

***A Disposable Light Source for
Topical Photodynamic Therapy***

***Licensing
&
Joint Venture
Opportunities***



Spectra Systems
CORPORATION



Background

Photodynamic therapy (PDT) uses site-specific drugs that are activated by targeted light to diagnose and treat cancer and other proliferative dermatological conditions such as actinic keratosis, acne, and psoriasis. In addition, PDT has also had success in cosmetic applications such as hair removal and the rejuvenation of sun-damaged skin.

Spectra's product is a disposable optical source for dermatological use with a variety of photosensitizers such as Photofrin®, ALA, Foscan®, Levulan, and others. Spectra Systems has a proprietary and patented photodynamic drug activation technology that uses chemical light generation (chemiluminescence) in the form of a patch to create the world's only disposable light source for photomedicine. This technology opens up the commercial possibility for a new large-scale consumables opportunity that complements sales of photosensitizer compounds.

Market Opportunity

Spectra Systems' light source products are targeted for the dermatology sector of PDT. Dermatology is the largest sector in PDT and includes psoriasis, actinic keratosis, acne, melanomas, and hair removal. Psoriasis is the most prevalent autoimmune disease in the United States with approximately 2.5% of the world population, or about 125 million people, suffering from this disease. Total direct and indirect healthcare costs for treating this disease exceed \$11 billion annually. In the United States, nearly 7 million people have psoriasis, and 150,000 new cases will be reported each year. Typical treatment with psoralen and UVA involves an estimated 25 physician visits, costing approximately \$1,500, and is accompanied by drugs costing \$200.

Actinic keratosis is the most common sun-exposure-related condition, and an estimated 60% of individuals older than 40 who are predisposed have at least one actinic keratosis or solar keratosis incident. Actinic keratosis lesions are diagnosed in 14% of all visits to the dermatologist, following only acne and dermatitis in frequency. In the northern hemisphere populations, 15-25% of adults have at least one lesion, while in Australia, 40%-60% have one.

Acne is one of the conditions most often leading to treatment by a dermatologist. Seventeen million Americans (approximately 85% of the population between the ages of



Spectra Systems Technology for Photodynamic Therapy

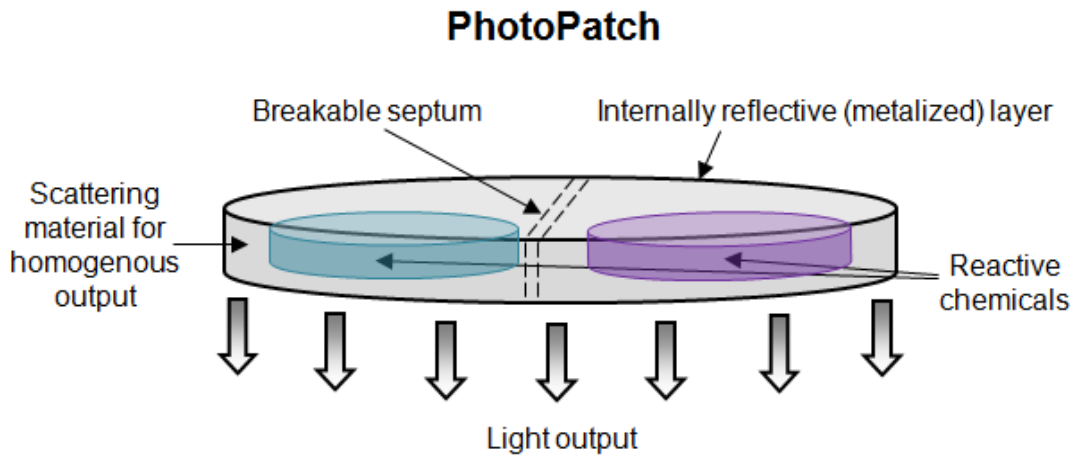
12 and 24) have acne, making it the most common skin disease. According to the American Dermatological Association, 20% of all adults have active acne, and 20 million Americans have acne severely enough to cause scarring.

The leading source of revenue from disposable light patches is expected to come from the treatment of acne vulgaris, actinic keratosis, and psoriasis, with acne accounting for at least 60% of that. Additional markets are available in the cosmetics sector for both hair removal and the rejuvenation of sun-aged skin. Estimated gross margins are expected to be in excess of 65%, leading to significant income opportunities beyond additional sales and marketing expenses. Spectra estimates that the market potential for a disposable light source at the average cost of \$0.50/treatment for an affected area of 15 cm² represents a potential market opportunity in excess of \$2 billion.

Chemiluminescent Drug Activation Technology: PhotoPatch

With the large number of dermatology-oriented photodynamic therapy applications and people's increasingly busy schedules, home-based therapy is an attractive option for patients. With work loss accounting for nearly \$4 billion dollars annually for psoriasis patients alone, the ability to treat the condition at home during sleep or non-work hours presents a significant incentive for disposable, home-use light sources. In addition, for obvious reasons such as cost and safety issues, lasers and other hardware sources such as LEDs and lamps are unlikely to make the transition to home-use technologies. Finally, the ability to use a disposable, patch-like light source while in any position and during sleep hours provides a very significant advantage over other light sources regardless of their cost or safety.

Spectra Systems has developed a technology for this potentially large consumables market using its chemiluminescence-based product PhotoPatch. In the same way that light sticks are familiar safety products, the use of chemiluminescent patches will allow for treatment using a chemically activated light source. Once a membrane is ruptured, reagent chemicals mix, and light of a specific wavelength is emitted for a defined period of time to activate a PDT drug on the skin's surface.



PhotoPatch Characteristics

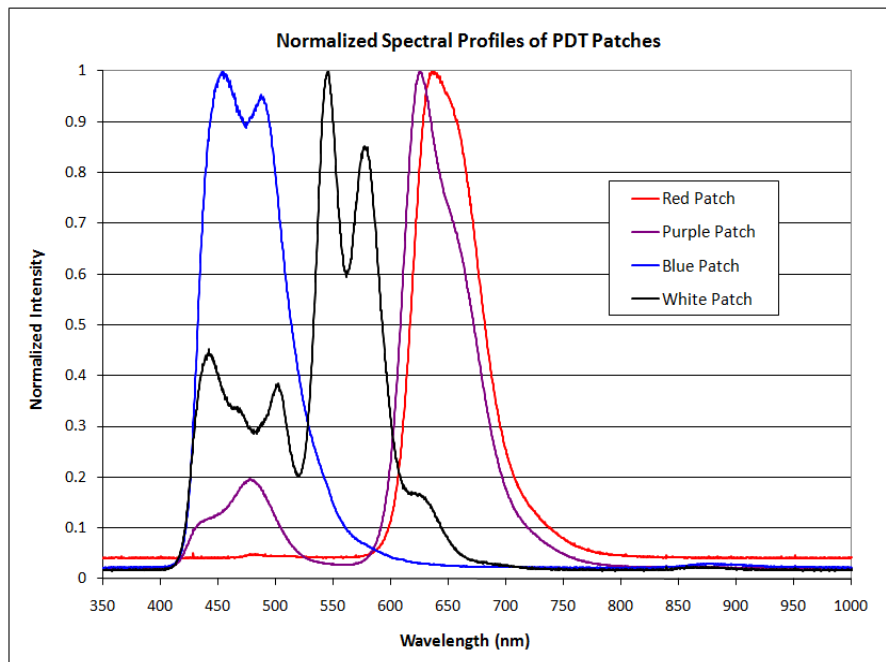
The photos and data below show a PhotoPatch prototype manufactured by OmniGlow (www.omniglow.com), a market leader and manufacturer of chemiluminescent light products. The emission lines that we have successfully produced provide significant fluencies at wavelengths that can be used to effectively excite several key drugs on the market today, including ALA and Levulan.



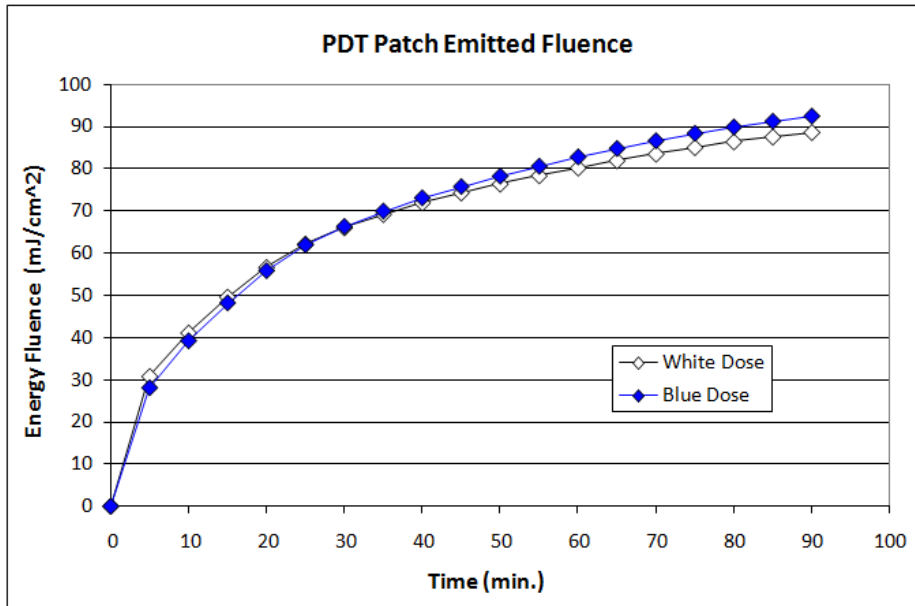
PhotoPatch before activation



PhotoPatch, post-activation



Various PhotoPatch emission spectra for use with different photosensitizers



The integrated PhotoPatch fluence dose with time



Status of PhotoPatch Efficacy Studies

Under a since-expired licensing agreement, Dr. Brian Zelickson, a highly respected, Mayo Clinic-trained dermatologist, conducted clinical studies using PhotoPatch for the treatment of acne with the well-established photosensitizer ALA for over two years. His studies, using a half-face protocol, showed positive and promising results. The photos below illustrate the efficacy observed by Dr. Zelickson using ALA and Photopatch to treat a patient with acne vulgaris.





The following article in *Dermatology Times* summarizes Dr. Zelickson's work with PhotoPatch.

Disposable light procedure promising treatment

Can inexpensive, 'toss-away' system be adapted for at-home use?

Publish date: Nov 1, 2004

By: Fred Wilson



Dallas — A chemiluminescent mask for photodynamic therapy (PDT) with 5-aminolevulinic acid (ALA) may have efficacy in mild-to-moderate acne, according to Brian Zelickson, M.D.

"This inexpensive, disposable light source could potentially be prescribed so patients could use it at home," Dr. Zelickson says. "The mask is a geared-up 'glow stick,' like the Halloween toy. Two chemicals mixed together become activated and produce light of many different wavelengths. We are initially testing the blue to blue-green wavelength range. Since fluences are defined by the mask, we don't have to set them, and that's the beauty of the technique," Dr. Zelickson says.

OmniGlow, the manufacturer of the light device, makes similar chemiluminescent sticks for the military, he adds.

Test subjects Dr. Zelickson's trial patients apply ALA for one to two hours, then wear the proprietary light mask for another hour.

"When we get the energy up higher, we will reduce the time the patient wears the mask," he explains.

Dr. Zelickson, who has used a similar treatment protocol and light device to treat actinic keratoses, presented the results of his pilot study with acne at the annual meeting of the American Society for Laser Medicine and Surgery (ASLMS) here.

Non-conventional treatments According to Dr. Zelickson, conventional treatment of acne includes topical and oral medications (primarily antibiotics), topical retinoids and oral hormones.

"Recently a blue light source and an infrared laser have been cleared by the FDA, but these are still not conventional treatments," he says. "Since we are seeing more and more patients with resistance to antibiotics and who don't want hormonal therapy or vitamin A derivatives such as isotretinoin, these new modalities are becoming popular."



How it works In ALA PDT for acne, topical ALA enters the pilosebaceous glands and is converted to photosensitive protoporphyrin IX (PpIX), according to Dr. Zelickson.

"We shine light to activate the PpIX, which injures the bacteria and pilosebaceous glands," he explains. "Studies over the past several years have shown good efficacy with this treatment model. We had a couple early patients with moderate to severe cystic lesions and they did quite well. My feeling is that treatment with our current light source might be better for mild-to-moderate inflammatory acne."

Although Dr. Zelickson currently gives isotretinoin to patients with a lot of cystic nodules, it may not be effective, he adds.

So far Dr. Zelickson has used the novel technique on seven or eight patients.

"Although we are still establishing treatment parameters, we currently give weekly treatments for four weeks," he tells **Dermatology Times**. "Retreatments are identical to the initial treatment — ALA for one hour, the mask for one hour, then go home. Some patients have seen improvement after the first treatment, but sometimes it takes two to three treatments."

One or two patients had exacerbation of acne within one week after the first treatment, similar to that seen with isotretinoin during the first few months, according to Dr. Zelickson.

"We let the exacerbation burn out, do another ALA PDT treatment, and it clears up," he says. "We have a strict study protocol, so we could not use any ancillary therapy."

Two of the trial patients have been followed for six months without recurrence of acne lesions, Dr. Zelickson says.

"There is some durability, but I suspect a lot of patients will need maintenance therapy. I don't see this as a cure of acne. In our early studies we saw 30 to 70 percent clearance." Although most trial patients have had Fitzpatrick skin types II to III, Dr. Zelickson has noted no difficulties in patients with darker skin. So far he has not tried the technique in combination with other treatments.

Refining parameters Dr. Zelickson plans to continue refining parameters such as shortening the light exposure time and generating more intense energy of the appropriate wavelength.



Intellectual Property and Development Pipeline

Spectra's use of chemical light for photodynamic therapy applications is a patented technology with several possibilities beyond the current PhotoPatch embodiment described in this document (US Pat. No. 5,845,640: "Chemiluminescent sources for photodynamic therapy and photomedicine"). In addition to the self-contained patch of chemical light for PDT, Spectra has been developing new approaches for treating larger areas of the skin surface with varying topography and shape. These new patent-pending approaches will allow the user to easily shape the light-illuminating areas for use anywhere on the body. In addition to the IP on disposable light sources, which is the critical technology, Spectra Systems has additional patents on solid-state-laser-based sources for higher intensity and fluence requirements. Both the chemical-light and solid-state-laser-source patents are included at the back of this document.

Licensing and Joint Venture Opportunities

Spectra Systems is seeking to work with a partner who will co-fund the new embodiments of the basic chemical-light-for-PDT technology as well as provide the necessary resources to advance the product to market. This can be accomplished either through a royalty-based licensing and R&D contract to complete the new advances, or through the financing of a joint venture. Spectra Systems is open to this joint venture approach with either another company or an equity financing source, preferably with experience in the medical device or biotechnology fields.

Interested parties should contact Dr. Nabil M. Lawandy, Spectra Systems CEO, directly.

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