the draw cycle begins (Claim 10).
3. Dynamic Recalculation: Re-evaluating the donor's hematocrit during the procedure and establishing a new target volume for subsequent draw cycles (Claim 1).
4. Electronic Data Input: Receiving donor parameters electronically from a separate control system (Claim 14)....

4. Litigation History of the Patent

Public records reflect that the 12171916 Patent has been the subject of the following litigation, which informs our view of the asserted claims and your client's enforcement posture:

- Haemonetics Corporation v. Terumo BCT, Inc. — 1:25-cv-01409 · United States District Court for the District of Colorado · filed 2025-05-05 · Ongoing
- Haemonetics Corporation v. Fresenius Kabi USA, LLC et al. — 1:25-cv-08680 · U.S. District

5. Request

In light of the foregoing, we request that your client (i) provide a detailed claim chart identifying each accused product or service and mapping every limitation of each asserted claim, (ii) identify any prior art known to your client, including any references cited during prosecution or reexamination, and (iii) substantiate the basis for any damages or licensing demand. We are prepared to discuss the matter further once we have received and reviewed the foregoing.

Sincerely,

[Your Name]

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