

THE PLUMPY'NUT PREDICAMENT: IS COMPULSORY LICENSING A SOLUTION?

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INTRODUCTION

Ready-to-use therapeutic foods (RUTFs) are nutritional products that are high in energy and protein and are enhanced with vitamins and minerals designed specifically to treat different forms of malnutrition.¹ RUTFs have several known applications, however, chief amongst them is the use of RUTFs to treat malnutrition in children or to supplement the diets of elderly patients with special nutritional requirements.² RUTFs can be made with a mixture of different proteins, carbohydrates, and fats and can potentially be manufactured without using water, which prevents spoilage.³ Shelf longevity and the ability to consume without cooking provide the key benefits of RUTFs.⁴

Over the past twenty years, RUTFs have become increasingly important in the global hunger context.⁵ The United Nations (UN) estimates that almost one-third of children in developing countries are malnourished, with malnourishment causing over 40% of the eleven million yearly deaths of children under the age of five in these countries.⁶ Malnourishment is defined as a state of being poorly nourished and is a result of insufficient caloric intake combined with a deficiency of protein and nutrients.⁷ Of particular geographic interest is Sub-Saharan Africa, where more than 42% of children suffer from moderate to severe malnourishment, with this number projected to increase to over 50% by 2025.⁸ The effect on children in Sub-Saharan Africa is amplified by low government effectiveness, violent conflicts, and rampant poverty.⁹ However,

* I would like to thank the Chicago-Kent Journal of Intellectual Property Editors for their help and Professor Chris Seaman for his invaluable contributions and assistance with this Article. And, of course, many thanks to my parents, Mr. Sheikh Rahim and Mrs. Noorussabah Bakhsh for their never-ending support and love.

¹ Steve Collins, *Community Therapeutic Care: A New Approach to Managing Acute Malnutrition in Emergencies and Beyond*, Food and Nutritional Technical Assistance, Technical Note No. 8, June 2004.

² S. Isanaka, *Effect of preventive supplementation with ready-to-use-therapeutic food on the nutritional status, mortality and morbidity of children 6 to 60 months in Niger: a cluster randomized trial*, J. AM. MED. ASSOC., Jan. 21, 2009; 301(3): 277–285.

³ *Id.*

⁴ *Id.*

⁵ Doctors Without Borders, *DWB Calls for Increased Use of Nutrient Dense RUTF to Save Malnourished Children's Lives*, Oct. 10, 2007, available at <http://www.worldhunger.org/articles/07/global/doctors.htm>.

⁶ World Hunger Education Service, 2011 World Hunger and Poverty Facts and Statistics, available at <http://www.worldhunger.org/articles/Learn/world%20hunger%20facts%202002.htm>.

⁷ UNICEF, *Malnutrition: The Big Picture*, available at http://www.unicef.org/nutrition/index_bigpicture.html

⁸ UNICEF, *Fighting Malnutrition to Save Lives*, available at <http://www.unicefusa.org/work/nutrition/>.

⁹ *Id.*

malnourishment is a condition that can consistently be treated successfully by an adequate diet for a period of approximately six months.¹⁰ RUTFs satisfy the nutritional requirements for a diet adequate to combat malnutrition and as such, are an essential tool against global hunger.¹¹

Plumpy'Nut is a RUTF that was developed by French pediatrician Andre Briend in 1996.¹² At the time, Briend was working for Institut de Recherche pour le Développement, a research institute that was collaborating with another French corporation, Nutriset, on a project to develop a commercially viable treatment specifically for malnutrition.¹³ After several failed trials, Plumpy'Nut was developed using a blend of peanut butter, powdered milk, sugar, and oil and is fortified with vitamins and minerals.¹⁴

Over the past five years, Plumpy'Nut has transformed the treatment of malnourishment.¹⁵ Plumpy'Nut quickly developed a reputation as a cure to malnutrition during the 2005 food crisis in Niger.¹⁶ This food crisis was the first time Plumpy'Nut was mass distributed as a solution to malnutrition.¹⁷ It was during this first distribution that Plumpy'Nut garnered excellent reviews and rocketed to worldwide popularity, with non-profit organizations labeling the RUTF a "wonder product," "silver bullet," and "life saver."¹⁸ Since then, Plumpy'Nut has maintained approximately 90% of the market share of RUTFs.¹⁹ Among the novel characteristics of Plumpy'Nut that make it the RUTF of choice for the UN and the World Health Organization (WHO) are that, unlike other RUTFs, there is no need to mix the product with water before consumption, and it is also the first RUTF with a solid texture.²⁰ Additionally, Plumpy'Nut can be consumed without supervision of a physician, which allows home treatment of malnutrition, easing the backlog on overburdened local hospitals.²¹ Most importantly, Plumpy'Nut has a good taste, making it desirable to children.²²

¹⁰ *Id.*

¹¹ *Id.*

¹² Nutriset, *Plumpy'Nut*, available at <http://www.nutriset.fr/en/product-range/produit-par-produit/plumpynut-ready-to-use-therapeutic-food-rutf.html>.

¹³ Nutriset, *Plumpy'Nut Timeline*, available at <http://www.nutriset.fr/en/about-nutriset/nutriset-timeline.html>.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ Hugh Schofield, *Legal Fight Over Plumpy'Nut, the Hunger Wonder-Product*, (8 April 2010), available at <http://news.bbc.co.uk/2/hi/europe/8610427.stm>.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.* (stating "In 2002 it took 2,000 staff to treat 10,000 children during a famine in Angola. In Niger we needed just 150 staff for the same number of patients. Thanks to Plumpy'Nut, mass treatment is suddenly possible.")

²² *Id.*

After the formula for Plumpy’Nut was developed, Nutriset immediately pursued patent protection in France.²³ Since 1997, Plumpy’Nut has been patented in thirty-eight countries, including much of Africa.²⁴ Nutriset has also aggressively protected its intellectual property, and because of this, the private company has been able to place a stranglehold on the RUTF market.²⁵ However, Nutriset has been unable to manufacture enough Plumpy’Nut to satisfy its growing demand from non-profit organizations and initially refused to license others to use the technology.²⁶ Nutriset currently possesses neither the production capacity nor the resources to expand production capacity to fill current standing orders of Plumpy’Nut.²⁷ Instead, the company has focused on its franchising system or else resorted to licensing strictly in countries where there is no patent protection or locations where the raw material costs make mass production impractical.²⁸ As a result, some children who suffer from malnutrition are unable to receive Plumpy’Nut in a timely fashion, and non-profit organizations that want to order additional quantities are limited by Nutriset’s production capabilities.²⁹ Finally, Nutriset has also taken legal action to prevent other non-profit organizations from manufacturing, transporting, or even storing similar and cheaper RUTFs, despite the strong international demand.³⁰

This Article suggests that in certain legislatively defined humanitarian instances, the United States government should issue compulsory licenses for patented technology in order to benefit non-domestic populations that may otherwise be disastrously affected. Specifically, by reapplying currently used principles from pharmaceutical and agricultural patents to food-related patents, and by implementing a novel compensation scheme, issues in which a patentee is unable or unwilling to license a patent can be compelled to do so while still benefitting from their patented technology. Legislation of this kind would still fall within the guidelines of the Trade-Related Aspects of Intellectual Property (TRIPS) agreement, of which the U.S. is a signatory. Part II of this article investigates compulsory licenses in intellectual property generally, as well as antitrust provisions relevant to compulsory licensing. Part III discusses the merits of the Plumpy’Nut patent protection and antitrust concerns. Part IV explains compulsory licensing under TRIPS and its subsequent effects on intellectual property. Finally, Part V

²³ Andrew Rice, *The Peanut Solution*, (2 September 2010), available at <http://www.nytimes.com/2010/09/05/magazine/05Plumpy-t.html?pagewanted=all>.

²⁴ *Id.*

²⁵ *Id.* (stating Nutriset has taken legal action even in states where there has not been manufacture, rather only storage or transit, even when there is no patent in the export or destination state, preventing the buildup of any reserve supply).

²⁶ Sasha S. Rao, *Improving Access to Patented Humanitarian Products Via TRIPS: A Study of the Plumpy’Nut Problem*, 15 MICH. ST. U. J. MED. & L. 111, 113-114 (2010) (stating Plumpy’Nut can be manufactured locally due to its simple process and use of raw materials that are available in most developing counties. The principal cost is the raw materials themselves. Nutriset has franchised some manufacturers to produce Plumpy’Nut. The output from these facilities is for situations or orders that require less than 50 tons of Plumpy’Nut annually. However, the franchisee must buy the vitamins, minerals, and additives directly from Nutriset.).

²⁷ *Id.*

²⁸ *Id.* at 114.

²⁹ *Id.*

³⁰ *Id.* at 115.

argues for reapplication of certain compulsory patent licensing guidelines to food patents, under certain circumstances.

I. LICENSING IN INTELLECTUAL PROPERTY

Licenses are commonplace in intellectual property and are simply contracts between the owner of the intellectual property, who becomes the licensor, and a second party, the licensee.³¹ License agreements have varying scope and each party is free to negotiate the terms of the contractual agreement.³² A license, however, cannot grant rights exceeding the rights of the intellectual property owner; a party cannot license more rights than it possesses.³³ Generally speaking, in U.S. patent and copyright law, the owner of intellectual property has an exclusive right to their intellectual property and maintains complete control over any licensing.³⁴ However, in some instances, the U.S. government has granted compulsory, or statutory, licenses.³⁵ A compulsory license is an involuntary contract between a willing licensee and an unwilling licensor.³⁶ These licenses are used in copyright and patent law.³⁷ At times, this compulsory license is mandated due to antitrust law and regulations.³⁸

A. Compulsory Licensing in Copyright Law

Compulsory licenses in copyright law allow a party to use a copyrighted work without the permission of the copyright owner.³⁹ Use of the copyrighted work is regulated by the U.S. Copyright Act and is subject to a standardized royalty.⁴⁰ A compulsory license in copyright law grants the licensee only the right to use the copyrighted material, not to distribute or reproduce it.⁴¹

In creating a compulsory license scheme in federal copyright law, the U.S. Congress aimed to balance the interests of authors, distributors, and the general public.⁴² Additionally, the implementation of compulsory licenses has allowed the law to keep pace with technology.⁴³ There are three primary public policy reasons for compulsory licenses in copyright law: 1) to assist public dissemination and author compensation; 2)

³¹ *Mixing Equipment Co. v. Innova-Tech, Inc.*, 228 U.S.P.Q. 221, 224 (E.D.Pa.1985).

³² Peter Maybarduk, *Compulsory Licenses: A Tool to Improve Global Access to the HPV Vaccine?* 35 AM. J.L. & MED. 323, 325 (2009).

³³ *Id.*

³⁴ *Id.*

³⁵ *See, e.g., id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ Jethro Dean, *Would You Like to Play Again? Saving Classic Video Games From Virtual Extinction Through Statutory Licensing*, 35 SW. U. L. REV. 405, 419 (2006).

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² Jason Rooks, *Constitutionality of Judicially Imposed Compulsory Licenses in Copyright Infringement Cases*, 3 J. INTEL. PROP. L. 255, 258 (1995).

⁴³ *Id.*

to avoid past market failure; and 3) to reduce free riding.⁴⁴ Compulsory licensing eliminates the need for individual licensing between the copyright owner and an interested licensee and facilitates timely distribution of a copyrighted work, while ensuring that the author is compensated in some manner.⁴⁵ Before compulsory licensing, the market allowed owners and licensees to contract with each other; however, this system proved unstable and led to situations in which parties were licensing identical works at different costs, and copyright enforceability became difficult due to inconsistent judicial determinations.⁴⁶ Finally, with modern technology, free riding has made it difficult to enforce copyright protection because copyrighted works can be distributed quickly over the internet.⁴⁷ Compulsory licenses assist in this regard by ensuring that the required license fee encourages users to obtain the compulsory license rather than infringe the copyright, thereby reducing free riding.⁴⁸

B. Compulsory Licensing in Patent Law

Patents are generally the strongest form of intellectual property protection.⁴⁹ The principal goals of the United States patent system are to encourage innovation, urge disclosure, and promote manufacture.⁵⁰ In exchange for disclosing an invention that is useful, novel, and non-obvious, the patentee is granted a limited exclusive right to exclude others from making, using, offering for sale, or selling the invention for a period of twenty years from the date of filing.⁵¹ An inventor may commercialize the invention or may choose not to, but can prevent others from using any part of the technology.⁵² Essentially, a patent is a limited term monopoly that rewards an inventor for their innovation.⁵³

Accordingly, compulsory licensing has found little support in patent law, other than as a remedy to an antitrust violation.⁵⁴ Any form of compulsory licensing is thought to negatively affect the policy goals of patent law by reducing security in the investment in developing new technology and subsequently obtaining patent protection and also by reducing the incentive to innovate, particularly in a field where compulsory licensing is an option.⁵⁵ Rather than developing new technology independently, a party could wait until someone else developed it, and then, if the invention was commercially successful,

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.* at 269-270.

⁴⁸ *Id.*

⁴⁹ See Kurt Saunders, *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression*, 15 HARV. J.L. & TECH. 389, 426 (2002).

⁵⁰ Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349, 357 (1993).

⁵¹ *Id.*

⁵² *Id.*

⁵³ See Saunders, *supra* note 49, at 426.

⁵⁴ *Id.* at 430-431.

⁵⁵ *Id.*

the party could obtain a compulsory license and enter the market without investing in the research.⁵⁶

However, patent protection is not unlimited.⁵⁷ For example, patents reading on standards-essential technology and patents owned by members of standards-setting organizations are generally subject to licensing at reasonable and non-discriminatory (RAND) terms, in order to facilitate the design of compatible products and interoperability of devices manufactured by different manufacturers.⁵⁸ Additionally, compulsory licensing in the patent context has been addressed by the United States legislature.⁵⁹ In 28 U.S.C. 1498(a), the U.S. government is given the authority to use, or to authorize a third party to use, any issued U.S. patent.⁶⁰ In exchange for this unlicensed use, the patentee is entitled to just compensation.⁶¹

The U.S. government has taken advantage of this statute on different occasions.⁶² In the Clean Air Act, the government utilized this authority by permitting compulsory licensing whenever the Attorney General finds that an otherwise unavailable patent is needed to accomplish the goals of the Act, and there is no reasonable alternative.⁶³ Similarly, the Atomic Energy Act allows compulsory licensing if the license would be in the interest of the public.⁶⁴ Other instances include the Plant Protection Act and the Bayh-Dole Act, which respectively allow compulsory licensing when it is necessary to ensure an adequate supply of food or when the technology is the result of federally funded research.⁶⁵ However, the provisions of these Acts have been interpreted narrowly, indicating a policy avoiding the use of compulsory licensing whenever possible.⁶⁶

C. Antitrust Law and Patents

Antitrust law aims to encourage competition, improve economic efficiency, and limit activity interfering with the normal effects of supply and demand in the free market.⁶⁷ There is an inherent tension between patent law and antitrust law; while one grants a temporary monopoly and can potentially confer monopoly power on the patentee, the other seeks to eliminate monopolies.⁶⁸ However, the interplay between a patent and monopoly power is not an automatic process.⁶⁹ Likewise, a monopoly is not an

⁵⁶ *Id.* (referring to this behavior as the “wait and see approach”).

⁵⁷ George Tsai, *Canada's Access to Medicines Regime: Lessons for the Compulsory Licensing Schemes Under the WTO Doha Declaration*, 49 VA. J. INT'L L. 1063, 1063 (2009).

⁵⁸ See Mark A. Lemley, *Intellectual Property Rights and Standard-Setting Organizations*, 90 CAL. L. REV. 1889, 1896 (2002).

⁵⁹ See, e.g., 28 U.S.C. §1498. (2011)

⁶⁰ Julian-Arnold, *supra* note 50, at 352.

⁶¹ See *Motorola, Inc. v. United States*, 729 F.2d 765, 772 (Fed. Cir. 1984).

⁶² Saunders, *supra* note 49 at 435.

⁶³ 42 U.S.C. §7608 (1994).

⁶⁴ *Id.* §2138(a) (1999).

⁶⁵ Saunders, *supra* note 49, at 446.

⁶⁶ *Id.*

⁶⁷ Arnold Calmann, *Understanding the Intellectual Property License*, 915 PLI/Pat 449, 465 (2007).

⁶⁸ Saunders, *supra* note 49 at 431.

⁶⁹ *Id.*

automatic violation of Section 2 of the Sherman Act, a provision that regulates monopolies in antitrust law.⁷⁰

The key difference in a monopoly created by a patent compared to a monopoly in the antitrust context is that patented technologies may compete with each other, thereby constraining monopoly pricing.⁷¹ In other words, a patented technology can be substitutable.⁷² Therefore, a patent only confers monopoly power on the patentee in the antitrust sense when there are no substitutes for the patented product.⁷³ As a result, when a patentee refuses to license a patent, this behavior is anticompetitive only when it creates or extends monopoly power in the relevant marketplace.⁷⁴

Section 2 of the Sherman Act regulates monopolization.⁷⁵ In order to violate the statute, a party must have monopoly power in the relevant market and must also exhibit monopoly conduct.⁷⁶ A critical step in determining whether a Section 2 violation has occurred is determining what the relevant market is.⁷⁷ Courts have used factors such as the substitutability of the product or supplier as well as the geographical market.⁷⁸ Monopoly power has been generally defined as 75% of market share in the relevant market, although this is considered on a sliding scale when there are significant barriers to enter the market.⁷⁹ Finally, monopoly conduct is fact specific and guided by case law.⁸⁰

II. THE PLUMPY’NUT PATENT

There are three primary types of patents: utility, design, and plant.⁸¹ Patents on foods fall under the utility category, as utility patents cover processes, machines, articles of manufacture, or compositions of matter.⁸² In order to be patentable, foods still need to meet the normal requirements of patentability.⁸³ This creates an additional hurdle for culinary patents, as utility patents are not generally granted for simple recipes; rather, to obtain a patent a food must be new and non-obvious in view of other recipes.⁸⁴ However, if a food meets these requirements, it is patentable under U.S. patent law.⁸⁵

⁷⁰ Robin C. Feldman, *The Insufficiency of Antitrust Analysis for Patent Misuse*, 55 HASTINGS L.J. 399, 401 (2003).

⁷¹ Saunders, *supra* note 49, at 431-432.

⁷² *See id.*

⁷³ *Id.* at 431.

⁷⁴ 35 U.S.C. §271(d)(4) (1994) (rationale for this rule lies in the belief that the primary social utility of a patent is in the disclosure of an invention rather than commercialization).

⁷⁵ 15 U.S.C §2 (1890).

⁷⁶ Feldman, *supra* note 70 at 401.

⁷⁷ *See, e.g.*, *Image Tech. Servs. V. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997).

⁷⁸ *See id.*

⁷⁹ *See id.*

⁸⁰ *See id.*

⁸¹ Emily Cunningham, *Protecting Cuisine Under the Rubric of Intellectual Property: Should the Law Play a Bigger Role in the Kitchen?*, 9 J. HIGH TECH. L. 21, 23 (2009).

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *Id.* at 25.

⁸⁵ *Id.*

Plumpy'Nut has been patented in the United States.⁸⁶ The '284 patent contains a single independent claim directed to a complete food or nutritional supplement which contains at most 10% by weight of water, develops an osmolality of less than 100 mOsm/kg after immersion in four times its own volume of water and is stable to oxidation, comprising a mixture of food-grade products, said mixture being coated with at least one lipid-rich substance derived from oleaginous seeds and being enriched in vitamins, soluble or insoluble mineral salts, enzymes or mixtures thereof.⁸⁷

The patent has been criticized as being potentially invalid because it seems overly broad as well as obvious in light of prior recipes.⁸⁸ Critics of the Plumpy'Nut patent argue that it covers essentially any nut-based RUTF paste and is thus impossible to design around, while others argue that the patent has essentially conferred monopoly power on Nutriset and thus violated the Sherman Act.⁸⁹

A. Should the '284 Patent Be Held Invalid?

Two non-profit organizations, Mama Cares Foundation and Breedlove Foods, Inc. have unsuccessfully attempted to bring legal action against the '284 patent for invalidity.⁹⁰ The primary argument for invalidity in this instance is that the single independent claim in the '284 patent is overly broad.⁹¹ While broad claims are patentable, these claims are susceptible to challenge on novelty grounds.⁹² The relevant statutes of the Patent Act are Sections 102 and 103.⁹³ Section 102 prevents patenting an invention that already exists or is described in prior art, and Section 103 prohibits patenting a claim that would be obvious, in light of prior disclosures, to someone having ordinary skill in the art.⁹⁴ Courts have employed a four factor test in determining non-obviousness: 1) the scope and content of the prior art; 2) the differences between the current claim and the prior art; 3) the level of ordinary skill in the art; and 4) any other objective evidence of non-obviousness.⁹⁵

⁸⁶ U.S. Patent No. 6,346,284.

⁸⁷ *Id.*

⁸⁸ Rice, *supra* note 23, (2 Sept. 2010).

⁸⁹ *Id.*

⁹⁰ Rao, *supra* note 26, at 114 (arguing that due to procedural difficulties and the risk of being counter sued for patent infringement, the organizations are headed towards an unsuccessful legal battle and have pursued other options, such as developing an open source formula).

⁹¹ *Id.* (stating the broad scope impacts the cost, quality, and security of the supply chain for RUTFs. Patent allows Nutriset to essentially limit the number of providers, and also precludes aid organizations from finding similar products that may be cheaper, in greater reserve, or of better quality.)

⁹² Cunningham, *supra* note 81, at 23.

⁹³ Rao, *supra* note 26 at 119-120.

⁹⁴ Sandra Schneider, *Scope of Biotechnology Inventions in the United States and in Europe - Compulsory Licensing, Experimental Use and Arbitration: A Study of Patentability of DNA-Related Inventions with Special Emphasis on the Establishment of an Arbitration Based Compulsory Licensing System*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 163, 183 (2004).

⁹⁵ Rao, *supra* note 26, at 120.

Section 102 does not apply to the instant case because there is no prior art describing the specific formula of Plumpy’Nut.⁹⁶ The four factors used to determine obviousness in Section 103, however, have stronger applicability.⁹⁷ The scope and content of prior art will be large and voluminous, including all prior RUTFs designed to treat malnourishment.⁹⁸ The differences between the claim here and the prior art are slightly more difficult to distinguish.⁹⁹ The claim is specific in defining a composition of acceptable products, yet it is broad in that it allows use of any oleaginous seed and all vitamins.¹⁰⁰ This differentiates the claim from the prior art by proportion and composition of nutrients, and potentially by whether the product is in liquid or solid form.¹⁰¹ Because of this, it is likely that it will be unique when compared in totality to the prior art.¹⁰² The ordinary skill in the art is presumably low, as the product uses common household materials and staple ingredients, and can be made in a household kitchen.¹⁰³ However, considering the objective factors of non-obviousness, the commercial success that Plumpy’Nut has enjoyed indicates that the claim is not obvious.¹⁰⁴ The commercial success, combined with the initial perception of the inventors regarding the product’s potential commercial success, weighs strongly against holding the claim obvious.¹⁰⁵

Courts have discussed the weight of each of the four factors in analyzing Section 103.¹⁰⁶ Following through the analysis, it would be up to a court to decide if the commercial success and potential differences between the current claim and the prior art outweigh what someone skilled in the art would have considered obvious, given the prior art.¹⁰⁷ However, a finding of invalidity may not solve the problem entirely.¹⁰⁸ If the patent were held invalid, this would only impact the U.S. patent.¹⁰⁹ To get the same result worldwide, legal action would have to be taken in each of the thirty-eight countries the patent is granted in to accommodate for shipping and transport of the product.¹¹⁰ This presents a sizeable legal undertaking and would require significant resources, time, and investment on behalf of the parties involved.¹¹¹

⁹⁶ *See id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *See id.*

¹⁰⁰ *See id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *See id.*

¹⁰⁶ *See, e.g.,* KSR Int’l Co. v. Teleflex, 550 U.S. 398 (2007).

¹⁰⁷ *See* Rao, *supra* note 26, at 121.

¹⁰⁸ *See id.* at 124.

¹⁰⁹ *See id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

B. Has the '284 Patent Conferred Monopoly Power on Nutriset?

If Nutriset has monopoly power in its relevant market, a finding of violation of Section 2 of the Sherman Act could potentially follow.¹¹² The '284 patent would only confer monopoly power on Nutriset if there are no substitutable products.¹¹³ If the '284 patent confers monopoly power on Nutriset, then Nutriset would also have to engage in monopoly conduct in order to violate Section 2 of the Sherman Act.¹¹⁴

The '284 patent has likely conferred monopoly power on Nutriset.¹¹⁵ When considering potential substitutable products, the specific advantages of Plumpy'Nut also have to be considered.¹¹⁶ The substitute would have to have a shelf life of two years without refrigeration, be fit for consumption without mixing with water, contain all of the vitamins and minerals necessary for a full day, and have a pleasant taste while maintaining a similar cost.¹¹⁷ There are currently no non-infringing products widely available for substitution.¹¹⁸ The 10% of the market share Nutriset does not own consists of RUTFs that have much shorter shelf lives, are substantially more expensive, or otherwise require supervision of a physician and multiple daily doses.¹¹⁹ For example, Meals-Ready-to-Eat (MRE), used by the American military, have a shelf life of three years.¹²⁰ However, they are not nutritionally composed to be consumed for more than twenty-one days in a row, while a Plumpy'Nut cycle lasts for a period of over six months.¹²¹ Also, because of expensive packaging requirements, each MRE costs the U.S. government over \$7, compared to just under \$1 for each unit of Plumpy'Nut.¹²² Because there are no substitutable products that do not infringe the '284 patent, the patent has likely conferred monopoly power on Nutriset.¹²³

Monopoly power alone does not create a legal cause of action.¹²⁴ The monopoly power must be in a relevant market, and monopoly conduct is required for a Sherman Act violation.¹²⁵ Defining a relevant market is a critical step in analyzing a Sherman Act violation.¹²⁶ Here, the market can be defined as the global market for RUTFs, of which Nutriset has a 90% market share.¹²⁷ Therefore, Nutriset has monopoly power in a relevant

¹¹² See 15 U.S.C §2 (1890).

¹¹³ See *Illinois Tool Works Inc. v. Independent Ink, Inc.*, 547 U.S. 28 (2006).

¹¹⁴ See generally *id.*

¹¹⁵ See *id.*

¹¹⁶ Sanjay Gupta, *The Funny Sounding Nut Paste That's Saving Children's Lives in Somalia*, CNN (Aug. 20, 2011), <http://eatocracy.cnn.com/2011/08/10/plumpynut/>.

¹¹⁷ *Id.*

¹¹⁸ CBSNews, *A Life Saver Called "Plumpynut"*, CBSNews (Feb. 11, 2009), <http://www.cbsnews.com/stories/2007/10/19/60minutes/main3386661.shtml>.

¹¹⁹ *Id.*

¹²⁰ British Broadcasting Corporation, *US Army's Hi-Tech, Two Year Old Sandwich Served Fresh*, BBC (Dec. 5, 2011), <http://www.bbc.co.uk/news/science-environment-15987343>.

¹²¹ *Id.*

¹²² Rice, *supra* note 23, (2 September 2010).

¹²³ *Id.*

¹²⁴ 15 U.S.C §2 (1890).

¹²⁵ *Id.*

¹²⁶ See *Walker Process Equip., Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172, 177 (1965).

¹²⁷ Rao, *supra* note 26, at 121.

market.¹²⁸ In addition to monopoly power in a relevant market, monopoly conduct is required.¹²⁹ Potential monopoly conduct could be the fact that Nutriset has refused to license its technology.¹³⁰ However, Section 271(d)(4) of the Patent Act states that “no patent owner otherwise entitled to relief for infringement . . . shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of having . . . refused to license or use any rights to the patent.”¹³¹ The United States Court of Appeals for the Federal Circuit has interpreted this statute, holding that refusals to license a patent are per se lawful, as long as there is no illegal tying, fraud on the U.S. Patent and Trademark Office or sham litigation to enforce the patent.¹³² Refusal to license a patent, therefore, does not constitute monopoly conduct and does not immediately give rise to an antitrust violation.¹³³ Accordingly, Nutriset’s behavior with the ‘284 patent likely does not violate the Sherman Act.¹³⁴

III. TRIPS

The Trade Related Aspects of Intellectual Property (TRIPS) is an international agreement developed by the World Trade Organization (WTO) that outlines legal standards that member nations are obligated to implement in their domestic legislation as a requirement of membership.¹³⁵ The United States is a founding member of the WTO and an early signatory.¹³⁶ TRIPS was drafted with the goal of creating intellectual property regulations that stress protection and exclusion rather than dissemination and competition, and the regulations apply to all intellectual property systems.¹³⁷ However, one of the main objectives of TRIPS is to increase the flow of patented exports to developing nations that are signatories of the agreement.¹³⁸ This is because by guaranteeing the minimum level of intellectual property enforcement required domestically by TRIPS, developed nations would have less concern and increased incentive to provide these developing nations with patented products and technology.¹³⁹

In certain instances, TRIPS allows member nations to grant compulsory licenses for patented technology.¹⁴⁰ In the Doha Declaration of 2001, these provisions of TRIPS

¹²⁸ *See id.*

¹²⁹ *See* 15 U.S.C. §2 (1890).

¹³⁰ *See* LOUIS ALTMAN, CALLMANN ON UNFAIR COMPETITION, TRADEMARKS AND MONOPOLIES, 1 CALLMANN ON UNFAIR COMP., TR. & MONO. §4:55 (4th ed. 2011).

¹³¹ 35 U.S.C. §271(d)(4).

¹³² *See, e.g.*, *Image Tech. Servs. V. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997); *CSU, L.L.C. v. Xerox Corp.*, 203 F.3d 1322 (Fed. Cir. 2000).

¹³³ Saunders, *supra* note 49, at 393.

¹³⁴ *See id.*

¹³⁵ Maria Barker, *The Use of Universities' Intellectual Property to Address Humanitarian Concerns in Developing Nations*, 19 TRANSNAT'L L. & CONTEMP. PROBS. 923, 932 (2011).

¹³⁶ *Id.*

¹³⁷ *Id.* (including patents, trademarks, copyright, and trade secrets).

¹³⁸ *Id.* at 933.

¹³⁹ *Id.* at 933-934 (stating many developing nations currently find it more beneficial to implement low levels of intellectual property protection, discouraging transactions with developed nations).

¹⁴⁰ Tsai, *supra* note 57, at 1066.

were reinforced.¹⁴¹ The Doha Declaration was adopted as part of TRIPS primarily to clarify the scope of the agreement and also to alleviate concerns of developing countries that feared the agreement was being interpreted narrowly.¹⁴² In the Doha Declaration, there are three paragraphs relevant to compulsory licensing of patented technology.¹⁴³ Specifically, these paragraphs indicate that TRIPS does not aim to prevent member states from taking measures to protect public health.¹⁴⁴ Additionally, the paragraphs identify, under the category of public health, access to essential medicines by all people as a central goal of the Doha Declaration.¹⁴⁵ In practice, the compulsory licensing provisions of the Doha Declaration have been principally applied to pharmaceuticals and, to a lesser extent, agriculture.¹⁴⁶ However, the provisions have been abused by some member nations and have also been criticized as reducing the incentive to innovate.¹⁴⁷

A. USE OF THE COMPULSORY LICENSING PROVISIONS OF TRIPS

Paragraph 4 of the Doha Declaration states that member states have the “right to protect public health and, in particular, to promote access to medicines for all.”¹⁴⁸ Paragraph 5(b) of the Doha Declaration provides member states with the power to grant compulsory licenses and also to determine the grounds upon which the license is to be granted.¹⁴⁹ Finally, Paragraph 5(c) limits the grant of compulsory licenses to situations of national emergency or extreme urgency, but allows each individual state to independently define the terms “national emergency” or “extreme urgency.”¹⁵⁰ Accordingly, as the only category of patented technology to be specifically mentioned in the Doha Declaration, pharmaceuticals have been routinely subjected to compulsory licensing by member states.¹⁵¹ To a lesser degree, compulsory licenses for agricultural products or processes have also been issued by member states.¹⁵²

Pharmaceuticals are patentable in almost every individual member state of TRIPS.¹⁵³ Pharmaceutical patents are important because they provide the primary form of intellectual property protection for the developer and are often the only way the developer can recover the sizable cost of development.¹⁵⁴ Compulsory licensing of

¹⁴¹ World Trade Organization, Ministerial Declaration of Nov. 14, 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).

¹⁴² *Id.*

¹⁴³ *Id.* at ¶¶4–6.

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ See, e.g., Cynthia Ho, *Patent Breaking or Balancing?: Separating Strands of Fact From Fiction Under TRIPS*, 34 N.C. J. INT'L L. & COM. REG. 371, 400-401 (2009).

¹⁴⁷ *Id.*

¹⁴⁸ World Trade Organization, Ministerial Declaration of Nov. 14 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*; see also Ho, *supra* note 146, at 400.

¹⁵¹ Ho, *supra* note 146, at 400.

¹⁵² *Id.*

¹⁵³ Tsai, *supra* note 57, at 1064.

¹⁵⁴ See, e.g., *Developing a New Drug Costs \$231 Million, Tufts Center Study Finds*, Pharmaceutical Manufacturers Association Newsletter 32 (Apr. 23, 1990): 4-5.

pharmaceuticals can have a positive effect in a humanitarian perspective.¹⁵⁵ By issuing a third party a compulsory license, a government can greatly reduce the cost of treatment.¹⁵⁶ For example, Malaysia issued compulsory licenses for three patented Acquired Immune Deficiency Syndrome (AIDS) drugs in 2003.¹⁵⁷ As a result, the cost of AIDS treatment in the country was reduced 81%, reducing a monthly cost of \$315 to \$58.¹⁵⁸ This reduced cost in turn allowed Malaysia to triple the number of patients treated for AIDS in government hospitals.¹⁵⁹ Other developing countries, such as Indonesia, Zimbabwe, and South Africa have also seen similar results after issuing compulsory licenses.¹⁶⁰ However, the use of compulsory licenses in developed countries has not produced equal results.¹⁶¹

For example, Canada enacted a domestic statute entitled, “Canada’s Access to Medicines Regime (CAMR),” which aimed to implement the compulsory licensing provisions of the Doha Declaration.¹⁶² The statute aimed to create a system to export generic drugs to developing countries via a compulsory license, while balancing the commercial interests of the patent holder with broader humanitarian objectives.¹⁶³ However, the statute as enacted created minimal practical benefit as it offered generic pharmaceutical manufacturers little incentive to produce medicines with a compulsory license.¹⁶⁴

As countries with significant generic pharmaceutical capabilities, Brazil and India have been among the most active WTO member states in issuing compulsory licenses for medicine.¹⁶⁵ However, the practice in these countries has been to manufacture the drugs not for their domestic population, but to export them to other developing countries that may not have the production capabilities.¹⁶⁶ Although this practice is technically legal under TRIPS, the practice has come under fire as an abuse of the compulsory licensing provision.¹⁶⁷ The result of these practices is that the original manufacturer is unable to sell the drug at a competitive cost and is ultimately unable to recover the investment in developing the medicine.¹⁶⁸ A tangential issue is that consumers of the drug in developed countries are expected to pay an even higher price for the drug, in order for the original manufacturer to combat the flooding of the market in developing countries with generic products.¹⁶⁹

¹⁵⁵ Maybarduk, *supra* note 32, at 328.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *See id.*

¹⁶² Tsai, *supra* note 57, at 1064.

¹⁶³ *Id.*

¹⁶⁴ *See id.*

¹⁶⁵ Horace Anderson Jr., *We Can Work it Out: Co-op Compulsory Licensing as the Way Forward in Improving Access to Anti-retroviral Drugs*, 16 B.U. J. SCI & TECH. L. 167, 168 (2010).

¹⁶⁶ *Id.*

¹⁶⁷ *Id.* at 169.

¹⁶⁸ Schmeider, *supra* note 94, at 175.

¹⁶⁹ *Id.* at 175-176.

A second area of patented technology that is subjected to compulsory licensing is agriculture, or biotechnology.¹⁷⁰ However, the majority of biotechnology patents are not effective in geographic areas that require them the most.¹⁷¹ For example, genetically engineered seeds for corn or soybean that improve crop yield are of little benefit to countries in Sub-Saharan Africa, where neither the climate nor infrastructure permit the growth of corn or soybeans.¹⁷² Also, there is little incentive to innovate or design new biotechnology geared towards a geographic market where the farmers will not be able to provide compensation.¹⁷³ As a business consideration, designing products for Sub-Saharan Africa will not generally result in a high return on investment; the farmers in the area are by no means wealthy.¹⁷⁴ Agricultural patents are not subjected to compulsory licensing as often as pharmaceuticals for another reason.¹⁷⁵ In most cases, an agricultural product may be covered by many patents, creating a patent thicket.¹⁷⁶ For example, in 2000, a group of non-profit organizations attempted to free the technology used to grow vitamin-enriched rice.¹⁷⁷ In order to do so, the group had to clear over seventy patents and licenses that were held by thirty-two organizations.¹⁷⁸

Because food has a direct impact on public health, patented food products or processes also fall within the potential compulsory licensing provisions of TRIPS.¹⁷⁹ However, there are limited examples of compulsory licenses for patented foods being granted by member states.¹⁸⁰ Part of the reason is that food patents are small in number, and when they exist, they cover novelty or special foods.¹⁸¹ For many developing countries, the desire or market for typical patented foods is slim, due to the fact that populations may not even have sufficient access to staple, unpatented foods.¹⁸² Additionally, granting a compulsory license for a patented food is generally not thought to be a lucrative investment on behalf of the generic manufacturer, due to the low demand.¹⁸³

¹⁷⁰ Michael Taylor, *American Patent Policy, Biotechnology, and African Agriculture: The Case for Policy Change*, 17 HARV. J.L. & TECH. 321, 324 (2004).

¹⁷¹ *Id.*

¹⁷² Ronald Phillips, *Intellectual Property Rights for the Public Good: Obligations of U.S. Universities to Developing Countries*, 6 MINN. J.L. SCI. & TECH. 177, 181 (2004).

¹⁷³ *Id.* at 179-180.

¹⁷⁴ Raj Paul, *Tools for Survival: Proposing a Research Exemption for Agricultural Biotechnology Patents to Alleviate Global Hunger*, 18 GEO. J. ON POVERTY L. & POL'Y 103, 123 (2010).

¹⁷⁵ See Phillips, *supra* note 172, at 182-183.

¹⁷⁶ Paul, *supra* note 174, at 123.

¹⁷⁷ Phillips, *supra* note 172, at 181.

¹⁷⁸ *Id.*

¹⁷⁹ Rao, *supra* note 26, at 115.

¹⁸⁰ *Id.*

¹⁸¹ See, e.g., U.S. Patent App. 11/118,954 (Apr. 9, 2005) (reading on a system to utilize a flavor alteration utensil having a retainer in which a flavor element may be retained and by engagement with the flavor alteration utensil, the flavor of food managed with the utensil is altered).

¹⁸² See Rao, *supra* note 26, at 116.

¹⁸³ See Julian-Arnold, *supra* note 50, at 357-358.

B. The Effect of Compulsory Licensing Under TRIPS on the Incentive to Innovate

Intellectual property law is broadly premised on reward and incentive.¹⁸⁴ The theory of granting intellectual property rights to an individual or entity implies the belief that reward for creativity is imperative to develop a cycle of continuous creativity and to increase the amount of valuable knowledge in the public domain.¹⁸⁵ Striking a balance between the interests of an inventor or creator and the public domain is an ongoing consideration when considering intellectual property rights, and particularly patent law.¹⁸⁶ Within the patent context, an issued patent provides an inventor with the possibility of commercial success.¹⁸⁷ Accordingly, subjecting a patent to a compulsory license seemingly divests the inventor of his or her intellectual property, as well as the potential for commercial success, and therefore directly affects an inventor's incentive to innovate.¹⁸⁸

The ability for individual states to define when a national emergency or situation of extreme urgency occurs has led to instances of abuse of the TRIPS agreement.¹⁸⁹ Member states have full discretion over the amount of compensation to the patentee for a compulsory license, which creates an additional impact on the incentive to innovate.¹⁹⁰ Because of this broad power given to each independent state, there is a substantial discrepancy between the compensation awarded to the patentee.¹⁹¹ For example, some states use a hypothetical negotiation standard, while others provide only token compensation.¹⁹²

One example of a member state that has issued compulsory pharmaceutical licenses is Thailand.¹⁹³ Considering the context of the Doha Declaration, the generally accepted intent of the compulsory licensing provisions was to allow the compulsory licensing of medicines that treated infectious diseases, as these diseases were rampant in developing countries and generally led to death.¹⁹⁴ However, the plain language of the agreement includes all medicines.¹⁹⁵ Some member states have utilized this fact to their advantage and have been criticized as abusing the provision.¹⁹⁶ For example, Thailand has consistently issued compulsory licenses for medicines treating non-infectious conditions, such as heart disease and cancer.¹⁹⁷ For the purposes of TRIPS, Thailand is

¹⁸⁴ Chidi Oguamanam, *Beyond Theories: Intellectual Property Dynamics in the Global Knowledge Economy*, 9 WAKE FOREST INTELL. PROP. L. J. 104, 117 (2009).

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* at 118.

¹⁸⁸ *See id.*

¹⁸⁹ *See, e.g.*, Ho, *supra* note 146, at 373.

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² *See id.* at 373-374.

¹⁹³ *Id.* at 373.

¹⁹⁴ *Id.* at 373-374.

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

considered a middle-income country, drawing further ire from other member states.¹⁹⁸ Finally, in granting compulsory licenses, Thailand has instituted a practice of issuing the license with little prior warning and at a royalty rate of less than one percent of the total sale price.¹⁹⁹ This rate, at times only one-half percent, is generally calculated on a sale price far below the market price at which the generic is sold, effectively destroying the market for the original product.²⁰⁰

From an economic perspective, compulsory licensing in a field as lucrative as pharmaceuticals can encourage manufacturers to adopt a wait-and-see approach rather than focusing on developing new drugs.²⁰¹ By eliminating the research and development costs of new drugs, manufacturers can wait until a drug is discovered and patented by another party and further wait and see if the drug is a commercial success.²⁰² If so, the manufacturer can subsequently begin mass production of the drug while relying on a compulsory license from the patentee.²⁰³ Creating a clearly defined category of products or other patented technology that may be subject to a compulsory license can combat this.²⁰⁴ By providing this information in a clear manner, inventors will be aware of the potential subjection to a compulsory license before they even obtain the patent.²⁰⁵ A bright line standard is essential, however, to prevent this from becoming a tool of bad faith for generic manufacturers that simply want to engage in the inventor's business.²⁰⁶

IV. REAPPLICATION OF PHARMACEUTICAL COMPULSORY LICENSING TO PLUMPY'NUT

Antitrust law is not a solution to the Plumpy'Nut problem because antitrust law has not proven effective in cases where there is failure to license by a patentee.²⁰⁷ Additionally, it is unlikely that Nutriset has violated any of the antitrust laws in the U.S.²⁰⁸ The issued '284 patent, although broad, is likely valid and enforceable, so Nutriset is under no obligation to license the technology to any party.²⁰⁹

TRIPS already includes a broad framework for when compulsory licensing is acceptable.²¹⁰ Although food falls within the realm of the safeguarding public interest provision of TRIPS, its practical application has been limited primarily to agriculture, and even then, the provision has been underutilized.²¹¹ As a signatory to the WTO, the United

¹⁹⁸ *Id.* at 396-397.

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

²⁰¹ Saunders, *supra* note 49, at 426.

²⁰² *Id.*

²⁰³ *Id.* at 428.

²⁰⁴ *See id.*

²⁰⁵ *See id.*

²⁰⁶ *Id.*

²⁰⁷ *See, e.g.,* Stanley McDonald v. Johnson & Johnson, 722 F.2d 1370 (8th Cir. 1983).

²⁰⁸ *See id.*

²⁰⁹ *See id.*

²¹⁰ Anderson Jr., *supra* note 165, at 171.

²¹¹ *Id.*

States is bound by TRIPS.²¹² Accordingly, any domestic legislation involving compulsory licensing of patents must fall within the guidelines set forth in the Doha Declaration.²¹³

The Plumpy’Nut patent is analogous to a pharmaceutical patent.²¹⁴ Traditionally, patents are thought to cover whole products, and lost profits or reasonable royalties measure damages.²¹⁵ With the rapid advancement of technology, these types of patents have become the exception rather than the rule.²¹⁶ For example, a handheld device such as the Apple iPhone is covered by over 120 patents, with each individual component potentially covered by several patents.²¹⁷ These patents, covering a small invention that is part of a larger product, have value essentially only as licensing tools because they are not commercially useful independently.²¹⁸ However, one area of technology where the patent usually covers the entire product is pharmaceuticals.²¹⁹ The entire compound is covered in one patent, and the compound can be sold in product form.²²⁰ In this regard, the Plumpy’Nut patent is like a pharmaceutical patent.²²¹ The patent discloses a formula that can be readily sold as a product, and a single patent covers the entire invention.²²² Accordingly, provisions of TRIPS applying to pharmaceutical law should readily be applied to food products such as Plumpy’Nut.²²³

In reapplying these principles to food products such as Plumpy’Nut, some of the considerations that have affected the use of compulsory licensing in regards to pharmaceuticals should be avoided.²²⁴ For example, the scope of legislation allowing compulsory licenses should be narrowly defined to avoid the pitfall of pharmaceutical compulsory licensing, in which any patented product is eligible.²²⁵ Also, the definition of an eligible product should be defined rather than leaving it open to interpretation by member states or countries.²²⁶ Such a limitation would reduce the potential for abuse that occurs within the pharmaceutical field.²²⁷ Also, remuneration should be addressed in a clear manner, eliminating the possibility of token compensation.²²⁸ While undertaking these considerations, however, they cannot be so restrictive as to create a lengthy

²¹² *Id.*

²¹³ *See id.*

²¹⁴ *See* Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1738 (2003).

²¹⁵ *Id.*

²¹⁶ *Id.*

²¹⁷ Christopher B. Seaman, *Reconsidering the Georgia-Pacific Standard for Reasonable Royalty Damages*, 2010 B.Y.U. L. REV. 1661, 1690 (2011).

²¹⁸ Lemley, *supra* note 214, at 1738.

²¹⁹ *Id.*

²²⁰ *Id.*

²²¹ *See id.*

²²² U.S. Patent No. 6,346,284.

²²³ *See* Lemley, *supra* note 214, at 1738.

²²⁴ *See* Barker, *supra* note 135, at 949.

²²⁵ *See* Tsai, *supra* note 57, at 1070-1071.

²²⁶ *See id.*

²²⁷ *Id.*

²²⁸ *See also* Ho, *supra* note 156, at 373.

bureaucratic process when an unforeseen emergency arises.²²⁹ A structure that considers these factors may encourage voluntary licensing because the licensor will be aware that a potential licensee has the option of a compulsory license.²³⁰ In creating a scheme to reapply these principles, both policy goals and practical issues should be considered.

A. Policy Considerations of Reapplication

In crafting legislation to allow compulsory licensing of a patent for the benefit of a non-domestic population, there are several factors that should be considered. First, the breadth of the patent must be considered.²³¹ If a patent is overly broad, this factor should weigh in favor of a compulsory license.²³² If not, then this factor should weigh against compulsory license due to the fact that potential licensees can design around the patent or otherwise innovate a different solution.²³³ To determine if a patent is broad, the availability of substitutes should be considered.²³⁴

A second policy consideration is that the incentive or reward associated with patents should remain intact.²³⁵ The original inventor is entitled to the rights to his or her invention and should be compensated accordingly.²³⁶ To do otherwise will reduce the incentive to innovate and potentially stymie the innovation that patent law seeks to drive.²³⁷ This can be achieved by creating a clear and brightline standard for patents that can potentially be subject to compulsory licensing.²³⁸ Rather than a broad category that is open to differing interpretation, such as the public interest umbrella in TRIPS, a concise definition of categories of patents and instances in which they will be subject to compulsory licensing will allow an inventor to realize this before investing in research.²³⁹ Although this may limit innovation in these specific areas, a balance must be struck between the needs of this statute and the policy goals of patent law.²⁴⁰ Plumpy'Nut is a narrow scenario in which there is a single primary producer and that producer refuses to license the patent, where the patent covers a technology vital to resolving a humanitarian crisis.²⁴¹ Another way in which this policy can be achieved is by temporarily suspending the patent during the term of the compulsory license and then adding the length of the term to the expiration date when the compulsory license expires.²⁴² In the Plumpy'Nut case, the '284 patent expires in 2017, leaving a relatively short length of time for Nutriset

²²⁹ *See id.*

²³⁰ *See id.*

²³¹ *See Rao, supra note 26, at 118.*

²³² *Schmeider, supra note 94, at 183.*

²³³ *Feldman, supra note 70, at 434.*

²³⁴ *Image Tech. Servs., 125 F.3d at 1207.*

²³⁵ *Ho, supra note 156, at 379.*

²³⁶ *Id.*

²³⁷ *See Thomas F. Cotter, Market Fundamentalism and the TRIPS Agreement, 22 CARDOZO ART & ENT. L.J. 307, 323-324 (2004).*

²³⁸ *See id.*

²³⁹ *See id.*

²⁴⁰ *Ho, supra note 156, at 377.*

²⁴¹ *Rao, supra note 26, at 113.*

²⁴² *Michael Ilg, Market Competition in Aid of Humanitarian Concern: Reconsidering Pharmaceutical Drug Patents, 9 CHI.-KENT J. INTELL. PROP. 149, 151 (2010).*

to profit on their invention.²⁴³ Because between 80-90% of patents never create any monetary return, Nutriset should be adequately compensated for their efforts and innovation.²⁴⁴

Enforcing patent rights should not be discouraged either.²⁴⁵ However, in an instance where a patent falls within the considerations of the proposed legislation, and the patentee fails to license or negotiate in good faith, this provision should apply.²⁴⁶ The global actions of the patentee should also be considered.²⁴⁷ For example, Nutriset owns patents in some of countries where demand is highest, such as in Chad, Congo, Sudan, Uganda, and Zimbabwe, creating a situation where no competitors can enter the market.²⁴⁸ Nutriset's past litigation history also shows threats to enforce rights in countries of transit and storage.²⁴⁹

Compulsory licensing has been used in the U.S. in the past, and the policy reasons for allowing such use are also applicable in the instant situation.²⁵⁰ In copyright law, compulsory licensing is allowed to balance the interests of authors and the public and to ensure compensation to the author.²⁵¹ Similarly, here, a compulsory license will balance the needs of a developing country while ensuring the patentee is compensated. Likewise, compulsory licensing for patents is not a new consideration.²⁵² Compulsory licenses are allowed for the benefit of the American public for non-life threatening situations, accordingly, a logical step implies that a compulsory license should be allowed for a life threatening situation in a developing country.²⁵³

Why should we, as Americans, care about non-domestic populations? In addition to moral obligations, because a starving population is most likely not going to be able to provide for itself, let alone manufacture a generic product.²⁵⁴ Even if they have the facilities, obtaining the raw materials can create delays and be prohibitively expensive.²⁵⁵ Thus there is a need to allow the manufacture in developed countries that have adequate resources.²⁵⁶

²⁴³ U.S. Patent No. 6,346,284.

²⁴⁴ Feldman, *supra* note 70, at 219.

²⁴⁵ Carleen Hawn, *Problem No. 3: Hunger and Malnutrition: Nutriset is Attacking a Huge Problem With a Surprisingly Small Product*, Business 2.0 Magazine, CNN (Jan. 26 2007), http://money.cnn.com/2007/01/24/magazines/business2/Prob3_HungerMalnutrition.biz2/index.htm.

²⁴⁶ *Id.*

²⁴⁷ *See id.*

²⁴⁸ Rao, *supra* note 26, at 117.

²⁴⁹ *Id.* For example, Compact is a third party manufacturer of a competing RUTF, and Nutriset threatened legal action if they failed to stop supplying Kenya and to cease storage in Denmark for forwarding on to other places in Africa.

²⁵⁰ Dean, *supra* note 39, at 419.

²⁵¹ *Id.*

²⁵² *See, e.g.*, 42 U.S.C. §7608 (1994).

²⁵³ *Id.*

²⁵⁴ Michael Taylor, *American Patent Policy, Biotechnology, and African Agriculture: The Case for Policy Change*, 17 HARV. J.L. & TECH. 321, 383-384 (2004).

²⁵⁵ *See id.*

²⁵⁶ *See id.*

B. Practical Aspects of Reapplication

A compulsory license would potentially reduce security in the investment of developing new technology, as well as reduce the incentive to innovate.²⁵⁷ A side effect may also be the creation of a market in which parties rely on compulsory licenses rather than innovating.²⁵⁸ Regardless, in some specifically defined instances, a carefully distributed compulsory license will save lives and minimize any negative side effects.²⁵⁹ In the Plumpy'Nut instance, granting a compulsory license to a third party to create and distribute a fixed volume of infringing product, as defined by currently outstanding orders placed by Non-Governmental Organizations (NGOs), for a specifically defined humanitarian cause, with a provision for payment to the patentee meeting certain guidelines, will be an ideal solution.

By considering orders for products placed by NGOs as opposed to states, the incentive for a state to overestimate its own needs and resell remaining product will be eliminated.²⁶⁰ Additionally, instituting an efficient procedure for issuing a compulsory license will allow for a timely response to a humanitarian crisis and further avoid a bureaucratic quagmire.²⁶¹ A problem unique to the RUTF industry is that demand is unpredictable and comes in surges.²⁶² Accordingly, although RUTFs potentially have a lengthy shelf life, a large reserve of supply may not be practical.²⁶³ For most purposes, the amount of RUTFs needed and the length of a humanitarian crisis are unforeseeable.²⁶⁴ Accordingly, any compulsory licensing statute or regulation will have to allow relief as soon as possible.²⁶⁵

Also, the costs of the generic producer should also be considered.²⁶⁶ Generic manufacturers costs include production, transaction, royalty, regulatory approval and quality assurance costs.²⁶⁷ There should remain incentive for generic manufacturers to produce generics or else the compulsory license will be ineffective in reaching its goals.²⁶⁸ The compulsory licensing regulation also should be couched in *ex ante* terms to

²⁵⁷ Saunders, *supra* note 49, at 426.

²⁵⁸ Ho, *supra* note 156, at 380.

²⁵⁹ Rao, *supra* note 26, at 113.

²⁶⁰ Ho, *supra* note 156, at 380.

²⁶¹ Rao, *supra* note 26, at 113.

²⁶² Rice, *supra* note 23 (Sept. 2 2010).

²⁶³ *See id.*

²⁶⁴ Rao, *supra* note 26 at 113.

²⁶⁵ *See id.*

²⁶⁶ Tsai, *supra* note 57, at 1066.

²⁶⁷ Rao, *supra* note 26, at 117. (For example, in 2008, Unicef's Plumpy'Nut shipment to Ethiopia had to be shipped by air, which account for almost 40% of the total costs. Studies show that if the product was produced locally, the transportation costs would have been reduced and the supply chain delay would shrink from eight weeks to one week. Although a compulsory license issued in the U.S. does not solve the transportation cost problem, the sheer volume of production can make the cost more palatable.)

²⁶⁸ Tsai, *supra* note 57, at 1066.

prevent an unwitting generic manufacturer from being held liable for patent infringement and potentially willful infringement.²⁶⁹

The compensation due to a party forced to grant a compulsory license compensation must be less than what their current profit margin is on the product, in order to avoid a situation in which the licensor will have an incentive to produce as little product as possible while relying on the generic manufacturer for “free” profit.²⁷⁰ This will avoid an outcome like the current situation in Thailand.²⁷¹ Licensors should not be deterred from increasing their own production capacity.²⁷² One additional consideration is required negotiating between a licensor and licensee before issuing a compulsory license.²⁷³ Prior negotiation is required by TRIPS but is undefined.²⁷⁴ By creating guidelines to ensure good faith negotiation, an independent agreement may be reached between the parties.²⁷⁵ A compulsory license may even act as a deterrent to bad faith negotiating, because both parties know that a compulsory license is an option.²⁷⁶

Any legislation must be simple, practical, predictable, and enforceable.²⁷⁷ By limiting compulsory licensing for the amount of outstanding orders placed that cannot be fulfilled, the licensor retains an incentive to innovate while the humanitarian crisis receives critical assistance.²⁷⁸ Finally, the terms “emergency” and “urgency” should be statutorily defined, to assist in the application of any compulsory licensing negotiations or issuance.²⁷⁹

CONCLUSION

By adopting a statute within these guidelines, the typical black market and free rider problems will not exist. Because the patents falling under its purview will be geared primarily towards developing countries, there will be little or no demand for the products manufactured via a compulsory license. In terms of the free rider problem, once again, the eligible patents will deal with industries and populations where there is little innovation or research and development to begin with, and the terms of the compulsory license will not allow a generic manufacturer to collect a windfall, thereby eliminating the incentive to free ride.

²⁶⁹ Antony Taubman, *Rethinking TRIPS: Adequate Remuneration for Non-voluntary Patent Licensing*, 11 J. INT'L ECON. L. 927, 928-929 (2008).

²⁷⁰ *Id.*

²⁷¹ Ho, *supra* note 156, at 373-374.

²⁷² *See* Tsai, *supra* note 57, at 1066.

²⁷³ *See* Schmeider, *supra* note 94, at 218.

²⁷⁴ Ho, *supra* note 156, at 399.

²⁷⁵ *See id.*

²⁷⁶ *Id.*

²⁷⁷ *See id.* at 437-438.

²⁷⁸ *See id.*

²⁷⁹ Megan Doyle, *The Global Health Licensing Program: A New Model for Humanitarian Licensing at the University Level*, 35 AM. J.L. & MED. 281, 288 (2009) (arguing universities have already defined humanitarian purposes when discussing whether to grant licenses to developing countries).

THE PLUMPY'NUT PREDICAMENT

By making clear what categories of patents can be covered by the provision, inventors can plan for a statutory license if they cannot meet the production, and they will have a fixed royalty rate by which to calculate potential profit. Using this data, they can gauge how much they would like to invest in the research of a new invention. Although this may seem to disincentivize innovation in these fields, a guaranteed royalty serves as consolation.

Under the proposed statutory considerations, the Plumpy'Nut problem would be solved. After being informed that Nutriset, the single producer of Plumpy'Nut, would not be able to fulfill its order in a timely manner, an NGO would file a report with an advisory committee. The advisory committee would then contact Nutriset directly and request a license on behalf of interested generic manufacturers in America. Nutriset would be given the opportunity to negotiate individual licenses with each of the parties for a reasonable period of time, given the severity of the humanitarian crisis. Were either of the parties to negotiate in bad faith, or otherwise be unable to come to an agreement, the US government would then issue a compulsory non-exclusive license to the interested manufacturers and could temporarily suspend the patent. This license would be limited in scope and duration, with the scope being for the identical product to be used specifically for the humanitarian crisis, and the duration being for a specific number of units. For example, if Nutriset was unable to fulfill an order of 25,000 tons of Plumpy'Nut, the compulsory license would equal that amount. Given the unpredictable nature and unpredictable time frames of humanitarian crises, this approach seemingly becomes cumbersome, however, the government is free to issue continuous limited licenses. As one expires, if there are additional outstanding orders, another license can be issued. If at any point during the compulsory license timeframe Nutriset is able to accommodate the new orders, the licensing would stop and the amount of time that had passed from the date the license was issued would be added to the expiration date of the patent.

For a treatable and solvable condition, such as world hunger, compulsory licensing should be allowed. The Plumpy'Nut problem blends issues of intellectual property law with economic, political, and moral considerations in which the inventor is trapped between a rock and a hard place, and this legislation will assist all parties involved.