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UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of	
CERTAIN WEARABLE ELECTRONIC DEVICES WITH ECG FUNCTIONALITY AND COMPONENTS THEREOF	**Inv. No. 337-TA-1266**

ORDER NO. 21: REGARDING COMPLAINANT ALIVECOR'S MOTIONS *IN LIMINE* NOS. 3, 4, AND 5

(March 21, 2022)

Complainant AliveCor, Inc. ("AliveCor") filed motions *in limine* nos. 3 ("MIL 3" (Mot. 1266-019)), 4 ("MIL 4" (Mot. 1266-014)), and 5 ("MIL 5" (Mot. 1266-016)) on March 7, 2022. Respondent Apple, Inc. ("Apple") timely filed oppositions ("MIL 3 Oppo.," "MIL 4 Oppo.," and "MIL 5 Oppo.," respectively), and the Commission's Office of Unfair Import Investigations ("Staff") filed an omnibus response ("Staff Resp."). AliveCor thereafter filed a motion for leave to file a reply in support of MIL 4 (Mot. 1266-027).

A. MIL 3

In its Prehearing Brief ("RPB"), Apple asserts that U.S. Patent Nos. 10,595,731 ("731 patent") and 9,572,499 ("499 patent") are prior art to U.S. Patent No. 10,638,941 ("941 patent"), and that either the 731 patent or the 499 patent, "independently," anticipate all asserted claims of the 941 patent. RPB at 69-73. AliveCor moves to preclude Apple from asserting that the 731 patent and 499 patent are prior art to the 941 patent, on the basis that the assertion was not included in Apple's contention interrogatory responses. *See* MIL 3 at 1, 8. The Staff supports the motion on the same basis. *See* Staff Resp. at 3-4. Apple does not deny that it failed to timely identify these references as prior art. *See* MIL 3 Oppo. Therefore, MIL 3 (Mot. 1266-019) is granted.

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B. MIL 4

In its Prehearing Brief ("CPB"), AliveCor asserts that one of its domestic industry products is the [redacted] "a smart watch being developed by Pegatron in conjunction with AliveCor." CPB at 19. In September, 2021, Apple requested and received a subpoena directed to Pegatron Corporation in Taiwan, seeking the testimony of a Pegatron corporate witness (following the model of Fed. R. Civ. P. 30(b)(6)), generally on the topic of products Pegatron works on with AliveCor, including the [redacted] *See* MIL 4, Ex. B. In lieu of a deposition, Apple agreed to accept the declaration of Ms. Jessica Ho ("Ho Declaration"), a Pegatron account manager. *See* MIL 4, Ex. C; RX-0295C.

Apple seeks the admission of the Ho Declaration to support its argument that the [redacted] has been "abandoned." RPB at 172-74. AliveCor moves to exclude the Ho Declaration because, among other things, its admission violates Ground Rule 10.2, which requires "[a]ll witness testimony [to] be made orally." *See* MIL 4 at 1, 6-8; Order No. 2. The Staff supports the motion on the same basis. *See* Staff Resp. at 5. In opposition, Apple asserts that Ground Rule 10.2 has not been violated, and requests that its experts be permitted to rely on and testify about the Ho Declaration. *See* MIL 4 Oppo. at 5-10.

In substance the Ho Declaration is a witness statement, and witness statements are not being used in this investigation, as Ground Rule 10.2 establishes. Moreover, there is no clear prejudice to Apple from exclusion. Ms. Ho acknowledges in her declaration that AliveCor and Pegatron executed a license agreement, but she never mentions the [redacted] *See* RX-0295C at ¶ 15. And Apple's Prehearing Brief states both that a Pegatron project called [redacted] "represents the [redacted] asserted in this Investigation," and that "AliveCor has no knowledge of" that project. RPB

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at 173. Apple's position is sufficiently confusing that it is impossible to assign any probative value at all to the Ho Declaration.

Nonetheless, it is the sort of evidence reasonably relied on by expert witnesses. *See, e.g.*, *Certain Mobile Electronic Devices and Radio Frequency and Processing Components Thereof*, Inv. No. 337-TA-1065, Order No. 42 at 3, 7 (EDIS Doc. ID 647537) ("*Mobile Electronic Devices*"). It is therefore inappropriate to "preclude any [expert] testimony about or based on the Ho Declaration," as AliveCor requests. MIL 4 at 1. And whether and to what extent the Ho Declaration may be used for impeachment purposes, and whether Ms. Ho will be allowed to testify orally, are questions that are not yet ripe. *See Mobile Electronic Devices* at 3; Motion for Leave to Amend Pre-Hearing Statement (Mot. 1266-028).

In sum, MIL 4 (Mot. 1266-014) is granted-in-part, in that the Ho Declaration (RX-0295C) is excluded from evidence, and otherwise denied. AliveCor's motion for leave to file a reply in support of MIL 4 (Mot. 1266-027) is granted.

C. MIL 5

The articles accused of infringement are certain models of Apple Watch. *See* CPB at 7. Apple received clearance from the U.S. Food and Drug Administration ("FDA") to market the accused products, subject to certain limitations, on September 11, 2018. *See* MIL 5 Oppo., Ex. 2 at RX-0004C.4. Apple intends to call Professor Erika Lietzan, an expert in FDA regulatory affairs, to explain certain aspects of FDA practice and regulation. *See* MIL 5 Oppo.; RPB at 4. In its Prehearing Brief Apple lists various specific testimony subjects, including that a particular feature of the Apple Watch "cannot [redacted] without further FDA clearance," and that configuring the Apple Watch such that the "ECG App could confirm" another feature's arrhythmia indication "would likely require new FDA

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clearance." RPB at 4, 53. The first subject appears to be an infringement opinion related to, for example, the requirement of claims 16 and 17 of the 499 patent that the system "alert" the user to record an ECG, and therefore likely outside the scope of Prof. Lietzan's expertise, and the second subject appears to be an inadmissible legal opinion.

In its response to MIL 5, however, Apple lists her testimony as covering three subjects that are not so facially improper: (1) "the scope of the FDA clearances . . . [and] the content of the underlying applications" (MIL 5 Oppo. at 4); (2) "why" certain Apple Watch features relevant to infringement "are designed the way they are," that is, "why the scope of the FDA's clearances led Apple to design the products the way that it did" (*id*. at 1, 6); and (3) "other topics," apparently including the FDA approval process and research related to that approval process (*id*. at 2 n.1). AliveCor moves to exclude Prof. Leitzan's testimony as irrelevant. *See* MIL 5 at 3-5. The Staff supports the motion to the extent it concerns "Apple's FDA clearances." *See* Staff Resp. at 6-7.

In opposition, Apple contends that AliveCor's motion is limited only to testimony on the first two topics above. *See* MIL 5 Oppo. at 2 n.1. Admittedly, the first two topics are the focus of AliveCor's motion, but the relief requested is clear and unqualified: AliveCor "requests that Ms. Lietzan's testimony be excluded as not relevant." MIL 5 at 9. And although there are unquestionably situations where the testimony of an FDA regulatory expert might be relevant and otherwise admissible, this is not such a situation. The first topic, regarding the scope of clearance and the applications underlying it, could seemingly be adequately ascertained by reviewing the FDA administrative record; certainly Apple has not shown why an expert's opinion would be helpful for that purpose. The second topic pertains to Apple's decision-making process in designing the accused products. This would be relevant if subjective intent were at issue, as with indirect infringement, but Apple identifies no such pertinent issue, and it is not clear why Prof.

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Lietzan would understand the subjective intent of the people who actually designed the product. The third topic is wide-ranging, and thus potentially relevant, but Apple does not address it in its opposition, other than simply to observe that it intends to offer Prof. Leitzan's testimony on "other topics." MIL 5 Oppo. at 2 n.1.

In short, the Staff is correct that Prof. Lietzan's proposed testimony, to the extent it is limited to non-legal opinions on FDA practice, "has no logical bearing whatsoever as to whether or not Apple infringes any asserted claim." Staff Resp. at 6. MIL 5 (Mot. 1266-016) is therefore granted. I note, however, that the admissibility of related evidence (such as excerpts of the FDA administrative record), and the propriety of arguments based on such evidence, are questions that have not been presented and so are not decided.

Within seven days of the date of this document, the parties shall submit to the Office of the Administrative Law Judges a joint statement as to whether or not they seek to have any portion of this document deleted from the public version. If the parties do seek to have portions of this document deleted from the public version, they must submit to this office a copy of this document with red brackets indicating the portion or portions asserted to contain confidential business information. The submission may be made by email and/or hard copy by the aforementioned date and need not be filed with the Commission Secretary.

SO ORDERED.

Cameron Elliot
Administrative Law Judge