#### UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOMBARDIER INC. Petitioner,

v.

THE LITEBOOK COMPANY LTD., Patent Owner.

> Case IPR2023-00192 Patent No. 7,678,140

PATENT OWNER THE LITEBOOK COMPANY LTD.'S PRELIMINARY RESPONSE UNDER 37 C.F.R. § 42.107

### TABLE OF CONTENTS

I. PRELIMINARY STATEMENT				
II.	BACKGROUND			
A.	The '140 Patent			
B.	Patent Owner's Patent Infringement Action			
C.	Petitioner's Grounds of Challenge			
	1. Summary of Weth			
	2. Summary of Weber			
III.	CLAIM CONSTRUCTION			
Patent Owner proposes the following two terms for construction				
IV.	THE PETITION SHOULD BE DENIED BECAUSE NO GROUND ESTABLISHES A REASONABLE LIKLIHOOD OF SUCCESS			
A.	Bombardier failed to show that Weth discloses "causing said optical radiation to be commonly therapeutically effective in humans."			
B.	Bombardier failed to show that Weth discloses "by employing a pre- established spectral composition that has been pre-identified as a maximally potent spectral composition."			
C.	Bombardier failed to show that Weth discloses "in the regulation of at least one of the human circadian, photoneural, or neuroendocrine systems." 12			
D.	Bombardier failed to show that Weth discloses "said pre-established spectral composition comprising at least one enhanced spectral region comprising at least one peak of emitted light within the range of 435-488 nm."			
E.	Bombardier failed to show that Weth discloses "stimulating the photoreceptor system for at least one of the circadian, photoneural or neuroendocrine systems of said at least one mammal."			
F.	Bombardier failed to show that Weth discloses "enabling at least the treatment or the prevention of at least one light responsive disorder in said at list one mammal."			
G.	The Addition of Weber Fails to Render Obvious the Challenged Claims 17			
V.	CONCLUSION			

### PATENT OWNER'S EXHIBIT LIST

Exhibit-2001 Complaint for Patent Infringement (ECF No. 1)		
	4:22-cv-615-P, The Litebook Company LTD. v. Bombardier	
	Aerospace Corporation and Netjets Aviation, Inc.	
Exhibit-2002	Study on fluorescence property of dopamine and	
	determination of dopamine by fluorimetry, Talanta 57	
	(2002) 899-907.	

#### I. <u>PRELIMINARY STATEMENT</u>

Petitioner Bombardier failed to demonstrate a reasonable likelihood of prevailing with respect to at least one challenged claim. The main reference asserted—Weth—relates to an ultraviolet (UV) light source to allegedly modify fibrinogen levels for treating arteriosclerosis, immunological disease, psychoses, and depressions, myocardial infarctions and strokes.

The '140 patent, on the other hand, relates to using a band of light in the blue wavelength region between 435-488 nm, which corresponds to the maximally potent region to stimulate melatonin to regulate the human circadian system. The '140 patent recognized this critical blue wavelength region for regulating melatonin. *See* '140 Patent at col. 4, lines 13-16.

To cobble together its anticipation theory, Bombardier deconstructed the claim limitations of the '140 Patent so that it could ignore the interplay between the critical blue wavelength region and the regulation of human circadian system. After ignoring the claimed blue wavelength, Petitioner relies on Weth's alleged disclosure of benefits alleged to be similar to the claimed subject matter. But Weth relies on a UV component to effectuate its alleged benefits. *See* Weth at p. 2, lines 34-36 ("The light of the illuminant according to the invention contains a UV component (UV-A and/or UV-B), *without which it could not develop the desired effects.*") (emphasis added). Weth fails to disclose the use of wavelengths in the

claimed region of 435-488 nm to regulate the human circadian system and to prevent or treat any light responsive disorder.

Petitioner fails to show that Weth anticipates numerous elements of the independent claim 1, including "causing said optical radiation to be commonly therapeutically effective in humans," (2) "by employing a pre-established spectral composition that has been pre-identified as a maximally potent spectral composition," (3) "in the regulation of at least one of the human circadian, photoneural, or neuroendocrine systems," (4) "said pre-established spectral composition comprising at least one enhanced spectral region comprising at least one peak of emitted light within the range of 435-488 nm," (5) "stimulating the photoreceptor system for at least one of the circadian, photoneural or neuroendocrine systems of said at least one mammal," and (7) "enabling at least the treatment or the prevention of at least one light responsive disorder in said at list one mammal." Accordingly, Bombardier failed to demonstrate a reasonable likelihood of prevailing with respect to at least one challenged claim of the '140 Patent.

#### II. <u>BACKGROUND</u>

#### A. The '140 Patent

The '140 Patent "involves a light system for stimulating or regulating neuroendocrine, circadian, and photoneural system in mammals based upon the

discovery of peak sensitivity ranging from 425-505 nm" and "involves a treatment of a wide variety of disorders" '140 Patent at Abstract. Claim 1 of the '140 Patent relates to "the treatment or prevention of at least one light responsive disorder." '140 Patent at cl. 1.

"The specific aim of the present study was to characterize the wavelength sensitivity of the photoreceptor system responsible for providing circadian input to the human pineal gland by establishing an action spectrum for light-induced melatonin suppression. The experiments defined an action spectrum that fits a retinaldehyde opsin template and identified 446-477 nm as the most potent wavelength region for regulating melatonin." '140 Patent at col. 4, lines 9-16.

#### **B.** Patent Owner's Patent Infringement Action

On July 18, 2022, patent owner The Litebook Company, Ltd. ("Patent Owner" or "Litebook") filed a Complaint for Patent Infringement against Petitioner in the United States District Court for the Northern District of Texas— Forth Worth Division, alleging that Bombardier Aerospace Corporation and NetJets Aviation, Inc. infringe U.S. Pat. No. 7,678,140. Ex. 2001.

#### C. Petitioner's Grounds of Challenge

Petitioner asserts two grounds of invalidity. As to Ground 1, Petitioner asserts that German patent application DE29618670U1 ("Weth," Ex. 1004) anticipates claims 1 and 6 of the '140 patent under 35 U.S.C. 102. For Ground 2,

Petitioner asserts the combination of Weth and U.S. Patent No. 6,531,230 ("Weber," Ex. 1022) to challenge claims 2-5 and 7-9 under 35 U.S.C. 103.

Throughout this Preliminary Response, Patent Owner will refer to these prior art references by the names indicated above, rather than by exhibit number. The prior art references relied on are described and addressed below, in conjunction with the argument represented in this Preliminary Response.<sup>1</sup>

#### 1. Summary of Weth

Weth describes an ultraviolent-based energy-saving lamp for therapeutic purposes emitting light at "the following spectral lines:  $251 \text{ nm} (\pm 5 \text{ nm})$ ,  $265 \text{ nm} (\pm 15 \text{ nm})$ ,  $290 \text{ nm} (\pm 15 \text{ nm})$ ,  $319 \text{ nm} (\pm 10 \text{ nm})$ ,  $335 \text{ nm} (\pm 15 \text{ nm})$ ,  $368 \text{ nm} (\pm 15 \text{ nm})$ . Weth at p. 1 at 33-36. The spectral lines "correspond to absorption lines of the following [unnamed] endogenous, essential substances." Weth at p. 2, lines 1-17. Weth also states that:

> provision can be made for the illuminant to emit light moreover including at least one spectral line of the following group: 380 nm ( $\pm 15$  nm), 410 nm ( $\pm 15$  nm), 438 nm ( $\pm 15$  nm), 490 nm

<sup>&</sup>lt;sup>1</sup> Patent Owner intends no waiver by any argument made or omitted at this stage and reserves its right to present additional argument and evidence related to these prior art references, consistent with the Board's Rules and practice.

(±15 nm), 515 nm (±15 nm), 540 nm (±15 nm), 580 nm (±15 nm), 610 nm (±15 nm), 650 nm (±15 nm), 690 nm (±15 nm), 710 nm (±15 nm), 740 nm 20 (±15 nm), 770 nm (±15 nm), 800 nm (±15 nm).

Weth at p. 3, lines 14-20. Weth states that those "spectral lines correspond to the absorption lines of the following endogenous, essential substances." Weth at p. 3, lines 23-24.

The disclosed lamp "can be used both as a tabletop lamp and as a ceiling lamp." Weth at p. 2, lines 24-25. Weth describes using the device "to yield a reduction in embolisms and thromboses arising, to below 0.1% because the fibrinogen level drops." Weth at p. 5, lines 28-30.

#### 2. Summary of Weber

Weber relates to "optical films that change color as a function of viewing angle. Weber at col 1, lines 5-7. "In one aspect, the present invention pertains to multilayer birefringement color shifting films and other optical bodies having particular relationships between the refractive indices of successive layers for light polarized along mutually orthogonal in-place axes (the x-axis and the y-axis) and along an axis perpendicular to the in-plane axes (the z-axis).

#### III. CLAIM CONSTRUCTION

Patent Owner proposes the following two terms for construction.

Term	Proposed Construction
"causing said optical radiation to be commonly therapeutically effective in humans by employing a preestablished spectral composition that has been pre- identified as a maximally potent spectral composition"	"that includes light having a pre- determined spectral composition for maximizing the potency of its therapeutic effect in humans"

The '140 patent describes a "light system for stimulating or regulating neuroendocrine, circadian, and photoneural systems in mammals based upon the discovery of peak sensitivity ranging from 425-500 nm. Fig. 11 shows the half saturation plots indicating the maximal potency of the therapeutic effect in humans illustrating the "resultant action spectra for human melatonin suppression." '140 Patent at col 19, lines 27-33.



Fig. 11

The peak of the wavelength curve for suppression of melatonin shown in Fig. 11 is centered around the wavelength range of about 433-488 nm. The peak shown in Fig. 11 illustrates the maximally potent therapeutic effect of melatonin. Thus, using light with wavelengths in the range of about 433-488 provides the maximally potent therapeutic on melatonin suppression.

Term	Proposed Construction
"in the regulation of at least one of the human circadian, photoneural, or neuroendocrine systems"	"in activating photoreceptors linked to the person's circadian, photoneural, or neuroendocrine system to generate a response"

The '140 Patent describes a specific photoreceptor system for melatonin regulation in humans with healthy intact eyes." '140 Patent at col 4, lines 1-2. The '140 Patent "characterize[d] the wavelength sensitivity of the ocular photoreceptor system for regulating the human pineal gland by establishing an action spectrum for light-induced melatonin suppression. The '140 Patent teaches that the melatonin suppression curve shown in Fig. 11 is drive by photoreceptors receiving light in the maximally potent region. '140 Patent at col.19, lines 33-38 ("When the data were aligned to the best-fit template for vitamin A-retinaldehyde photopigments, this action spectrum predicted a peak spectral sensitivity (1 max) of 464 nm. There was a strong coefficient of correlation between the data and this fitted opsin nomogram ( $R^2$ =0.91).") Accordingly, the '140 Patent teaches the control and regulation of the human circadian, photoneural, or neuroendocrine systems through linked photoreceptors.

#### IV. <u>THE PETITION SHOULD BE DENIED BECAUSE NO GROUND</u> ESTABLISHES A REASONABLE LIKLIHOOD OF SUCCESS.

Petitioner has failed to show that any of its Grounds 1 and 2 establish a reasonable likelihood that at least one of the claims challenged in the petition is unpatentable. Weth does not anticipate claims 1 and 6 of the '140 Patent.

Bombardier cobbled together analyses of small phrase snippets of claim 1 to create an invalidity theory using Weth. However, its analysis highlights multiple deficiencies in its anticipation theory. Bombardier failed to show that Weth disclosed multiple limitations of claim 1. Among other limitations, Weth fails to disclose a light source with a pre-identified maximally potent spectral composition with a peak in 435-488 nm to perform the claimed regulation. Instead, Weth's lamp requires "a UV component (UV-A and/or UV-B), without which it could not develop the desired effects." Weth at p. 2, lines 34-36. Consequently, Weth cannot anticipate claims 1 and 6 of the '140 Patent because the effects of Weth are generated by light having wavelengths from 251nm-368 nm, which is outside the claimed region of 435-488 nm.

#### A. Bombardier failed to show that Weth discloses "causing said optical radiation to be commonly therapeutically effective in humans."

Bombardier relies on Weth's therapeutic descriptions of medical therapies. The medical therapies include "fibrinogen levels," "immunological measured values," "erythrocyte sedimentation rate," "C-reactive protein," "tumour necrosis factors, the interleukins, the prostaglandins," "myocardial infarctions and acute strokes," "improved receptor sensitivity," "improved Vitamin D formation," "improved low-density lipoprotein concentration," "improved Hamilton Rating Scale parameters for depression," "reduction in C-reactive protein," "improved activity of daily life," "increased interferon levels," stimulation of hypophysis hormones an suppression of appetite," "regression in the paranoid symptoms," and "prevention of pathological amino acids." Paper No. 3, Bombardier IPR Petition, ("Pet.") at 23-24.

Weth describes none of the conditions as a "light responsive disorder" or as part of the "human circadian, photoneural, or neuroendocrine system" as recited in claim 1. Furthermore, Bombardier relied only on the UV wavelength region, Pet. at 23-24 (citing Weth at p. 1, lines 32-36 ("illuminant for therapeutic purposes comprising optical radiation of 'the following spectral lines: 251 nm ( $\pm$ 5 nm), 265 nm ( $\pm$ 15 nm), 290 nm ( $\pm$ 15 nm), 319 nm ( $\pm$ 10 nm), 335 nm ( $\pm$ 15 nm), 368 nm ( $\pm$ 15 nm)")), rather than the recited region with a peak of 435-488 nm. It had to because the only disclosure of an effective wavelength region in Weth is the UV region. *See* Weth at p. 2, lines 33-36.

Accordingly, Bombardier failed to show that Weth discloses this element.

# B. Bombardier failed to show that Weth discloses "by employing a pre-established spectral composition that has been pre-identified as a maximally potent spectral composition."

This feature and the following claim language relates to a spectral composition that is pre-identified as a maximally potent spectral composition with respect to the regulation of at least one of the human circadian, photoneural, or neuroendocrine systems. Weth fails to describe any spectral composition that has been pre-identified as a maximally potent spectral composition.

Weth describes that the spectral composition of its light source "is specifically set to correspond to a subject's 'absorption lines of the following endogenous, essential substances." Weth at p. 2, lines 1-17; see also Weth at p. 3, line 22 to p. 4, line 13. Yet Weth *never* identifies a single "endogenous, essential substance[]" that would correspond to the spectral composition of the light source. And Bombardier recognizes this deficiency. Rather than identifying any such substance disclosed in Weth (because there is none), Bombardier attempted to equate the nebulous phrase "endogenous, essential substances" with the equally ambiguous phrase "the subject's light sensitive substances." Pet. at 25. At best, Weth discloses that its invention requires a UV component—which is different from the 435-488 nm region recited in claim 1— "to develop the desired effects." Weth at p. 2, lines 34-36. Weth fails to disclose a lamp that has a maximally potent spectral composition in the visible spectrum blue region to treat a light responsive disorder.

Bombardier's argument that the spectral composition of Weth improves vigilance and quality of sleep and avoids myocardial infarctions and strokes, reduces embolisms and thromboses, prevents diseases caused by coagulation disorders and reduces depression is not tethered to the claimed 435-488 range, let alone any wavelength band (other than the required UV spectrum). Pet. at 26. Instead, Bombardier relies on the '140 Patent itself to teach a maximally potent region. Pet. at 26 (relying on '140 Patent 4:13-16 ("The experiments [of the present study] defined an action spectrum that fits a retinaldehyde opsin template and identified 446-477 as the most potent wavelength region for regulating melatonin.")). This is improper hindsight, explicitly using the challenged patent as instructions, and should be rejected as improper. Indeed, reliance on the '140 Patent illustrates that Weth does not disclose a maximally potent region as recited in claim 1 of the '140 Patent.

#### C. Bombardier failed to show that Weth discloses "in the regulation of at least one of the human circadian, photoneural, or neuroendocrine systems."

Bombardier relies on Weth's disclosure of dopamine. Pet. at 26 ("For example, Weth's lamp 'leads to an **increase in the dopamine level**, that is to say vigilance increases' and also '**improves quality of sleep**."") But Weth does *not* disclose that dopamine is part of the human circadian system. Instead, Bombardier argues that "the sleep-wake cycle" is "controlled by the circadian system through, in part, the release of the neurochemical melatonin." Pet. at 8 (citing EX1027,

EX1011, EX1010), and further that "Dopamine, a neurotransmitter made in the brain, also influences sleep-wake." Pet. at 9. Bombardier argues that the combination of EX1027, EX1011, EX1010, and Weth teach the circadian system controls or regulates the sleep-wake cycle, including dopamine.

Bombardier's argument is premised on the circadian system regulating dopamine, rather than dopamine regulating the circadian system, and therefore cannot anticipate this feature. Moreover, Weth does not disclose a specific spectral composition of light that regulates dopamine, let alone any aspect of the human circadian or neuroendocrine system. Rather, Weth discloses that the UV component is a necessary wavelength region to obtain the desired effects. Weth at p. 2, lines 33-36 ("without" the UV component "it could not develop the desired effects.").

Bombardier's reliance on dopamine also fails to show that Weth anticipates this feature for another reason. Dopamine is known to absorb light in the UV region (*e.g.*, light with wavelengths less than 300 nm), not light having the claimed 435-488 nm range. The absorption spectrum of dopamine (below) shows that dopamine is not excited by light having wavelengths longer than 300 nm:



Fig. 1. Exitation and emission spectra of dopamine. Excitation spectrum (a) ( $\lambda_{ex} = 279$  nm) and emission spectrum (b) ( $\lambda_{em} = 315$ nm) of dopamine in the absence of methanol. Excitation spectrum (c) ( $\lambda_{ex} = 279$  nm) and emission spectrum (d) ( $\lambda_{em} = 320$  nm) of dopamine in the presence of methanol. Excitation spectrum (e) and emission spectrum (f) of reagent blank. Concentration of dopamine: 0.5 µg ml<sup>-1</sup>. pH 3.6 HOAc/ NaOAc buffer solution.

See Ex. 2002 at 902. The peak absorption—the maximally potent region—for dopamine is 279 nm (Ex. 2002 at 901), which is far from from the claimed 435-488 range. Because the maximally potent region for dopamine is centered around 279 nm and does not extend beyond 300 nm, Weth does not disclose the feature "in the regulation of at least one of the human circadian, photoneural, or neuroendocrine systems" (even if Bombardier's erroneous argument about the relationship between dopamine and the circadian system is ignored).

**D.** Bombardier failed to show that Weth discloses "said preestablished spectral composition comprising at least one enhanced spectral region comprising at least one peak of emitted light within the range of 435-488 nm."

Bombardier alleges that this element is met by Weth's description that its lamp may emit "at least one spectral line of the following group: . . . 438 nm ( $\pm$ 15 nm)." However, Weth does not disclose why such a region would be selected. Weth discloses no aspect of the human circadian system that would be regulated by a spectral region having a peak in the 435-488 nm region. Nor has Bombardier shown that Weth discloses the use of light in the 435-488 nm region having *any therapeutic effect*. Instead, Weth relies on a UV component for its therapeutic effect. Weth at p. 2, lines 34-36. Moreover, as discussed above, dopamine is excited by light having wavelengths less than 300 nm. Dopamine is not excited by light having a wavelength in the range of 435-488 nm. Accordingly, Bombardier failed to show this limitation.

# E. Bombardier failed to show that Weth discloses "stimulating the photoreceptor system for at least one of the circadian, photoneural or neuroendocrine systems of said at least one mammal."

Bombardier points to "an increase in the dopamine level" as meeting this element. Pet. at 29. However, Weth does not disclose that any such increase in the dopamine level was the result of stimulating the circadian system. Weth does not disclose that "dopamine is part of the wake-sleep cycle" as asserted by Bombardier. Pet. at 29. Instead, Bombardier points to external references as evidence of this limitation, which serves as an admission that Weth does not disclose this feature. Thus, Weth cannot anticipate this claim. And even if Weth disclosed this feature, Weth does not disclose that dopamine is stimulated by the light source having a peak in the 435-488 nm range. Nor could it because dopamine is not excited by light having wavelengths longer than 300 nm. Indeed, Weth is clear that any desired effects emanate from the required UV component of the lamp. Weth at p. 2, lines 34-36. Accordingly, Weth does not disclose this element.

#### F. Bombardier failed to show that Weth discloses "enabling at least the treatment or the prevention of at least one light responsive disorder in said at list one mammal."

Bombardier relies on disorders that Weth does not link to circadian, photoneural or neuroendocrine systems. Instead, Bombardier points to "'fibrinogen level, arteriosclerosis, immunological disease, psychoses, depressions,' 'embolisms and thromboses,' 'improves quality of sleep,' prevention of 'the formation of pathological amino acids,' 'diseases caused by coagulation disorders,' and 'myocardial infarctions and strokes.'" Indeed, Weth does not disclose treating any of these disorders with light having a wavelength in the 435-488 nm range. The Weth lamp requires a UV spectrum "to develop the desired effects. Weth at p. 2, lines 34-36. Thus, Weth does not disclose this limitation.

Accordingly, Petitioner cannot show that Weth anticipates independent claim 1 and claim 6 therefrom.

## G. The Addition of Weber Fails to Render Obvious the Challenged Claims

Bombardier alleges that Weber discloses the additional limitations found in dependent claims 2-5, and 7-9. Because Weber does not address the deficiencies of Weth discussed above, the combination of Weth and Weber does not teach the features of dependent claims 2-5 and 7-9. Therefore, the combination of Weth and Weber does not render obvious dependent claims 2-5 and 7-9.

Accordingly, Petitioner cannot show that Weth invalidates independent claim 1, and dependent claim 6, and the remaining claims dependent therefrom. Accordingly, Petitioner cannot show a reasonable likelihood of prevailing with respect to at least one challenged claim.

#### V. <u>CONCLUSION</u>

On the merits, Bombardier's arguments fail to teach key limitations of the

challenged claims. Bombardier has failed to meet its burden, and for the foregoing reasons, denial of institution is appropriate.

Respectfully submitted,

Date: March 23, 2023

/Cabrach Connor/ Cabrach Connor Registration No. 53,837 Lead Counsel for Patent Owner John Shumaker Registration No. 52,223 Backup Counsel for Patent Owner CONNOR LEE & SHUMAKER PLLC

#### **CERTIFICATION UNDER 37 CFR § 42.24**

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Patent Owner's Preliminary Response totals 3,229 words, which is fewer than the 14,000 allowed under 37 CFR § 42.24.

Dated: March 23, 2023

/Cabrach Connor/ Cabrach Connor Registration No. 53,837 Lead Counsel for Patent Owner CONNOR LEE & SHUMAKER PLLC

#### **CERTIFICATE OF SERVICE**

Undersigned counsel certifies that on March 23, 2023, a complete and entire

copy of this Patent Owner's Preliminary Response and all supporting exhibits were

provided via E-Mail to the Petitioner pursuant to 37 CFR §§ 42.6(e)(4)(i) et seq.

and 42.105(b) by serving the correspondence addresses of record as follows:

Monica Grewal, Reg. No. 40,056 (Lead Counsel) Jonathan P. Knight, Reg. No. 69,866 (First Backup Counsel) Louis Tompros (Backup Counsel) Xiaowei Sun, Reg. No. 80,954 (Backup Counsel)

WILMER CUTLER PICKERING HALE AND DORR LLP 60 State Street Boston, MA 02109 Phone: (617) 526-6000

Monica.grewal@wilmerhale.com Jonathan.knight@wilmerhale.com Louis.tompros@wilmerhale.com Xiaowei.sun@wilmerhale.com

> <u>/Cabrach Connor/</u> Cabrach Connor Registration No. 53,837 Lead Counsel for Patent Owner CONNOR LEE & SHUMAKER PLLC