

THE PATENT UTILITY REQUIREMENT AND ITS IMPACT ON ALTERNATIVE MEDICAL TREATMENTS FOR LYME DISEASE

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Abstract: Alternative medicine has made its way to the forefront of medical innovation, changing the way both doctors and patients approach complex health issues. Patenting medical inventions promotes advancement by increasing the exchange of vital information. This crucial benefit to society is particularly important for patients suffering from chronic illnesses who are dissatisfied with conventional medicine. Though the patent system requires that patented inventions are “useful,” there is no guarantee that the product is effective or even safe to use. The medical field must grapple with this trade-off between the benefit of new treatments made easily available to people who desperately need relief, and the potential that expensive, ineffective, and unsafe products are placed in the market. This issue is brought to light for patients with Lyme Disease who have turned to the patented treatment, UVLrx. UVLrx is a therapeutic light system that delivers various wavelengths of ultraviolet light to a patient’s bloodstream, with the intent of killing bacteria and diseased cells. Some argue that this futuristic treatment has the potential to change a person’s life, while others contend that it is an expensive and risky waste of time.

I. INTRODUCTION

Patent protection is crucial for companies developing innovative medical treatments.¹ The patent system allows companies to recoup high costs associated with medical research and development (R&D) through an exclusive right to market the patented product during the patent term of twenty years.² Though patentability allows the public to gain the advantage of access to advanced medical treatments, there is no guarantee that a patented invention is safe or that it actually functions as claimed.³ As a policy matter, however, it is important to provide a patent as incentive to encourage

¹ See Anatole Krattiger, *Promoting Access to Medical Innovation*, WIPO MAGAZINE (June 2013), http://www.wipo.int/wipo_magazine/en/2013/05/article_0002.html, noting that high medical R&D costs are a result of rigorous regulatory oversight, liability issues, and a high failure rate.

² 35 U. S. C § 154 (2013).

³ See Sean B. Seymore, *Making Patents Useful*, 98 MINN. L. REV. 1046, 1047 (2014).

companies to develop medical treatments to combat public health issues.⁴ Today, the development of alternative treatments is at the forefront of medical innovation.⁵ Alternative medical treatments are those that are generally not available from conventional doctors, such as hyperbaric oxygen therapy, plasmapheresis, and stem cell therapy.⁶

Historically, state medical acts have inhibited the integration of alternative medicine into modern healthcare.⁷ However, due to patients' recent dissatisfaction with conventional medicine, modern medicine is shifting away from traditional medical treatments and towards alternative therapies.⁸ Evidenced by their funding of the National Center for Complementary and Integrative Health ("NCCIH"), the United States government recognizes that researching alternative medical treatments is worthwhile.⁹

⁴ See Krattiger, *supra* note 1.

⁵ See Jennie Rothenberg Gritz, *The Evolution of Alternative Medicine The Atlantic* (2015), <https://www.theatlantic.com/health/archive/2015/06/the-evolution-of-alternative-medicine/396458/>.

⁶ See ProHealth, Inc., *Alternative and Complementary Treatments for Lyme Disease*, <http://www.prohealth.com/lyme/lyme-disease-alternative-treatments.cfm> for a discussion of oxygen therapy (breathing pure oxygen), plasmapheresis (returning blood plasma back to the body after extracting and treating the blood), and stem cell therapy.

⁷ See *People v. Amber*, 349 N.Y.S.2d 604, 612 (N.Y. Sup. Ct. 1973) (finding that acupuncture fell under the state's medical statute designed to protect patients against unskilled and unlicensed practitioners); Michael H. Cohen, *Holistic Health Care: Including Alternative and Complementary Medicine in Insurance and Regulatory Schemes*, 28 ARIZ.L.REV. 83, 86 (1996).

⁸ See Weidong Pan & Hua Zhou, *Integrative Medicine: A Paradigm Shift in Clinical Practice*, INTERNATIONAL JOURNAL OF INTEGRATIVE MEDICINE, 1–6 (2013); Kristina L. McFadden et al., *Attitudes Towards Complementary and Alternative Medicine Influence Its Use*, 6 EXPLORE: THE JOURNAL OF SCIENCE AND HEALING, 380–88 (2010).

⁹ See *NCCIH's Facts-at-a-Glance and Mission*, NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH (2017), <https://nccih.nih.gov/about/atagance> for NCCIH's mission "to define, through rigorous scientific investigation, the usefulness and safety of complementary and integrative health interventions and their roles in improving health and health care."

NCCIH funds and conducts research on nondrug approaches to healthcare with a primary focus on research related to chronic pain.¹⁰

Lyme disease (“Lyme”) is a public health issue where patients are suffering from chronic pain, dissatisfied with traditional treatments, and seeking alternative medicine.¹¹ Early symptoms of Lyme include fatigue, chills, fever, headache, muscle and joint aches, and swollen lymph nodes.¹² Absent a bull’s-eye-rash, early diagnosis of Lyme is difficult.¹³ Though an estimated 30,000 Americans are diagnosed each year, the tests are 56% sensitive, assuring that many patients will go undiagnosed.¹⁴ Patients with a late diagnosis may develop Chronic Lyme Disease (“CLD”), which can cause serious symptoms such as arthritis, neurological, or cardiac problems.¹⁵

Antibiotics are the primary treatment of Lyme but prolonged courses of antibiotics do not necessarily benefit CLD patients.¹⁶ Frustrated with the mainstream medical community for difficulties in obtaining a diagnosis and effective treatment, some patients turn to alternative treatments.¹⁷ However, insurance companies generally do not

¹⁰ See *NCCIH's Funding Priorities and Research Focus*, NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH (2017), <https://nccih.nih.gov/about/researchfocus>.

¹¹ See Joseph B. Franklin, Note, *Antibiotic Maximalism: Legislative Assaults on the Evidence-Based Treatment of Lyme Disease*, 90 WASH. U. L. REV. 199, 200 (2012).

¹² *Lyme Disease*, CENTERS FOR DISEASE CONTROL AND PREVENTION (2016), https://www.cdc.gov/lyme/signs_symptoms/.

¹³ See Margaret Dayhoff-Brannigan, *Lyme Disease: The First Sign is Not Always a Rash*, National Center For Health Research (2017), <http://www.center4research.org/lyme-disease-first-sign-not-always-rash/> for information on a bull’s-eye-rash, (providing conclusive evidence of Lyme but less than 50% of people recall having the rash).

¹⁴ See Raphael B. Stricker & Lorraine Johnson, *Lets Tackle the Testing*, 335 THEBMJ 1008, 1008 (2007) (finding that tests “miss 88 of every 200 patients with Lyme. By comparison, AIDS tests miss only one of every 200 AIDS cases.”); *Lyme Disease*, CENTERS FOR DISEASE CONTROL AND PREVENTION (2015), <https://www.cdc.gov/lyme/stats/humancases.html>.

¹⁵ *Lyme Disease*, CENTERS FOR DISEASE CONTROL AND PREVENTION (2017), <https://www.cdc.gov/lyme/postlds/index.html>

¹⁶ See *id.*

¹⁷ See Paul M. Lantos, *Chronic Lyme Disease*, 29 INFECTIOUS DISEASE CLINICS OF NORTH AMERICA 325, 325–40 (2015); See *Lyme Quick Facts*, THE INTERNATIONAL LYME AND

provide coverage for alternative treatments for Lyme.¹⁸ As a result, CLD patients spend, on average, \$53,000 per year on out-of-pocket expenses.¹⁹ Thus, CLD highlights the need for R&D in innovative treatments to reduce the burden of the disease and concomitant costs.²⁰ Accordingly, patent protection is imperative for alternative medical treatments for CLD.²¹

Though patents are required to be “useful,” it is not required that the invention is safe or functions as claimed.²² Accordingly, patented alternative medical treatments may be ineffective or harmful to patients, posing a serious risk to people who are already in poor health. UVLrx Therapeutics’ UVLrx Treatment System™ (“UVLrx”), U.S. Patent No. 9,814,899, is an example of an alternative treatment for Lyme disease that has received patent protection.²³ Though patent protection affords exclusivity and encourages innovation, it also permits inventors to charge more for the treatments they create.²⁴ As a result, it may cost patients more to access UVLrx in comparison to conventional treatments, subjecting them to a heavy economic burden.²⁵

ASSOCIATED DISEASES SOCIETY (2017), <http://www.ilads.org/campaign/lyme-campaign-quickfacts.php> (finding that the average Lyme patient sees five doctors over two years before being diagnosed)

¹⁸ See *Fundraisers, Lyme Stats*, http://lymestats.org/assets/98_fundraisers.pdf (discovering over 23,000 crowd-funding campaigns for CLD patients since insurance does not cover treatment due to current IDSA/CDC guidelines, which claim that CLD does not exist.)

¹⁹ *Out-of-Pocket Expenses, Lyme Stats*, http://lymestats.org/assets/003_oop.pdf.

²⁰ See Johnson, *supra* note 14.

²¹ See Krattiger, *supra* note 1.

²² See Sean B. Seymore, *Making Patents Useful*, 98 MINN. L. REV. 1046, 1047 (2014).

²³ See U.S. Patent No. 9,814,899, (issued Nov. 14, 2017); Britt Marie Hermes, *UVLrx Therapy Lights Up Charlatans Dealing In Medical Devices*, FORBES (2016), <https://www.forbes.com/sites/brittmariehermes/2016/09/26/uvlrx-therapy-charlatans-medical-devices/#50ba03ab2c5d>.

²⁴ See Krattiger, *supra* note 1.

²⁵ See *id.*

II. THE PATENT UTILITY REQUIREMENT IN MEDICINE

A. United States Supreme Court Case Law on Patent Utility

To be patentable, an invention must be novel, useful, and non-obvious.²⁶ However, congress has not defined the usefulness requirement established in 35 U.S.C. § 101.²⁷ In 1817, in *Bedford v. Hunt*, Justice Story enumerated a *de minimis* interpretation of “useful,” providing that an invention is patentable if it has *some* beneficial use to the public and does not offend the morals, health, or good order of society.²⁸ This low-utility threshold is compatible with the patent system’s broader policy goal of encouraging companies to disclose their inventions to promote innovation and public welfare.²⁹

Justice Story’s interpretation prevailed into the twentieth century until, in 1966, the United States Supreme Court decided *Brenner v. Manson*.³⁰ *Manson*’s modern utility requirement abandoned the *de minimis* standard to adapt to the drastic increase in patent applications for pharmaceutical inventions.³¹ In *Manson*, the Court found that a chemical compound whose “sole utility” consisted of its potential as an object for use in future testing was not patentable.³² *Manson* requires that an invention have a specific benefit in its current form.³³ In other words, an invention is not “useful” unless it operates to produce the intended result.³⁴ The subjective test for operability is whether a person having ordinary skill in the art (“PHOSITA”) has reason to doubt the applicant’s

²⁶ 35 U.S.C. §§ 101, 102, 103 (2017).

²⁷ *Making Patents Useful*, *supra* note 3.

²⁸ *See* *Bedford v. Hunt*, 3 F. Cas. 37, 37 (C.C.D. Mass. 1817).

²⁹ *See* *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 264 (1979).

³⁰ *See* *Brenner v. Manson*, 383 U.S. 519, 535 (1966).

³¹ *Id.*

³² *See id.*

³³ *See id.*

³⁴ *See id.*

assertions.³⁵ This modern utility requirement has become a gatekeeper that allows the patent office and courts to subjectively decide when an invention can be patented.³⁶

For example in 2005, in *In re Fisher*, the United States Court of Appeals for the Federal Circuit held that a patent for five genes that encoded protein and protein fragments in maize plants lacked utility because it was considered a “research intermediate,” having only a generic use to assist research.³⁷ The court reasoned that use in research is not sufficient utility because an invention must have an immediate benefit, not one that is made evident in the future after research is performed.³⁸ In his dissent, Judge Rader argued that the patent had utility in a research context, categorizing the invention as a “research tool” instead of a “research intermediate.”³⁹ Though not binding on the court, Judge Rader relied on §2107.01 of the Manual of Patent Examining Procedure (MPEP) to argue that research tools have a clear, specific, and unquestionable utility so the patent satisfied 35 U.S.C. § 101.⁴⁰

B. Proving Utility Per the Manual of Patent Examining Procedure

The MPEP is a guideline for patent examiners to understand the law.⁴¹ MPEP §2107 states that, if it is apparent that the invention has a “well-established” utility then the patent will not be rejected on the basis of lack of utility.⁴² An invention’s utility is well-established if: (1) a PHOSITA would appreciate why the invention is useful based on the characteristics of the invention, and (2) the utility is specific, substantial, and

³⁵ See Sean B. Seymore, *Patently Impossible*, 64 VAND. L. REV. 1489, 1493 (2011).

³⁶ See *id.*

³⁷ *In re Fisher*, 421 F.3d 1365, 1379 (Fed. Cir. 2005).

³⁸ See *id.*

³⁹ See *id.*

⁴⁰ See *id.*

⁴¹ See *id.*

⁴² MPEP §2107.02 Procedural Considerations Related to Rejections for Lack of Utility [R-5].

credible.⁴³ Since general utility will not suffice, an applicant must claim specific utility in their patent application.⁴⁴ Nonetheless, courts have demonstrated an exception for proving utility for pharmacological or therapeutic inventions.⁴⁵ For example, courts have found that when there is an “immediate benefit to the public” in these “well-established” areas, the utility requirement is satisfied without further proof.⁴⁶ Conversely, when the technology is nascent or the area is less established, an applicant must identify specific utility.⁴⁷ This specific utility is presumed to be true unless it is more likely than not that a PHOSITA would question the truth of the asserted utility.⁴⁸

III. A PATENTED ALTERNATIVE TREATMENT FOR LYME: THE UVLRx TREATMENT SYSTEM

A. Description of the UVLRx Treatment System

UVLRx Therapeutics’ UVLRx Treatment SystemTM is one alternative treatment for Lyme that has received patent protection.⁴⁹ UVLRx is a therapeutic light system that delivers various wavelengths of ultraviolet (“UV”) light to a patient’s bloodstream, with the intent of killing bacteria and diseased cells.⁵⁰ The UV blood irradiation (“UBI”) is administered in sixty minutes through an intravenous catheter.⁵¹ Although UVLRx already has a patent, clinical studies for investigation into its use to treat Lyme are currently in

⁴³ *Id.*

⁴⁴ *See In re Fisher*, 421 F.3d at 1379.

⁴⁵ *See e.g.*, *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980) (finding that the identification of a pharmaceutical compound was an immediate benefit to the public).

⁴⁶ *See id.*

⁴⁷ *See* MPEP § 2107.02.

⁴⁸ *See id.*

⁴⁹ *See* U.S. Patent No. 9,814,899, (issued Nov. 14, 2017).

⁵⁰ *See* UVLRx Therapeutics, *What is the UVLRx System*, ULTRAVIOLET LIGHT THERAPY <http://uvlr.com/what-is-the-uvlr-system.html>.

⁵¹ *See* UVLRx Therapeutics, *Medical FAQ*, ULTRAVIOLET LIGHT THERAPY. <http://uvlr.com/physicians/faqs.html>.

progress.⁵² Dubbed a “natural antibiotic,” UBI is an attractive option for CLD patients for whom antibiotic treatment is not working.⁵³

B. The UVLrx Treatment System Patent

The UVLrx patent is novel and non-obvious because the device involves irradiation of blood *in vivo*, whereas similar past devices were extracorporeal—they extracted blood from the body before irradiating it.⁵⁴ Moreover, the patent is the first to combine UV light with red and green wavelengths.⁵⁵ Nevertheless, the utility of the ULVrx patent is unclear.⁵⁶

The UVLrx patent does not put forth any specific claims about what the device actually does.⁵⁷ In fact, UVLrx Therapeutics’ managing director, Paul LeMert, confirmed that due to the strict regulatory process, the company is not making any specific claims regarding the device’s function.⁵⁸ To satisfy the utility requirement, the patent relies on the fact that UV irradiation of blood has existed for a long time.⁵⁹ The patent notes that in the early 1900s, blood was irradiated with light to enhance a person’s immune response and eliminate the amount of bacteria present in the body.⁶⁰ Similarly, the UVLrx Therapeutics website cites the 1903 Nobel Prize in Physiology or Medicine where the

⁵² UVLrx Therapeutics, *Summary of Clinical Data*, ULTRAVIOLET LIGHT THERAPY <http://uvlrx.com/physicians/summary-of-clinical-data.html>.

⁵³ See Riordan Clinic, *Ultraviolet Blood Irradiation*, <https://riordanclinic.org/what-we-do/ultraviolet-blood-irradiation/>.

⁵⁴ See U.S. Patent No. 9,814,899, (issued Nov. 14, 2017).

⁵⁵ See *id.*; UVLrx Therapeutics, *Everything You Need to Know About IV Treatments*, uvlrx.com/everything-you-need-to-know-about-iv-treatments.html.

⁵⁶ See U.S. Patent No. 9,814,899, (issued Nov. 14, 2017).

⁵⁷ See *id.*

⁵⁸ Meghana Keshavan, *Bringing blood irradiation back en vogue: Startup uses UV phototherapy treat infections in the bloodstream*, MEDCITY NEWS (2017), <https://medcitynews.com/2015/02/uvlrx-feature/>.

⁵⁹ See U.S. Patent No. 9,814,899, (issued Nov. 14, 2017).

⁶⁰ *Id.*

Danish physician, Niels Finsen, used UV light to treat tuberculosis.⁶¹ According to the UVLrx patent, the development of antibiotics led to the demise of UVL to treat diseases.⁶² Nonetheless, the utility in the patent appears to be based on the fact that this technique was useful in the past.⁶³ As a result, the most specific claim that the patent makes is that light wavelengths can induce damage to specific cells and subsequently repair the resulting damage.⁶⁴

IV. SAFETY AND QUALITY IMPLICATIONS OF THE UVLrx TREATMENT SYSTEM AND OTHER PATENTED ALTERNATIVE TREATMENTS FOR LYME

As demonstrated in 1977 in *In re Sichert* and reiterated in 1994 in *Scott v. Finney*, The Federal Circuit has sustained that therapeutic utility sufficient under patent law does not coincide with FDA safety and efficacy requirements.⁶⁵ In fact, FDA approval is not required as a prerequisite for patenting pharmaceuticals and medical devices.⁶⁶ The MPEP reasons that this is because an invention becomes “useful” “well before it is ready to be administered to humans.”⁶⁷ If the extensive testing required for FDA approval were necessary to satisfy the patent utility requirement, associated costs would likely deter companies from pursuing new inventions.⁶⁸ Alternatively, if companies were to develop

⁶¹ See UVLrx Therapeutics, *Timeline*, ULTRAVIOLET LIGHT THERAPY (2017) <http://uvlrx.com/timeline.html>.

⁶² See U.S. Patent No. 9,814,899, (issued Nov. 14, 2017).

⁶³ See *id.*

⁶⁴ See *id.*

⁶⁵ See *Scott v. Finney*, 34 F.3d. 1058, 1063 (Fed. Cir. 1994) (finding that testing for safety and effectiveness of a patented prosthetic device is properly left to the FDA); *In re Sichert*, 566 F.2d 1154, 1160 (C.C.P.A. 1977) (rejecting the lack of safety as a challenge to the utility of a drug designed to treat stoppages in the lymph system).

⁶⁶ See *Finney*, 34 F.3d. at 106.

⁶⁷ MPEP §2107.01.

⁶⁸ See *id.*

inventions and perform the necessary testing despite the increased costs, the inventor would pass the costs along to the consumer in the form of increased prices.⁶⁹

The FDA has not yet approved UVLrx, but has authorized its use in approved clinical trials to collect safety and effectiveness data.⁷⁰ The FDA inspected UVLrx Therapeutics, Inc. to determine whether activities and procedures in their clinical study complied with the Code of Federal Regulations (CFR).⁷¹ On September 25, 2017, the FDA issued a warning letter stating that the company violated several sections of 21 C.F.R. §812.⁷² Namely, the company failed to obtain Institutional Review Board (“IRB”) approval for a clinical trial and failed to adequately monitor the UVLrx device.⁷³ IRB approval is crucial, and the lack thereof means that there are no assurances that subjects were given informed consent, which puts the rights and welfare of the subjects at risk.⁷⁴ Additionally, the IRB determines whether the device poses a “significant risk” or “non-significant risk.”⁷⁵ Despite the lack of IRB approval, UVLrx Therapeutics claims that the treatment system was deemed a non-significant risk in the United States.⁷⁶

⁶⁹ *See id.*

⁷⁰ *See* Center for Devices and Radiological Health, *Device Advice: Investigational Device Exemption (IDE)*, U.S. FOOD AND DRUG ADMINISTRATION, <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm>.

⁷¹ *See* Compliance Actions and Activities, *UVLRX Therapeutics Warning Letter 9/25/17*, U.S. FOOD AND DRUG ADMINISTRATION, www.fda.gov/iceci/enforcementactions/warningletters/2017/ucm580994.htm.

⁷² *Id.*

⁷³ *See id.* (stating that several UVLrx machines were sent to unapproved and unqualified investigators, putting subjects and data at risk); Office of the Commissioner, *Guidance for Institutional Review Boards and Clinical Investigators* U.S. FOOD AND DRUG ADMINISTRATION, <https://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm> (explaining that the IRB is an ethics committee that ensures protection of the rights and welfare of human subjects).

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *See* UVLrx Therapeutics, *Regulatory Information*, uvlrx.com/regulatory.html.

It is uncertain whether there is any proven benefit to UVLrx; although, it appears that there is no significant risk to using the machine.⁷⁷ According to Dr. Jeremy Kalslow, M.D., a practitioner of internal medicine, there are over 60 scientific and clinical papers on UBI that show a complete absence of harmful effects.⁷⁸ Dr. Kalslow enumerates several benefits of the treatment to combat viral and bacterial infections, inflammatory conditions, and circulatory conditions.⁷⁹ Conversely, according to Dr. Edward Ernst, M.D., a leading authority on alternative medicine, there is no proof that UBI is effective, and “[t]he claims made for the therapy that it deactivates pathogens, stimulates the immune system or increases oxygen saturation are pure fantasy.”⁸⁰ Despite these conflicting reports, CLD patients have reported noticeable improvements from the treatment.⁸¹

Though there are no official studies available regarding the use of UVLrx specifically for CLD, patients have shared accounts of their experiences online and are generally satisfied.⁸² For example, a CLD patient reported that fatigue and pain caused her to be sitting all day long for four months.⁸³ After UBI, she was able to move around all day without sitting.⁸⁴ Another CLD patient suffered from her heart racing at least once a day, which resulted in dizziness, fainting spells, and lethargy.⁸⁵ After UBI, the patient

⁷⁷ See Jeremy E Kaslow MD, *UVBI*, www.drkaslow.com/html/uvbi.html.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ Hermes, *supra* note 22.

⁸¹ *UVL Therapy for Lyme?.*, LYMENET FLASH DISCUSSION, <http://flash.lymenet.org/scripts/ultimatebb.cgi/topic/1/132409>.

⁸² *See id.*

⁸³ See Riordan Clinic, *Journey to Healing: Finding New Life with Lyme Disease* (2016), <https://riordanclinic.org/2016/06/journey-healing-finding-new-life-lyme-disease/>.

⁸⁴ *Id.*

⁸⁵ See Monica Nicole, *Blood Treatment #20*, MY JOURNEY FIGHTING LYME DISEASE (2013), <https://lymegirlfighter.wordpress.com/2013/04/09/blood-treatment-20/>.

reported an alleviation of her symptoms, with her heart racing only once per month.⁸⁶ Because of the lack of official information regarding CLD patient satisfaction, further research should be conducted.⁸⁷

V. ECONOMIC IMPLICATIONS OF THE UVLRx TREATMENT SYSTEM AND OTHER PATENTED ALTERNATIVE TREATMENTS FOR LYME

Though patients rely on doctors to determine their best course of treatment, it is important for patients to have the freedom to access a variety of medical treatments.⁸⁸ Patients should have the opportunity to try a controversial treatment, even if its effectiveness has not yet been proven.⁸⁹ This is true especially for CLD patients who may be suffering to no avail, and want to explore other treatment options despite the cost.⁹⁰

Since insurance does not provide coverage, patients must pay substantially for the treatment with no assurances that it will improve their illness.⁹¹ UVLRx Therapeutics does not disclose a price for the UVLRx treatment nor does it state how often a patient should receive the treatment.⁹² According to a GoFundMe page, however, the cost is estimated to be \$280 per treatment.⁹³ Thus, if a patient were to receive the treatment twice per week, it would cost over \$29,000 per year.⁹⁴ Patients who opt to receive the UVLRx treatment find that the prospect of a healthier life outweighs the treatment cost.⁹⁵ The cost

⁸⁶ *Id.*

⁸⁷ *See id.*

⁸⁸ Krattiger, *supra* note 1.

⁸⁹ *See id.*

⁹⁰ *See id.*

⁹¹ *See* Karen Harris, *Saving AnnaMarie*, GOFUNDME.COM, <https://www.gofundme.com/savingannamarie>.

⁹² *See* UVLRx Therapeutics, ULTRAVIOLET LIGHT THERAPY (2017) <http://uvlrx.com/>.

⁹³ *See id.*

⁹⁴ *See id.*

⁹⁵ *See UVL Therapy for Lyme?*, *supra* note 80.

of administering long-term antibiotics is also substantial, however, so there might not be a significant difference in cost between UVLrx treatment and long-term antibiotics.⁹⁶

VI. CANADA'S PATENT ACT: ANOTHER APPROACH TO PATENT UTILITY

Similar to the United States, Canada's *Patent Act* requires that all patented inventions be "useful," but does not state how courts should interpret utility.⁹⁷ Canadian courts have traditionally applied a "promise of the patent" standard, which asks whether the invention could predictably do everything it promised to do.⁹⁸ If the patent could not perform at least one of the promised claims, then it would be invalid.⁹⁹ Recently, however, on June 30, 2017, in *AstraZeneca Inc. v. Apotex Inc.*, the Canada Supreme Court rejected the "promise of the patent" standard and returned the utility requirement to a low bar.¹⁰⁰

Although the United States does not have an explicit rule regarding patent promises, the "assertion of utility" standard is similarly applied in the Canadian "promise of the patent" standard.¹⁰¹ McGill University Professors Richard Gold and Michael Shortt have argued that the United States' analogs to Canada's promise doctrine can be even stricter due to the substantial and specific utility requirement.¹⁰² As it stands, it appears that establishing specific utility for alternative medical treatments is not required.¹⁰³ With

⁹⁶ *See id.*

⁹⁷ Patent Act, R.S.C., 1985, c. P-4.

⁹⁸ *See* E. Richard Gold & Michael Shortt, *The Promise of the Patent in Canada and Around the World*, 30 CANADIAN INTELLECTUAL PROPERTY REVIEW (2014).

⁹⁹ *Id.*

¹⁰⁰ *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36.

¹⁰¹ *See* Gold, *supra* note 97.

¹⁰² *Id.*

¹⁰³ *See e.g.*, U.S. Patent No. 9,814,899, (issued Nov. 14, 2017).

the growth of alternative medicine and its inherent allowance for nascent technologies, it is possible that this standard may change.¹⁰⁴

United States courts, legislators, and scholars should follow the changes in Canada's patent laws and consider whether the United States should adopt the lower utility requirement.¹⁰⁵ This is true despite the fact that a lower utility requirement may result in low-quality patents which, in turn, may hinder progress, diverting investments and other decisions away from high-quality inventions.¹⁰⁶ A lower-utility requirement is preferable because without it, important treatments are unlikely to be developed if it is unlikely that the inventor can obtain exclusive marketing rights.¹⁰⁷

VII. CONCLUSION

An inventor must prove a patent's utility either by identifying a specific and substantial utility for the invention, or disclosing enough information about the invention to make its usefulness apparent to a PHOSITA.¹⁰⁸ Though there is not a clear answer, the broadest possible granting of patents to combat CLD is preferable, leaving it to the FDA to determine the efficacy of the inventions.¹⁰⁹ Patients suffering with chronic illnesses should gain the advantage of new treatment options at the risk of inheriting the increased

¹⁰⁴ See Darshan Shankar, *Conceptual framework for new models of integrative medicine*, 1 JOURNAL OF AYURVEDA AND INTEGRATIVE MEDICINE 3, 3–5 (2010).

¹⁰⁵ See Gold, *supra* note 97.

¹⁰⁶ See Jonathan D. Putnam & Andrew B. Tepperman, *Revisiting the Cost of Bad Patents: For Whom is "Rational Ignorance" Rational?*, 11 INTELLECTUAL PROPERTY TODAY 17, 18 (2004).

¹⁰⁷ See *Patently Impossible*, *supra* note 34.

¹⁰⁸ See *Understanding the Patent Law Utility Requirement*, IPWATCHDOG.COM, PATENTS & PATENT LAW (2016), <http://www.ipwatchdog.com/2015/11/07/understanding-the-patent-law-utility-requirement/id=63007/>.

¹⁰⁹ See *Finney*, 34 F.3d. at 1063.

costs and the risk that the invention may not yet be proven to work.¹¹⁰ As such, the preceding analysis of the UVLrx patent with respect to its safety, quality, and economic implications can be applied to other alternative treatments for chronic diseases where patients are dissatisfied with conventional medicine.¹¹¹

¹¹⁰ See Krattiger, *supra* note 1.

¹¹¹ See *id.*