

Declaration of Dr. Craig Heller  
In Support of Petition for *Inter Partes* Review  
of U.S. Patent No. 7,678,140

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BOMBARDIER INC.  
Petitioner

v.

THE LITEBOOK COMPANY LTD.,  
Patent Owner

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Case IPR2023-00192  
U.S. Patent No. 7,678,140

**DECLARATION OF DR. HORACE CRAIG HELLER IN SUPPORT OF  
THE PETITION FOR *INTER PARTES* REVIEW**

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Declaration of Dr. Craig Heller  
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of U.S. Patent No. 7,678,140

1. I, Horace Craig Heller, Ph.D., declare as follows:
2. My name is Craig Heller.
3. I have been retained by Bombardier Inc. to provide opinions in this proceeding related to U.S. Patent No. 7,678,140 (“’140 patent”).

**I. BACKGROUND**

4. I received a Ph.D. in Biology from Yale University in 1970.
5. I am currently the Lorry I. Lokey/Business Wire Professor in the Department of Biology at Stanford University. I have served on the faculty of Stanford University for 50 years starting in 1972 through the present (2022).
6. Throughout my tenure at Stanford, I have served as a Professor in the Department of Biology and since about 1980 also in the Program in Human Biology. Prior to my appointment as the Lorry I. Lokey/Business Wire Professor in 1993, I held the endowed chair Bing Professor of Human Biology for several years. I am also the William and Lynde Steere University Fellow since 2004.
7. I have also held various administrative positions at the Stanford University. I have served as the associate Director and then the Director of the Program in Human Biology. I was the Chair of the Biological Sciences from 1997-2001. I served as the Associate Dean of Research from 1994-1997. I had been the Chair of the Academic Senate of Stanford University and the chair of

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several University committees including Committee on Research, Committee on Undergraduate Studies, and the Advisory Committee on Financial Responsibility.

8. As a faculty member, I have taught and continue to teach courses and direct research in neurobiology of sleep, circadian rhythm, regulation of body temperature, mammalian hibernation, human exercise physiology, and retinal photo-transduction that entrains the circadian system. I received the Walter J. Gores Award for Excellence in Teaching in 1977 and the Kenneth M. Cuthertson Award for Exceptional Contributions to Stanford University in 2010.

9. Outside of Stanford, I have served on and also chaired the Defense Science Research Council of DARPA. I have been a Board Member of the Sleep Research Society, and served as SRS President. I am currently President of the Associated Professional Sleep Societies. I am also on the Board of BSCS, a non-profit organization to improve STEM education.

10. I have authored more than 242 journal articles and conference papers in the areas noted above. In particular, I have conducted research and published peer-reviewed research findings in several high impact factor journals in the fields of neuroscience, sleep research, and human biology. Below I have provided several representative examples:

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- In “*Melatonin influences Fos expression in the rat suprachiasmatic nucleus*,” my coauthors and I reported that melatonin can affect immediate early gene expression within the suprachiasmatic nucleus (SCN), the putative biological clock of mammals. [Kilduff, T.S., Landel, H.B., Nagy, G.S., Sutin, E.L., Dement, W.C., and Heller, H.C., *Molecular Brain Research* 16:47-56 (1992)]. The pineal hormone melatonin was injected into rats to induce expression of Fos protein in the SCN. The results showed that Fos expression is dependent on circadian phase: late night injections cause Fos expression while the daytime injection were ineffective.
- In “*Circadian and light-induced expression of immediate early gene mRNAs in the rat suprachiasmatic nucleus*,” my coauthors and I investigated whether immediate early genes are involved in the phase-shifting of the circadian pacemaker to light. [Sutin, E.L. and Kilduff, T.S., *Molecular Brain Research* 15:281-290 (1992)]. The experiment involved a systematic examination of the immediate early genes *fos* under photic-stimulation (i.e., light-induced) across the circadian cycle. In contrast to the previously reported light-induced phase shifts of the activity rhythm, we found no such direct relationship between the two.

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- In “*Melatonin attenuates photic disruption of circadian rhythms in Siberian hamsters*,” my coauthors and I showed that melatonin administration can mitigate circadian rhythm dysfunction due to unusual light disruptions.. [Ruby, N.F., Kang, T., and Heller, H.C., American Journal of Physiology 273:R1540-R1549 (1997)]. By phase delaying the light-dark (LD) cycle and injecting melatonin in Siberian hamsters, we observed that melatonin can arrest the loss of entrainment caused by phase shifting of the LD cycle but it cannot restore entrainment in free-running animals.
- In “*Circadian system of mice integrates brief light stimuli*,” my coauthors and I showed that extremely short pulses of light (milliseconds) at certain times of the day can phase shift the circadian pacemaker and therefore serve as a mitigation of jet lag. [Van den Pol, A.N., Cao, V., and Heller. H.C., American Journal of Physiology 275(44):R654-657 (1998)]. A train of short pulse of light (2-ms light pulses delivered at 5 or 60 s with a total duration of 120 s), delivered at certain times of the day to mice, was shown to cause significant phase shifts of several hours that lasted for weeks. In contrast, a single short pulse (2 ms) was ineffective in causing the phase shifting. The result showed that a series of extremely brief light stimuli, each of which is

too small to cause any phase shifting by itself, can cause significant and enduring change in circadian response.

- In “*Siberian hamsters that fail to reentrain to the photocycle have suppressed melatonin levels,*” my coauthors and I observed that Siberian hamsters reentrained to a 3-h phase delayed light but not a 5-h phase delayed light. [Ruby, N. F., Dubocovich, M. L., and Heller, H. C., American Journal of Physiology 278:R757-R762 (2000)]. Melatonin levels were unaffected by the 3-h phase delay but were undetectable after a 5-h phase delay, suggesting that circadian entrainment is influenced by changes to melatonin production subsequent to the phase shifting of the light exposure.
- In “*Melanopsin as a Sleep Modulator: Circadian Gating of the Direct Effects of Light on Sleep and Altered Sleep Homeostasis in Opn4<sup>-/-</sup> Mice,*” my coauthors and I assessed the contribution of melanopsin, a retinal photopigment that conveys nonvisual light information to the brain with a peak light absorption at 480 nm in mediating the direct effects of light such as the alertness and promotion of sleep. [Tsai, J.W., Hannibal, J., Hagiwara, G., Colas, D., Ruppert, E., Ruby, N.F., Heller, H.C., Franken, P., Bourgin, P., PLoS Biology 7, e1000125 (2009)]. The time of the day of exposure to



blue light was shown to modulate acute effects on sleep in *Opn4*<sup>-/-</sup> mice and to play a role in sleep homeostasis.

- In “*Role of Melanopsin in Circadian Responses to Light*,” my coauthors and I studied the role of melanopsin as a photoreceptive molecule for the entrainment of mammalian circadian rhythms. [Ruby, N.F., Brennan, T.J., Xie, X., Cao, V., Franken, P., Heller, H.C. and O’Hara, B., Science 298, 2211-2213 (2002)]. We showed that mice lacking melanopsin were able to entrain to a light/dark cycle and exhibit phase shifts after light pulses at the appropriate circadian phase. However, the magnitude of these effects were 40% lower than in mice with melanopsin. Thus melanopsin is not essential for the circadian clock to receive photic input.
- In “*The acute effects of light on murine sleep during the dark phase: importance of melanopsin for maintenance of light-induced sleep*,” my coauthors and I examined the direct effect of light on sleep and wakefulness by exposing mice to a broad range of light intensities. [Muindi, F., Zeitzer, J.M., Colas, D., Heller, H.C., European Journal of Neuroscience 37(11):1727-36 (2013)]. The results highlight the selective effects of light on the sleep cycle of mice, and suggest that melanopsin-based photoreception is primarily involved in sustaining light-induced sleep.

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- In “*Retino-hypothalamic regulation of light-induced murine sleep*,” my coauthors and I provided scientific review of the effects of light in regulating sleep-wake cycles via circadian clock and homeostatic processes. [Muindi, F., Zeitzer, J.M., Heller, H.C., *Frontiers in Systems Neuroscience* 8:135 (2014)]. The role played by rods, cones, and melanopsin based photoreceptors in inducing the sleep initiations and maintenance was also analyzed.
- In “*Response of the Human Circadian System to Millisecond Flashes of Light*,” my coauthors and I investigated the impact of duration of the light exposure in synchronizing the circadian clock with the diurnal cycle. [Zeitzer, J. M., Ruby, N. F., Fiscario, R. A., Heller, H. C., *PLoS ONE* 6 (7): e22078 (2011)]. In response to exposure to flashes of light, a phase shifting in circadian clock and an immediate alerting were observed, both these effects being consistent with the hypotheses that circadian system can accommodate brief light exposures.

11. I am an inventor, and I have been awarded numerous patents, including U.S. Patent No. 6,623,512 (“Circadian rhythm reset method and device”). This patent provides a method and a device for phase shifting the

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circadian pacemaker or treating seasonal affective disorder that includes exposing a subject's eye region to a given-intensity light flash.

12. My additional patent awards include U.S. Patent Nos. 9,789,119 (“Cognitive function”), 9,041,542 (“System and method for detecting and preventing drowsiness”), 8,287,581 (“Methods and devices for prevention of hypothermia in a mammal during prolonged exposure to extreme cold”), 8,277,496 (“Methods and devices for manipulating the thermoregulatory status of a mammal”), 8,177,826 (“Methods and devices for extracting thermal energy from the body core of a mammal”), 7,947,068 (“Controlled heat transfer with mammalian bodies”), 7,862,600 (“Methods and devices for prevention of hypothermia in a mammal during prolonged exposure to extreme cold”), 7,330,123 (“Sonar based drowning monitor”), 7,182,776 (“Methods and devices for manipulating the thermoregulatory status of a mammal”), 7,122,047 (“Controlled heat transfer with mammalian bodies”), 6,974,442 (“Methods and devices for extracting thermal energy from the body core of a mammal”), 6,966,922 (“Methods and devices for prevention of hypothermia in a mammal during prolonged exposure to extreme cold”), 6,673,099 (“Methods and devices for prevention of hypothermia in a mammal during prolonged exposure to extreme cold”), 6,656,208 (“Methods and devices for extracting thermal energy from the

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body core of a mammal”), and 6,602,277 (“Methods and devices for manipulating the thermoregulatory status of a mammal”).

13. Overall, I have over 50 years of experience in the fields of neurobiology of sleep, circadian rhythms, mammalian hibernation, and human exercise physiology. A copy of my *curriculum vitae*, including references to the publications I authored, is attached to my Report as Appendix A.

14. In light of the foregoing, I consider myself to be an expert in the field of neurobiology of sleep and circadian rhythms, and believe that I am qualified to provide an opinion as to what a person of ordinary skill in the art would have understood, known, or concluded regarding the subject matter of the ’140 patent at the time of its alleged invention.

15. I am being compensated at my normal consulting rate of \$600 an hour for my work. My compensation is not dependent on the outcome of this IPR proceeding or related litigation, nor is my compensation tied to any positions I take in this Declaration, and therefore it does not affect the substance of my statements in this Declaration.

16. I have no financial interest in Petitioner. I have no financial interest in the ’140 patent.

## **II. LEGAL PRINCIPLES**

17. I am not an attorney. For purposes of this declaration, I have been informed about and understand certain aspects of the law that are relevant to my analysis and opinions.

### **A. Anticipation**

18. I have been informed and understand that a patent claim is invalid as anticipated if each element of that claim is present either explicitly or inherently in a single prior art reference. I have also been informed that, to be an inherent disclosure, the prior art reference must necessarily disclose the limitation, and the fact that the reference might possibly practice or possibly contain a claimed limitation is insufficient to establish that the reference inherently teaches the limitation.

### **B. Obviousness**

19. I have been informed and understand that a patent claim can be considered to have been obvious to a person of ordinary skill in the art at the time of the alleged invention. This means that, even if all the requirements of a claim are not found in a single prior art reference, the claim is not patentable if the differences between the subject matter in the prior art and the subject matter in the

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claim would have been obvious to a person of ordinary skill in the art at the time of the alleged invention.

20. I have been informed and understand that a determination of whether a claim would have been obvious should be based upon several factors, including, among others:

- the level of ordinary skill in the art at the time the application was filed;
- the scope and content of the prior art; and
- what differences, if any, existed between the claimed invention and the prior art.

21. I have been informed and understand that the teachings of two or more references may be combined if such a combination would have been obvious to one having ordinary skill in the art. In determining whether a combination based on multiple references would have been obvious, it is appropriate to consider, among other factors:

- whether the teachings of the prior art references disclose known concepts combined in familiar ways, and when combined, would yield predictable results;

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- whether a person of ordinary skill in the art could implement a predictable variation, and would see the benefit of doing so;
- whether the claimed elements represent one of a limited number of known design choices, and would have a reasonable expectation of success by those skilled in the art;
- whether a person of ordinary skill would have recognized a reason to combine known elements in the manner described in the claim;
- whether there is some teaching or suggestion in the prior art to make the modification or combination of elements claimed in the patent; and
- whether the claimed invention applies a known technique that had been used to improve a similar device or method in a similar way.

22. I have been informed and understand that one of ordinary skill in the art has ordinary creativity, and is not an automaton.

23. I have been informed and understand that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the patent being considered.

### **III. SUMMARY OF OPINION**

24. For the reasons explained below, I have concluded that there is nothing inventive about claims 1-9 of U.S. Patent No. 7,678,140 (the “’140 patent”) and that these claims are either anticipated or rendered obvious by the prior art. In reaching my opinion I have considered, among other things, the following specific references as prior art:

- German Patent No. 29618670 (“Weth”) (Ex. 1004)<sup>1</sup>
- U.S. Patent No. 6,531,230 (“Weber”) (Ex. 1022)

25. In my opinion, claims 1 and 6 of the ’140 patent are anticipated by Weth and claims 2-5 and 7-9 of the ’140 patent are rendered obvious by Weth in combination with Weber (the “Weth-Weber combination”).

### **IV. RELEVANT FIELD**

26. I have reviewed and understand the specification, claims, and file history of the ’140 patent. I have also reviewed the exhibits listed in the Table of Materials Considered attached hereto. Based on my review of these materials, I submit that the relevant field for purposes of my analysis is circadian biology,

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<sup>1</sup> When I refer to Ex. 1004, I am referring to the certified translation of the German publication provided to me by counsel and included in Ex. 1004.



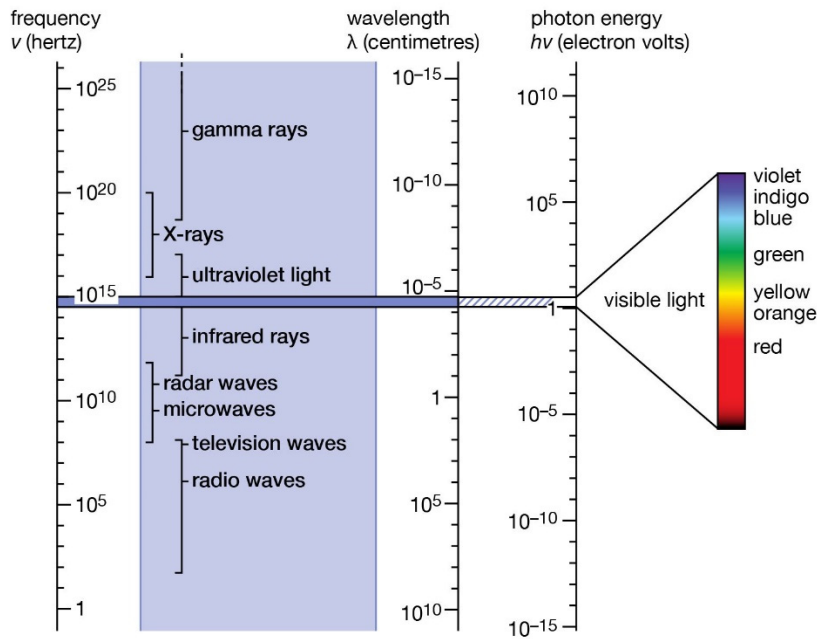
including the areas of neurology, neuroscience, endocrinology, and retinal phototransduction, including relevant experience with phototherapy. In the next section I provide a brief introduction to the technical background relevant to these well-known concepts.

## **V. BRIEF DESCRIPTION OF THE TECHNOLOGY**

### **A. Light Spectrum**

27. Electromagnetic waves with wavelengths in the range of approximately 100 nm to 1 mm inclusive of the ultraviolet (UV), visible, and infrared components of the electromagnetic spectrum is known as optical radiation. Ex. 1030, 16. Ex. 1031, 539. Ultraviolet radiation includes wavelengths in the range of approximately 100-400 nm. Ultraviolet radiation is not visible to the human eye. Ex. 1030, 16. Visible light, in contrast, is that portion of the electromagnetic spectrum which can be perceived by the human eye. Ex. 1006, 10.

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Ex. 1009, 1.

28. The spectrum of visible light consists of wavelengths in the range of approximately 400 nanometers (nm) to approximately 700 nm. This spectrum may be subdivided into a family of colors corresponding to the following approximate wavelength ranges, however the spectrum is a continuous function of wavelengths and not a collection of discrete bands as assigned subjectively to specific colors:

- violet 400–450 nm;
- blue: 450-500 nm;
- cyan: 500-550 nm
- green: 550-580 nm;
- yellow: 580–600 nm;

- orange: 600–650 nm; and
- red: 650–700 nm.

Ex. 1003, 2.

**B. Light Filters**

29. A light filter is a device which selectively transmits a particular range of wavelengths of light. Ex. 1006, 53. In the 1600s, light filters in the form of colored glass, crystals, and prisms were known. Work in the area of optics in the last century included absorption filters which selectively absorb particular wavelengths or ranges of wavelengths (Ex. 1006, 53) and interference filters which reflect unwanted wavelengths. Ex. 1006, 53. In addition, it has long been known and practiced since the last century at least that materials of construction could be selected to achieve either a transparent or translucent light filter. Ex. 1006, 53.

**C. Light Therapy**

30. Therapy based on exposure of a subject to light was well known long before 1999. Ex. 1006, 1. Ex. 1007, 3. For example, in the 1980's the human retina was exposed to light for seasonal affective disorder, depression, sleep disorders, and circadian disruption. Ex. 1008, 245 (“the [light-dark] cycle may have a direct synchronizing effect on the human circadian timing system”). Ex. 1013, 193 (light treatment for non-pharmacological intervention in certain forms of

depressive illness). Since many, if not most, biomedical conditions treated by light involve circadian rhythms, it is relevant that specific patterns and timings of light exposure can correct circadian rhythm dysfunctions as was first shown by Aschoff and coworkers in 1969. Ex. 1026, 58. Since then and prior to 1999, many physiological conditions have been shown to be influenced by circadian disruption and therefore treatable by light therapy that can normalize those circadian rhythms. For example, melanopsin in the retina has been shown to mediate regulation of the circadian rhythm and suppression of pineal melatonin rather than contributing to vision formation. Ex. 1028, 600, 604. Further examples are contained in a series of consensus reports published in the *Journal of Biological Rhythms* in 1995 – for example, Campbell et al., 1995, *Light treatment for sleep disorders: consensus report I*. Ex. 1027, 105-108. Thus, light treatment with the visible spectrum for many disorders has been shown to be effective long before the patent '140 was filed.

31. A person of ordinary skill in the art also understood that exposure of the eyes to light of different colors (i.e., wavelengths) would potentially cause different effects on melatonin secretion, a hormone that plays an important role in regulating circadian rhythm. Ex. 1023, 667. For example, light with spectral

peaks of 430 nm (in the blue spectrum) and 540 nm (in the green spectrum) were known to suppress melatonin during nighttime. Ex. 1023, 667-668.

**D. Using Light To Prevent and/or Treat a Disorder**

32. By 1990, a person of ordinary skill in the art understood that circadian rhythms, seasonal cycles, and neuroendocrine system responses were primarily regulated through exposure of a subject's eyes (including in humans and many other mammals) to optical radiation. Ex. 1010, 1267. Ex. 1016, 556 ("The light-dark (LD) cycle is the most powerful synchronizing stimulus acting on the human circadian timing system.").

33. Many aspects of physiology are regulated by circadian rhythms generated by the body's internal clock in the brain—the suprachiasmatic nucleus through neurochemical systems. Ex. 1032, 5. Light received by the retinas of the eyes have direct effects on the suprachiasmatic nucleus and therefore on any physiological systems, such as the sleep-wake cycle that are controlled by the circadian system through, in part, by the release of the neurochemical melatonin. Ex. 1027, 105-106; Ex. 1011, 667; Ex. 1010, 1267. Sleep-wake is also influenced by dopamine release which Weth claims is controlled by the energy-saving light. Ex. 1032, 8-9, 12. Dopamine influences other bodily functions including memory, pleasure, motivation, attention, and mood. Ex. 1033, 1-3; Ex. 1034, 518.

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34. A person of ordinary skill in the art understood that light therapy was effective for treating seasonal affective disorders, sleep problems, and circadian disruptions. Ex. 1011, 667 (sleep disorders may be treated using properly-timed exposure to bright light); Ex. 1012, 1:25-28 (“In order to avoid jet-lag or shift lag, the sufferers have been told to restrict sunlight from reaching the eyes to avoid the biological internal clock from being reset at an undesired time.”). Melatonin secretion was shown to be suppressed by light, thereby influencing the human circadian rhythm. Ex. 1010 [Lewy], 1267. I note that Lewy was publicly accessible to and would have been referred to by a person of ordinary skill in the prior art before 1999, and I agree with the declaration of Dr. Sylvia Hall-Ellis in this regard. *See* Ex. 1024, ¶65. Ex. 1023, 669 (green and blue lights had been shown to inhibit nocturnal melatonin secretion).

35. In addition, a person of ordinary skill in the art knew that specific ranges of wavelengths would increase a physiological response to light. Light has its effects by its interactions with specific proteins such as the opsins that function in vision. Different opsin proteins are maximally sensitive to different wavelengths – the mechanism underlying color vision. Depending on which receptive cells express which opsins and the neural pathways activated by those cells, different physiological processes may be affected. However, broadband or

white light affects all of the opsins and therefore all of the responses. There is no physiological response only activated by one or even a small number of wavelengths. For example, it has been shown that white light suppresses melatonin release, but for a given intensity, “melatonin suppression is more sensitive to the middle wavelengths of light (green) as opposed to the longer (red) ... wavelengths.” Ex. 1016, 564. Ex. 1023, 669 (the green and blue lights were shown to have a greater inhibitory effect on nocturnal melatonin secretion than the red light). As another example, short to medium wavelength components (*e.g.*, blue, green and yellow) of broad spectrum light contributed heavily to the therapeutic effect of broad spectrum light on seasonal affective disorder. Ex. 1015, 117. Ex. 1014, 476 (blue light found more potent than full-spectrum light in treatment of neonatal jaundice, which is due to an entirely different light-protein interaction than those involving opsins).

**E. Side Effects of Broad Spectrum Light Therapy**

36. By 1998, a person of ordinary skill in the art knew that potentially undesirable side effects could be triggered by specific ranges of wavelengths

within broad spectrum light. Ex. 1013 [Wirz-Justice], 200.<sup>2</sup> For example, a person of ordinary skill in the art knew that yellow light (with wavelengths in the range of 580-600 nm) triggered headache, nausea, agitation, and irritability. Ex. 1013, 200 (yellow light gave headache and nausea, agitation and irritability and worsening of depression).

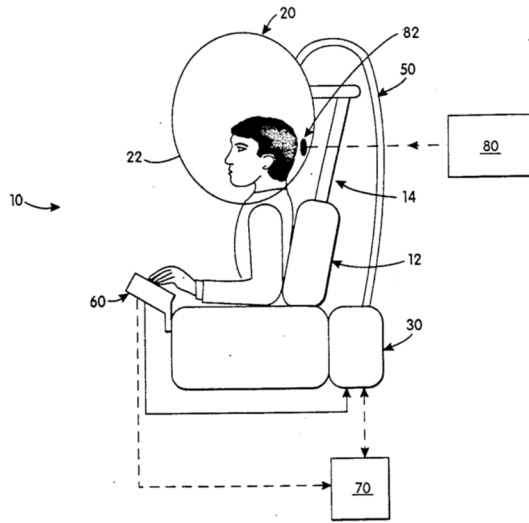
**F. Light Therapy Devices**

37. By 1998, a person of ordinary skill in the art was aware of devices configured to prevent and/or treat disorders through ocular exposure to light (either broad spectrum or narrow band). For example, the light device disclosed in U.S. Patent No. 5,047,006 (Ex. 1018) uses a reclining chair equipped with a light source to provide a field of broad spectrum light for mental and physical therapy:

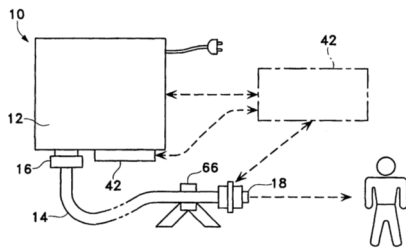
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<sup>2</sup> I note that Wirz-Justice was publicly accessible to and would have been referred to by a person of ordinary skill in the prior art before 1999, and I agree with the declaration of Dr. Sylvia Hall-Ellis in this regard. *See* Ex. 1024, ¶65.





Ex. 1018, Fig. 1, Abstract. U.S. Patent No. 5,849,027 (Ex. 1019) describes a non-contact system for delivering designated light wavelengths to a patient's body:



Ex. 1019, Fig. 1, Abstract.

## VI. LEVEL OF ORDINARY SKILL IN THE ART

38. I have considered the invalidity issues addressed in this declaration from the perspective of a person of ordinary skill in the art at the time the '140 patent application and the related applications that were filed in 2000 and 2001.

39. I have been informed and understand that a person of ordinary skill in the art means a hypothetical person to whom an expert in the field could assign a

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routine task with reasonable confidence that the person could successfully carry it out. I have also been informed and understand that prior art references evidence the level of ordinary skill in the art.

40. I am very familiar with the knowledge and capabilities that a person of ordinary skill in the art would have possessed at these times. Specifically, my experience in the industry, with colleagues from academia, with graduate students whose work I supervised, and with industry practitioners during the relevant timeframe allowed me to become personally familiar with the knowledge and capabilities of a person of ordinary skill in the art. Unless otherwise noted, my testimony below refers to the knowledge of one of ordinary skill in the art at the time the '140 patent application and the related applications were filed in 2000 and 2001.

41. In my opinion, a person of ordinary skill in the art would have had at least a Ph.D. or M.D., with a background in circadian biology, neuroscience, physiology, and phototherapy, or at least 5 years of professional experience in one or more of those fields. I believe I possess such experience and knowledge, and am qualified to opine on the '140 patent from the perspective of a person of ordinary skill in the art.

## **VII. CLAIM CONSTRUCTION**

42. I have been informed and understand that in an *inter partes* review, claims are construed using the standard of claim construction a District Court would use to construe the claim in a civil litigation action. That is, I have been informed and understand that the ordinary and customary meaning, as understood by a person of ordinary skill in the art at the time of the alleged invention in light of the patent's prosecution history and specification, must be given to the claim terms.

43. For purposes of my analysis in this Declaration, I have assumed the ordinary and customary meaning of claim terms, but I reserve the right to address any proposed constructions by Patent Owner pertaining to the '140 patent. In my view, resolving potential disputes over claim construction is unnecessary for my analysis because those terms are taught by the cited prior art references regardless of the construction.

## **VIII. THE '140 PATENT**

### **A. Overview**

44. The '140 patent "generally relates to the fields of neurology, neuroscience, and endocrinology and to light systems, light meters, lamps, filters, transparent and translucent materials, and methods of treating a variety of

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mammalian disorders and, more particularly to a light system for stimulating or regulating neuroendocrine, circadian, and photoneural systems in mammals.” Ex. 1001, Abstract. Ex. 1001, 1:27-34:

The present invention generally relates to the fields of neurology, neuroscience, and endocrinology and to light systems, light meters, lamps, filters, transparent and translucent materials, and methods of treating a variety of mammalian disorders and, more particularly to a light system for stimulating or regulating neuroendocrine, circadian, and photoneural systems in mammals based upon the discovery of peak sensitivity ranging from 425-505 nm ....

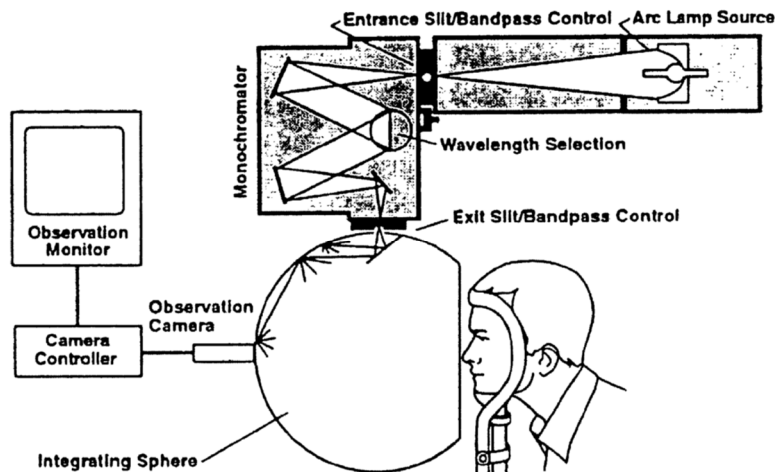
**Ex. 1001, 1:27-34.**

45. The '140 patent acknowledges that it was well-known in the prior art that “light is the primary stimulus for regulating circadian rhythms, seasonal cycles, and neuroendocrine responses in many species including humans.” Ex. 1001, 1:48-50 (“Light is the primary stimulus for regulating circadian rhythms, seasonal cycles, and neuroendocrine responses in many species including humans.”).

46. The alleged invention of the '140 patent is “based upon the discovery of” using light with a “peak sensitivity ranging from 425-505 nm” (Ex. 1001, 1:33-

34) for the treatment of “a wide variety of disorders” such as “light responsive disorders, eating disorders, menstrual cycle disorders, non-specific alerting and performance deficit, hormone-sensitive cancers, and cardiovascular disorders.”

Ex. 1001, 1:40-44, 9:12-16. The '140 patent also discloses a device that provides “a light system for stimulating or regulating neuroendocrine, circadian, and photoneural systems in mammals.” Ex. 1001, 1:31-33. This device is illustrated in Figure 5 of the '140 patent. It includes an “experimental electronic, optic and ganzfeld dome exposure array” (Ex. 1001, 9:51-52) that provides “light stimuli” into the eyes of a subject without the need to mount the system to the body of the subject. Ex. 1001, 14:62-64.



Ex. 1001, Fig. 5.

**B. Prosecution History**

47. The '140 patent resulted from Application No. 09/853,428 on May 10, 2001, and lists Provisional Application No. 60/228,493, filed on August 28, 2000 (Ex. 1020, the "'493 provisional application") and Provisional Application No. 60/203,308, filed on May 10, 2000 (Ex. 1021, the "'308 provisional application"), as related U.S. applications. Ex. 1001, Cover.

**IX. OVERVIEW OF PRIOR ART REFERENCES**

**A. Weth**

48. Weth's "energy-saving lamp" produces a predetermined light composition for "therapeutic purposes and/or illumination purposes." Ex. 1004 [Weth], 1:3-6. Weth's custom light spectrum comprises broad spectrum light and one or more spectral peaks in UV and visible range (Ex. 1004 [Weth], 2:34-36, 3:13-20, 18:14-19) that is "very close to sunlight" and "differs fundamentally from the light spectrum of conventional daylight lamps. Ex. 1004 [Weth], 1:19-21, 2:19-26:

The light spectrum of the illuminant according to the invention consequently differs fundamentally from the light spectrum of conventional daylight lamps and is very close to sunlight, and so the illuminant according to the invention could also be referred to as a sunlight lamp. It

can be used both as a tabletop lamp and as a ceiling lamp for the purposes of avoiding disease and increasing the well-being and performance.

**Ex. 1004 [Weth], 2:19-26.**

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.

**Ex. 1004 [Weth], 2:34-36.**

According to a particularly preferred embodiment of the invention, 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 ( $\pm 15$  nm), 515 nm ( $\pm 15$  nm), 540 nm ( $\pm 15$  nm), 580 nm ( $\pm 15$  nm), 610 nm ( $\pm 15$  nm), 650 nm ( $\pm 15$  nm), 690 nm ( $\pm 15$  nm), 710 nm ( $\pm 15$  nm), 740 nm ( $\pm 15$  nm), 770 nm ( $\pm 15$  nm), 800 nm ( $\pm 15$  nm).

**Ex. 1004 [Weth], 3:13-20.**

The illuminants according to Figures 1 and 2 emit light largely corresponding to insolation in comparison with conventional illuminants. Different carrier gases also allow the broad light spectrum, by means of which a full spectrum effect which is important to the eye and also of importance to the clinical effect is achieved.

**Ex. 1004 [Weth], 18:14-19.**

According to Weth, such light is “substantially more pleasant to the eye” than the light spectrum of conventional lamps because the broad spectrum component of the light emitted by the lamp “largely correspond[s] to the insolation [i.e., sunlight].” Ex. 1004 [Weth], 5:8-17. Ex. 1004 [Weth], 18:14-19 (“The illuminants ... emit light largely corresponding to insolation in comparison with conventional illuminants.”). Ex. 1004 [Weth], 5:8-11:

On account of the novel light spectrum of the energy saving lamp according to the invention, which is substantially more pleasant to the eye than the spectrum of conventional illuminants.

**Ex. 1004 [Weth], 5:8-11.**

Weth also reported that fewer lamps were required to achieve a target level of illumination. Ex. 1004 [Weth], 5:11-17:

a given illumination task requires a smaller number of illuminants, for example only two thirds the number of illuminants required when commercially available, conventional illuminants are used. Thus, significant savings of the order of 70% are also provided by the energy-saving lamp according to the invention.

**Ex. 1004 [Weth], 5:11-17.**



49. The therapeutic and preventative effects of Weth's light composition is attributed to one or more spectral peaks in both the UV and visible spectrum (Ex. 1004 [Weth], 1:32-2:17, 3:13-4:13) including peaks at 251 nm, 265 nm, 290 nm, 319 nm, 335 nm, 368 nm, 380 nm, 410 nm, 438 nm, 490 nm, 515 nm, 540 nm, 580 nm, 610 nm, 650 nm, and 690 nm, which "correspond to the absorption lines of ... endogenous, essential substances." Ex. 1004 [Weth], 3:13-4:13. Ex. 1004 [Weth], 1:32-2:17:

According to the invention, this object is achieved by an illuminant for therapeutic purposes, which emits light including 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).

These spectral lines, which as is made clear by the bandwidth specifications need not necessarily be extremely narrow band lines, correspond to the absorption lines of the following endogenous, essential substances which, incidentally, are also present in plants:

...

**Ex. 1004 [Weth], 1:32-2:17.**

According to a particularly preferred embodiment of the invention, 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 ( $\pm 15$  nm), 515 nm ( $\pm 15$  nm), 540 nm ( $\pm 15$  nm), 580 nm ( $\pm 15$  nm), 610 nm ( $\pm 15$  nm), 650 nm ( $\pm 15$  nm), 690 nm ( $\pm 15$  nm), 710 nm ( $\pm 15$  nm), 740 nm ( $\pm 15$  nm), 770 nm ( $\pm 15$  nm), 800 nm ( $\pm 15$  nm).

**Ex. 1004 [Weth], 3:13-20.**

50. Weth's light composition is effective for treating and preventing light responsive disorders such as coagulation system and arteriosclerosis, myocardial infarctions and acute strokes, osteoporosis metabolism, depression, psychoses. Ex. 1004 [Weth], Title ("Energy-saving lamp for medical therapies"), 1:3-6, 5:19-6:34. Ex. 1004 [Weth], 5:19-25:

[T]he use of the energy-saving lamp according to the invention allows the fibrinogen level, arteriosclerosis, immunological diseases, psychoses, depressions and further diseases to be influenced, e.g., the avoidance of myocardial infarctions and strokes, and also allows the immune system to be strengthened and the ageing process to be slowed down.

**Ex. 1004 [Weth], 5:19-25.**

Weth uses its energy-saving lamp for "improv[ing] [the] quality of sleep," (Ex. 1004 [Weth], 12:34-35) "avoidance of myocardial infarctions and strokes," (Ex.

Declaration of Dr. Craig Heller  
In Support of Petition for *Inter Partes* Review  
of U.S. Patent No. 7,678,140

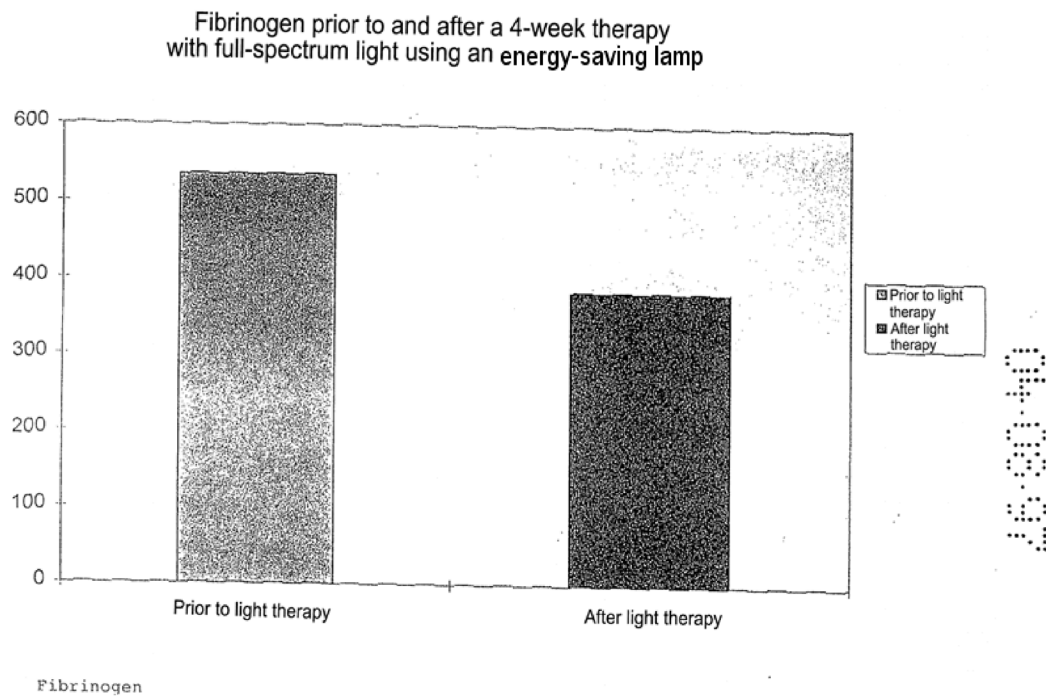
1004 [Weth], 5:19-30) “reduction in embolisms and thromboses,” (Ex. 1004 [Weth], 5:27-30) “prevent[ing] diseases caused by coagulation disorders,” (Ex. 1004 [Weth], 5:37-6:3) and “lead[ing] to significant improvement in [depression].” Ex. 1004 [Weth], 13:25-30. This disclosure significantly overlaps with the list of light responsive disorders such as “seasonal affective disorders, sleep disorders, circadian disruption, ... hormone-sensitive cancers ... , and cardiovascular disorders” as described in the '140 patent. Ex. 1001, 8:44-50. Notably, Weth reports a study in which 110 patients with coronary artery disease (CAD) were treated with “a twice daily half-hour irradiation” to the light from the energy-saving lamp for four weeks. Ex. 1004 [Weth], 6:33-7:9. Results in the graph on page 22 of Weth show that the fibrinogen level (an increased level of fibrinogen is attributable to CAD) (Ex. 1004 [Weth], 6:24-25) dropped from 543 mg/dl before the treatment to 389 mg/dl following the treatment. Ex. 1004 [Weth], 6:33-7:9:

Page 22 of the German application – fibrinogen – shows, as a result of the investigation for the individual diseases performed on 110 patients, a drop in the fibrinogen level as a result of the treatment with the energy-saving lamp according to the invention in the context of the aforementioned diseases.

As shown in the **graph**, the fibrinogen levels drop significantly. Thus, the fibrinogen level in the case of

CAD (coronary artery disease) was 543 mg/dl before the treatment with the energy-saving lamp according to the invention and dropped to 389 mg/dl following a four-week treatment term with a twice daily half-hour irradiation by way of the energy-saving lamp according to the invention.

**Ex. 1004 [Weth], 6:33-7:9 (bold in original).**



**Ex. 1004 [Weth], p. 22.**

51. Weth's light therapy obviates the need for the "[w]hole-body irradiation, like in the case of the previously known therapies." Ex. 1004 [Weth], 7:34-38. This is similar to the '140 patent's disclosure in claim 1 to "expos[e] at least a portion of the retina of at least one eye" to the therapeutic light.

52. Exposure of the eyes to the disclosed light composition results in an “[i]mprovement in the receptor sensitivity” and therefore “quality of sleep.” Ex. 1004 [Weth], 12:30-37. Weth lists several practical embodiments of its lamp that are not as part of an apparatus to be attached to the body of a subject, including as “both as a tabletop lamp and as a ceiling lamp,” Ex. 1004 [Weth], 2:24-26.

**B. Weber**

53. Weber discloses color filters including simple color filters based on multilayer optical films. Ex. 1022 [Weber], 19:21-31 (“birefringent multilayer stacks which have a relatively small z-index mismatch can function as non polarizing color filters in certain special cases.”). The color filters are “useful for concentrating light of the desired wavelengths” and “may be combined with artificial broadband light sources to control the wavelength of light emitted from the source.” Ex. 1022 [Weber], 94:41-45. Weber’s Figure 19 (reproduced below), for instance, shows a transmission of over 50% of light for wavelengths of approximately 425-500 nm (inclusive of the **blue spectrum**<sup>3</sup> of light) while filtering out more than 90% of the light intensity in the spectrum range of between

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<sup>3</sup> I have added all annotations and emphases in this petition except where noted otherwise.

525 nm and 725 nm (inclusive of the **yellow spectrum** of light). Weber's filter transmits light in the UV spectrum (unless specially configured with "UV stabilized films or coatings"). Ex. 1022 [Weber], 79:35-39 ("The films and optical devices of the present invention may be protected from UV radiation through the use of UV stabilized films or coatings.").

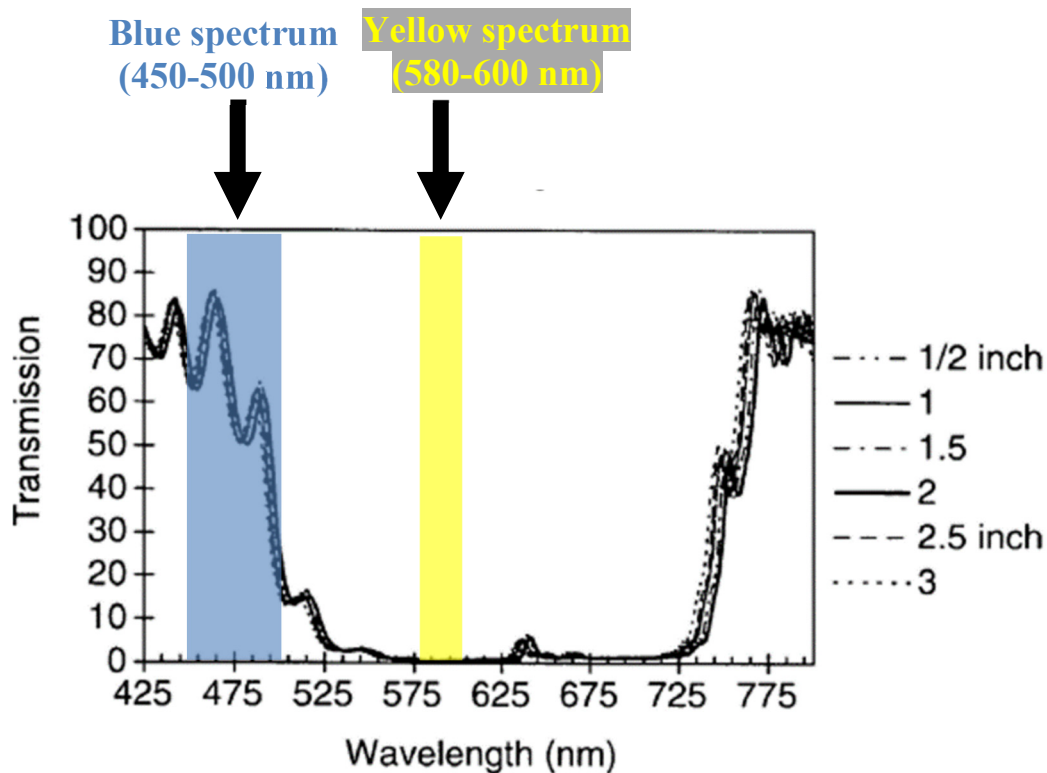


FIG. 19

Ex. 1022 [Weber], Fig. 19 (annotated).

**C. Analogous Art**

54. A person of ordinary skill in the art would have been aware of both Weth and Weber, and would have considered both of these references to be in the same field as and pertinent to the technical problems faced by the inventors of the '140 patent. Weth and the '140 patent address “treatment of mammals with a wide variety of disorders or deficits, including light responsive disorders.” Ex. 1001, Abstract. Ex. 1004 [Weth], 1:5-6 (“The invention relates to an energy-saving lamp for therapeutic purposes ....”), 5:19-34, 8:36-9:8. Weber discloses techniques to use light filters to control wavelengths present in a transmitted light spectrum. Weber’s techniques would have been considered by a person of ordinary skill in the art to be directly relevant to the task of selecting a light composition in accordance with the claimed invention of the '140 patent. Ex. 1022 [Weber], 85:57-62 (“The optical films of the present invention may also be used to provide decorative fenestrations which transmit light of specific wavelengths.”), 6:31-33, 11:20-30.

**X. SPECIFIC GROUNDS FOR UNPATENTABILITY**

55. In my opinion, claims 1 and 6 of the '140 patent are unpatentable because they are anticipated by Weth.

56. In my opinion, claims 2-5 and 7-9 of the '140 patent are unpatentable because they are obvious in view of the teachings of Weth and Weber.

57. In the sections that follow, I provide a detailed explanation of my opinion of how those prior art references show that the claims are unpatentable.

**A. Ground I: Claims 1 and 6 Are Anticipated By Weth**

**1. Independent Claim 1**

- i. Element [1-Pre]: “*A method of at least treating or preventing at least one light responsive disorder in at least one mammal, said method comprising the steps of:*”**

58. I understand that this limitation forms part of the preamble of this claim and therefore may not be limiting. To the extent the Board treats element [1-pre] as limiting, Weth discloses it.

59. Weth teaches “an energy-saving **lamp for therapeutic purposes**” (Ex. 1004 [Weth], 1:3-6) that is used for influencing “the fibrinogen level, **arteriosclerosis**, immunological diseases, psychoses, **depressions** and further **diseases**” and for “**avoidance of myocardial infarctions and strokes.**” Ex. 1004 [Weth], 1:3-6, 5:19-25. Ex. 1004 [Weth], 19:3-7 [claim 1]. Weth found the light to “yield a **reduction in embolisms and thromboses**” (Ex. 1004 [Weth], 7:27-29) and for “**prevent[ion of] diseases** caused by coagulation disorders.” Ex. 1004 [Weth], 5:19-6:34. Ex. 1004 [Weth], 8:36-9:8:



The tumour necrosis factors, the interleukins, the prostaglandins, etc. are also influenced. All of these parameters are influenced positively by way of this lamp light.

In order to possibly completely prevent the aforementioned diseases, the illuminant according to the invention may also be used as a prophylaxis, as already mentioned, by virtue of being used as a tabletop or ceiling lamp.

**Ex. 1004 [Weth], 8:36-9:8.**

60. Weth also found its lamp to be useful for preventing light responsive disorders, including as a tabletop or ceiling lighting unit that may be used for “**completely prevent[ing] the aforementioned diseases**” or as a “**prophyla[ctic]**” measure. Ex. 1004 [Weth], 9:4-8, 10:18-26.

**ii. Element [1a]: “*utilizing at least one light source, said at least one light source emitting optical radiation*”**

61. Weth teaches “*utilizing at least one light source, said at least one light source emitting optical radiation.*” Weth’s “**lamp**” is “*at least one light source.*” Ex. 1004 [Weth], cover (title “Energy-saving lamp for medical therapies”). Ex. 1004 [Weth], 1:5-6 (“energy-saving lamp for therapeutic purposes and/or illumination purposes”). Ex. 1004 [Weth], 2:24-26 (lamp can be “used both as a **tabletop lamp and as a ceiling lamp** for the purposes of avoiding disease and

increasing the well-being and performance”). Ex. 1004 [Weth], 19:17-18 [claim 3] (“**space saving lamp**”). Section IX. A [Overview of Weth].

62. Furthermore, the lamp taught by Weth “*emit[s] optical radiation*” comprising ultraviolet radiation and visible light. Section V.A [Technical Background—Light Spectrum] (optical radiation comprises ultraviolet radiation and visible light). For example, the lamp emits **ultraviolet radiation** “including 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).” Ex. 1004 [Weth], 1:32-36, 19:3-7 [claim 1]. Section V.A [Technical Background—Light Spectrum] (ultraviolet radiation consists of wavelengths in the range of approximately 100-400 nm). In a “particularly preferred embodiment,” the lamp also emits **visible light** including “at least one spectral lines of the following group: ... 410 nm ( $\pm 15$  nm), 438 nm ( $\pm 15$  nm), 490 nm ( $\pm 15$  nm), 515 nm ( $\pm 15$  nm), 540 nm ( $\pm 15$  nm), 580 nm ( $\pm 15$  nm), 610 nm ( $\pm 15$  nm), 650 nm ( $\pm 15$  nm), [and] 690 nm ( $\pm 15$  nm).” Ex. 1004 [Weth], 3:13-20, 19:9-15 [claim 2]. Section V.A [Technical Background—Light Spectrum] (visible light consists of wavelengths in the range of 400-700 nm).

- iii. **Element [1b]: “*causing said optical radiation to be commonly therapeutically effective in humans by employing a pre-established spectral composition that has been pre-identified as a maximally potent spectral composition in the regulation of at least one of the human circadian, photoneural, or neuroendocrine systems, 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;*”**

63. Weth discloses limitation [1b].

- a. **“*causing said optical radiation to be commonly therapeutically effective in humans*”**

64. Weth teaches “*causing said optical radiation*” because Weth’s “lamp” is **used in common human settings** such as “schools, hospitals, especially in ICUs, prisons and nurseries as we found out that the well-being of both the patients and the staff improves” (Ex. 1004 [Weth], 3:7-11) and “can be screwed into any illuminant socket.” Ex. 1004 [Weth], 2:28-29. Ex. 1004 [Weth], 2:24-26 (The invention can be “used both as a **tabletop lamp and as a ceiling lamp** for the purposes of avoiding disease and increasing the well-being and performance”). Ex. 1004 [Weth], 19:17-18 (Energy-saving lamps according to Claim 1 or 2, embodied as a space saving lamp). Furthermore, Weth causes the optical radiation to be used by making the “illuminant ... substantially more pleasant than that of conventional luminaires.” Ex. 1004 [Weth], 5:1-3. Ex. 1004 [Weth], 5:8-11 (the

novel light spectrum of the energy-saving lamp ... is substantially more pleasant to the eye than the spectrum of conventional illuminants).

65. Weth additionally teaches “*commonly therapeutically effective in humans*” because Weth’s lamp provides a light composition designed “for **therapeutic purposes**” (Ex. 1004 [Weth], 1:5-6) including “**medical therapies.**” Ex. 1004 [Weth], 1:5-6. Ex. 1004 [Weth], title ( “Energy-saving lamp for medical therapies”). Human “**patients** have significantly improved clinical findings [] as a result of using the energy-saving lamp according to the invention.” Ex. 1004 [Weth], 7:31-34. A study of 110 patients identified “a drop in the fibrinogen level as a result of the treatment with the energy-saving lamp” (Ex. 1004 [Weth], 6:33-38) whereas the “[e]xtent and severity of coronary sclerosis correlate significantly with the value of the fibrinogen level.” Ex. 1004 [Weth], 11:12-13. Ex. 1004 [Weth], 1:32-36 (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).”) Ex. 1004 [Weth], 8:10-14 (Therapeutic effects comparable to those obtained using the energy-saving lamp according to the invention could not be obtained previously. Moreover, many new clinical effects, not known before, arose as a result of using the energy-saving lamp according to the invention.”). Ex. 1004 [Weth], 8:31-9:2 (“The

tumour necrosis factors, the interleukins, the prostaglandins, etc. are also influenced. All of these parameters are influenced positively by way of this lamp light). Ex. 1004 [Weth], 11:36-12:28 (improved fibrinogen level). Ex. 1004 [Weth], 12:30-37 (improvement in the receptor sensitivity). Ex. 1004 [Weth], 13:1-12 (improved Vitamin D formation). Ex. 1004 [Weth], 13:14-21 (improved low-density lipoprotein concentration). Ex. 1004 [Weth], 13:23-35 (improved Hamilton Rating Scale parameters for depression). Ex. 1004 [Weth], 13:37-14:9 (improved stimulation of immune system). Ex. 1004 [Weth], 14:11-24 (reduction in C-reactive protein associated with chronic fatigue syndrome). Ex. 1004 [Weth], 14:26-15:3 (improved ADL status). Ex. 1004 [Weth], 15:5-10 (reduction in interleukin 6 level). Ex. 1004 [Weth], 15:12-17 (stimulation of the hypophysis hormones). Ex. 1004 [Weth], 15:19-27 (improved exanthema). Ex. 1004 [Weth], 15:29-38 (regression in the paranoid symptoms). Ex. 1004 [Weth], 16:1-7 (prevention of pathological amino acids).

***b. “by employing a pre-established spectral composition that has been pre-identified as a maximally potent spectral composition,”***

66. Weth teaches “*by employing a pre-established spectral composition that has been pre-identified as a maximally potent spectral composition*” because its lamp produces a “pre-established **spectral composition**” including “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)” (Ex. 1004 [Weth], 1:34-36) and “380 nm ( $\pm 15$  nm), 410 nm ( $\pm 15$  nm), 438 nm ( $\pm 15$  nm), 490 nm ( $\pm 15$  nm), 515 nm ( $\pm 15$  nm), 540 nm ( $\pm 15$  nm), 580 nm ( $\pm 15$  nm), 610 nm ( $\pm 15$  nm), 650 nm ( $\pm 15$  nm), 690 nm ( $\pm 15$  nm), 710 nm ( $\pm 15$  nm), 740 nm ( $\pm 15$  nm), 770 nm ( $\pm 15$  nm), 800 nm ( $\pm 15$  nm).” Ex. 1004 [Weth], 3:16-20, 1:19-21, 2:19-26, 2:34-36, 3:13-20, 18:14-19. Ex. 1004 [Weth], 19:3-15 [claims 1 and 2]:

1. Energy-saving lamps for therapeutic purposes and/or illumination purposes, emitting light including 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).
2. Energy-saving lamps according to Claim 1, emitting 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 ( $\pm 15$  nm), 515 nm ( $\pm 15$  nm), 540 nm ( $\pm 15$  nm), 580 nm ( $\pm 15$  nm), 610 nm ( $\pm 15$  nm), 650 nm ( $\pm 15$  nm), 690 nm ( $\pm 15$  nm), 710 nm ( $\pm 15$  nm), 740 nm ( $\pm 15$  nm), 780 nm ( $\pm 15$  nm), 800 nm ( $\pm 20$  nm).

**Ex. 1004 [Weth], 19:3-15 [claims 1 and 2].**

The light spectrum of the illuminant according to the invention consequently differs fundamentally from the light spectrum of conventional daylight lamps and is very close to sunlight, and so the illuminant according to the invention could also be referred to as a sunlight lamp. It can be used both as a tabletop lamp and as a ceiling lamp for the purposes of avoiding disease and increasing the well-being and performance.

**Ex. 1004 [Weth], 2:19-26.**

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.

**Ex. 1004 [Weth], 2:34-36.**

According to a particularly preferred embodiment of the invention, 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 ( $\pm 15$  nm), 515 nm ( $\pm 15$  nm), 540 nm ( $\pm 15$  nm), 580 nm ( $\pm 15$  nm), 610 nm ( $\pm 15$  nm), 650 nm ( $\pm 15$  nm), 690 nm ( $\pm 15$  nm), 710 nm ( $\pm 15$  nm), 740 nm ( $\pm 15$  nm), 770 nm ( $\pm 15$  nm), 800 nm ( $\pm 15$  nm).

**Ex. 1004 [Weth], 3:13-20.**

The illuminants according to Figures 1 and 2 emit light largely corresponding to insolation in comparison with conventional illuminants. Different carrier gases also allow the broad light spectrum, by means of which a full spectrum effect which is important to the eye and also of importance to the clinical effect is achieved.

**Ex. 1004 [Weth], 18:14-19.**

67. The spectral composition disclosed in Weth is a “maximally potent spectral composition” for therapy. The spectral composition is “maximally potent” because it is selected to correspond to a subject’s light response mechanism vis-à-vis “**absorption lines of**” “**endogenous, essential substances**” (*i.e.*, the subject’s light sensitive substances). Ex. 1004 [Weth], 3:22-4:13 (“these spectral lines correspond to the absorption lines of the ... **endogenous, essential substances**”). Ex. 1001, 4:9-16 (characterizing the “wavelength sensitivity of the photoreceptor system responsible for providing circadian input to the human pineal gland” of 446-477 nm as the “most potent wavelength region for regulating melatonin.”). The resulting spectral composition is effective for “improv[ing] the quality of sleep” (Ex. 1004 [Weth], 12:30-37), “avoidance of myocardial infarctions and strokes” (Ex. 1004 [Weth], 5:19-25), “reduction in embolisms and thromboses” (Ex. 1004 [Weth], 5:27-30), “prevent[ing] diseases caused by coagulation



disorders” (Ex. 1004 [Weth], 5:37-6:3), and “lead[ing] to significant improvement in [depression].” Ex. 1004 [Weth], 13:25-30.

*c. “in the regulation of at least one of the human circadian, photoneural, or neuroendocrine systems,”*

68. Weth teaches “*in the regulation of at least one of the human circadian, photoneural, or neuroendocrine systems*” by disclosing, for example, that use of its lamp can “increase in the dopamine level, that is to say vigilance increases” and also use of the lamp “**improves quality of sleep.**” Ex. 1004 [Weth], 12:32-35. As explained in Section V.D [Technology Background—Using Light], circadian rhythm includes the wake-sleep cycle and dopamine is a neurotransmitter that influences sleep. Thus, Weth teaches a spectral composition “*in the regulation of ... the human circadian ... or neuroendocrine system[.]*”

*d. “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;”*

69. Weth teaches “*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*” because its lamp emits “**at least one spectral line** of the following group: ... **438 nm** ( $\pm 15$  nm).” Ex. 1004 [Weth], 19:9-15 [claim 2]. This at least one spectral line is “*at least one enhanced spectral region*

*comprising at least one peak of emitted light*” because it includes a spectral line that is discernable from other parts of the spectrum emitted from Weth’s lamp.

iv. **Element [1c]: “*exposing at least a portion of the retina of at least one eye of at least one mammal to said pre-established spectral composition of optical radiation such that said light source is not mounted on the body of said at least one mammal;*”**

70. Weth teaches “*exposing at least a portion of the retina of at least one eye of at least one mammal*” because it teaches that Weth’s lamp is for both “therapeutic purposes and/or **illumination** purposes.” Ex. 1004 [Weth], 1:3-6. In addition, Weth discloses that “light from the energy-saving lamp according to the invention **enters the eyes of the observer** when the latter looks at an image displayed by means of the cathode-ray tube.” Ex. 1004 [Weth], 9:21-24. Ex. 1004 [Weth], 2:24-26, 19:17-18 [claim 3]. Weth’s disclosures of providing illumination and entering the eyes teach “*exposing at least a portion of the retina*” of one of the eyes to its pre-established spectral composition.

71. Weth’s teaching that a therapeutic effect is “**obtained purely by way of the eyes**” such that “[w]hole-body irradiation, like in the case of the previously known therapies, thus is no longer required” (Ex. 1004 [Weth], 7:34-38) also inherently discloses “*exposing at least a portion of the retina*” to its pre-established spectral composition to obtain the therapeutic benefits described by Weth,

including “fibrinogen level, arteriosclerosis, immunological diseases, psychoses, depressions and further diseases to be influenced” (Ex. 1004 [Weth], 5:19-25) and stimulation of Vitamin D formation. Ex. 1004 [Weth], 13:1-12. Ex. 1004 [Weth], 1:32-36, 8:10-14, 8:31-9:2, 11:12-13, 11:36-12:28, 12:30-37, 13:14-21, 13:23-35, 13:37-14:9, 14:11-24, 14:26-15:3, 15:5-10, 15:12-17, 15:19-27, 15:29-38, 16:1-7. Section X.A.1.iii.b [element [1b]]. Ex. 1017, 1 ([t]he retina is a complex transparent tissue consisting of several layers, only one of which contains light-sensitive photoreceptor cells.)

72. Weth further teaches “*to said pre-established spectral composition of optical radiation such that said light source is not mounted on the body*” because, for example, Weth’s lamp is “used both as a **tabletop lamp and as a ceiling lamp** for the purposes of avoiding disease and increasing the well-being and performance.” Ex. 1004 [Weth], 2:24-26. These are embodiments of a light source that is not mounted on the body of a subject.

**v. Element [1d]: “*stimulating the photoreceptor system for at least one of the circadian, photoneural or neuroendocrine systems of said at least one mammal;*”**

73. Weth teaches “*stimulating the photoreceptor system.*” The therapeutic effect of Weth’s lamp is “obtained **purely by way of the eyes.**” Ex. 1004 [Weth], 7:34-37. Section X.A.1.iv [element [1c]]; Ex. 1017, 1 ([t]he retina is

a complex transparent tissue consisting of several layers, only one of which contains light-sensitive photoreceptor cells.)

74. Furthermore, the stimulation is “*for at least one of the circadian, photoneural or neuroendocrine systems of said at least one mammal*” because Weth’s lamp can “increase in the dopamine level, that is to say vigilance increases” and also use of the lamp “**improves quality of sleep.**” Ex. 1004 [Weth], 12:32-35. As I explained in Section V.D [Technology Background—Using Light], circadian rhythm includes the wake-sleep cycle and dopamine is a neurotransmitter that influences sleep. *See also* Section X.A.1.iii [element [1b]]. Ex. 1004 [Weth], 12:32-35. Thus, Weth teaches limitation [1d].

**vi. Element [1e]: “*enabling at least the treatment or the prevention of at least one light responsive disorder in said at least one mammal.*”**

75. Weth teaches limitation [1e]. As I discussed above in Section X.A.1.i [element [1-pre]]. light responsive disorders are addressed by Weth’s lamp enabling “**fibrinogen level, arteriosclerosis, immunological diseases, psychoses, depressions and further diseases to be influenced,**” “immune system to be strengthened and the ageing process to be slowed down.” Ex. 1004 [Weth], 5:19-25. Treatment with the lamp also “yield[s] a reduction in embolisms and thromboses” (Ex. 1004 [Weth], 5:27-30), “improves quality of sleep” (Ex. 1004

[Weth], 12:34-35), and “[leads] to a significant improvement in” depression. Ex. 1004 [Weth], 13:24-33. Furthermore, the lamp enables prevention of “the formation of pathological amino acids,” (Ex. 1004 [Weth], 16:1-7) “diseases caused by coagulation disorders” (Ex. 1004 [Weth], 5:37-6:3) and “myocardial infarctions and strokes.” Ex. 1004 [Weth], 5:19-23:

The use of the energy-saving lamp according to the invention allows the fibrinogen level, arteriosclerosis, immunological diseases, psychoses, depressions and further diseases to be influenced, e.g., the avoidance of myocardial infarctions and strokes, and also allows the immune system to be strengthened and the ageing process to be slowed down.

**Ex. 1004 [Weth], 5:19-23.**

The use of the energy-saving lamp according to the invention causes the fibrinogen levels to be lowered to normal values and consequently prevents diseases caused by coagulation disorders (elevated fibrinogen).

**Ex. 1004 [Weth], 5:37-6:3.**

The formation of pathological amino acids is prevented by the use of the energy-saving lamp according to the invention. Homocysteine reduces by 30% in the case of pathologically elevated values.

**Ex. 1004 [Weth], 16:1-7.**

**2. Dependent Claim 6**

- i. **Claim 6:** *“The method of claim 1, said method further comprising enabling the prevention of at least one light responsive disorder in said at least one mammal.”*

76. As I explained in Section X.A.1 [claim 1], Weth discloses “[t]he method of claim 1.”

77. Weth further teaches “said method further comprising enabling the prevention of at least one light responsive disorder in said at least one mammal.”

Weth’s lamp may be embodied as “a tabletop or ceiling lamp” for “possibly completely **prevent[ing]**” or at least as a “**prophyla[ctic]**” measure (Ex. 1004 [Weth], 9:5-8) for “**avoidance** of myocardial infarctions and strokes” (Ex. 1004 [Weth], 5:19-25) and “**prevent[ion of]** diseases caused by coagulation disorders.” Ex. 1004 [Weth], 5:37-6:3. “[N]one of the [1000] subjects and patients [who were treated with light from the energy-saving lamp] had a myocardial infarction or stroke.” Ex. 1004 [Weth], 10:18-26. Section X.A.1.i [element [1-pre]]. Section X.A.1.iii [element [1b]]. Therefore, Weth anticipates claim 6.

**B. Ground II: Claims 2-5 and 7-9 Would Have Been Obvious Over Weth in Combination with Weber**

**1. Combination of Weth and Weber (“Weth-Weber”)**

78. Weth identifies the need for a light composition that reduces “unpleasant side effects” (Ex. 1004 [Weth], 1:8-14) and is “substantially more

pleasant to the eye than the spectrum of conventional illuminants” (Ex. 1004 [Weth], 5:10-11) yet provides therapeutic components for prevention and/or treatment of light-related disorders. Section IX.A [Overview of Prior Art—Weth].

79. Weth identifies “headaches and nausea” as undesirable side effects that are avoided by maintaining the luminosity of its lamp below 6000 lux. Ex. 1004 [Weth], 1:9-14 (“the illuminants or lamps used to [whole-body light therapy] cause unpleasant side effects on account of producing more than 6000 lux”). However, Weth observes that the reduced luminosity may limit use of its lamp to the environments which are already at least partially illuminated, for example, “at the place of work.” Ex. 1004 [Weth], 1: 23-25. Ex.1004, 9:29-32. Thus, Weth’s lamp may be limited to certain environments requiring only limited illumination. A person of ordinary skill in the art would have recognized that Weth’s lamp luminosity was not sufficient in all work environments (or environments in general) to provide enough lighting for a particular task. A person of ordinary skill in the art would have also known that increased light intensity can improve the effectiveness of certain therapies. Ex. 1010, 1267 (increased light intensity improves control of circadian rhythm through suppression of melatonin).

80. A person of ordinary skill in the art would have been motivated to address such needs by considering pertinent techniques in the prior art for

providing Weth's light composition at higher luminosity while still avoiding side effects such as "headaches and nausea." As I explained in Section V.E [Technology Background—Side Effects of Broad Spectrum Light Therapy], for example, a person of ordinary skill in the art would have known that headache and nausea may be attributed to the yellow component (approximately 580-600 nm) in sunlight. Ex. 1013, 200 (yellow light gave headache and nausea, agitation and irritability and worsening of depression). In addition, because Weth's light composition "is very close to sunlight" (Ex. 1004 [Weth], 2:21-22) and because 580 nm is among the spectral lines optionally emitted by the lamp, a person of ordinary skill in the art would have expected yellow light to be present. Ex. 1004 [Weth], 3:13-20:

According to a particularly preferred embodiment of the invention, 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 ( $\pm 15$  nm), 515 nm ( $\pm 15$  nm), 540 nm ( $\pm 15$  nm), **580 nm** ( $\pm 15$  nm), 610 nm ( $\pm 15$  nm), 650 nm ( $\pm 15$  nm), 690 nm ( $\pm 15$  nm), 710 nm ( $\pm 15$  nm), 740 nm ( $\pm 15$  nm), 770 nm ( $\pm 15$  nm), 800 nm ( $\pm 15$  nm).

**Ex. 1004 [Weth], 3:13-20.**



Thus, a person of ordinary skill in the art would have considered the use of a suitable light filter to remove the yellow portion of the light spectrum emitted from Weth's lamp. In particular, as I discussed in Section IX.C [Analogous Art], a person of ordinary skill in the art would have been aware of Weber, which discloses filters that can substantially filter the yellow spectrum. Weber's Figure 19 discloses the performance of a filter that removes nearly all of the **yellow spectrum** while transmitting a substantial portion of the spectrum below 500 nm:

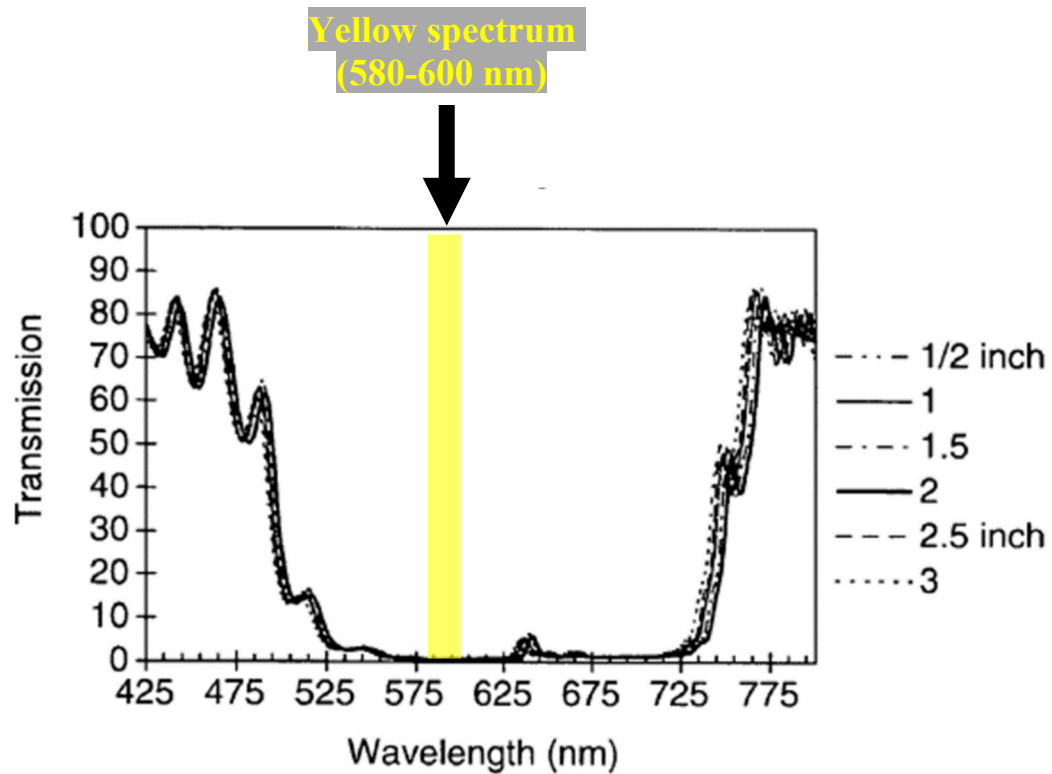


FIG. 19

Ex. 1022 [Weber], Fig. 19 (annotated). Section IX.B [Overview of Prior Art—Weber].

81. In my opinion, a person of ordinary skill in the art would have found it obvious to combine Weth's lamp with Weber's filter by arranging the two components such that Weth's light composition passed through the filter before reaching a subject. Effecting this combination would have amounted to applying a known technique (light filtering using Weber's filter) to a known device ready for improvement (Weth's lamp) to yield the predictable result of a lamp that can be operated at higher luminosities without introducing the undesirable side effects of headaches and nausea identified by Weth. Ex. 1004 [Weth], 1:9-14 ("Patients complain about blinding effects (the eyes must be closed), and some complain of headaches and nausea.").

82. Weber's filter would have also made the light more desirable for viewing by a subject, for example to increase the exposure of the subject's eyes to the light during a therapy session. For example, Weber teaches that its filter provides a "colored display[]" in an "eye-catching manner" that "draw[s] attention." Ex. 1022 [Weber], 1:10-14.

83. In my opinion, a person of ordinary skill in the art combining Weth's lamp with Weber's filter would have reasonably expected to succeed, and would

have succeeded, to produce a therapeutically effective spectrum light that could be operated at a higher luminosity without introducing undesirable side effects. A person of ordinary skill in the art would have known that the luminosity of Weth's lamp could be increased to a desired level suitable to a particular environment or to a particular therapeutic use by increasing the illuminance of the lamp. Notably, Weber's film is designed to be used in conjunction with a lamp. Ex. 1022 [Weber], 86:35-49 (simple filter is "used as a filter in a backlit light fixture" such as a lamp).

**2. Dependent Claim 2**

- i. **Claim 2: "*The method of claim 1, said method further comprising providing at least one light filtering component in conjunction with said at least one light source; and causing said at least one light filtering component to transmit therapeutically effective optical radiation.*"**

84. As I explained above in Section X.A.1 [claim 1], Weth discloses "[t]he method of claim 1." Weber further discloses "*said method further comprising providing at least one light filtering component in conjunction with said at least one light source.*" UV and visible components of optical radiation with wavelengths below 500 nm (Ex. 1022 [Weber], 6:31-33, 11:23, Fig. 19) are transmitted by Weber's filter, includes "*therapeutically effective optical radiation*" from Weth's light source including "**spectral lines** [at] 251 nm ( $\pm 5$  nm), 265 nm

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( $\pm 15$  nm), 290 nm ( $\pm 15$  nm), 319 nm ( $\pm 10$  nm), 335 nm ( $\pm 15$  nm), 368 nm ( $\pm 15$  nm)” (Ex. 1004 [Weth], 1:34-36) and “380 nm ( $\pm 15$  nm), 410 nm ( $\pm 15$  nm), **438 nm** ( $\pm 15$  nm), 490 nm ( $\pm 15$  nm), 515 nm ( $\pm 15$  nm), 540 nm ( $\pm 15$  nm), 580 nm ( $\pm 15$  nm), 610 nm ( $\pm 15$  nm), 650 nm ( $\pm 15$  nm), 690 nm ( $\pm 15$  nm), 710 nm ( $\pm 15$  nm), 740 nm ( $\pm 15$  nm), 770 nm ( $\pm 15$  nm), 800 nm ( $\pm 15$  nm).” Ex. 1004 [Weth], 3:16-20. Ex. 1004 [Weth], 19:9-15 [claims 2]:

2. Energy-saving lamps according to Claim 1, emitting 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 ( $\pm 15$  nm), 515 nm ( $\pm 15$  nm), 540 nm ( $\pm 15$  nm), 580 nm ( $\pm 15$  nm), 610 nm ( $\pm 15$  nm), 650 nm ( $\pm 15$  nm), 690 nm ( $\pm 15$  nm), 710 nm ( $\pm 15$  nm), 740 nm ( $\pm 15$  nm), 780 nm ( $\pm 15$  nm), 800 nm ( $\pm 20$  nm).

**Ex. 1004 [Weth], 19:9-15 [claim 2].**

The transmitted optical radiation would comprise Weth’s spectral peak at 438 nm.

85. Thus, the Weth-Weber combination discloses claim 2.

3. Dependent Claim 3

- i. Claim 3: “*The method of claim 2 wherein said method further comprises providing at least one transparent composition in conjunction with said at least one light filtering component.*”

86. As I explained above in Section X.B.2 [claim 2], the Weth-Weber combination discloses “[t]he method of claim 2.” Weber further discloses “*wherein said method further comprises providing at least one transparent composition in conjunction with said at least one light filtering component.*” Weber’s color filter (Ex. 1022 [Weber], 19:21-31) may be placed on a substrate that is “transparent (transparent to certain colors, i.e., clear without diffusers, but colored).” Ex. 1022 [Weber], 73:31-32. Furthermore, the resulting transparent color filter transmits optical radiation in a range of at least 425 nm to 500 nm, including Weth’s spectral peak at 438 nm. Ex. 1022 [Weber], Figs. 19 and 32:

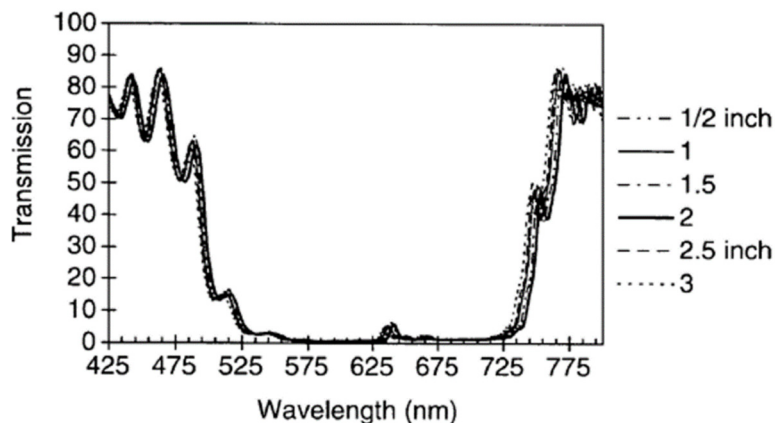


FIG. 19

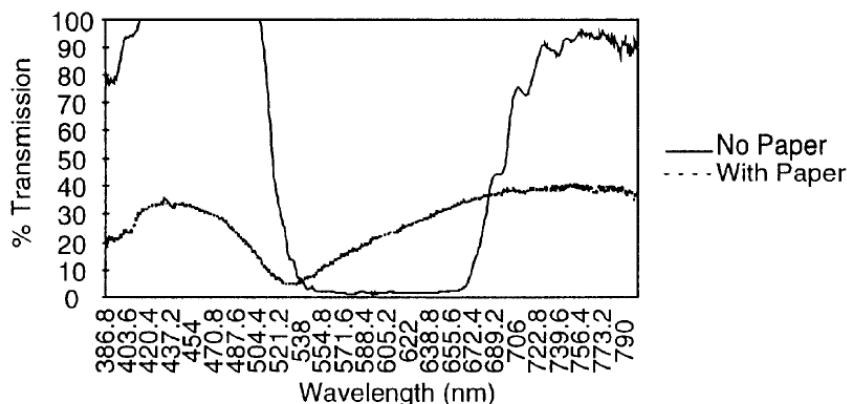


FIG. 32

87. Thus, the Weth-Weber combination discloses claim 3.

#### 4. Dependent Claim 4

- i. **Claim 4:** *“The method of claim 2 wherein said method further comprises providing at least one translucent composition in conjunction with said at least one light filtering component.”*

88. As I explained above in Section X.B.2 [claim 2], the Weth-Weber combination discloses “[t]he method of claim 2.” Weber further discloses “wherein said method further comprises providing at least one translucent composition in conjunction with said at least one light filtering component.” For example, Weber’s color filter film (Ex. 1022 [Weber], 19:21-31), may be placed on a substrate that is “translucent (diffusely transmitting, with various amounts of haze).” Ex. 1022 [Weber], 73:30-31. Furthermore, the resulting transparent color

filter transmits optical radiation in a range of at least 425 nm to 500 nm, including Weth's spectral peak at 438 nm. Ex. 1022 [Weber], Figs. 19 and 32:

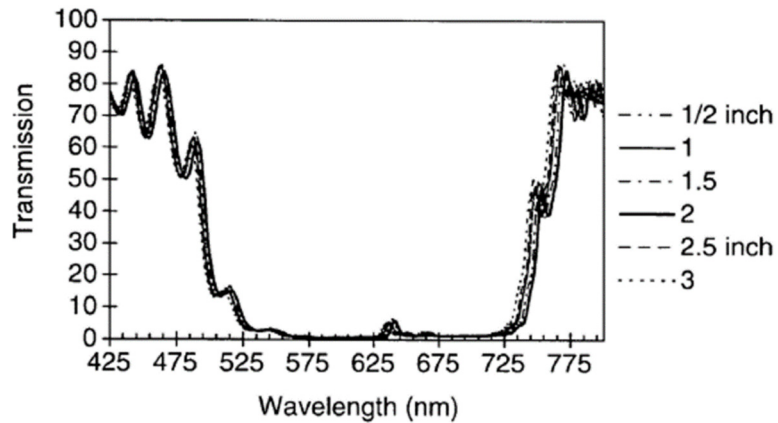


FIG. 19

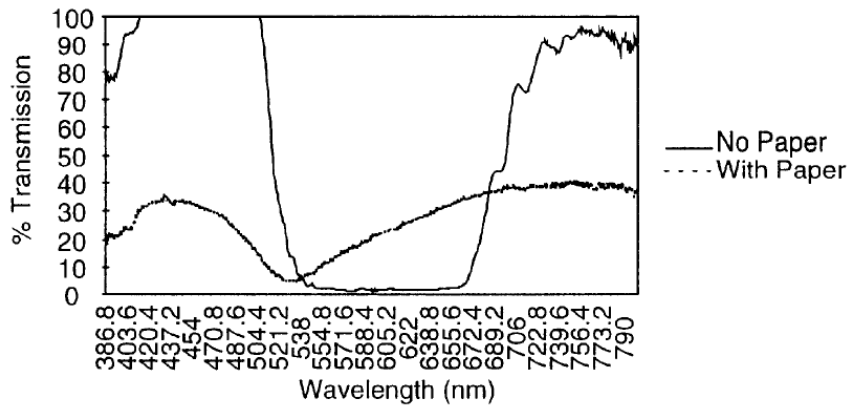


FIG. 32

89. Therefore, the Weth-Weber combination discloses claim 4.

**5. Dependent Claim 5**

- i. **Claim 5:** “*The method of 2 wherein said light filtering component further comprises at least one translucent composition.*”

90. As I explained above in Section X.B.2 [claim 2], the Weth-Weber combination discloses “[t]he method of claim 2.” As I discussed above in Section X.B.4 [claim 4], Weber further discloses “*said light filtering component further comprises at least one translucent composition*” for the same reasons given in Section X.B.4 [claim 4]. Therefore, the Weth-Weber combination renders claim 5 obvious.

**6. Dependent Claim 7**

- i. **Claim [7]:** “*The method of claim 6, said method further comprising providing at least one light filtering component in conjunction with said at least one light source; and causing said at least one light filtering component to transmit therapeutically effective optical radiation.*”

91. As I explained above in Section X.A.2 [claim 6], Weth discloses “[t]he method of claim 6.” As I discussed above in Section X.B.2 [claim 2], the Weth-Weber combination further renders obvious “*said method further comprising providing at least one light filtering component in conjunction with said at least one light source; and causing said at least one light filtering component to*



*transmit therapeutically effective optical radiation.*” Therefore, the Weth-Weber combination renders claim 7 obvious.

**7. Dependent Claim 8**

- i. **Claim 8:** “*The method of claim 7 wherein said method further comprises providing at least one transparent composition in conjunction with said at least one light filtering component.*”

92. As I explained above in Section X.B.6 [claim 7], the Weth-Weber combination renders obvious “[t]he method of claim 7.” As I discussed in Section X.B.3 [claim 3], the Weth-Weber combination further renders obvious “*wherein said method further comprises providing at least one transparent composition in conjunction with said at least one light filtering component.*” Therefore, the Weth-Weber combination renders claim 8 obvious.

**8. Dependent Claim 9**

- i. **Claim 9:** “*The method of claim 7 wherein said method further comprises providing at least one translucent composition in conjunction with said at least one light filtering component.*”

93. As I explained above in Section X.B.6 [claim 7], the Weth-Weber combination renders obvious “[t]he method of claim 7.” As I discussed in Section X.B.4 [claim 4], Weth-Weber further renders obvious “*wherein said method further comprises providing at least one translucent composition in conjunction*

*with said at least one light filtering component.”* Therefore, the Weth-Weber combination renders claim 9 obvious.

## **XI. CONCLUSION**

94. Based on the foregoing, claims 1 and 6 of the '140 patent are anticipated by prior art and claims 2-5 and 7-9 of the '140 patent recite subject matter that would have been obvious to a person of ordinary skill at the relevant times.

## **XII. AVAILABILITY FOR CROSS-EXAMINATION**

95. In signing this declaration, I recognize that this declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

## **XIII. RIGHT TO SUPPLEMENT**

96. I reserve the right to supplement my opinions in the future to respond to any arguments that the Patent Owner raises and to take into account new information as it becomes available to me.

**XIV. ACKNOWLEDGMENT**

97. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the full knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States code.

Dated: December 1, 2022



Dr. H. Craig Heller

Declaration of Dr. Craig Heller  
In Support of Petition for *Inter Partes* Review  
of U.S. Patent No. 7,678,140

**TABLE OF MATERIALS CONSIDERED**

Exhibit Number	Description
1001	U.S. Patent No. 7,678,140
1002	File History of U.S. Patent No. 7,678,140
1003	Encyclopædia Britannica, The visible spectrum (online). Available at <a href="https://www.britannica.com/science/color/The-visible-spectrum">https://www.britannica.com/science/color/The-visible-spectrum</a> . Visited November 21, 2022.
1004	German Patent No. 29618670U1 (“Weth”) (certified translation attached “Energy-saving lamp for medical therapies”)
1006	Grossweiner et al., <i>The Science of Phototherapy: An Introduction</i> . Springer, First Edition (2005)
1007	Choukroun and Geoffroy, <i>Light Therapy in Mood Disorders: A Brief History with Physiological Insights</i> , Chronobiol Med., 1(1):3-8 (2019)
1008	Czeisler et al., <i>Entrainment of Human Circadian Rhythms by Light-Dark Cycles: A Reassessment</i> , Photochemistry and Photobiology, 34, 239 (1981).
1009	Britannica, “The electromagnetic spectrum.” Available at <a href="https://www.britannica.com/science/electromagnetic-spectrum#/media/1/183297/106806">https://www.britannica.com/science/electromagnetic-spectrum#/media/1/183297/106806</a> . Visited November 21, 2022.
1010	Lewy et al., <i>Light suppresses melatonin secretion in humans</i> , Science, 12;210 (4475):1267-69 (1980) (“Lewy”)
1011	Czeisler et al., <i>Bright Light Resets the Human Circadian Pacemaker Independent of the Timing of the Sleep-Wake Cycle</i> , Science, 233(4764):667-671 (1986)

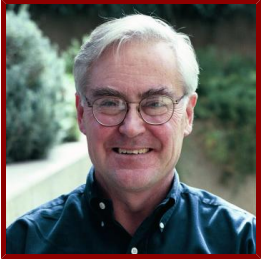
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Exhibit Number	Description
1012	Canada Patent No. 2209694
1013	Wirz-Justice et al., <i>Light treatment of seasonal affective disorder in Switzerland</i> , Acta Psychiatrica Scandinavica, 74:193-204 (1986) (“Wirz-Justice”)
1014	Ennever, <i>Blue Light, Green Light, White Light, More Light: Treatment of Neonatal Jaundice</i> , Clinics in Perinatology, 17(2): 467-481 (1990)
1015	Lee et al., <i>Spectral properties of phototherapy for seasonal affective disorder: a meta-analysis</i> , Acta Psychiatrica Scandinavica, 96: 117-121 (1997)
1016	Shanahan et al., <i>Resetting the Melatonin Rhythm with light in Humans</i> , Journal of Biological Rhythms, 12(6): 556-567 (1997)
1017	Britannica, “retina.” Available at <a href="https://www.britannica.com/science/retina">https://www.britannica.com/science/retina</a> . Visited November 21, 2022.
1018	U.S. Patent No. 5,047,006
1019	U.S. Patent No. 5,849,027
1020	Provisional Application No. 60/228,493
1021	Provisional Application No. 60/203,308
1022	U.S. Patent No. 6,531,230 (“Weber”)
1023	Morita et al., <i>Inhibitory Effect of Light of Different Wavelengths on the Fall of Core Temperature during the Nighttime</i> , Japanese Journal of Physiology, 45: 667-671 (1995)

Declaration of Dr. Craig Heller  
In Support of Petition for *Inter Partes* Review  
of U.S. Patent No. 7,678,140

Exhibit Number	Description
1024	Declaration of Dr. Sylvia Hall-Ellis
1026	Aschoff et al., <i>Circadian rhythms in men under as influenced by light-dark cycles of various periods</i> , Pflugers Arch. 306:58-70 (1969)
1027	Campbell et al., <i>Light treatment for sleep disorders: consensus report. I. Chronology of seminal studies in humans</i> , Review J. Biol. Rhythms., 10(2):105-9 (1995)
1028	Provencio et al., <i>A Novel Human Opsin in the Inner Retina</i> , The Journal of Neuroscience 20(2): 600-605 (2000)
1029	RESERVED
1030	World Health Organization, “Lasers and Optical Radiation” (1982)
1031	International Commission on Non-Ionizing Radiation Protection, <i>Guidelines on Limits to Exposure to Broad-Band Incoherent Optical Radiation (0.38 to 3 <math>\mu</math>M)</i> , Health Physics: 73(3):539-554 (1997)
1032	Levine, “Chapter 1: An Introduction to Neuroendocrine Systems,” Handbook of Neuroendocrinology, Fink et al. Eds. Academic Press, 3-19 (2012)
1033	Cleveland Clinic, “Dopamine.” Available at <a href="https://my.clevelandclinic.org/health/articles/22581-dopamine">https://my.clevelandclinic.org/health/articles/22581-dopamine</a> . Visited November 28, 2022.
1034	Watson et al., <i>Neuropharmacology of Sleep and Wakefulness</i> , Sleep Med. Clin., 5:513-528 (2010)

# APPENDIX A



## H. Craig Heller

Lorry I. Lokey/Business Wire Professor  
Biology

### CONTACT INFORMATION

- **Alternate Contact**

May Chin - Administrative Assistant

**Email** maychin@stanford.edu

**Tel** 650 725 1827

### Bio

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### ACADEMIC APPOINTMENTS

- Professor, Biology
- Member, Bio-X
- Member, Cardiovascular Institute
- Member, Wu Tsai Human Performance Alliance
- Member, Wu Tsai Neurosciences Institute

### ADMINISTRATIVE APPOINTMENTS

- Associate Dean, Dean of Research, (1994-1997)
- Chair, Biological Sciences, (1997-2001)
- Chair, Wallenberg Global Learning Network Steering Committee, (2001- present)
- Chair, Curriculum Committee, Human Biology, (2006- present)
- Executive Committee, Human Biology, (2006- present)

### HONORS AND AWARDS

- Walter J. Gores Award for Excellence in Teaching, University (1977)
- Bing Professor of Human Biology, Human Biology (1987-1993)
- Lorry I. Lokey Business Wire Professor, Biology/Human Biology (1993-present)
- William and Lynde Steere University Fellow, University (2004-present)
- Kenneth M. Cuthertson Award for Exceptional Contributions to Stanford University, University (2010)

### PROFESSIONAL EDUCATION

- PhD, Yale University , Biology (1970)

### LINKS

- Website: <https://dsresearch.stanford.edu>



## Research & Scholarship

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### CURRENT RESEARCH AND SCHOLARLY INTERESTS

Neurobiology of sleep, circadian rhythms, regulation of body temperature, mammalian hibernation, and human exercise physiology. We study neural mechanisms controlling arousal states and arousal state transitions, the function of sleep, and the neural mechanisms of circadian rhythms. Research on human exercise physiology focuses on the effects of body temperature on physical conditioning and performance. The focus on Down syndrome is exploring the mechanism whereby reduction of GABA activity restores learning and memory in DS mice and also in mouse models of Alzheimer's disease.

## Teaching

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### COURSES

#### 2022-23

- The Human Organism: HUMBIO 4A (Spr)
- The Neurobiology of Sleep: BIO 149, BIO 249, HUMBIO 161, PSYC 149, PSYC 261 (Win)

#### 2021-22

- The Human Organism: HUMBIO 4A (Spr)
- The Neurobiology of Sleep: BIO 149 (Win)

#### 2020-21

- The Human Organism: HUMBIO 4A (Spr)

#### 2019-20

- Physiology: BIO 84 (Win)
- The Human Organism: HUMBIO 4A (Spr)
- The Neurobiology of Sleep: BIO 149, BIO 249, HUMBIO 161 (Spr)

### STANFORD ADVISEES

#### Undergraduate Major Advisor

Ashlyn Callan, Caroline Dunn

### GRADUATE AND FELLOWSHIP PROGRAM AFFILIATIONS

- Biology (School of Humanities and Sciences) (Phd Program)
- Neurosciences (Phd Program)

## Publications

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### PUBLICATIONS

- **Reversible Suppression of Fear Memory Recall by Transient Circadian Arrhythmia** *FRONTIERS IN INTEGRATIVE NEUROSCIENCE*  
Steiger, A., Farfan, J., Fisher, N., Heller, H., Fernandez, F., Ruby, N. F.  
2022; 16: 900620
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