

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

HYDRAFACIAL LLC,

Plaintiff,

v.

AESTHETIC MANAGEMENT PARTNERS,
LLC and AESTHETIC MANAGEMENT
PARTNERS INC.,

Defendants.

Civil Action No. 2:24-cv-02480-SHL-tmp

**AMP'S OPPOSITION TO HYDRAFACIAL'S
MOTION FOR A PRELIMINARY INJUNCTION**

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¹ Plaintiffs Liqwd, Inc. and Olaplex LLC moved to substitute Olaplex, Inc. as the petitioning party for the Federal Circuit appeal. The Federal Circuit granted the motion to substitute. *Olaplex, Inc. v. L'Oreal USA, Inc.*, 845 F. App'x 943, 945 (Fed. Cir. Mar. 4, 2021). Plaintiffs Liqwd, Inc. and Olaplex LLC are the same parties that HF cites in its brief. Br. at 14 (citing *Liqwd, Inc. v. L'Oreal USA, Inc.*, 2019 WL 1873281, *4 (D. Del. Apr. 26, 2019)). For simplicity, in this brief, this line of cases is referred to as *Liqwd, Inc. v. L'Oreal USA Inc.*

² Plaintiffs Liqwd, Inc. and Olaplex LLC moved to substitute Olaplex, Inc. as the petitioning party for the Federal Circuit appeal. The Federal Circuit granted the motion to substitute. *Olaplex, Inc. v. L'Oreal USA, Inc.*, 855 F. App'x 701, 702 (Fed. Cir. May 6, 2021). Plaintiffs Liqwd, Inc. and Olaplex LLC are the same parties that HF cites in its brief. Br. at 14 (citing *Liqwd, Inc. v. L'Oreal USA, Inc.*, 2019 WL 1873281, *4 (D. Del. Apr. 26, 2019)). For simplicity, in this brief, this line of cases is referred to as *Liqwd, Inc. v. L'Oreal USA Inc.*

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1	U.S. Patent Application Publication No. 2003/0212415 (“Karasiuk”)
2	<i>Sinclair Pharma Ltd. v. HydraFacial LLC</i> , IPR2025-00145, Paper 12, Institution Decision (June 2, 2025)
3	<i>Eunsung Global Corp. v. HydraFacial LLC</i> , IPR2024-01491, Paper 17, Institution Decision (Apr. 11, 2025)
4	<i>Sinclair Pharma Ltd. v. HydraFacial LLC</i> , IPR2025-00145, Petition for <i>Inter Partes</i> Review of U.S. Patent No. 11,865,287 (Nov. 25, 2024)
5	U.S. Patent No. 5,199,604 (“Palmer”)
6	<i>Certain Hydrodermabrasion Sys. & Components Thereof</i> , Inv. No. 337-TA-1416, Case Management Conference Transcript (Dec. 10, 2024)
7	<i>Sinclair Pharma Ltd. v. HydraFacial LLC</i> , IPR2025-00145, Declaration of Eric Simon in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 11,865,287 (Sept. 30, 2024)
8	<i>Eunsung Global Corp. v. HydraFacial LLC</i> , IPR2024-01491, Paper 7, Patent Owner’s Preliminary Response (“POPR”) (Jan. 15, 2025)
9	<i>Eunsung Global Corp. v. HydraFacial LLC</i> , IPR2024-01491, Declaration of Karl R. Leinsing (Jan. 15, 2025)
10	<i>Sinclair Pharma Ltd. v. HydraFacial LLC</i> , IPR2025-00145, Patent Owner’s Request for Director Review (June 16, 2025)
11	<i>Sinclair Pharma Ltd. v. HydraFacial LLC</i> , IPR2025-00145, Paper 11, Patent Owner’s Notice of Waiver of POPR (Mar. 12, 2025)
12	Pending Claims in U.S. Patent Application No. 18/638,470
13	Claim comparison of U.S. Patent No. 11,865,287 and U.S. Patent Application No. 18/638,470
14	Final Rejection of U.S. Patent Application No. 18/638,470, dated January 6, 2025
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15F	Web Capture, dated July 10, 2025 – Diamond Glow Instagram; https://www.instagram.com/p/DFng-EYPafp/

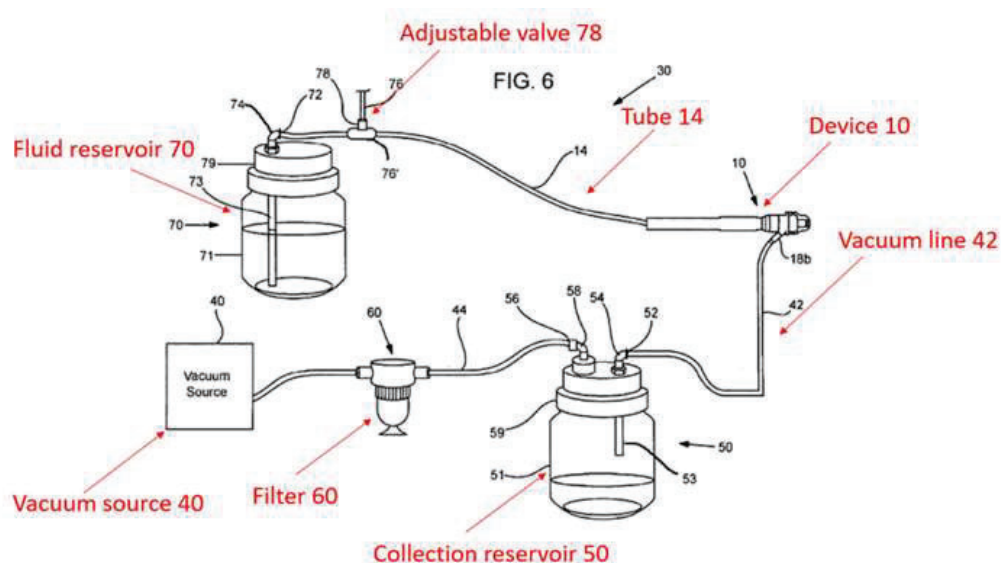
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16A	Web Capture, dated July 10, 2025 – AquafirmeXS – Scottsdale Skin Boutique & Dermatology; https://www.scottsdaleskinboutique.com/aquafirmexs/
16B	Web Capture, dated July 10, 2025 – HydraFacial – Scottsdale Skin Boutique & Dermatology; https://www.scottsdaleskinboutique.com/hydrafacialtm/
16C	Web Capture, dated July 10, 2025 – AquaFirmeXS de la Belle; https://delabelle.net/procedure/aquafirmexs/
16D	Web Capture, dated July 10, 2025 – HydraFacial Memphis de la Belle; https://delabelle.net/procedure/hydrafacial/
16E	Web Capture, dated July 10, 2025 – HydraFacial in Hoover – Smart Skin; https://smartskinmedspa.com/treatments/hydrafacial-in-hoover/
16F	Web Capture, dated July 10, 2025 – AquaFirme Facial in Hoover – Smart Skin; https://smartskinmedspa.com/treatments/aquafirme-facial-in-hoover/
16G	Web Capture, dated July 10, 2025 – AquaFirme XS Beautiful Glowing Skin without Hassle; https://newskinmedicalspa.com/aquafirme-xs-augusta-ga/
16H	Web Capture, dated July 10, 2025 – Top HydraFacial Provider New Skin Medical Spa Augusta, GA; https://newskinmedicalspa.com/hydrafacial-augusta-ga/
16I	Web Capture, dated July 10, 2025 – HydraFacial MD and Microdermabrasion Palm Coast, Florida; https://allnewu.com/facials-and-more/
16J	CBI – AquaFirme Sales
17	Declaration of Professor Alexander Slocum
17A	Curriculum Vitae of Professor Alexander Slocum
17B	Expert Witness History of Professor Alexander Slocum
18	<i>Aesthetic Mgmt. Partners, LLC v. HydraFacial LLC</i> , IPR2025-00169, Declaration of Eric Simon in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 9,550,052 (July 3, 2025)
19	<i>Aesthetic Mgmt. Partners, LLC v. HydraFacial LLC</i> , IPR2025-00169, Petition for <i>Inter Partes</i> Review of U.S. Patent No. 9,550,052 (July 3, 2025)
20	<i>Eunsung Global Corp. v. HydraFacial LLC</i> , IPR2025-00445, Petition for <i>Inter Partes</i> Review of U.S. Patent No. 9,550,052 (Jan. 10, 2025)
21	<i>Eunsung Global Corp. v. HydraFacial LLC</i> , IPR2025-00445, Declaration of Eric Simon in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 9,550,052 (Jan. 10, 2025)
22	<i>Eunsung Global Corp. v. HydraFacial LLC</i> , IPR2025-00445; IPR2025-00452; IPR2025-00453, Paper 14, Decision Referring the Petitions to the Board (July 11, 2025)

Exhibit	Description
23	Web Capture, dated March 3, 2005 – Wayback Machine; https://web.archive.org/web/20050304001729/http://www.edgesystem.net/Testimonials.htm , produced in Inv. No. 337-TA-1416 (JDG-0005176)
24	<i>Certain Hydrodermabrasion Sys. & Components Thereof</i> , Inv. No. 337-TA-1408, Evidentiary Hearing Tr. (pp. 541-777)
25	<i>Certain Hydrodermabrasion Sys. & Components Thereof</i> , Inv. Nos. 337-TA-1408, 337-TA-1416, Janine Sevy Deposition Transcript, dated November 11, 2024
26	<i>Certain Hydrodermabrasion Sys. & Components Thereof</i> , Inv. Nos. 337-TA-1408, 337-TA-1416, Elmina Pangan Deposition Transcript, dated November 13, 2024
27	<i>Certain Hydrodermabrasion Sys. & Components Thereof</i> , Inv. Nos. 337-TA-1408, 337-TA-1416, Pei Pei Wang Deposition Transcript, dated November 13, 2024
28	<i>Certain Hydrodermabrasion Sys. & Components Thereof</i> , Inv. No. 337-TA-1416, Commission Determination to Deny Complainant's Petition for Reconsideration of the Commission's Decision Not to Review an Initial Determination Setting a Target Date, dated November 21, 2024 (EDIS Doc. ID 837816)
29	Settlement Agreement between Luvo Medical Technologies, Inc.; Clarion Medical Technologies Inc.; Healthcare Markets, Inc. (collectively, "Luvo Parties") and HydraFacial LLC
30	Web Capture, dated July 10, 2025 – Beauty Health News Release; https://investors.beautyhealth.com/news-releases/news-release-details/beautyhealth-reports-full-year-and-fourth-quarter-2024-financial

HydraFacial's ("HF") success in the microdermabrasion business is not due to any patentable advance. To the contrary, HF adopted technology created by Mr. Ken Karasiuk, founder of Envy Medical. Mr. Karasiuk's patent application published in 2003—three years before HF filed the original patent application that ultimately led to its '052 and '287 patents.

The PTAB has already found—twice—that it is “reasonably likely” Mr. Karasiuk's patent publication (Ex. 1) renders claim 22 of the '287 patent obvious. Ex. 2 at 18; Ex. 3 at 16.

The following figure from Karasiuk (as annotated in AMP's IPR petition, Ex. 4 at 5) shows a system in which, when handpiece device 10 is pressed against a patient's skin, a vacuum circuit is created such that vacuum source 40 draws treatment material from reservoir 70, through tube 14, into handpiece 10 (treating the skin), and then draws the resulting waste through vacuum line 42 into collection reservoir 50. *E.g.*, Ex. 1, [0017]-[0024], [0063]-[0066].



This is exactly how HF's system works, except HF's system has multiple fluid reservoirs, selectable via a manifold, facilitating application of different serums. However, that feature was also well-known in the prior art, *e.g.*, in Palmer (Ex. 5). The PTAB found a “reasonable likelihood” that Karasiuk and Palmer invalidate '287 patent claim 22. Ex. 2 at 18; Ex. 3 at 16.

Given the similarity of the '287 and '052 patents, the PTAB's decisions create a "substantial question" of validity preventing a preliminary injunction as to both patents. *E.g.*, *Alexion Pharms., Inc. v. Samsung Bioepis Co.*, 2024 WL 2111988, *2 (D. Del. May 6, 2024) ("Numerous courts have found that the institution of IPR, by itself, raises a substantial question of validity."). Further, HF's brief does not even address the merits of the PTAB's decisions, let alone show that the PTAB's conclusion "lacks substantial merit," as required to overcome a substantial patent validity challenge in the preliminary injunction context. *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1379 (Fed. Cir. 2009). *Infra* §§ III.A.1-III.A.2.

Further, discovery at the ITC showed that HF put the invention claimed in its patents into public use more than a year before filing its patent application, thus invalidating its patents for "public use" under pre-AIA 35 U.S.C. § 102(b). Even in a preliminary evaluation, the ALJ stated that, while "we don't want to be pre-emptive, obviously, of Complainant's [HF's] rights, we do recognize there's some legitimacy" to the public use argument, and invited AMP to consider filing an early summary determination motion on it. Ex. 6 at 24:9-11; 21:12-22:2. (Ultimately, HF dropped the ITC case before AMP filed a summary determination motion.) The public use defense plainly also presents a "substantial question" of patent validity. *Infra* § III.A.4.

AMP's noninfringement arguments, discussed below, also raise substantial questions precluding a preliminary injunction under the "likelihood of success" prong. *Infra* § III.A.5.

HF also cannot show irreparable harm. HF routinely tolerates alleged infringement. In AMP's case, HF waited to file a preliminary injunction motion until more than three years after AMP launched the accused product, 20 months after sending AMP a threat letter, and more than 11 months after filing this lawsuit. These delays, coupled with the lack of any evidence that HF is being irreparably harmed, independently compel denial of the motion. *Infra* § III.B.

The balance of hardships and the public interest also disfavor a preliminary injunction.

Infra § III.C.

I. LEGAL STANDARD

A party seeking a preliminary injunction must establish that: (1) it is likely to succeed on the merits; (2) it is likely to suffer irreparable harm absent the preliminary relief; (3) the balance of equities tips in its favor; and (4) an injunction is in the public interest. *Winter v. NRDC, Inc.*, 555 U.S. 7, 20 (2008); *see also DexCom, Inc. v. Abbott Diabetes Care, Inc.*, 89 F.4th 1370, 1375 (Fed. Cir. 2024). “[A] movant cannot be granted a preliminary injunction unless it establishes both of the first two factors, *i.e.*, likelihood of success on the merits and irreparable harm.” *PHG Techs., LLC v. St. John Companies, Inc.*, 469 F.3d 1361, 1365 (Fed. Cir. 2006). Injunctive relief is “an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.” *Winter*, 555 U.S. at 22; *Takeda Pharms. U.S.A., Inc. v. Mylan Pharms. Inc.*, 967 F.3d 1339, 1345 (Fed. Cir. 2020).

II. FACTUAL BACKGROUND

The ’052 patent issued in 2017 and the ’287 patent issued in 2024. Since 2017, HF or its predecessor have filed 14 lawsuits alleging infringement of one or both of these patents.³ Yet HF has filed only two preliminary injunction motions, both in the last two months—in this case and in 2:24-cv-00855 (D. Nev.) against a company called Medicreations. HF still has six other cases pending (bolded in the footnote)—some for over a year—against various alleged infringers in which it has *not* sought a preliminary injunction.

³ This case plus ITC Inv. Nos. **1408** and 1416; **0:25-cv-61262 (S.D. Fla.)**; **1:25-cv-00418 (D. Del.)**; 8:24-cv-01865 (C.D. Cal.); **2:24-cv-00587 (D. Utah)**; **2:24-cv-06250 (C.D. Cal.)**; 2:24-cv-00855 (D. Nev.); **2:24-cv-04253 (E.D.N.Y.)**; 4:20-cv-04335 (S.D. Tex.); 2:20-cv-06082 (E.D.N.Y.); 2:17-cv-08699 (C.D. Cal.); 2:17-cv-04597 (C.D. Cal.).

III. ARGUMENT

A. HF Is Unlikely to Succeed on the Merits

A patentee fails to establish a likelihood of success on the merits “[i]f the accused infringer raises a substantial question concerning either infringement or validity.” *LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361, 1366 (Fed. Cir. 2013). Raising a substantial question of validity means “the alleged infringer has presented an invalidity defense that the patentee has not shown lacks substantial merit.” *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1379 (Fed. Cir. 2009). At the preliminary injunction stage, “a showing of a substantial question of invalidity requires less proof than the clear and convincing standard to show actual invalidity.” *Erico Int’l Corp. v. Vutec Corp.*, 516 F.3d 1350, 1356 (Fed. Cir. 2008).

As detailed below, HF fails to show that AMP’s challenges to the validity of the patent claims at issue lack substantial merit. Indeed, HF does not even address the merits of the PTAB’s preliminary conclusion that there is a “reasonable likelihood” that claim 22 of the ’287 patent is obvious. Further, earlier this year, the USPTO again found that the combination of Karasiuk (Ex. 1) and Palmer (Ex. 5) renders obvious a similar claim that HF sought in a continuation patent application. As noted previously, the ITC ALJ found the public use defense worthy of serious consideration. There is also a substantial question whether the accused products infringe, which provides an independent reason why the preliminary injunction motion should be denied.

1. There Is a Substantial Question Whether ’287 Claim 22 Is Obvious

On April 11, 2025, in ruling on a third-party’s IPR against the ’287 patent, the PTAB denied the petition discretionarily, but found that the *merits* of the petition met the institution standard (Ex. 3 at 16)—*i.e.*, a “reasonable likelihood” of success in showing the ’287 patent claims are unpatentable, 35 U.S.C. § 314—essentially the opposite of the burden HF bears here.

The PTAB later instituted AMP's IPR and expressly found a "reasonable likelihood" that Karasiuk and Palmer render claim 22 of the '287 patent obvious. Ex. 2 at 18. In particular, the PTAB found "the combination of Karasiuk and Palmer discloses or suggests the limitations of the challenged claims," and credited the testimony of AMP's expert (Ex. 7) that "a person having ordinary skill in the art [POSA] would have been motivated to combine" Karasiuk and Palmer, with a reasonable expectation of success. Ex. 2 at 17-18. Despite HF being well aware of the IPR, neither HF's brief (pp. 14-15) nor its expert's declaration (ECF No. 42-2 ¶¶ 75-89) address the merits of the PTAB's institution decisions, much less show that the PTAB's obviousness conclusion "lacks substantial merit."

Indeed, HF's brief never so much as mentions either Karasiuk or Palmer. HF's expert, Mr. Leinsing, gives them only perfunctory treatment. His three conclusory assertions regarding the Karasiuk-Palmer combination fail to show that the PTAB's findings lack substantial merit.

First, he contends that Karasiuk "discloses only a single container." ECF No. 42-2 ¶ 87. This is irrelevant since, as the PTAB correctly understood, in the Karasiuk-Palmer combination it is Palmer that provides the "teaching of multiple containers." Ex. 2 at 18.

Second, he contends that a POSA would not have looked to Palmer "to modify skin treatment devices" because Palmer describes a "dental irrigation tool," not a microdermabrasion system. ECF No. 42-2 ¶ 88. This, however, merely recycles the unsuccessful argument HF made to the PTAB to the same effect. Ex. 8 (POPR) at 23, 39-40; Ex. 9 (Leising IPR Decl.) ¶ 46. The PTAB was unpersuaded by this wooden argument, which improperly treats a POSA as an automaton. Ex. 3 at 16; *see also* Ex. 2 at 18; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) ("A person of ordinary skill is also a person of ordinary creativity, not an automaton.").

Third, his assertion that “Greenberg teach[es] away from the use of fluids in its system” (ECF No. 42-2 ¶ 88) is irrelevant to Karasiuk-Palmer. Greenberg is a different prior art reference, applied in separate and independent IPR grounds (Ex. 4, Grounds 2A-2B), which the PTAB did not rely upon when instituting AMP’s IPR. Ex. 2 at 17-31.⁴

In short, Mr. Leinsing’s three conclusory assertions fail to show that the PTAB’s obviousness findings as to the Karasiuk-Palmer combination lack substantial merit.

Attempting to downplay the IPR institution decision, HF says it plans to seek USPTO Director Review. Br. at 14. HF filed that request on June 16, 2025. Ex. 10. The request does not even attempt to revisit the merits of the institution decision; instead, HF asks the Director to deny institution discretionarily based on a procedural issue—a pending ITC case. *Id.* Given HF’s prior waiver (Ex. 11), AMP expects the request to be denied, but in any event a discretionary denial would be irrelevant to the issue before this Court: namely, whether Karasiuk-Palmer presents a substantial challenge to claim 22’s validity. The PTAB has answered that question affirmatively, and HF’s Director Review request does not challenge that aspect of the PTAB’s decision. Ex. 10.

“Numerous courts have found that the institution of IPR, by itself, raises a substantial question of validity.” *Alexion*, 2024 WL 2111988, at *2; *see also Adidas Am., Inc. v. Skechers USA, Inc.*, 2017 WL 2604310, *6 (D. Or. June 12, 2017) (denying preliminary injunction: “based on the PTAB’s instituting IPR ... [patentee] cannot, at this time, show a likelihood of success on the merits”); *Murata Mach. USA, Inc. v. Daifuku Co.*, 2016 WL 4287040, *2 (D. Utah Aug. 15, 2016) (denying preliminary injunction: “As long as the IPRs are pending ... [patentee] will not be able to demonstrate a likelihood of success on the merits.”).

⁴ Because Karasiuk-Palmer plainly raises a substantial question of invalidity, AMP does not address Greenberg in the limited space available in this brief.

The cases cited by HF are distinguishable. In *Tinnus Enters., LLC v. Telebrands Corp.*, 846 F.3d 1190 (Fed. Cir. 2017), the PTAB clearly erred in its indefiniteness analysis. The district court and the Federal Circuit recognized the error, 846 F.3d at 1202 n.7, and ultimately the Federal Circuit reversed the PTAB's decision on appeal. *Tinnus Enters., LLC v. Telebrands Corp.*, 733 F. App'x 1011, 1020 (Fed. Cir. 2018). Here, as noted above, HF does not allege such error by the PTAB. In *Liqwd, Inc. v. L'Oreal USA, Inc.*, the district court ultimately **declined** to enter a preliminary injunction, 845 F. App'x 943, 946 n.3 (Fed. Cir. Mar. 4, 2021), and after an appeal of the PGR, on remand the PTAB again found the claims unpatentable, and the patent owner gave up on them. 855 F. App'x 701, 702 (Fed. Cir. May 6, 2021). Thus, *Liqwd* strongly cautions against entering a preliminary injunction based on claims the PTAB finds unpatentable.

Recently, in a subsequent continuation (Serial No. 18/638,470) with very similar claims (Ex. 12 at 2-4; Ex. 13), the USPTO rejected the claims over Karasiuk-Palmer (Ex. 14 at 10-19)—further confirming the obviousness of the combination, contrary to HF's expert. *Supra* p. 5.

2. There Is a Substantial Question Whether '052 Claim 1 Is Obvious

The '052 and '287 patents share a specification and similar claims. The PTAB's decision to institute IPR for the '287 raises a substantial question as to the validity of '052 patent claim 1. *E.g., DNA Genotek Inc. v. Spectrum Sols. L.L.C.*, 2016 WL 8738225, *3 (S.D. Cal. Oct. 6, 2016) (IPR of related patent precluded preliminary injunction). Further, AMP and a third party filed IPRs against the '052 (Exs. 18, 19, 20, 21) based on Karasiuk-Palmer, and the Director already denied HF's request for discretionary denial of the third-party IPR against the '052, finding that the original patent examiner "overlooked certain teachings in Karasiuk that appear to disclose the allowable features of the claims." Ex. 22 at 3. It is difficult to imagine more powerful evidence that a substantial question of validity exists with respect to claim 1 of the '052 patent.

HF's brief merely asserts that the "console" limitation of '052 patent claim 1 is missing, without offering any analysis. Br. at 15. HF's expert once again offers nothing more.

First, HF's expert says Karasiuk "draws liquid from just one container" and fails to disclose "different containers." ECF No. 42-3 ¶¶ 79-80. However, both his '052 analysis and HF's brief ignore Palmer, which discloses multiple containers and the manifold. Ex. 19 at 15-19.

Second, HF's expert contends Karasiuk's system is "inoperable" because "a breather line 76 and adjustable valve 78" would cause "vacuum source 40 to draw only air through tube 14." ECF No. 42-3 ¶ 80. He ignores Karasiuk's teaching that "[u]pon forming the vacuum loop ... the *fluid contents in reservoir 70 are drawn through tube 14.*" Karasiuk, [0064]. In short, his cursory assertion directly contradicts Karasiuk itself. *See also* Ex. 22 at 3.

Third, HF cites a summary judgment decision, from a different case, finding '052 claim 1 not invalid. Br. at 15. HF misleadingly omits that its summary judgment motion in that case was addressed to *different* prior art; the Karasiuk-Palmer combination was not even before the court. *Edge Systems LLC v. Cartessa Aesthetics, LLC*, 2023 WL 3847138, *1 (E.D.N.Y. June 6, 2023).

3. Secondary Considerations Do Not Outweigh the Evidence that '287 Claim 22 and '052 Claim 1 Are Obvious

HF's expert discusses "secondary considerations," arguing that their nexus to the claims is using multiple containers and a manifold. ECF No. 42-2 ¶¶ 116-120. Those features, however, are from prior art (*e.g.*, Palmer) as the USPTO repeatedly found. Ex. 2; Ex. 14 at 11-12. Nexus cannot arise from prior art. *Tokai Corp. v. Easton Enter.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011). There also is no "presumed" nexus to HF's products because HF contends that unrelated patents cover them (<https://hydrafacial.com/patents>). *Fox Factory, Inc. v. SRAM, LLC*, 994 F.3d 1366, 1373-78 (Fed. Cir. 2019). In any event, secondary considerations cannot overcome a strong case of obviousness. *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368, 1378 (Fed. Cir. 2022).

4. There Is a Substantial Question Whether Prior Public Use Renders the Asserted Claims Invalid

Discovery at the ITC revealed that HF publicly used its inventions more than a year before the alleged priority date of December 30, 2005. Such public use is invalidating prior art. *Ingenico Inc. v. IOENGINE, LLC*, 136 F.4th 1354, 1361 (Fed. Cir. 2025).

HydraFacial advertised, at least as early as March 4, 2005, that it had performed “HydraFacial” treatments (*i.e.*, using the patented HydraFacial console) on third parties. Ex. 23. Multiple third parties testified that this occurred in about November 2004—well before the December 30, 2004 critical date. For example, Ms. Janine Sevy testified it was “very likely” her first treatment was in November 2004. Ex. 24 (ITC Inv. No. 1408 Hearing Transcript), 662:9-17. Her testimony was corroborated by documentary evidence and her own personal written record. *Id.*, 651:9-652:5 (discussing JX-0021, HydraFacial Commercial Video); *see also* Ex. 25 (Sevy Depo. Tr.), 28:12-25. Another witness, Ms. Elmina Pangan, testified she was “90% sure” her first treatment was in 2004. Ex. 26 (Pangan Depo. Tr.), 31:2-19; *see also id.*, 23:15-25. Another individual, Ms. Pei Pei Wang, likely received a HydraFacial treatment even earlier than the others. *See* Ex. 24 at 647:14-22. None of the witnesses who received the treatments were asked to sign non-disclosure agreements or otherwise keep the treatments secret. Ex. 25 at 16:22-17:2; Ex. 26 at 22:2-12; Ex. 27 at 21:13-22. After preliminary evaluation of this evidence, the ALJ stated that, while “we don’t want to be pre-emptive, obviously, of Complainant’s [HF’s] rights, we do recognize there’s some legitimacy” to the public use argument, and invited AMP to consider filing an early summary determination motion on it (though, as noted previously, HF ended up dropping the ITC case before AMP filed such a motion). Ex. 6 at 24:9-11, 21:12-22:2. Despite all this, HF’s brief and expert totally ignore the public use issue.

5. HF Fails to Show It Will Likely Prove that the AquaFirme XS Infringes '052 Claim 1 or '287 Claim 22

The AquaFirme XS does not infringe either of the claims at issue here.

For '052 claim 1, the AquaFirme XS lacks a “manifold [that] is configured to control a flow of treatment material” from first and second fluid containers. As AMP’s expert explains, in the AquaFirme XS, there are solenoid valves—separate from any structure that could possibly be considered a “manifold”—that control the flow of serum from each bottle. Ex. 17 ¶¶ 23-25; ECF No. 42-2 at 12 (HF’s expert separately labeled “manifold” and “solenoid control valves”). The tubes and connectors that could potentially be considered a “manifold” are always open, and thus cannot control flow. Ex. 17 ¶¶ 26-29. Notably, the '052 patent discloses two different arrangements: valves in a manifold so the manifold itself controls fluid flow, versus valves in a console rather than the manifold. '052 patent, 9:4-8 (valves “may alternatively be located in the console 12 or manifold system 24”); *compare id.*, 17:5-17 (manifold embodiment) *with* 18:27-34 (console embodiment); Ex. 17 ¶ 30. Claim 1 covers the manifold embodiment. Ex. 17 ¶ 31. Since the AquaFirme XS practices a disclosed but unclaimed embodiment (Ex. 17 ¶ 32), as a matter of law there can be no infringement even under the doctrine of equivalents. *Johnson & Johnston Assoc. Inc. v. R.E. Serv. Co., Inc.*, 285 F.3d 1046, 1054-55 (Fed. Cir. 2002) (en banc).

'287 claim 22 requires that the handpiece is in fluid communication with a vacuum source. The '287 patent defines “fluid” as “treatment material” ('287 patent, 5:52-54), which in the AquaFirme XS is liquid. The AquaFirme XS lacks the claimed “fluid communication” because it has a filter that blocks any liquid from entering the vacuum pump. Ex. 17 ¶¶ 35-40.

Prof. Slocum’s testimony independently supports denying the motion. *Novartis Pharms. Corp. v. MSN Pharms., Inc.*, 2024 WL 4969281, *5 (Fed. Cir. Dec. 4, 2024) (preliminary injunction properly denied where defendant presented rebuttal evidence on infringement).

B. HF Fails to Show Irreparable Harm

The irreparable harm factor is “indispensable: If the plaintiff isn’t facing imminent and irreparable injury, there’s no need to grant relief now as opposed to at the end of the lawsuit.” *DeHority v. Chamberlain*, 2025 WL 1243073, *4 (W.D. Tenn. Apr. 29, 2025). In other words, “a district court is ‘well within its province’ when it denies a preliminary injunction based solely on the lack of an irreparable injury.” *Id.* Because HF fails to establish it would be irreparably harmed absent injunctive relief, the motion should be denied.

1. HF’s Unreasonable Delay Precludes a Finding of Irreparable Harm

A substantial delay between learning of alleged infringement and seeking a preliminary injunction undermines a patent owner’s assertion that it suffers irreparable harm. *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1321, 1325-26 (Fed. Cir. 2012); *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995) (17 months is a “substantial period of delay that militates against the issuance of a preliminary injunction by demonstrating that there is no apparent urgency to the request for injunctive relief”).

In this case, AMP began selling the accused product in February 2022. Ex. 16 ¶ 7. While AMP is confident HF knew of AMP’s sales promptly, HF indisputably was aware of them by October 10, 2023, when HF sent AMP a threat letter. ECF No. 1 (Compl.) ¶ 29. Thus, HF delayed **at least 20 months** before seeking a preliminary injunction. This delay is fatal. *E.g.*, *T.J. Smith and Nephew Ltd. v. Consol. Med. Equip., Inc.*, 821 F.2d 646, 648 (Fed. Cir. 1987) (no irreparable harm where patentee waited 15 months to seek preliminary injunction); *Manlove v. Volkswagen Aktiengesellschaft*, 2019 WL 2291894, *15 (E.D. Tenn. May 17, 2019) (no irreparable harm where plaintiff waited a year and a half to sue); *Doughtie & Co., Inc. v. Rutherford Cty.*, 2013 WL 3995277, *2 (M.D. Tenn. Aug. 5, 2013) (same).

Further, HF waited 9 months after its October 2023 letter to file this suit on July 8, 2024. ECF No. 1. HF could have sought a preliminary injunction from this Court on all patents not asserted in its parallel ITC case, but instead agreed to stay this case in its entirety⁵ and, ultimately, waited 11 months after filing this suit to seek a preliminary injunction. That delay, too, shows lack of irreparable harm. *Doughtie*, 2013 WL 3995277, at *2 (no irreparable harm where plaintiff waited three months after filing suit to file preliminary injunction motion).

Further, HF pursued a deliberate litigation strategy that delayed any conceivable relief when it proceeded against AMP at the ITC despite receiving a 19-month schedule that made it impossible for HF to secure any exclusion order from the ITC before the asserted patents expire in March 2026. Over HF's objection, on November 21, 2024, the ITC declined to reconsider the target date. Ex. 28. At that point the ITC case was unquestionably futile, yet HF continued litigating it for ***another three months***, wasting AMP's time and resources, before filing a motion to terminate the investigation on February 18, 2025.

HF weakly attempts to justify its delay on the basis that it "did not obtain an AquaFirme XS until early 2025" (Br. at 2), but this argument is belied by HF's filing of the complaint in this Court in July 2024, before which it was required to complete a pre-filing investigation (and, of course, HF could have sought prompt discovery in this Court enabling it to inspect an AquaFirme XS immediately after filing, if HF felt such inspection was needed).

HF's extreme delay in seeking injunctive relief is, alone, a sufficient basis to deny its motion for preliminary injunction.

⁵ Under 28 U.S.C. § 1659, AMP was statutorily entitled to a stay only as to the two patents (of the five asserted) that overlapped with the 1416 ITC case. *Telefonaktiebolaget LM Ericsson v. Lenovo (United States), Inc.*, 5:23-cv-00569, ECF No. 96, 7 (E.D.N.C. Dec. 10, 2024) (denying stay as to patent not asserted in ITC case).

2. HF's Previous Agreement to a Stay Also Strongly Undercuts Any Suggestion of Irreparable Harm

The fact that HF jointly moved for, and the Court granted, a stay in this case, strongly undercuts any allegation by HF of irreparable harm. Indeed, a court “ordinarily should not grant both a preliminary injunction and a stay.” *Proctor & Gamble Co. v. Kraft Foods. Glob., Inc.*, 549 F.3d 842, 849 (Fed. Cir. 2008). “The main reason that a court should not ordinarily grant both a preliminary injunction and a stay is that the factors that weigh in favor of issuing a stay are often the same factors that weigh against issuing a preliminary injunction.” *Murata Mach. USA, Inc. v. Daifuku Co.*, 2016 WL 4287040, *2 (D. Utah Aug. 15, 2016). Thus, the fact that HF *agreed* it would not be prejudiced by a stay (ECF No. 19) confirms that HF will not experience irreparable harm absent a preliminary injunction.

3. HF's Failure to Seek Preliminary Injunctive Relief Against Numerous Purported Infringers Also Undercuts Any Suggestion that AMP's Sales Are Causing Irreparable Harm

HF's years-long pattern of *not seeking* preliminary injunctions—despite alleging infringement of the '287 and '052 patents in many cases, *supra* § II—undermines its current assertion of irreparable harm. *Wave Studio, LLC v. trivago N.V.*, 2023 WL 3720079, *9 (S.D.N.Y. May 30, 2023) (“[T]he fact that Plaintiff has alleged violations of the same copyrighted works against other similar defendants as early as 2013 also undermines Plaintiff's argument that the harm will be irreparable should an injunction not be issued now.”); *Pharmacia Corp. v. Alcon Lab'ys, Inc.*, 201 F. Supp. 2d 335, 383-84 (D.N.J. 2002) (“[A] seven-month delay and failure to move against other potential infringers ‘conclusively refutes’ claim of irreparable harm.”). HF does not even attempt to suggest that AMP's sales damage it more than sales by other alleged infringers, against which HF has *not* sought a preliminary injunction.

4. That the Asserted Patents Expire in Nine Months Weighs Against Injunctive Relief

HF argues that injunctive relief is important because the asserted patents are set to expire soon. To the contrary, the fact that the patents expire in March 2026 contradicts any assertion of irreparable harm. *Baxalta Inc. v. Genentech, Inc.*, 2018 WL 3742610, *11 (D. Del. Aug. 7, 2018) (denying preliminary injunction because patents would expire in three years: “this is not a case where a jury would be tasked with calculating speculative damages for an ongoing loss of market share that cannot be recouped”); *Humanscale Corp. v. CompX Int’l, Inc.*, 2010 WL 1779963, *4 (E.D. Va. Apr. 29, 2010) (“the infringing activity will necessarily end in six weeks when the CompX Patents expire, which counsels against a finding of irreparable harm”).

5. HF’s Alleged Harm Is Speculative and/or Compensable With Monetary Damages

HF does not claim any of the traditional concrete forms of irreparable harm such as price erosion or decline in market share. Nor could it, because HF’s sales have significantly increased. According to Form 10-K filings by HF’s parent company, between 2021 and 2023, the installed base of HF’s systems increased by over 50%, from more than 20,000 units to more than 30,000 units. Exs. 15A-C (SEC filings) at 7. Such growth is inconsistent with the irreparable harm necessary to support a preliminary injunction. Further, this growth occurred despite HF’s self-inflicted wound of introducing an admittedly defective new model of its console, the Syndeo, which led to significant customer dissatisfaction and write-downs. Ex. 15D at 123.

Instead, HF points to purported reputational harm and loss of customers. Yet HF fails to support those speculative allegations, and its injuries (if any) are compensable with damages. *Automated Merch. Sys., Inc. v. Crane Co.*, 357 F. App’x 297, 301 (Fed. Cir. 2009) (patentee has “burden to demonstrate that its potential losses cannot be compensated by monetary damages.”);

Waters Corp. v. Agilent Techs. Inc., 410 F. Supp. 3d 702, 714 (D. Del. 2019) (“[The patentee] must demonstrate that immediate irreparable harm is likely in the absence of injunctive relief – not merely that irreparable harm may possibly occur at some point in the future.”); *see also D.T. v. Sumner Cty. Sch.*, 942 F.3d 324, 327 (6th Cir. 2019) (“To merit a preliminary injunction, an injury must be both certain and immediate, not speculative or theoretical.”).

HF’s alleged reputational harm is purely speculative. As a threshold matter, HF does not even establish that it has a reputation as an innovator. Its sole evidence on this point is a footnote citation to three webpages, which appear to be solicited press releases and marketing materials by interested third-party providers of HF treatments. Br. at 17 n.2. Further, HF fails to provide any evidence that damage to its reputation has occurred or will occur. *DeHORITY v. Chamberlain*, 2025 WL 1243073, *7 (W.D. Tenn. Apr. 29, 2025) (finding similar bare-bones assertions speculative and insufficient to establish irreparable harm). Although courts have previously considered reputational harm “where there was evidence of consumer confusion, a loss of product distinctiveness, or some risk to that plaintiff’s status as an innovator,” HF has not presented evidence on any of these alleged harms. *Baxalta*, 2018 WL 3742610, at *11 (finding speculative assertions insufficient to support irreparable harm to reputation). Tellingly, the declaration of HF’s executive, Vipul Savsani (ECF No. 42-23) says nothing about reputational harm.

HF’s conclusory assertions of irreparable harm from continued sales of allegedly infringing consoles are also inconsistent with HF’s recent settlements with other companies, in which HF permitted them to continue selling their allegedly infringing product for seven months. Ex. 29. Having agreed to allow others to continue selling allegedly infringing consoles, HF cannot claim its reputation will be irreparably harmed by AMP doing the same thing.

HF also claims it will be irreparably harmed absent a preliminary injunction due to loss of customers. Again, however, HF makes conclusory, speculative statements without any evidence. In any event, “lost sales (without more) are presumed to be compensable through damages, so they do not require injunctive relief.” *Automated*, 357 F. App’x at 301. The only support for HF’s assertion that it will “lose critical customer relationships” that will be “felt for many years” is the conclusory declaration of its executive Mr. Savsani. HF presents no evidence beyond Mr. Savsani’s say-so that there are no non-infringing alternatives to the HF console on the market,⁶ that sales of AMP’s AquaFirme XS are lost sales for HF, or that there will be “substantial entrenchment” and “ripple effects” absent an injunction.⁷ These unsupported conclusions and attorney argument are insufficient to establish that HF would lose sales to AMP absent a preliminary injunction. *Hoist Fitness Systems, Inc. v. Tuffstuff Fitness Int’l, Inc.*, 2017 WL 5640562, *3 (C.D. Cal. Oct. 31, 2017) (“The unsupported, conclusory assertions of the movant’s CEO are simply not sufficient to establish these facts.”); *TeleSign Corp. v. Twilio, Inc.*, 2015 WL 12532491, *6 (C.D. Cal. Oct. 19, 2015) (“[T]he Court is troubled by Plaintiff’s factual evidence, as it consists almost entirely of testimony from Plaintiff’s vice president.”);

⁶ There is no indication that Mr. Savsani is qualified to opine about non-infringing alternatives. Indeed, his testimony is plainly incorrect, as HF has never even tried to argue that the DiamondGlow (Exs. 15E-15F), which originated with Mr. Karasiuk (of the Karasiuk prior art) infringes, despite admitting that DiamondGlow is a competitor. Ex. 15A at 12; Ex. 15B at 14; Exs. 15C-15D at 13. Further, when Mr. Savsani says he has “been informed” and “understands” various conclusions, he is offering inadmissible hearsay from an unidentified declarant.

⁷ These unsupported conclusions and attorney argument are a far cry from the 112-page expert economist report and detailed technical declaration that supported the patentee’s irreparable harm argument in *Natera, Inc. v. NeoGenomics Lab’ys, Inc.*, No. 1:23-cv-000629 (M.D.N.C.), ECF Nos. 7, 14. They are also far less detailed than the underlying evidence submitted in *Illumina, Inc. v. Qiagen, N.V.*, No. 3:16-cv-02788, ECF Nos. 14, 16. HF also neglects to inform the Court that the “infrequent[] and irregular[]” purchases in *Illumina* were the result of needing to “win government approval for use of any new DNA-sequencing equipment” a fact which is not present here. *Illumina, Inc. v. Qiagen, N.V.*, 207 F. Supp. 3d 1081, 1093 (N.D. Cal. 2016).

Mallinckrodt Pharms. Ireland Ltd. v. Airgas Therapeutics LLC, 2025 WL 472557, *8 (D. Del. Feb. 12, 2025) (denying preliminary injunction where patentee “offered insufficient analysis to allege how much of the market share it will lose should Airgas not be enjoined and why money could not compensate any lost contracts”).

Further, the fact that the AquaFirme XS has alternative uses, such as for hair replacement, undermines any claimed irreparable harm. Crosby Decl. ¶¶ 6, 12. Indeed, it is common for customers to purchase **both** the AquaFirme XS and a HF console—undermining any suggestion that AMP is necessarily taking sales from HF. *Id.* ¶ 13; Exs. 16A-I. Irreparable injury requires “causal nexus” between the alleged infringement and the alleged harm to the patentee. *Apple*, 678 F.3d at 1324. In order to establish a “causal nexus,” HF must show that purchasing decisions are motivated by the allegedly infringing features. *TeleSign*, 2015 WL 12532491 at *6. HF presents no such analysis and fails to address that the alternative uses of the AquaFirme XS can and do drive purchasing decisions. Ex. 16C at 2; Ex. 16F at 2; Ex. 16G at 2-3. This, too, undermines HF’s assertion of irreparable harm.

Moreover, any alleged injury would be compensable by monetary damages. Per the Federal Circuit, “[l]ost sales (without more) are presumed to be compensable through damages, so they do not require injunctive relief.” *Automated*, 357 F. App’x at 301. HF offers no competent evidence (and certainly no economic expert testimony) that monetary damages could not be calculated. In fact, HF’s own expert previously calculated the precise amount of profit HF generates per month in consumables for each sale of a HF console. ECF No. 42-23 ¶ 11. Injunctive relief is not available under these circumstances. *Otsuka Pharm. Co., Ltd. v. Torrent Pharms. Ltd., Inc.*, 99 F. Supp. 3d 461, 501 (D.N.J. 2015) (collecting cases finding similar types of harms compensable through damages).

C. The Remaining Factors Cannot Justify a Preliminary Injunction

HF's failure to demonstrate a likelihood of success on the merits or irreparable harm, is dispositive, meaning the Court need not reach the final two factors. *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 973-74 (Fed. Cir. 1996). Should the Court nevertheless reach the final two factors, they both disfavor preliminary injunctive relief.

1. The Balance of Hardships Disfavors a Preliminary Injunction

HF cannot show any hardship given its delay in seeking a preliminary injunction for patents that will expire in under nine months. *Finjan, Inc. v. Blue Coat Sys., LLC*, 2016 WL 6873541, *7 (N.D. Cal. Nov. 22, 2016) (balance of hardships did not favor preliminary injunction where patentee delayed filing preliminary injunction motion for a year after filing suit, and patent-in-suit would expire in two months: "the hardship that [Plaintiff] would suffer from a denial of a preliminary injunction seems speculative and short-lived at best."). On the other hand, enjoining AMP—a much smaller company⁸—for nine months from selling a product it has been selling for over three years would dramatically harm AMP's business. Crosby Decl. ¶¶ 7-12.

Given the disparity in the size of the parties, and hence their abilities to shoulder any burden from grant or denial of a preliminary injunction, the balance of hardships disfavors a preliminary injunction. *Litton Sys. Inc. v. Sundstrand Corp.*, 750 F.2d 952, 959 (Fed. Cir. 1984) ("An injunction should not be granted if its impact on the enjoined party would be more severe than the injury the moving party would suffer if it is not granted."); *Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990) ("The hardship on a preliminarily enjoined manufacturer who must withdraw its product from the market before trial can be devastating.").

⁸ In 2024, AMP had revenues of approximately [REDACTED] (Crosby Decl. ¶ 17), while HF had net sales of \$334.3 million. Ex. 30.

Any injunction would be additionally prejudicial to AMP given that the AquaFirme XS has features and functions that even HF does not claim are infringing; for example, hair restoration. Crosby Decl. ¶¶ 6, 12; Ex. 16C at 2; Ex. 16F at 2; Ex. 16G at 2-3.

2. The Public Interest Disfavors a Preliminary Injunction

Bizarrely, HF requests that injunctive relief be granted “until such a time as this matter can be tried,” which certainly will be after the patents have expired. Br. at 20. No court has the power to grant such an injunction, and the request for such an injunction amounts to an attempt at patent misuse. *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1550 (Fed. Cir. 1994) (precluding injunctive relief because the requested injunction would extend beyond the patent’s expiration). In any event, the public interest is not served by allowing HF to use invalid patents to prevent legitimate competition through an injunction. *Fleet Connection Solutions LLC v. C.R. England*, 2024 WL 5679163, *7 (C.D. Cal. 2024). Here, the public is entitled to a competitive market in skin restoration devices, particularly where AMP’s system has indisputably non-infringing uses, e.g., hair replacement treatments. Crosby Decl. ¶¶ 6, 12; *Apple Inc. v. Samsung Elecs. Co. Ltd.*, 735 F.3d 1352, 1372-73 (Fed. Cir. 2013) (affirming denial of preliminary injunction that “would have the effect of depriving the public to a large number of non-infringing features”).

D. If the Court Grants a Preliminary Injunction, the Court Should Require HF to Post a Bond in the Amount of [REDACTED]

In the event that the Court were to grant HF’s motion, HF should be required to post a substantial bond to cover the damages that AMP would incur from wrongful enjoinder.

Rule 65(c) requires that “[n]o ... preliminary injunction shall issue except upon the giving of security by the applicant.” Fed. R. Civ. P. 65(c). The Court has discretion to and should set a large bond because the harm to AMP could be staggering. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1385 (Fed. Cir. 2006).

Indeed, it is well-settled that district courts should “err on the high side” in setting the bond amount for a preliminary injunction because “[a]n error in setting the bond too high ... is not serious,” whereas “an error in the other direction produces irreparable injury, because the damages for an erroneous preliminary injunction cannot exceed the amount of the bond.” *Mead Johnson & Co. v. Abbott Labs.*, 201 F.3d 883, 888 (7th Cir. 2000) (citing *W.R. Grace & Co. v. Rubber Workers*, 461 U.S. 757, 770 n.14 (1983)). AMP’s historical sales establish that it will likely lose [REDACTED] in gross profits from sales of the AquaFirme XS consoles per month, for a total of [REDACTED], if enjoined from selling the AquaFirme XS consoles⁹ from July 2025 until the asserted patents expire on March 29, 2026. Crosby Decl. ¶¶ 9-11. Accordingly, AMP requests that, should the Court decide to issue a preliminary injunction, the Court require HF to post a bond in the amount of at least [REDACTED].

IV. CONCLUSION

The Court should deny HydraFacial’s Motion for Preliminary Injunction.

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Respectfully submitted,

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⁹ HF has not sought to enjoin AMP from selling serums, tips, or any other accessory.

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CERTIFICATE OF SERVICE

I certify that this document is being filed through the Court's electronic filing system, which serves counsel for other parties who are registered participants as identified on the Notice of Electronic Filing (NEF). Any counsel for other parties who are not registered participants are being served by first class mail on the date of electronic filing.

/s/ Nicole Berkowitz Riccio

Nicole Berkowitz Riccio