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Limb Law: Licensing Solutions for the Prosthetic Industry's Patentability and Cost Crisis

Ryan J. Mumper

University of Georgia School of Law

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LIMB LAW: LICENSING SOLUTIONS FOR THE PROSTHETIC INDUSTRY'S PATENTABILITY AND COST CRISIS

Ryan J. Mumper*

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I. INTRODUCTION

Two million Americans suffer from limb loss.¹ If the status quo persists, experts estimate this number will double in the next four decades.² For the fortunate, a prosthetic limb, or the “artificial substitute or replacement of a part of the body . . .” is oftentimes available.³ Modern science has created prosthetics for all arrays of body parts including fingers, hands, arms, legs, and feet.⁴ Recently, the advent of new plastics and materials has “allowed artificial limbs to be stronger and lighter, limiting the amount of extra energy necessary to operate the limb.”⁵ Despite scientific ingenuity and monumental strides in research, amputees face far more than just physical pain.⁶

A. A GROWING FIELD

The practice of Orthotics and Prosthetics (O&P) is working to restore Americans with mobility and independence, and has undergone tremendous growth in recent years.⁷ Just two decades ago, the field was widely considered a “trade” in which budding prosthetists and orthotists shadowed senior practitioners.⁸ Much like the legal profession however, which moved from apprenticeships to a nationally standardized curriculum and rules under the American Bar Association, the O&P field has enlarged and become more demanding of prospective practitioners.⁹

The National Commission on Orthotic and Prosthetic Education (NCOPE) “develops, implements, and assures compliance with standards for orthotic and prosthetic education through accreditation and approval processes that promote exemplary patient care.”¹⁰ In order to become fully licensed today, U.S. practitioners must receive a Master’s Degree from one of twelve accredited

¹ *Limb Loss Statistics*, AMPUTEE COALITION, <http://www.amputee-coalition.org/limb-loss-resource-center/resources-by-topic/limb-loss-statistics/limb-loss-statistics/#1> (last visited Mar. 1, 2017).

² *Definition: Defining the Meaning of Prosthesis and Prosthetic*, DISABLED WORLD, <http://www.disabled-world.com/assistivedevices/prostheses/> (last visited Mar. 1, 2017).

³ *Id.*

⁴ *Id.*

⁵ *Id.*

⁶ *Healthy Living for Amputees*, WAR AMPS, <http://www.waramps.ca/ways-we-help/living-with-amputation/#Health> (last visited Mar. 1, 2017).

⁷ *Id.*

⁸ *Master of Science in Prosthetics and Orthotics*, GEORGIA INSTITUTE OF TECHNOLOGY, <http://mspo.gatech.edu/the-program/> (last visited Mar. 1, 2017).

⁹ *Accreditation Process*, NATIONAL COMMISSION ON ORTHOTIC AND PROSTHETIC EDUCATION, <http://ncope.org/accredited/process/> (last visited Mar. 1, 2017).

¹⁰ *Mission*, NATIONAL COMMISSION ON ORTHOTIC AND PROSTHETIC EDUCATION, <http://www.ncope.org/about/mission/> (last visited Mar. 1, 2017).

Masters of Science in Prosthetics and Orthotics (MSPO) programs, as well as complete a mandatory residency program in orthotics, prosthetics, or both.¹¹

Concurrent with the recent growth in O&P university programs has been the rise of technological development in the field.¹² The high-tech, computer-driven prostheses of today are a far cry from the earliest prototypes.¹³ The “Capua Leg” is considered to be the world’s first lower-extremity prosthetic, dating back to 300 BC Italy.¹⁴ Throughout the Renaissance, European practitioners increasingly experimented with prosthetic limb replacement and made great strides in the study of amputations.¹⁵ Global prosthetics then hit a new level of advancement as a direct result of the bloodiest war in American history.¹⁶ In four years of the Civil War, over 70,000 Americans lost limbs, a cruel side-effect of an insufficient knowledge of emergency medicine.¹⁷

One of the earliest pioneers to enter the prosthetic industry was James Edward Hanger, a Confederate soldier who lost his own leg due to a cannonball.¹⁸ After the war, Hanger created J.E. Hanger & Company, and filed a series of patents as early as the 1880’s.¹⁹ Numbered U.S. Patent 951989,²⁰ the first Hanger patent detailed the blueprint of a noiseless artificial foot that operated using pneumatic devices.²¹

In 2016, Hanger Inc. was valued at over \$1 Billion,²² and is “[t]he world’s premier provider of orthotic and prosthetic (O&P) services and products, offering the most advanced prosthetics and orthotics. . . .”²³ While Hanger produces some of its own orthotic and prosthetic devices, it primarily depends on distribution companies for most of its high-end limbs.²⁴ The distributors,

¹¹ *Accredited Practitioner Programs*, NATIONAL COMMISSION ON ORTHOTIC AND PROSTHETIC EDUCATION, <http://www.ncope.org/accredited/practitioner/> (last visited Mar. 1, 2017).

¹² Steve Brachmann, *The Evolution of Prosthetic Devices: A Patent History*, IPWATCHDOG (Dec. 1, 2014), <http://www.ipwatchdog.com/2014/12/01/the-evolution-of-prosthetic-devices-a-patent-history/id=52227/>.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *The J.E. Hanger Story*, HANGER, <http://www.hanger.com/history/Pages/The-J.E.-Hanger-Story.aspx> (last viewed Mar. 1, 2017).

¹⁹ *Id.*

²⁰ U.S. Patent No. 951989 (filed July 9, 1908).

²¹ *Id.*

²² Brachmann, *supra* note 12.

²³ *About Hanger*, HANGER, <http://www.hanger.com/about/Pages/default.aspx> (last visited Mar. 1, 2017).

²⁴ *Products and Services*, HANGER, <http://www.hanger.com/about/Pages/Product-and-Services-Business.aspx> (last visited Mar. 1, 2017) (outlining Hanger Inc.’s primary business partnerships for O&P products and services).

including Southern Prosthetic Supply, move the products of some of the world's largest component manufacturers.²⁵ The component manufacturing groups are global behemoths, with just a few companies dominating the worldwide market.²⁶

Ottobock is another one of the major players in the global prosthetic market.²⁷ It was founded as a medical technology company in 1919, and in its nearly one-hundred-year history, the company has brought massive change to the industry.²⁸ In 1997, Ottobock developed the C-Leg, "the world's first fully microprocessor-controlled lower limb prosthesis system. . . ."²⁹ This landmark invention was quickly followed by the above-knee prostheses, the X3.³⁰ Dubbed the "World's most technologically advanced prosthetic leg," the X3 is the product of a collaboration with the United States military.³¹

B. THE INSURANCE DEBACLE

In the days following the 2013 Boston Marathon Bombing, fourteen people required amputations of limbs.³² Although prosthetic devices gave the survivors the chance to walk again, the costs of the limbs were staggering.³³ Today, a standard prosthetic leg can range from \$5,000 to \$50,000.³⁴ Even worse than the initial cost is the fact that most legs need to be replaced after three to five years, and other componentry and gadgetry are often not included in the initial fitting.³⁵

Fortunately for many Boston Marathon survivors, Massachusetts required state residents to have health insurance, leaving an uninsured population of

²⁵ *Supplier*, SOUTHERN PROSTHETIC SUPPLY, <http://www.spsco.com/by-supply-chain-partner.html> (last visited Mar. 1, 2017).

²⁶ *Orthopaedic Prosthetics Market*, PRNEWswire (June 28, 2016, 1:56 PM), <http://www.prnewswire.com/news-releases/orthopaedic-prosthetics-market-global-industry-analysis-and-opportunity-assessment-2016-2026-300291508.html>.

²⁷ *History*, OTTOBOCK, <http://www.ottobock.com/en/company/history/> (last visited Mar. 1, 2017).

²⁸ *Id.*

²⁹ *Id.*

³⁰ *X3 Prosthetic Leg*, OTTOBOCK, <http://www.ottobock.com/prosthetics/lower-limb-prosthetics/solution-overview/x3-prosthetic-leg/> (last visited Mar. 1, 2017).

³¹ *Id.*

³² Gillian Mohny, *Health Care Costs for Boston Marathon Amputees*, ABC NEWS (Apr. 25, 2013), <http://abcnews.go.com/Health/health-care-costs-boston-marathon-amputees-add-time/story?id=19035114>.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

approximately 3%.³⁶ Many survivors were also graciously supported by public funding and donations following the catastrophe.³⁷

On the other hand, many other amputees rely on public insurance plans including Medicare.³⁸ As the largest insurance provider in the United States, Medicare has approximately 150,000 amputees in its network.³⁹ Currently, Medicare covers most prosthetic legs under Plan B.⁴⁰ Also, like most private insurance companies, Medicare charges a 20% copay for covered devices.⁴¹ There are pending federal legislature proposals, however, to the Medicare coverage scheme that many fear will limit access to top-of-the-line prosthetic devices.⁴²

If the new proposals are enacted, “Medicare would establish more stringent requirements to obtain advanced prosthetics, reduce the role of the prosthetist who creates and maintains prostheses, and eliminate some of the universal codes that all providers use to cover prosthetic care.”⁴³ There is also the concern that these changes could stall research and development, because Medicare would likely refuse to cover more advanced and expensive technology.⁴⁴

Furthermore, Medicare could hamper patients’ ability to receive the best device for their mobility and lifestyle needs.⁴⁵ According to a consumer report by Amputee-Coalition.org, a 2011 Office of the Inspector General report “concluded that Medicare inappropriately paid \$43 million for lower-limb prosthetic claims that did not meet the established requirements for payment, such as missing information about the patient’s ability to walk or prosthetic devices that were medically unnecessary because the patient’s functional level did not correspond to the device delivered.”⁴⁶ The same report also highlighted over \$60 million in claims from patients who had no record of meeting with a referring doctor in the past half-decade.⁴⁷ Medicare responded to the report by

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Medicare for People with Limb Loss*, AMPUTEE COALITION (May 1, 2015), <http://www.amputee-coalition.org/resources/medicare-for-people-with-limb-loss/>.

³⁹ Nadia Kounang, *Amputees Fight Medicare Proposal to Limit Prosthetics*, CNN (Aug. 26, 2015, 5:13 PM), <http://www.cnn.com/2015/08/26/health/amputees-prosthetic-medicare-rule-change/>.

⁴⁰ *Prosthetic Devices*, MEDICARE.GOV, <https://www.medicare.gov/coverage/prosthetic-devices.html> (last visited Feb. 28, 2017).

⁴¹ *Id.*

⁴² *Medicare for People with Limb Loss*, *supra* note 38.

⁴³ Kounang, *supra* note 39.

⁴⁴ *Id.*

⁴⁵ *Medicare Coverage for Prosthetic Devices*, AMPUTEE COALITION, <http://www.amputee-coalition.org/medicare-coverage-for-prosthetic-devices/> (last visited Feb. 22, 2017).

⁴⁶ *Id.*

⁴⁷ *Id.*

asking its contractors who process Medicare claims to “more closely scrutinize what prosthetists submit.”⁴⁸ Under this approach, Medicare has essentially sought to reduce prosthetist autonomy in favor of general medical practitioners.⁴⁹

Amputee-Coalition is an amputee advocacy group that is worried that these possible changes are going to create failures in the quality of health care and supply of necessary prosthetic devices.⁵⁰ For instance, a prosthetist could fit a patient for a prosthesis that accurately fits their needs and activity level; however, if the medical doctor’s records differ from the prosthetist, and Medicare auditors catch the difference, they could go after the prosthetist for the cost of the device.⁵¹ Given this very possible conundrum, practitioners have “become increasingly concerned about delivering prosthetic devices to Medicare beneficiaries.”⁵²

Medicare currently uses “K-levels” to determine an “individual’s ability or potential to ambulate and navigate their environment.”⁵³ According to the American Academy of Orthotists and Prosthetists, once a patient’s K-level is calculated, the prosthetist can determine what componentry is covered by Medicare.⁵⁴ The lowest activity level is a K0, which means the patient “does not have the ability or potential to ambulate or transfer safely” and the patient would not be eligible for a prosthesis.⁵⁵ On the other hand, a K4 means that the patient’s activity level exceeds basic skills and exhibits “high impact, stress, or energy levels,” and any ankle/foot prosthetic system is considered an appropriate product for them.⁵⁶

C. A PUBLIC HEALTH CRISIS

The combination of ever-increasing costs⁵⁷ and proposed Medicare changes,⁵⁸ along with the inaccuracies and discrepancies in fitting devices,⁵⁹ has created a public health crisis in the United States. An astonishing two million

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ *K-Levels*, AMERICAN ACADEMY OF ORTHOTISTS AND PROSTHETISTS, http://www.oandp.org/olc/course_extended_content.asp?frmCourseId=ACA066EC-443A-4822-822C-89BC1CBD684E&frmTermId=k-levels (last visited Jan. 5, 2017).

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ Mohny, *supra* note 32.

⁵⁸ Kounang, *supra* note 39.

⁵⁹ *Medicare Coverage for Prosthetic Devices*, *supra* note 45.

Americans live without a limb.⁶⁰ The annual cost of health care services following limb amputations is \$8.3 billion, even before the costs of prosthetic limbs and rehabilitative care.⁶¹

In the U.S., approximately 54% of limb amputations are due to vascular issues, including diabetes and peripheral arterial disease.⁶² Trauma is the second most common cause of amputation at 45%.⁶³ Unfortunately, amputations do not strike equally at all races and ethnicities, as black Americans are up to four times as likely to need amputations as whites.⁶⁴ Also, due to America's aging population, some studies have even estimated that the national amputation rate will increase by 50% in the next fifteen years, mostly due to increases in peripheral arterial disease.⁶⁵

Adrienne Haslet-Davis, a Boston Marathon bombing survivor, wants people to stop thinking about prosthetic legs as simply medical devices, and instead, realize that "these are human body parts."⁶⁶ For the nearly two million American's living with limb loss, it can be a devastating condition that takes years to come back from.⁶⁷ However, with support groups and the right prosthetist, amputees can oftentimes have almost the same life as before.⁶⁸ According to Haslet-Davis, the possible Medicare coverage changes are standing in the amputees' way of their "human rights, to walk, dream, to be unstoppable."⁶⁹ Also arguably standing in amputees' way is another driving force behind the high costs of prosthetic devices: Patents.⁷⁰

D. PATENTS

While patents issued before 1976 are searchable only by issue date, patent number, or current U.S classification, a post-1976 search for the terms

⁶⁰ *Limb Loss Statistics*, *supra* note 1.

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ Venkat Kalapatapu, *Lower Extremity Amputation*, UPtODATE (Jan. 21, 2016), <http://www.uptodate.com/contents/lower-extremity-amputation>.

⁶⁶ Kounang, *supra* note 39.

⁶⁷ *Learning to Live as an Amputee*, NPR (Apr. 22, 2013, 1:00 PM), <http://www.npr.org/2013/04/22/178436361/learning-to-live-as-an-amputee>.

⁶⁸ *Id.*

⁶⁹ Kounang, *supra* note 39.

⁷⁰ Timothy Holbrook, *The Real Reason the EpiPen and Other Off-Patents are so Expensive*, RAWSTORY (Aug. 25, 2016, 6:46 PM), <http://www.rawstory.com/2016/08/the-real-reason-the-epipen-and-other-off-patents-are-so-expensive/>.

common strategy employed by patent-holding corporations—hiking the price just before the end of the patent's life.⁸¹

While prosthetic companies spend millions of dollars on costly litigation, many of the 185,000 Americans who undergo amputations each year⁸² cope with two main issues. First, many struggle to ensure the limb that best fits their activity level is properly assigned to them by their practitioner.⁸³ Second, many are unable to afford the limb, even with 80% covered by most private and public insurance plans.⁸⁴

E. LICENSING

Licensing is a legal shortcut to intellectual property law.⁸⁵ Licensing schemes, whether compulsive or voluntary, can create beneficial contracts in which a patent owner's permission is not required for use of their product, “provided that the user follows certain rules and pays fees set by law.”⁸⁶ Currently, compulsory licensing is found in a plethora of industries including cable, webcasting, and music contexts.⁸⁷ In the copyright realm, a license is typically granted by sending notice to the holder of the copyright, along with a statutory fee that is set by the U.S Copyright Office.⁸⁸

In the patent universe, compulsory licensing is already deeply rooted in global agreements.⁸⁹ Compulsory agreements have been recognized as “one of the flexibilities on patent protection included in the WTO's⁹⁰ [World Trade Organization] agreement on intellectual property. . . .”⁹¹ In 1995, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement took effect, following the completion of the 1994 Uruguay Round of WTO Discussions.⁹² In the Agreement, member-states reached the general understanding that compulsory licensing would be used when generic copies of products, including pharmaceuticals, were to be produced for the domestic market, as opposed to

⁸¹ *Id.*

⁸² *Limb Loss Statistics*, *supra* note 1.

⁸³ Kounang, *supra* note 39.

⁸⁴ *Prosthetic Devices*, *supra* note 40.

⁸⁵ Rich Stim, *Copyright and Compulsory Licenses*, NOLO, <http://www.nolo.com/legal-encyclopedia/copyright-compulsory-license.html> (last visited Mar. 19, 2017).

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Compulsory Licensing of Pharmaceuticals and TRIPS*, WORLD TRADE ORGANIZATION (Sept. 2006), https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.

⁹⁰ *What is the WTO?*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm (last visited Mar. 19, 2017).

⁹¹ *Id.*

⁹² *Id.*

export.⁹³ Furthermore, according to the WTO, a common misunderstanding was that the TRIPS Agreement was only applicable in emergency situations.⁹⁴ In reality, the WTO has stated that there is no specific or limited list of reasons for which a member-state may allow compulsory licensing.⁹⁵

However, the TRIPS Agreement did list a number of conditions that must be met for issuing compulsory licenses. This includes the requirement that the group petitioning for a license “has to have tried to negotiate a voluntary license with the patent holder on reasonable commercial terms.”⁹⁶ Moreover, it asserted that “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.”

The TRIPS Agreement has been called “[a] step forward for international IP aficionados.”⁹⁷ Even recently, however, the TRIPS Agreement’s language and intent have been contested in the U.S. federal courts as to their effect on imported products under patent protection.⁹⁸ In the WTO’s Uruguay Round, it was also determined that the standard patent term in the United States was to be changed from seventeen years after the patent was granted to twenty years from the date of patent filings.⁹⁹ This change extended the patent term for a number of industries including domestic pharmaceuticals.

F. LICENSING SCHEMES AS A LOW-RISK SOLUTION

In the background section, this Note will dive into greater examination of current patents on prosthetics and associated components. In highlighting this concern, patents held by the major global prosthetic componentry manufacturers will be examined, including Ottobock’s liners and prostheses.¹⁰⁰ The Note will also take a deeper look at the nature of patent protection, and the

⁹³ *TRIPS and public health*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/trips_e/pharapatent_e.htm (last visited Mar. 19, 2017).

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ Daniel Gervais, *TRIPS (and the TPP) make it to the Fed Circuit*, TRIPSAGREEMENT.NET (Feb. 13, 2016, 4:31 PM), <http://www.tripsagreement.net/?p=551>.

⁹⁸ *Id.*

⁹⁹ James Packard Love, *Recent Examples of the Use of Compulsory Licenses on Patents*, KNOWLEDGE ECOLOGY INTERNATIONAL (Mar. 31, 2007), http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf.

¹⁰⁰ *See generally* C-Leg Above Knee Prosthetic Leg, Ottobock, <http://www.ottobockus.com/prosthetics/lower-limb-prosthetics/solution-overview/c-leg-above-knee-system/> (last visited Mar. 1, 2017).

unfortunate side-effects of such litigation, by analyzing the recent WillowWood patent infringement case.¹⁰¹

Furthermore, two recent case studies will briefly be explored, in which compulsory licensing and voluntary licensing agreements were successfully implemented into problematic economic or health crises. First, a case study on the licensing of HIV pharmaceuticals following the 2001 Doha Round of WTO trade negotiations will be analyzed.¹⁰² In this case, compulsory licensing was used to allow member-states to overcome patent obstacles to life-saving retroviral drugs in declared emergencies.¹⁰³ A plethora of developing nations mandated the issuing of licenses in an “attempt to cut growing healthcare costs by encouraging the production and import of generic versions of the patented medicine.”¹⁰⁴ Then, another case study will be examined in which a court granted *Toyota* a compulsory license on hybrid technologies created by Paice, LLC, which resulted in the companies settling on a voluntary license.¹⁰⁵

In the analysis section, the Note will examine the takeaways of the two case studies and go on to discuss both the pros and cons of licensing in the context of prosthetic limbs. Several variations of patent licensing will be discussed, including compulsory and voluntary, and alternatives such as government investigative committees will be offered. Finally, other options will also be analyzed as to their projected effect on prosthetic patentability and pricing, including 3-D printing and open sourcing. The Note will finally advocate for legal and policy change to implement voluntary licensing-type practices to address the patent and cost/supply conundrum in the national prosthetic health crisis.

G. LIMITATIONS ON NOTE INQUIRY

This Note recognizes several notable limitations to its inquiry. First and foremost, it acknowledges that there are different insurance schemes which will undeniably affect the manner in which prosthetic limbs are chosen for patients, as well as the out-of-pocket expenses that the patient will have. Although it will discuss Medicare as well as private insurance plans, the focal point of the Note is to examine the effect of licensing schemes on prosthetic cost and accessibility.

¹⁰¹ See *Ohio Willow Wood Co. v. Alps S., LLC*, 843 F.3d 1350, 1361 (Fed. Cir. 2016).

¹⁰² See *The Doha Round*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/dda_e/dda_e.htm (last visited Mar. 1, 2017).

¹⁰³ See *Thailand Issues Compulsory License for Patented AIDS Drug*, INTERNATIONAL CENTER FOR TRADE AND SUSTAINABLE DEVELOPMENT (Dec. 13, 2006), <https://www.ictsd.org/bridges-news/bridges/news/thailand-issues-compulsory-licence-for-patented-aids-drug>.

¹⁰⁴ *Id.*

¹⁰⁵ Love, *supra* note 99.

Secondly, in addressing the prosthetic cost and patent crisis, the Note will only consider civilian patients in the United States. While prosthetics are often considered in a military context, the Amputation System of Care (ASoC) program within the Department of Veterans Affairs is simply not applicable to the majority of Americans with limb loss.¹⁰⁶

Third, the Note concedes that while its primary goal is to posit opportunities to make prosthetic limbs more affordable in the U.S. domestic market, several of the component and limb manufacturers discussed are not American companies.¹⁰⁷

II. BACKGROUND

The O&P field currently patents not only prosthetic limbs in their entirety, but also specific componentry within.¹⁰⁸ For instance, Ottobock holds patents on materials as simple as the “alignable coupling assembly for connecting two prosthetic limb components,” and as complex as entire micro-processor controlled knee joints.¹⁰⁹ In 2015, Ottobock was granted Patent 9,192,488 for its “Liner for vacuum sockets, and use of the liner.”¹¹⁰ The patent describes the device as “[a] liner for receiving an amputation stump and for placement within a prosthetic vacuum socket.”¹¹¹

Similarly, WillowWood, an American competitor to German Ottobock, received a patent in February 2016 for its “Fabric covered polymeric prosthetic liner.”¹¹² The patent, numbered 9,265,629, was described as “[a] prosthetic cushion liner and cushion locking liner for use as a standalone interface between an amputee’s residual limb and the interior of a prosthetic socket.”¹¹³

¹⁰⁶ See generally *Amputation System of Care (ASoC)*, DEPARTMENT OF VETERANS AFFAIRS (June 10, 2015), <http://www.prosthetics.va.gov/asoc/index.asp>.

¹⁰⁷ See *Mobility for People*, OTTOBOCK, <http://www.ottobock.com/en/company/ottobock-to-day/> (last visited Mar. 1, 2017).

¹⁰⁸ Search Results for “ottobock” and “prosthetic” on U.S. Patent and Trademark Office Database, <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahml%2FPTO%2Fsearch-bool.html&r=0&f=S&l=50&TERM1=ottobock&FIELD1=&co1=AND &TERM2=prosthetic&FIELD2=&d=PTXT> (follow hyperlink; then search both terms “ottobock” and “prosthetic”) (last visited Mar. 1, 2017).

¹⁰⁹ *Id.*

¹¹⁰ *Liner for vacuum sockets, and use of the liner*, JUSTIA PATENTS (Nov. 12, 2008), <http://patents.justia.com/patent/9192488>.

¹¹¹ *Id.*

¹¹² *Fabric Covered Polymeric Prosthetic Liner*, Patent No. 9,265,629, U.S. PATENT AND TRADEMARK OFFICE (Feb. 23, 2016), <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahml%2FPTO%2Fsearch-bool.html&r=1&f=G&l=50&co1=AND&d=PTXT&s1=9,265,629&OS=9,265,629&RS=9,265,629>.

¹¹³ *Id.*

Just four years prior, WillowWood also received Patent Number 8,317,873 on the “Polymeric prosthetic liner with controlled stretch characteristics.”

While those close to the industry may be able to denote these seemingly subtle differences between the aforementioned WillowWood patents, a layperson may not be able to. This liberal patenting practice is nothing new for American prosthetic manufacturers. The United States has dominated the world’s prosthetic patent-filing market in recent years.¹¹⁴ For instance, “Entities in the U.S. were granted 610 of the 810 prosthetic patents issued in the first half of 2015.”¹¹⁵ With these many patents, the U.S. prosthetic industry has also demonstrated it will fight tooth and nail to protect its products.¹¹⁶

A. CASE STUDY: THE *OHIO WILLOW WOOD COMPANY V. ALPS SOUTH, LLC*.

Litigation between these two prosthetic manufacturers began in 2004 when The Ohio Willow Wood Company (OWW) charged Alps South, LLC (Alps) with infringement of U.S. Patent No. 5,830,237 (hereby referred to as the ‘237 patent).¹¹⁷ The patent for “Gel and Cushioning Devices,” was originally filed by OWW in 1996.¹¹⁸ According to the U.S. Patent and Trademark Office, the ‘237 patent was described as “Articles of apparel for an amputee’s residuum and for non-amputees who desire or require padding or joint support.”¹¹⁹ Specifically, these articles included a “cushion liner, cushion locking liner, open-ended cushion knee or elbow sleeve and cushion flat sheet all useful for increasing the comfort of the wearer.”¹²⁰ The purpose behind the liner was to provide suspension for prosthetic devices while also creating friction with the patient’s knee sleeve.¹²¹

Following multiple reexaminations by the US Patent and Trademark Office (USPTO), the district court granted Alps’s motion for Summary Judgement “of invalidity as to all the asserted claims of the ‘237 patent.”¹²² However, throughout the patent reexamination stages, a claim was also brought against

¹¹⁴ *Medical Device Patents*, MEDICAL ALLEY (Aug. 14, 2015), https://www.medicalalley.org/media/16223/8_17_15_medical_device_patents_q1_q2_2015.pdf.

¹¹⁵ *Id.*

¹¹⁶ *See* *Ohio Willow Wood Co. v. Alps S., LLC*, 813 F.3d 1350, 1361 (Fed. Cir. 2016).

¹¹⁷ *Id.*

¹¹⁸ *Gel and Cushioning Devices, Patent No. 5,830,237*, U.S. PATENT AND TRADEMARK OFFICE (Nov. 3, 1998), <http://patft.uspto.gov/netacgi/nph-Parser?Sect2=PTO1&Sect2=HITOFF&p=1&u=/netahtml/PTO/search-bool.html&r=1&f=G&l=50&d=PALL&RefSrch=yes&Query=PN/5830237>.

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Ohio Willow Wood Co.*, 813 F.3d at 1354.

OWW for inequitable conduct.¹²³ Specifically, the court found OWW's attorney was in a position to correct misrepresentations he had made as to the submitted evidence.¹²⁴ Due to unethical lawyering, the district court ruled the '237 Patent to be unenforceable and demanded OWW pay a fine to Alps.¹²⁵

OWW appealed and in 2016 the case went before the U.S. Court of Appeals.¹²⁶ During litigation, OWW argued about the physical characteristics of the liner in question, going so far as to compare the thickness of the materials.¹²⁷ The Court also found the patent unenforceable for inequitable conduct in the second patent reexamination phase.¹²⁸ According to IP Attorney Joshua Branson, "This case suggests that (1) in-house individuals who substantively participate in a USPTO proceeding on behalf of a patent owner may be held to the duty of candor even if a screen exists between the USPTO proceeding and litigation concerning the same patent. . . ."¹²⁹ After twelve years of litigation, WillowWood lost the case and was forced to vacate its patent.¹³⁰

B. CASE STUDY: THAILAND'S COMPULSORY LICENSING OF EFAVIRENZ

In November 2006, Thailand's government followed in the footsteps of Indonesia, Zambia, and a host of other developing nations, by allowing a compulsory license for Merck's HIV drug, Efavirenz.¹³¹ The license was granted to encourage "the production and import of generic versions of the patented medicine."¹³² Under the licensing agreement, the government's Ministry of Public Health granted the Government Pharmaceutical Organization the right to legally create generic variations of Merck's drug through the year 2011.¹³³ The Thai government emphasized that the license met the WTO rules on generic production of medicines, "specifically citing the 2001 Doha Declaration on the TRIPS Agreement and Public Health," which permitted licenses in instances of emergency and public utility.¹³⁴ The WTO's

¹²³ *Id.* at 1354.

¹²⁴ *Id.* at 1356.

¹²⁵ *Id.* at 1357.

¹²⁶ *Id.* at 1350.

¹²⁷ *Id.* at 1358.

¹²⁸ *Id.* at 1360.

¹²⁹ Joshua Branson, *Federal Circuit Upholds Inequitable Conduct Ruling in Ohio Willow Wood Company*, BAKER HOSTETLER: IP INTELLIGENCE BLOG (May 14, 2016), <https://www.ipintelligencereport.com/2016/03/14/federal-circuit-upholds-inequitable-conduct-ruling-in-ohio-willow-wood-company/>.

¹³⁰ *Id.*

¹³¹ *Thailand Issues Compulsory License for Patented AIDS Drug*, *supra* note 103.

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.*

TRIPS agreement enumerates that in such emergency cases, governments are not required to consult with the patent holder.¹³⁵

Not everyone was pleased with Thailand's emergency declaration and subsequent acceptance of generics medication, however.¹³⁶ Following the announcement, the American Chamber of Commerce in Thailand became an outspoken critic of the deal, stating that it would send a negative image to international investors.¹³⁷ On the contrary, Médecins Sans Frontières¹³⁸ offered praise for the licensing system, even calling for licensing to be expanded to other expensive and under-supplied drugs.¹³⁹ While initially disappointed in the lack of notice from the Thai government, U.S.-based Merck stated it would "negotiate with the Thai government to agree on a 'voluntary license' for the generic production of efavirenz, or offer it a lower price for [the] drug."¹⁴⁰

Despite differing takes on the emergency decision, the licensing provision set forth clear terms for the duration of its existence.¹⁴¹ First and foremost, the license was capped at supplying 200,000 people per year.¹⁴² Secondly, the Thai Government Pharmaceutical Organization stated it could "pay Merck a royalty fee of 0.5% of the total sale value of the imported or locally-produced generic."¹⁴³ The plan also called for the importation of an Indian-made efavirenz until Thailand's generic manufacturers could begin their own sufficient production process.¹⁴⁴

However, following the notice of the government's licensing plan, Merck vehemently rejected the 0.5% royalty figure.¹⁴⁵ As negotiations fell through with Merck, other options presented themselves, including U.S.-based Abbott Laboratories.¹⁴⁶ In early 2007, a compulsory license was issued for lopinavir/ritonavir, an Abbott medicine sold under the brand-name Kaletra.¹⁴⁷ Despite protests from foreign nations, as well as the Thai Pharmaceutical Research and Manufacturers Association (PREMA), the nation's Health

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *About MSF*, MEDECINS SANS FRONTIERES, <http://www.msf.org/en/about-msf> (last visited Mar. 19, 2017).

¹³⁹ *See* Thailand Issues Compulsory License for Patented AIDS Drug, *supra* note 103.

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *The Campaign for Use of Compulsory Licensing in Thailand*, MAKE MEDICINES AFFORDABLE (Feb. 18, 2015), <http://makemedicinesaffordable.org/en/the-campaign-for-use-of-compulsory-licensing-in-thailand/>.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

Minister chose another option and “signed the licenses and imported a generic version of Efavirenz from Indian Pharmaceutical company, Rambaxy.”¹⁴⁸ Various estimates predict that if the Abbott license had been signed, Kaletra would have saved Thailand up to \$24 million per year.¹⁴⁹

Soon after being denied, Abbott Labs denied Thailand the ability to access Aluvia, another one of its brand-name HIV drugs.¹⁵⁰ In opposition to the authorized license, Abbott withdrew all its “medications awaiting registration in addition to refusing to register any new pharmaceutical products in Thailand.”¹⁵¹ As a result of the American manufacturer’s actions, scores of HIV/AIDS activist groups and organizations rallied against the pharmaceutical industry’s suggested financial greed and uncooperative demeanor.¹⁵²

The world watched as protests were held, and demands were made by both parties.¹⁵³ Despite the rising tensions, the events created a strong push towards the pro-generic camp’s initial goal of price reduction.¹⁵⁴ Following the issuing of the Ranbaxy compulsory license, “Thai health authorities purchased a WHO pre-qualified generic form of Efavirenz.”¹⁵⁵ Ranbaxy offered the generic at a price of \$20 per bottle, compared to Merck’s brand-name price tag of \$43 per bottle.¹⁵⁶

Furthermore, the move resulted in Merck and Abbott reducing their prices to create competition with the Indian generic, with Merck offering to reduce its drug to \$23 per bottle.¹⁵⁷ While the offer was again rejected, it proved that the signing of the compulsory license played a large role in driving down the costs of patented medical necessities.¹⁵⁸

C. CASE STUDY: PAICE-TOYOTA HYBRID LICENSING AND ROYALTY AGREEMENT

In 2004, Paice, LLC, an automotive hybrid technology company,¹⁵⁹ brought suit against *Toyota*, claiming the car manufacturer infringed upon three of the

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *See id.* (pointing to Abbot’s “plans to reduce the cost of Kaletra in Thailand and more than 40 low- and –low-middle income countries for more than half”).

¹⁵⁹ PAICE HYBRID, <http://www.paicehybrid.com/> (last visited Jan. 10, 2017).

company's patents.¹⁶⁰ The Paice claim included two patents for the use of a clutch to provide torque to the vehicle's engine,¹⁶¹ and one patent for a microprocessor and torque unit that "accepts torque input from both the ICE [internal combustion engine] and the electric motor."¹⁶² These devices were installed in the *Toyota Highlander* and *Prius*, and the *Lexus RX 400h* vehicles.¹⁶³

In District Court, the jury found two patents were infringed upon, and offered a remedy in the form of a \$25 per vehicle royalty on the infringing models, but the Court denied a permanent injunction.¹⁶⁴ Upon appeal, the Federal Circuit Court held that there was no sufficient reasoning behind the royalty rate.¹⁶⁵ As such, the case was remanded to the District Court to explain why a specific rate was appropriate.¹⁶⁶ In a concurring opinion at the Federal Circuit, Justice Rader stated that the court should "require the district court to allow the parties an opportunity to set the ongoing royalty rate. . . ."¹⁶⁷ The judge was of the opinion that a royalty was equivalent to a compulsory license if the parties never had the opportunity to negotiate outside court.¹⁶⁸

On remand from the Federal Circuit, the ongoing royalty rate was set at \$98 per vehicle.¹⁶⁹ Then, much to the appeasement of Justice Rader's call for private negotiation, Paice and *Toyota* settled in 2010.¹⁷⁰ In the same year, Paice also engaged in private licensing negotiations with Ford.¹⁷¹

According to Paice, the company now has "licensed all or part of its hybrid vehicle technology portfolio to Toyota, Hyundai/Kia, and Ford. . . ."¹⁷² These companies maintain approximately 90% of the market share for hybrid cars in the United States.¹⁷³

Although studied briefly, the three aforementioned case studies demonstrate the long and contentious process that can ensue when large companies engage in patent protection and litigation. First, the WillowWood case demonstrates

¹⁶⁰ Paice LLC v. Toyota Motor Corp., 504 F.3d 1293, 1317 (Fed. Cir. 2007) (Rader, J., concurring).

¹⁶¹ *Id.* at 1299.

¹⁶² *Id.* at 1296.

¹⁶³ *Id.* at 1299.

¹⁶⁴ *Id.* at 1303.

¹⁶⁵ *Id.* at 1316.

¹⁶⁶ *Id.*

¹⁶⁷ *Id.* at 1317.

¹⁶⁸ *Id.*

¹⁶⁹ Paice LLC v. Toyota Motor Corp., 609 F. Supp. 2d 620, 630 (E.D. Tx. 2009).

¹⁷⁰ *Licensing Agreements*, PAICE HYBRID, <http://www.paicehybrid.com/about/paices-work-with-toyota-and-ford/> (last visited Feb. 20, 2017).

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ *Id.*

the oftentimes painstaking process that patent litigation can create.¹⁷⁴ Second, the Thailand case study demonstrates the emergency context in which compulsory licensing can be defended under the WTO's TRIPS Agreement.¹⁷⁵ More importantly, the case illustrates the downward pressure on price that compulsory licensing can bring, as competition attempts to flood a market, increasing supply.¹⁷⁶ Finally, the Paice case study offers a taste of licensing agreements in the domestic market.¹⁷⁷ Although the case dealt with hybrid vehicles, it similarly showcases the impact that the threat of court-appointed royalties may have on large corporations.¹⁷⁸ As Justice Rader stated, "[C]alling a compulsory license an 'ongoing royalty' does not make it any less a compulsory license."¹⁷⁹ Fortunately, private negotiation and settlement is a possibility.

III. ANALYSIS

Several alternatives will now be examined as potential price-reduction schemes to apply to the heavily-patented U.S. prosthetic market. First, utilizing concepts from the Thailand case study, compulsory licensing will be analyzed as a tool through which the government can dramatically decrease the prices of prosthetic devices while also ensuring increased supply.

Second, voluntary licensing will be examined as a lighter approach to overcoming patentability obstacles. The Paice case will be utilized as support for voluntary negotiations and the private establishment of royalties between corporations, as opposed to those flowing via legal or governmental surrogate.

Third, an alternative remedy will be put forth in which a government committee is set up to examine the patent and pricing models on high-tech prosthetic devices. This model would follow in the footsteps of the 2016 Senate Judiciary Committee request for investigations into the pricing structure of the EpiPen product.¹⁸⁰

Finally, the Note will attempt to analyze the future of the prosthetic industry if the suggested licensing schemes were proven futile. In doing so, the growing

¹⁷⁴ See *Ohio Willow Wood Co. v. Alps S., LLC*, 813 F.3d at 1352 (stating, "This case marks the latest chapter in a long-roaming dispute . . .").

¹⁷⁵ See *The Campaign for Use of Compulsory Licensing in Thailand*, *supra* note 145.

¹⁷⁶ See *id.*

¹⁷⁷ See *Paice*, 504 F.3d at 1296.

¹⁷⁸ See *id.* at 1316.

¹⁷⁹ See *id.* at 1317 (Rader J., concurring).

¹⁸⁰ Zachary Brennan, *Updated: Senate Judiciary Committee Members Call for Investigation Into Price Increases of Mylan's EpiPen*, REGULATORY AFFAIRS PROFESSIONALS SOCIETY (Aug. 22, 2016), <http://www.raps.org/Regulatory-Focus/News/2016/08/22/25670/Updated-Senate-Judiciary-Committee-Members-Call-for-Investigation-Into-Price-Increases-of-Mylan's-EpiPen/>.

open-source and 3-D printing movements will be discussed as possible patent-alternative, price-cutting mechanisms.

A. COMPULSORY LICENSING

Compulsory licensing is one alternative to bypassing the monopoly rights given to patent owners.¹⁸¹ This form of licensing is created when the government forces the “holder of a right to grant the use of that right to other[s] upon the terms decided by the government.”¹⁸² In a traditional compulsory licensing scheme, the government pays royalties to the patent-holding individual or corporation, as a quid pro quo for taking the patent without consent.¹⁸³

While compulsory licensing can be considered a form of government-mandated piracy, it does have benefits.¹⁸⁴ For instance, by having access to the intellectual property rights of advanced nations, developing countries are able to advance their own fields of science and technology.¹⁸⁵ Furthermore, allowing for the reproduction of patented products may increase employment, and thus, have a positive economic impact.¹⁸⁶ However, due to the patent system’s incentivization of research and development, many developed countries are opposed to any form of compulsory schemes.¹⁸⁷ Moreover, in a pure compulsory licensing system, the royalties paid by the government are almost certainly unable to match the extra revenue that patent-holder would have made had the government not interfered with the exclusive right to the product in question.¹⁸⁸

In applying the scheme to prosthetics, take Ottobock’s revolutionary C-Leg for example. The lower limb prosthetic has been fitted on over 60,000 qualified amputees since 1997.¹⁸⁹ Furthermore, Ottobock has continued to update the C-Leg system with new patented additions.¹⁹⁰ If compulsory licensing were applied to the prosthetic market, in theory, the government could force Ottobock to pass on its patents for the C-Leg prosthesis and componentry to

¹⁸¹ Muhammad Zaheer Abbas, *Pros and Cons of Compulsory Licensing*, 3 INT’L J. SOC. SCI. & HUMANITY 254, 254–58 (2013).

¹⁸² *Id.* (quoting T. Jain, *Compulsory Licenses Under TRIPS and Its Obligation for Member Countries*, 8 INT’L J. INTELL. PROP. RTS. 1 (2009)).

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ *Id.* at 255.

¹⁸⁹ *C-Leg 4*, OTTOBOCK, <http://www.ottobockus.com/media/local-media/prosthetics/lower-limb/c-leg/files/cleg4brochure.pdf> (last visited Mar. 21, 2017).

¹⁹⁰ *The C-Leg 4 Microprocessor Knee*, OTTOBOCK, http://www.ottobock.co.uk/prosthetics/lower_limb_prosthetics/prosthetic-product-systems/c-leg-4/ (last visited Mar. 21, 2017).

another manufacturer who could in turn produce an identical product for much less. Ottobock would certainly have disdain for the government's move, as it would rob the company of a great deal of potential revenue and market share.¹⁹¹ However, the potential positive implications of such cannot be ignored.

Like its competitors, Ottobock has faced the familiar burden of balancing technological advancement with accessibility and costs. According to Miki Fairley of *The O&P Edge*, "As has been the case in other areas of O&P, reimbursement issues and gaps in research are impediments to technological advances and patient access."¹⁹² Unfortunately, in this payment scheme, "payers often allow providers to only fit components that may actually decrease the patient's safety and functionality."¹⁹³ Moreover, according to Brown University, the C-Leg prosthetic can cost \$50,000, or, if fit with a prosthetic foot as well, \$70,000 or more.¹⁹⁴

In the Thailand case study, the extreme prices of Western anti-retroviral drugs lead the government to issue a compulsory license for the importation of Merck's generic drug.¹⁹⁵ While that license did not come to fruition, it forced Merck to drop the price of its life-saving drug from \$43 per bottle to \$23 per bottle.¹⁹⁶

Compulsory licensing could create a similar price reduction in name-brand products, should Ottobock's monopoly be taken away and given to smaller manufacturers. As suggested in the *International Journal of Social Science and Humanity*, legal piracy "can ensure availability of needed goods and services to their citizens at affordable prices" in developing countries.¹⁹⁷ This raises the question of whether compulsory licensing is able to address the similar problem of cost and supply here at home.

Compulsory licensing is also likely to rouse loud critics as well. According to Joanna Thurston, an IP attorney, "Allowing governments to intervene in patent matters in this way . . . is a dangerous precedent. . . ."¹⁹⁸ At the forefront would be the argument that forced licensing deprives developers of their full property rights, thereby discouraging further investment in products in specific

¹⁹¹ Abbas, *supra* note 181, at 255.

¹⁹² Miki Fairley, *Microprocessor-Controlled Knees: Evolution of a Game Changer*, O&P EDGE (June 2014), http://www.oandp.com/articles/2014-06_01.asp.

¹⁹³ *Id.*

¹⁹⁴ *Prosthetic Leg Cost*, COST HELPER, <http://health.costhelper.com/prosthetic-legs.html> (last visited Jan. 10, 2017).

¹⁹⁵ *Thailand Issues Compulsory License for Patented AIDS Drug*, *supra* note 103.

¹⁹⁶ *Id.*

¹⁹⁷ Abbas, *supra* note 181, at 254.

¹⁹⁸ Caio Rodrigues Da Silva, *Compulsory Licenses: Necessity or Threat?*, CHEMISTRY WORLD (May 23, 2013), <https://www.chemistryworld.com/opinion/compulsory-licences-necessity-or-threat/6200.article>.

markets.¹⁹⁹ In the case of prosthetics, one fear is that by depriving Ottobock, Hanger, and other device manufacturers of their exclusive rights, it would discourage their future investment in life-changing limbs. However, this concern would need to be weighed against other potential positives, including increased supply and decreased cost.

Furthermore, there is the textual-based argument that the TRIPS agreement stated compulsory licensing should only be used in particular instances, including national emergencies.²⁰⁰ In rebuttal, while government-mandated licensing is likely to draw concern from skeptics, statistics point to the existence of a national health emergency that may justify the action. Today, over 133 million Americans have at least one chronic disease.²⁰¹ These diseases, including diabetes, are disabling and bring a host of other health problems, including amputations.²⁰² Every thirty seconds in the United States, a lower limb is “amputated as a consequence of diabetes.”²⁰³ While the magnitude of this health crisis issue can be debated, it is apparent that chronic diseases have a role in limb loss, and compulsory licensing is one way to combat the emergency by ensuring widespread access and lower costs.

B. VOLUNTARY LICENSING

Voluntary licensing is another alternative method to overcoming patentability obstacles. However, unlike compulsory licensing, the government is not involved in the negotiation or agreement process between the licensee and licensor.²⁰⁴ According to the World Health Organization (WHO), voluntary licensing agreements may “afford opportunities for significant cost-containment.”²⁰⁵ Perhaps the most important factors in a successful voluntary licensing scheme are the specific terms of the license and the capacity of the licensee, or recipient of the patent.²⁰⁶

In a traditional voluntary licensing agreement, the patent-holding company or individual may license their patent at their discretion, in an exclusive or non-

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

²⁰¹ *The Growing Crisis of Chronic Disease in the United States*, PARTNERSHIP TO FIGHT CHRONIC DISEASE 1, http://www.fightchronicdisease.org/sites/default/files/docs/GrowingCrisisofChronicDiseaseintheUSfactsheet_81009.pdf (last visited Mar. 21, 2017).

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ Germán Velásquez et al., COST CONTAINMENT MECHANISMS FOR ESSENTIAL MEDICINES, INCLUDING ANTIRETROVIRALS, IN CHINA 7 (Dec. 11–13, 2002), <http://apps.who.int/medicine/docs/pdf/s4907e/s4907e.pdf>.

²⁰⁵ *Id.*

²⁰⁶ *Id.*

exclusive fashion.²⁰⁷ The agreement may include any or all typical aspects of product development, including manufacturing, importation, and distribution.²⁰⁸ There are two common arrangements often made between licensees and licensors: one in which a licensee acts as an agent of the licensor patent-holder, and one in which the licensee is “free to set the terms of sale and distribution within a prescribed market or markets, contingent on payment of a royalty.”²⁰⁹ The WHO has deemed both arrangements viable options for price reduction on patented pharmaceutical products.²¹⁰ As such, it is possible to foresee potential existing in the prosthetics industry as well.

In the Paice patent infringement case study, the District Court threatened Toyota with a royalty payment to Paice at the rate of \$98 per vehicle.²¹¹ However, prior to remand, Justice Radar of the Federal Circuit had stated that the creation of an ongoing royalty simply created a compulsory license, unless the Court gave the litigants the opportunity to negotiate privately.²¹² Fortunately for the parties involved, the threat of a court-made license resulted in a private voluntary license.²¹³

Similarly, in the realm of prosthetics limbs, voluntary licensing agreements could promote mutually beneficial outcomes while forcing prices downward. In the *WillowWood* infringement case,²¹⁴ had the parties been able to reach a voluntary royalty rate for the patented componentry, millions of dollars of costly litigation and lost revenue may have been saved.

Unfortunately, one downside to voluntary licensing is likely an inherent difficulty in forcing conversation amongst the current manufacturers of prosthetics. The American Orthotic and Prosthetic Association (AOPA)²¹⁵ has calculated that the U.S. O&P industry spends over \$3.5 billion annually on patient services.²¹⁶ Like many corporations, it may be difficult to talk industry giants into granting licenses on the technology they have so closely guarded. However, if the goal of the prosthetic movement is to push for cheaper, more accessible limbs, these conversations are pertinent.

Furthermore, another key requirement in a voluntary licensing scheme is that the patent-holders have other corporations to bestow a license upon.

²⁰⁷ *Id.*

²⁰⁸ *Id.*

²⁰⁹ *Id.*

²¹⁰ *Id.*

²¹¹ See *Paice*, 609 F. Supp. 2d at 630.

²¹² See *Paice*, 504 F.3d at 1316.

²¹³ See *Licensing Agreements*, *supra* note 170.

²¹⁴ See generally *Ohio Willow Wood Co. v. Alps S., LLC*, 813 F.3d 1350 (Fed. Cir. 2016).

²¹⁵ *American Orthotic and Prosthetic Association*, <http://www.aopanet.org/> (last visited Feb. 28, 2017).

²¹⁶ *AOPA Fact Sheet*, AMERICAN ORTHOTIC AND PROSTHETIC ASSOCIATION, <http://www.aopanet.org/media/fact-sheet/> (last visited Mar. 1, 2017).

While courts could suggest voluntary licenses, as seen in *Paice, LLC v. Toyota*, the choice to grant a license to a smaller prosthetic company is a choice that could ideally be left up to consenting corporations in the free market.²¹⁷ Using WillowWood as an example, one will find a plethora of smaller prosthetic suppliers, fitters, and manufacturers within a short distance of their primary production facility.²¹⁸ Should WillowWood and its competitors wish to cooperate and play their role in supplying America's amputee population with more accessible products, they need look no further than their backyard.

C. GOVERNMENT COMMITTEE

The third approach to navigating the burdensome patentability obstacles in the prosthetic market again involves governmental interference. However, unlike compulsory licensing, which may include government-induced production and royalty schemes, this approach is more economically laissez-faire while still allowing the government to bring attention to the national health crisis. The recent epinephrine pricing controversy provides a fair illustration of the role the government can play in price-reduction without infringing on patents.²¹⁹

In 2016, as a direct result of the egregious EpiPen price surge, U.S. Senator Amy Klobuchar asked the Senate Judiciary Committee to investigate the 400% price increase of EpiPens.²²⁰ The Senator also called for the Federal Trade Commission to examine the alleged price gouging, and for the Commission to report to Congress on the cause of the price increase and their proposed solutions to “ ‘better protect consumers within 90 days.’ ”²²¹ In agreement with the Senator, the administrator of the U.S Centers for Medicare and Medicaid Services stated, “We can make drug inflation more transparent & [sic] address unchecked increases without damaging innovation.”²²²

In 2007, Mylan acquired the EpiPen, which cost just over \$100.²²³ However, by 2016, the cost had increased to approximately \$600 per unit.²²⁴ This price explosion has followed a common trend in the medical industry: dramatically raising prices just before a generic competitor enters the market.²²⁵

²¹⁷ See *Paice*, 504 F.3.d at 1316.

²¹⁸ Search Results for O&P Facilities within 100 miles of The Ohio Willow Wood Company, http://www.oandp.com/facilities/search.asp?qry_zipcode=43143&qry_distance=100&method=zipCode (last visited Mar. 1, 2017).

²¹⁹ Brennan, *supra* note 180.

²²⁰ *Id.*

²²¹ *Id.*

²²² *Id.*

²²³ Pollack, *supra* note 79.

²²⁴ *Id.*

²²⁵ *Id.*

It is difficult, however, to determine the degree to which this same trend is happening in the prosthetic market.

However, regardless of the differences in prosthetic limbs and epinephrine medication, as well as the variables that affect price for each, one thing remains clear: Congress and the U.S Department of Health and Human Services may similarly benefit from forming a commission to examine the pricing models for prosthetic limbs. If this were to happen, not only could the publicity force major prosthetic manufacturers to decrease the cost of their patented limbs and componentry, the action could also have the effect of creating dialogue between major manufacturers and smaller companies with an interest in generic production, thus opening the door to voluntary licensing relationships.

D. STATUS QUO

What if nothing were done by corporations or the courts to combat the extreme price of prosthetic technology and their accessibility-blocking patents? Should the status quo continue to exist without the enactment of any of the aforementioned alternatives, there may still be hope for cheaper and more accessible limbs via open source initiatives and 3-D printing.

In 2005, Marine engineer Jonathan Kuniholm lost most of his right arm while on patrol in Iraq.²²⁶ After surgery, Kuniholm was fitted with a myoelectric arm at Walter Reed Military Hospital in Bethesda, Maryland.²²⁷ However, he was not impressed with the design, which limited mobility and weight-bearing activities.²²⁸ Fortunately, as an engineer, Kuniholm and fellow Duke University students founded a non-profit known as The Open Prosthetics Project.²²⁹

The Open Prosthetics Project “applies the ethical and intellectual property foundation of open-source software to the task of building better artificial limbs.”²³⁰ The Project allows anyone to publish and share their prosthetic projects in hopes of saving thousands of dollars and creating change in the prosthetics industry.²³¹ Today, Open Prosthetics Project continues to share experimental designs that any member is able to download, alter in CAD software, and submit to 3-D printing companies.²³²

²²⁶ *An Open Source Approach to Better Prosthetics*, NATIONAL PUBLIC RADIO (Nov. 10, 2009), <http://www.npr.org/templates/story/story.php?storyId=120271945>.

²²⁷ *Id.*

²²⁸ *Id.*

²²⁹ *Id.*

²³⁰ *Id.*

²³¹ *Id.*

²³² *Id.*

Kuniholm's company is not the only one of its kind. Other start-ups, including the Open Hand Project, realize the benefit that 3-D printing can create for amputees who otherwise have to pay upwards of six figures for new limbs.²³³ If these alternative methods continue to develop, there exists a very real possibility that they will also force prosthetic manufacturers to lower prices, or even follow in the foot-steps of Tesla and open source their own patents.²³⁴

In order to be classified as open source by the Open Source Initiative, no royalty or sale fee may be collected.²³⁵ However, the official definition of the term makes no mention of restrictions on turning patents into open source products. As Elon Musk, co-founder and CEO, has recently stated, patents now stifle progress and "receiving a patent really just meant that you bought a lottery ticket to a lawsuit. . . ."²³⁶ If the prosthetic industry also adopted this mindset, perhaps the future holds potential for collaboration between the growing generic sector and large corporate industry.

IV. CONCLUSION

Despite a number of limitations in this Note, voluntary licensing is the best approach for the domestic prosthetic market to take in order to lower costs, increase supply, and avoid costly patent litigation. Much like the Paice case study, this pathway promotes mutually-beneficial outcomes without resorting to government licensing controls.

Voluntary licensing also offers a more moderate approach to overhauling the prosthetic patent system.²³⁷ Compulsory licensing, on the other hand, would require a governmental (often judicial-based) mandate to allow for replication of patented-materials.²³⁸ As demonstrated in the Paice case, American courts may be more inclined to allow private companies to sort out their own licensing agreements before resorting to the judiciary.²³⁹

While the primary goal of encouraging voluntary licensing agreements would be circumventing patenting practices to result in price-reduction and increased supply, voluntary agreements do not always guarantee lower costs.²⁴⁰ However, since most of these agreements are made at the discretion of the patent holder,

²³³ OPEN HAND PROJECT, <http://www.openhandproject.org/> (last visited Mar. 1, 2017).

²³⁴ Elon Musk, *All Our Patent Are Belong to You*, TESLA (June 12, 2014), <https://www.tesla.com/blog/all-our-patent-are-belong-you>.

²³⁵ *The Open Source Definition*, OPEN SOURCE INITIATIVE, <https://opensource.org/osd-annotated> (last visited Mar. 1, 2017).

²³⁶ Musk, *supra* note 234.

²³⁷ See Velásquez, *supra* note 204.

²³⁸ *Compulsory Licensing of Pharmaceuticals and TRIPS*, *supra* note 89.

²³⁹ See Paice, 504 F.3d at 1316.

²⁴⁰ Velásquez, *supra* note 204, at 7.

rather than the government, they are often used strategically; for instance, to foster market entry.²⁴¹ If this methodology were used in the domestic prosthetics market, it could foster relationships between prosthetic behemoths and smaller regional-based manufacturing companies. By granting licenses for production to smaller companies, the large corporations could ideally devote more time to R&D, while allowing for increased supply and greater competition in future markets. Furthermore, down the road, such arrangements, contingent on royalties, “may allow for substantial price reductions.”²⁴²

The future of the prosthetics industry is uncertain. While there are signs of great promise, including revolutionary technologies like microprocessor-based limbs,²⁴³ there have also been controversies pertaining to Medicare, primary care providers, and licensed O&P practitioners.²⁴⁴ However, a number of case studies, some international, and other domestic, have attempted to demonstrate possible channels that the prosthetics industry can follow to alleviate price and supply pressures resulting from frivolous patents and lawsuits. In alleviating this public health crisis, voluntary agreements are the ideal starting point for negotiations. Should this fail, judicial intervention may prove to be a necessity in order to swiftly and justly provide more accessible healthcare to millions of Americans.

²⁴¹ *Id.*

²⁴² *Id.*

²⁴³ See *X3 Prosthetic Leg*, *supra* note 30.

²⁴⁴ Kounang, *supra* note 39.