Patenting Ready-To-Use-Therapeutic Food: The Plumpy'nut Controversy

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Abstract

In recent years, ready-to-use therapeutic food (RUTF) has emerged as a highly successful cure for severe acute malnutrition in children, a condition that contributes to about one million child deaths per year. Advocates have raised concerns, however, that patent rights are obstructing access to needed RUTF. The first RUTF, a product called Plumpy'nut, was patented shortly after its invention. Evidence suggests that patent protection of Plumpy'nut is in fact limiting global RUTF supply and preventing RUTF price reductions. Because evidence also demonstrates that patent rents are likely to be of lesser importance for incentivizing innovation in the therapeutic food industry, solutions for broadening access should be explored, even if such solutions impinge on patent holders' exclusive patent rights. This paper considers the prospect of using compulsory licensing to facilitate broader access to RUTF. Compulsory licensing could be a useful tool for expanding the RUTF supplier base and driving down prices. Because the circumstances leading to nutritional crises can simultaneously disrupt local manufacturing, the availability of compulsory licensing for the export of RUTF, in particular, is desirable. At present, however, the WTO international treaty regime largely prevents the export of RUTF under compulsory licensing for WTO Members. This paper argues for easing the current restrictions on the use of compulsory licensing for the export of RUTF as an act that would be consistent with the rationale and spirit of existing agreements among WTO Members relating to intellectual property and public health.

Introduction

Malnutrition is a critical global health problem. As of 2010, the Food and Agriculture Organization of the United Nations (FAO) estimates that there are 925 million undernourished people worldwide.[1] Children under age five are at particular risk for malnutrition, which accounts for over one-third of the deaths of children in this age group.[2] Approximately 20 million children globally suffer from severe acute malnutrition,[3] a particularly serious form of undernourishment, and severe acute malnutrition contributes to the deaths of about 1 million children every year.[4]

In recent years, ready-to-use therapeutic food (RUTF) has emerged as a "miracle product" for combating severe acute malnutrition in children.[5] RUTF is a vitamin-enriched, energy-dense product, often in the form of a nut-based paste, that contains all of the nutrients needed for a severely malnourished child to make a complete recovery.[6] It also provides a

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[1] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, THE STATE OF FOOD INSECURITY IN THE WORLD: ADDRESSING FOOD INSECURITY IN PROTRACTED CRISES 4 (2010), *available at* http://www.fao.org/docrep/013/i1683e/i1683e.pdf.

[2] *Severe Acute Malnutrition*, WORLD HEALTH ORGANIZATION, http://www.who.int/nutrition/topics/malnutrition/en/index.html (last visited Nov. 25, 2010).

[3] A child is considered to be suffering from severe acute malnutrition if the child exhibits a very low weight to height ratio, visible severe wasting, or nutritional oedema (swelling resulting from excess fluids). *Id.*

[4] COMMUNITY-BASED MANAGEMENT OF SEVERE ACUTE MALNUTRITION: A JOINT STATEMENT BY THE WORLD HEALTH ORGANIZATION, THE WORLD FOOD PROGRAMME, THE UNITED NATIONS STANDING COMMITTEE ON NUTRITION AND THE UNITED NATIONS CHILDREN'S FUND 2 (2007) [hereinafter JOINT STATEMENT], *available at* http://www.who.int/entity/nutrition/topics/Statement_community_based_man_sev_acute_mal_eng.pdf.

[5] Andrew Rice, *The Peanut Solution*, NEW YORK TIMES, Sept. 2, 2010, *available at* http://www.nytimes.com/2010/09/05/magazine/05Plumpy-t.html.

[6] Mark J. Manary, *Local Production and Provision of Ready-To-Use Therapeutic Food (RUTF) Spread for the Treatment of Severe Childhood Malnutrition*, 27 FOOD AND NUTRITION BULLETIN, no. 3 (supplement), 2006 at S83, S83, *available at* www.fantaproject.org/downloads/pdfs/FNB_27_3_2006_e.pdf. Plumpy'nut's efficacy has been repeatedly verified in numerous clinical studies. *See* ANN ASHWORTH, EFFICACY AND

substantial advantage over prior treatment methods in that it requires neither refrigeration nor preparation, has a relatively long shelf-life, and can be administered to children at home without the help of a health-care professional.[7]

Advocates have raised concerns, however, that intellectual property rights may be hindering access to RUTF. The first RUTF, a product marketed as Plumpy'nut, was patented shortly after its invention. The patent rights to Plumpy'nut are jointly owned by Nutriset, a for-profit French company that develops and manufactures nutritional supplements aimed at fighting malnutrition in developing countries, and the Institut De Recherche Pour Le Developpement ("IRD"), a French public research institute.[8] Nutriset and IRD have patented Plumpy'nut in over thirty countries,[9] with patents in force in the United States, Canada, the European Union, and much of Africa.[10]

While Plumpy'nut is not the only RUTF formula on the market,[11] it has been clinically verified and appears to be the most widely used;[12] moreover, the Plumpy'nut patent is broad

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EFFECTIVENESS OF COMMUNITY-BASED TREATMENT OF SEVERE MALNUTRITION 7 (2005), *available at* www.who.int/nutrition/topics/backgroundpapers_Efficacy_effectiveness.pdf.

[7] JOINT STATEMENT, *supra* note 4, at 4; Manary, *supra* note 6, at S86.

[8] Mem. of Law in Support of Defs.' Mot. to Dismiss Pls.' First Amended Complaint at 2-3, Mama Cares Foundation v. Nutriset Societe Anonym France, No. 1:09-cv-02395 (D.D.C. filed May 26, 2010).

[9] For ease of reference, I will refer to the Plumpy'nut patent as "Nutriset's patent" going forward.

[10] Mem. of Law in Support of Defs.' Mot. to Dismiss Pls.' First Amended Complaint, *supra* note 8, at 3-4.

[11] Two U.S.-based companies have recently begun producing their own versions of RUTF. Tabatchnick Fine Foods has a nut-based RUTF called Nutty Butta, and Challenge Dairy is marketing a milk-based RUTF. Rice, *supra* note 5; *Challenge Dairy Now Certified UNICEF Supplier for Ready-to-Use Therapeutic Food*, DAIRY FOR GLOBAL NUTRITION (Feb. 25, 2010), http://dairyglobalnutrition.org/AboutUs/newsdetail.cfm?ItemNumber=89646. UNICEF is now purchasing small amounts of RUTF from both of these producers. *See* JAN KOMRSKA, OVERVIEW OF UNICEF'S RUTF PROCUREMENT IN 2010 AND PAST YEARS 13 (2010), *available at* http://www.unicef.org/supply/files/Overview_of_UNICEF_RUTF_Procurement_in_2010.pdf. It is unclear whether either product has been clinically proven to be as effective as the Plumpy'nut formula or is in fact covered by the Plumpy'nut patent. Nutriset sent a letter to Tabatchnick Fine

enough to cover numerous RUTF formulas.[13] Nutriset has announced a policy of licensing the Plumpy'nut patent almost exclusively to producers in the developing world,[14] and it has granted a license to only one U.S. manufacturer, a not-for-profit organization called Edesia.[15] Although Nutriset has been expanding the number of licensees of the Plumpy'nut patent worldwide, Nutriset remains the predominant supplier of the Plumpy'nut product.[16] Critics argue that reliance on one main global supplier is risky, particularly in the event of large-scale nutritional emergencies, and that the monopoly granted by the patent is keeping Plumpy'nut prices undesirably high.[17]

This tension between intellectual property rights and free access to humanitarian goods is not new. The topic has been especially well explored in the context of access to medicines, and

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Foods in September 2009 warning Tabatchnick that its product "bear[s] some similarities" to Plumpy'nut and "draw[ing] [Tabatchnick's] attention" to the fact that producing products covered by the Nutriset patent might constitute infringement. Letter from Thomas Couaillet to Benjamin Tabatchnick (Sept. 21 2009), Mem. of Law in Opp. to Defs.' Mot. to Dismiss Pls.' First Amended Complaint, Ex. 4, Mama Cares Foundation v. Nutriset Societe Anonym France, No. 1:09-cv-02395 (D.D.C. filed June 14, 2010). At present, however, Nutriset does not appear to have initiated infringement proceedings against either producer.

[12] For example, UNICEF, the largest purchaser of RUTF globally, purchased half of its RUTF from Nutriset in 2010 and about another quarter from Nutriset partners. *See* KOMRSKA, *supra* note 11, at 12.

[13] For a full description of Nutriset's U.S. patent, see *infra* notes 39-45 and accompanying text.

[14] *Patents for Development*, NUTRISET, http://www.nutriset.fr/en/access/patents-for-development.html (last visited Nov. 25, 2010).

[15] *Networks for Nutritional Autonomy*, NUTRISET, http://www.nutriset.fr/en/international-networks/networks-for-nutritional-autonomy.html (last visited Nov. 25, 2010).

[16] *See Mission and Vision of the PlumpyField Network*, NUTRISET, http://www.nutriset.fr/en/international-networks/plumpyfield-network/plumpyfield-mission-and-vision.html (last visited Nov. 25, 2010) (noting that the network of licensees' production capacity is expected to reach over 50% of worldwide production in 2014).

[17] *See, e.g.*, Letter from Tido von Schon-Angerer, Executive Director, Campaign for Access to Essential Medicines, Medecins Sans Frontieres International, to Isabelle Lescanne, General Manager, Nutriset (Nov. 13, 2009), *available at* http://www.msfaccess.org/fileadmin/user_upload/diseases/malnutrition/MSF%20letter%20to%20Nutriset%20Nov_13_2009.pdf.

numerous proposals have been made for both working within the patent system[18] and replacing patent rights for pharmaceutical products[19] in order to ensure access to medicines for those in need. The debate over access to medicines has helped shape the treaty-based international intellectual property regime as well.[20]

Two U.S. not-for-profit corporations have now brought this debate before a U.S. federal court, challenging the validity of Nutriset's U.S. patent. The plaintiffs, Breedlove Foods and the Mama Cares Foundation, have each taken steps to develop their own RUTF, and the suit seeks a declaratory judgment that Nutriset's patent is invalid, as well as a ruling that plaintiffs' products do not infringe any valid claims of the Plumpy'nut patent.[21] While the complaint does not specify plaintiffs' legal grounds for challenging the patent's validity under U.S. patent laws, it decries Nutriset's restrictive licensing policy within the United States, emphasizing the humanitarian nature of the Plumpy'nut product and arguing that the United States is especially well-positioned to manufacture the product because of its large surplus of nuts.[22]

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[18] *See, e.g.*, Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317 (2005) (discussing the use of compulsory licensing for ensuring access to medicines); Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031 (2005) (advocating universities' adoption of a licensing scheme facilitating open licensing for producers providing drugs to developing countries).

[19] *See, e.g.*, James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 CHI.-KENT L. REV. 1519 (2007) (advocating the adoption of a prize fund to incentivize and reward pharmaceutical R&D).

[20] The most important international treaty governing intellectual property law is the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). For a complete discussion of TRIPS, see *infra* notes 113-127 and accompanying text. The 2001 Declaration on the TRIPS Agreement and Public Health, adopted at a ministerial conference in Doha, affirmed that the TRIPS Agreement should be interpreted in a manner to "promote access to medicines for all." World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration].

[21] First Amended Complaint at 7, Mama Cares Foundation v. Societe Anonym France, No. 1:09-cv-02395 (D.D.C. filed Apr. 27, 2010).

[22] *Id.* at 5.

This paper examines the feasibility and desirability of using compulsory licensing[23] to allow U.S. "generic" production of Plumpy'nut if Nutriset's U.S. patent is upheld,[24] in light of the constraints of the World Trade Organization ("WTO") Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS").[25] While I focus on the U.S. patent, the analysis applies equally in determining all WTO Members' limitations under TRIPS regarding the use of compulsory licensing for the supply of RUTF. I demonstrate that in its current form, TRIPS is likely to effectively prevent the United States from producing RUTF under a compulsory license, due to a restriction on the use of compulsory licensing for export. Under Article 31(f) of the TRIPS Agreement, compulsory licenses must be issued predominantly for the supply of the domestic market. This restriction has crucial implications for the global usefulness of compulsory licensing in facilitating access to RUTF, because the crisis situations that lead to demand for Plumpy'nut make reliance on domestic production risky and make export a particularly important option. While the export restriction has been waived by subsequent agreement among WTO Members in relation to concerns over access to medicines, this waiver is limited to pharmaceuticals. I argue that the rationale behind the existing waiver, along with the

[23] Compulsory licensing may be defined as an "authorization[] permitting a third party to make, use, or sell a patented invention without the patent owner's consent." Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 Berkeley Tech. L.J. 853, 857-58 (2003) (internal quotation omitted).

[24] An evaluation of the validity of the U.S. Plumpy'nut patent is beyond the scope of this paper. As a threshold matter, food is patentable subject matter in the United States. *See Frequent Questions and Their Answers*, USPTO KIDS' PAGES, http://www.uspto.gov/web/offices/ac/ahrpa/opa/kids/kidprimer.html (last visited Nov. 25, 2010). A recent presentation by the law firm representing Mama Cares and Breedlove suggests that plaintiffs intend to challenge the patent based on the existence of prior art and inadequate disclosure. Fulbright & Jaworski L.L.P., Presentation, *Mama Cares v. Nutriset* (June 18, 2010) (on file with author).

[25] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 81 (1994) [hereinafter TRIPS].

spirit of the TRIPS Agreement and subsequent related agreements, supports extending the waiver to the export of RUTF under a compulsory license in addition to pharmaceuticals.

This paper proceeds in four parts. In Part I, I provide an overview of the Plumpy'nut product and Nutriset's patenting and licensing practices. Part II addresses the contention that the Nutriset patent is hindering access to the Plumpy'nut product, exploring whether the patent is in fact preventing malnourished children from receiving needed RUTF. Part III examines the relative importance of patents for incentivizing innovation in the field of humanitarian food products. Part IV explores the possibility of using compulsory licensing, which has received the bulk of the attention among possible access tools in the medicines context, for ensuring access to RUTF, and argues for amending the existing treaty regime to facilitate its use for therapeutic food.

I. Plumpy'nut: The Product and the Patent

A. The "Miracle Food"

Prior to the emergence of RUTF, the standard treatment for severe acute malnutrition in children was a fortified milk powder known as F100.[26] Treatment with F100 had several drawbacks, however. The powder must be mixed with clean water before being fed to children, and it spoils easily if left unrefrigerated. It must be consumed almost immediately after the powder and water are mixed. As a result, F100 is only administered in specialized feeding centers where children must remain, often with a supervising caretaker, for several weeks.[27] Treatment with F100 thus depends on the availability of clean drinking water, requires inpatient care, and necessitates absenting a caretaker from the home, which may be detrimental for other

[26] Martin Enserink, *The Peanut Butter Debate*, SCIENCE, Oct. 3, 2008, at 36, 37. F100 is not under patent and, in fact, was never patented. *Id.* at 38.
[27] Enserink, *supra* note 26, at 37.

children in the home and damaging to a family's economic situation.[28] Inpatient treatment also puts children at risk for cross-infection.[29]

The invention of Plumpy'nut addressed many of these problems. Developed in the mid-1990s by a childhood nutrition expert named Andre Briend, [30] Plumpy'nut is a vitamin-fortified, peanut-based paste that is high in energy.[31] While it is nutritionally equivalent to F100,[32] Plumpy'nut has several advantages over the fortified milk product. Plumpy'nut can be eaten directly out of the packet it arrives in. It has a shelf life of two years and does not require refrigeration.[33] Due to its low water content, it is at low risk for contamination, and it does not spoil after being opened.[34] Additionally, because it requires no preparation, Plumpy'nut can be administered at the child's home, thereby avoiding the need for costly and potentially risky inpatient care.[35]

Plumpy'nut has also proved itself to be immensely effective at combating child malnutrition.[36] Home-based treatment with RUTFs like Plumpy'nut was jointly endorsed by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition, and the United Nations Children's Fund (UNICEF) in 2007 as the

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[28] *Id.*
[29] El Hadji Issakha Diop et al., *Comparison of the Efficacy of a Solid Ready-To-Use Food and a Liquid, Milk-Based Diet for the Rehabilitation of Severely Malnourished Children: A Randomized Trial*, 78 AM. J. CLIN. NUTR. 302, 302 (2003).
[30] Rice, *supra* note 5.
[31] Enserink, *supra* note 26, at 36-37.
[32] *Plumpy'nut® Ready-To-Use Therapeutic Food (RUTF)*, NUTRISET, http://www.nutriset.fr/en/product-range/produit-par-produit/plumpynut-ready-to-use-therapeutic-food-rutf.html (last visited Nov. 25, 2010).
[33] *Id.*
[34] Enserink, *supra* note 26, at 37.
[35] *Id.* at 36-37.
[36] *See, e.g.*, M.J. Manary et al., *Home Based Therapy for Severe Malnutrition with Ready-To-Use Food*, 89 ARCH. DIS. CHILD. 557 (2004).

preferred treatment for severe acute malnutrition in children.[37] Since then, the demand for Plumpy'nut has risen steadily, and treatment with F100 has correspondingly decreased.[38]

B. The Plumpy'nut Patent

Nutriset's U.S. patent for Plumpy'nut was granted on February 12, 2002.[39] The patent claims a "[c]omplete food or nutritional supplement" with specified water weight and osmolality,[40] "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."[41] The patent also claims the process of preparing the product and the method of using the product for renourishment, either as a stand-alone food or nutritional supplement.[42] While Plumpy'nut itself uses a peanut base for its "lipid rich substance" and milk powder for its "food-grade product," the patent also claims products that use cocoa beans, almonds, walnuts, hazelnuts, coconuts, or pistachio nuts instead of peanuts, as well as products using powdered yogurt, sucrose, glucose, fructose, maltodextrin, whey, vegetable or animal fats, or flour made out of maize, wheat, millet, oats, rice, cassava or potato starch instead of milk powder.[43]

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[37] *See* JOINT STATEMENT, *supra* note 4.
[38] THE NUTRITION ARTICULATION PROJECT, A SUPPLY CHAIN ANALYSIS OF READY-TO-USE THERAPEUTIC FOODS FOR THE HORN OF AFRICA 2 (2009) [hereinafter SUPPLY CHAIN ANALYSIS], *available at* http://globalhealthtechnologyaccess.org/nutrition/attachments/125_RUTFSupplyChainProject-UNICEF_DUKE-UNC_May09.pdf.
[39] U.S. Patent No. 6,346,284 (filed Nov. 19, 1998).
[40] Osmolality is a measure of the concentration of certain kinds of solutions. OXFORD ENGLISH DICTIONARY, http://dictionary.oed.com. People who are undernourished do not tolerate foods with osmolality above a certain level. '284 Patent.
[41] '284 Patent, Claim 1.
[42] *Id.* Claims 20, 21.
[43] *Id.* Claims 8, 10.

In addition to the U.S. patent, Plumpy'nut is patented in Canada, and its European Patent Convention patent has been validated in Belgium, Denmark, France, Germany, Great Britain, Ireland, the Netherlands, and Spain.[44] It is also patented in much of Africa.[45] Several of the African countries in which the patent is registered have the highest rates of undernourishment in the world, at over 35% of each country's population.[46] Ten of the countries where Plumpy'nut is patented are deemed by the FAO to be in "protracted crisis" due to a combination of natural and human-induced disasters, resulting in high levels of food insecurity.[47]

Nutriset claims to use its patents as a "tool to aid development of developing countries."[48] In October 2010, Nutriset announced that it was making the Plumpy'nut patent available online for eligible entities to obtain online "Patents Usage Agreements."[49] These licenses allow the licensee to produce and distribute products covered by the Plumpy'nut patent, though the licensee must develop its own formula, quality assurance system, and marketing brand.[50] The licenses are non-exclusive and non-transferable, and licensees are authorized to export to other

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[44] Mem. of Law in Support of Defs.' Mot. to Dismiss Pls.' First Amended Complaint, *supra* note 8, at 3-4.

[45] Nutriset affirms that it has registered patents in Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Democratic Republic of Congo, Côte d'Ivoire, Gabon, Gambia, Ghana, Guinea, Guinea Bissau, Kenya, Lesotho, Malawi, Mali, Mauritania, Mozambique, Niger, Senegal, Sierra Leone, Sudan, Swaziland, Tanzania, Togo, Uganda, and Zimbabwe. *Id.* at 4; *Nutriset/IRD's Patents Usage Agreement*, NUTRISET, http://www.nutriset.fr/en/access/patents-for-development/online-patent-usage-agreement.html (last visited Nov. 25, 2010). Nutriset's lists on its website and in its lawsuit papers are not precisely coextensive.

[46] These countries include Chad (37% undernourished), Central African Republic (40% undernourished), Democratic Republic of Congo (69% undernourished), and Mozambique (38% undernourished). *Hunger*, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, http://www.fao.org/hunger/en (last visited Nov. 25, 2010).

[47] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, *supra* note 1, at 13-14.

[48] *Patents for Development*, *supra* note 14.

[49] *Malnutrition: The Plumpy'nut® Patent Now Accessible On-line*, NUTRISET, http://www.nutriset.fr/en/news-media/press-releases/malnutrition-the-plumpynut%C2%AE-patent-now-accessible-on-line.html (last visited Nov. 25, 2010).

[50] *Nutriset/IRD's Patents Usage Agreement*, *supra* note 45.

countries covered by the Patents Usage Agreement.[51] In order to be eligible for a license, an organization must be a "real and legitimate" entity with its production, place of business, headquarters, and at least 51% of its capital share based in one of the several African countries in which Plumpy'nut is patented.[52] Entities in Mozambique and Niger are not eligible for licenses because Nutriset previously granted exclusive licenses in those countries. Entities based in Canada, the European Union, and the United States are not eligible. Nutriset has announced that it will not be charging any royalties for these licenses.[53]

In addition to these licensing arrangements, Nutriset has formed partnerships with manufacturers in ten developing countries and one U.S. producer, Edesia. Known as the "PlumpyField Network," these partners are granted access to Nutriset's patents, trademarks, know-how, training, and quality assurance system.[54] Nutriset has clearly communicated its intent to limit licensing in the United States, Canada, and the European Union in favor of licensing local producers in developing countries.[55]

II. Is the Plumpy'nut Patent Hindering Access to RUTF for the Malnourished?

Nutriset's critics contend that the Plumpy'nut patent will prevent malnourished children from receiving needed RUTF. There are three main ways in which the patent might hinder access: (1) by limiting the number of suppliers; (2) by keeping prices well above marginal cost; and (3) by preventing follow-on innovation if such improvements are dependent on or fall entirely within the scope of the Plumpy'nut patent. These outcomes are possible whenever a

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[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *The PlumpyField Network*, NUTRISET, http://www.nutriset.fr/en/access/patents-for-development/join-the-plumpyfield-network.html (last visited Nov. 25, 2010).
[55] *See* Mem. of Law in Opp. to Defs.' Mot. to Dismiss Pls.' First Amended Complaint, *supra* note 11, at Ex. 3.

product is patented; however, whether any given patent creates these effects varies with context. For instance, the patentee may choose to license the technology widely enough so as to create a diverse supplier base or drive down prices. The existence of substitute products may also keep prices low by providing indirect competition in the same market, despite the patentee's monopoly on the particular patented product.[56]

A. The Global RUTF Supply

RUTF is purchased predominantly by humanitarian aid organizations. The largest purchaser of RUTF globally is UNICEF, followed by Medecins Sans Frontieres (MSF) and the Clinton Foundation.[57] As the largest global buyer, UNICEF's experience with supplies of RUTF is instructive. A comprehensive study of UNICEF's RUTF supply chain, completed in April 2009, identified a number of supply problems.[58] The study found that demand for RUTF was increasing steadily, with limited production capacity available to meet this heightened demand.[59] Nutriset was found to be operating at maximal capacity for several months out of the year, causing longer order production times and fewer actual deliveries.[60] Supplies were sufficiently limited that last-minute unexpected orders of RUTF from one buyer caused delays and resulted in reduced availability of RUTF for other purchasers.[61] Such last-minute surges in demand were also found to be quite common, as emergency orders of RUTF—defined by unexpected increases in demand due to disaster situations—accounted for over half of UNICEF's orders.[62]

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[56] F. SCOTT KIEFF ET AL., PRINCIPLES OF PATENT LAW 61-62 (4th ed. 2008).
[57] *Nutrition*, CLINTON FOUNDATION, http://www.clintonfoundation.org/what-we-do/clinton-health-access-initiative/our-approach/access-programs/nutrition (last visited Nov. 25, 2010).
[58] *See* SUPPLY CHAIN ANALYSIS, *supra* note 38.
[59] *Id.* at 3.
[60] *Id.* at 89.
[61] *Id.* at 10.
[62] *Id.* at 15.

Supply limitations have several direct effects on children's health. First, delays in RUTF delivery caused by limited production capacity cause delays in treatment. Treatment delays can have significant consequences, as serious complications arise the longer malnutrition goes untreated.[63] UNICEF staff also reported that mothers would stop coming to seek RUTF for their children altogether if they learned that supplies were not currently available.[64] The study further cautioned that reliance on one dominant supplier reduces the supply chain's surge capacity in the event of large-scale emergencies and risks halting all production if Nutriset's factory were ever compromised.[65] The study recommended diversifying the supplier base to better serve global need.[66]

UNICEF's experience suggests that Nutriset's patent monopoly is indeed creating supply inadequacies. Nutriset argues, however, that its own production and patent management policies adequately address supply concerns. Indeed, Nutriset has expanded its production capacity recently, and the number of local producers that are either members of Nutriset's PlumpyField Network or are operating under license agreements with Nutriset has expanded since the 2009 UNICEF study.[67] Nutriset also maintains that its own factory's production capacity remains well above demand and claims to be capable of further increasing capacity in a few months' time.[68] UNICEF reports to have avoided RUTF stock-outs since the 2009 study through better procurement planning; it has also diversified its supplier base, with around 50%, rather than

[63] *See* JOINT STATEMENT, *supra* note 4, at 3.
[64] SUPPLY CHAIN ANALYSIS, *supra* note 38, at 44.
[65] *Id.* at 25.
[66] *Id.* at 79.
[67] *Nutriset's Industrial Know-How: Flexibility and Performance*, NUTRISET, http://www.nutriset.fr/en/production/nutriset-industrial-know-how.html (last visited Nov. 25, 2010).
[68] *Id.*

89%, of RUTF orders now placed through Nutriset and the rest obtained from local producers in the country of distribution or other foreign producers.[69]

Nevertheless, allowing additional production in a country like the United States would be significant for ensuring access. The 2009 study indicated that demand was increasing at such a drastic rate that Nutriset's planned expansion would only be able to satisfy demand until 2014 at the latest, by which time demand would again exceed capacity and require further scale-up.[70] The study further cautioned that reliance on local producers—who make up the majority of the expanded supplier base—could be problematic, as the same factors that cause nutrition crises, such as droughts and civil unrest, may disrupt local production.[71] The production capacities of the local manufacturers are also significantly lower than Nutriset's.[72] Some additional RUTF products have recently entered the market in the United States, produced by Tabatchnick Fine Foods and Challenge Dairy. While these products do have the potential to meaningfully

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[69] KOMRSKA , *supra* note 11, at 12.

[70] SUPPLY CHAIN ANALYSIS, *supra* note 38, at 24. It is also unclear whether the study's projected demand increase is a measure of actual need or projected order quantities. Order quantities are generally not a measure of actual need, as funding limitations and other obstacles prevent aid agencies from reaching all malnourished children in need of the product.

[71] *Id.* at 80. For example, RUTF has been used recently to treat malnutrition in the wake of the earthquakes in Haiti, massive flooding in Pakistan, and post-election political violence in Kenya. *See id.* at 13; Ban Al-Dhayi & Vivian Siu, *Young Flood Survivors in Pakistan Face an Uphill Struggle Against Malnutrition*, UNICEF (Oct. 13, 2010), http://www.unicef.org/nutrition/pakistan_56479.html; Roshan Khadivi, *UNICEF and Partners Promote Infant and Young Child Nutrition in Post-Quake Haiti*, UNICEF (Feb. 10, 2010), http://www.unicef.org/infobycountry/haiti_52741.html. While Plumpy'nut is not patented in Haiti or Pakistan, these cases are illustrative of the circumstances under which RUTF might be needed in patent-covered countries, circumstances likely to disrupt—or even entirely destroy—local production and require large-scale nutritional interventions.

[72] Members of the PlumpyField Network, for example, have maximum production capacities ranging from 540 metric tons to 6,000 metric tons per year. Nutriset's annual production capacity is 33,000 tons per year. MEMBERS OF THE NETWORK, PLUMPYFIELD, *available at* http://www.nutriset.fr/assets/files/FichesPlumpyField/MembersSummaryEnglish.pdf (last visited Nov. 25, 2010). UNICEF has also raised concerns about quality control for the locally produced product, citing weak regulatory frameworks and unreliable lab testing in the host countries. *See* JAN KOMRSKA, UNICEF REQUIREMENTS FOR RUTF MANUFACTURERS 17 (2010).

contribute to RUTF supply, it is unclear whether the comparative efficacy of these RUTF formulas has yet been established through clinical trials; it is also unclear whether either of these products might in fact infringe the Plumpy'nut patent.[73] At minimum, in the absence of the Plumpy'nut patent, entry into the market of additional global suppliers would allow for a more stable supply base and would ensure the existence of large-scale producers other than Nutriset to meet demand in the event of an emergency.

B. The Effect of Patenting on RUTF Pricing

The second way in which the Plumpy'nut patent might affect access is through pricing. Patents can create deadweight losses in the form of higher prices for consumers because of the monopoly power granted to the patentee.[74] The World Health Organization recommends that children with severe acute malnutrition receive ten to fifteen kilograms of RUTF over the course of six to eight weeks for a full treatment regimen.[75] With Plumpy'nut priced at 2.70 euros/kg in 2010, this puts the price of treatment at about $37 to $55 per child.[76] While the price of Plumpy'nut has decreased over the past two years,[77] price remains a substantial concern for the aid organizations that distribute Plumpy'nut. For UNICEF, for example, price directly affects how many children the organization treats, because RUTF order quantities are dictated by

[73] *See supra* note 11. The scope of competition introduced by these products further depends on whether either is ultimately patented. Tabatchnick Fine Foods has filed a patent application for its product, though it claims the patent will be open source. *Food: Making Peanut Butter Gets Stickier*, IRIN GLOBAL, Nov. 11, 2009, http://www.irinnews.org/Report.aspx?ReportId=86979.
[74] *See* Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CALIF. L. REV. 1571, 1580 (2009).
[75] JOINT STATEMENT, *supra* note 4, at 4.
[76] Nutriset Flyer on Plumpy'nut Pricing (on file with author). See *infra* notes 88-90 and accompanying text for a discussion of the relative price of the product manufactured by Nutriset's licensees.
[77] *Id.*

available funding levels rather than identified need in the populations UNICEF serves.[78] In 2010, UNICEF estimated that there were 4,880,000 children in Africa suffering from severe acute malnutrition, translating into need for 67,000 tons of RUTF; however, only 15,109 tons of RUTF were ordered.[79]

The Plumpy'nut patent monopoly is not currently leading to price mark-ups analogous to those seen, for example, in the pharmaceutical context. While patented pharmaceuticals are sometimes priced at more than thirty times the marginal cost of production,[80] Nutriset reports that raw materials account for over sixty percent of the price of the majority of its products.[81] Cost breakdowns of locally produced RUTF[82] show similar percentages.[83] Notably, the cost of the milk powder alone can account for over twenty-five percent of RUTF price.[84]

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[78] SUPPLY CHAIN ANALYSIS, *supra* note 38, at 12. UNICEF officials have also at times reported higher prices than those publicly quoted by Nutriset. Emily Goldsmith, Technology, Patents, and Humanitarian Aid: A Comparative Study of Plumpy'nut, Golden Rice, and Oral Rehydration Therapy 19 (Aug. 14, 2010), *available at* http://ecommons.cornell.edu/handle/1813/17314.

[79] KOMRSKA, *supra* note 11, at 30. While pricing is not the only reason for this low coverage, it certainly plays a significant role. Other obstacles include identifying and reaching the population in need.

[80] Kevin Outterson, *Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries*, 32 AM. J.L. AND MED. 159, 159-60.

[81] *An Inappropriate Confusion Between Nutriset and the Pharmaceutical Industry*, NUTRISET, http://www.nutriset.fr/en/access/patents-for-development/nutriset-ird-patents/an-inappropriate-confusion-between-nutriset-and-the-pharmaceutical-industry.html (last visited Nov. 25, 2010). In addition to Plumpy'nut, Nutriset markets a line of related supplementary food products and other ready-to-use foods. *Nutriset's Product Range*, NUTRISET, http://www.nutriset.fr/en/product-range/nutriset-product-range.html (last visited Nov. 25, 2010). Nutriset does not specify whether this sixty-percent figure applies specifically to Plumpy'nut.

[82] I use the term "locally produced RUTF" to refer to RUTF manufactured in the country of distribution. This term encompasses the PlumpyField network and licensees in developing countries, but not Edesia, strictly speaking, as Edesia's U.S.-manufactured product is produced for export.

[83] Stephane Doyon, What Are the Different Strategies To Reduce Price? 2-3 (Sept. 11-12, 2008), *available at* http://www.doctorswithoutborders.org/events/symposiums/2008/nutrition/assets/files/presentations/wg-presentations/Doyon.pdf.

[84] *Id.*

Even without mark-ups of pharmaceutical-like scale, however, the patent is likely preventing buyers from obtaining RUTF more cheaply. In the pharmaceutical context, experience shows that introducing generic competition always drives prices lower than voluntary price reductions by patentees, even if the patentee claims to be selling at cost.[85] Furthermore, while Nutriset might claim that its licensing policy in the developing world should ensure reasonably low prices, the effect of the open licensing policy on cost is currently ambiguous. First, if the non-exclusive licenses are to bring down prices through competition, Nutriset must actually grant a significant number of such licenses; it is unclear at this point how many such licenses will in fact be granted.[86] Second, there is mixed evidence as to the relative overall cost of locally produced RUTF compared to Nutriset's mass-produced RUTF. While there have been some reports of local production at reduced cost,[87] buyers have also reported higher prices from local manufacturers.[88] Local production allows purchasers to avoid paying a premium for shipping costs and import taxes; however, local producers generally must import many of the key RUTF ingredients, such as the milk powder and/or the vitamin mix.[89] Additionally, the smaller size of the local factories keeps production costs higher and makes it harder to achieve

[85] Kapczynski, *supra* note 18, at 1093.
[86] At present, only one organization in Mali is listed on Nutriset's website as a beneficiary of one of the "Patents Usage Agreements," though of course the agreements were only made available quite recently. *Beneficiaries of a Patents Usage Agreement*, NUTRISET, http://www.nutriset.fr/en/access/patents-for-development/online-patent-usage-agreement/beneficiaries-usage-agreement.html (last visited Nov. 25, 2010).
[87] Heidi Sandige et al., *Home-Based Treatment of Malnourished Malawian Children with Locally Produced or Imported Ready-toUse Food*, 39 J. OF PEDIATRIC GASTROENTEROLOGY AND NUTRITION 141, 145 (2004).
[88] Goldsmith, *supra* note 78, at 21. UNICEF also reported in 2010 that the price of imported RUTF was about $800 cheaper per metric ton than locally produced RUTF, though the report does not make clear whether this accounts for shipping and import costs. KOMRSKA, *supra* note 11, at 17.
[89] *See, e.g.*, SUPPLY CHAIN ANALYSIS, *supra* note 38, at 37.

economies of scale.[90] Nutriset's restriction of its licenses to developing countries thus cannot be expected to have the same effect as would open licensing of producers with more extensive production capacity and easier access to raw materials. It is an empirical question as to whether more robust competition might drive down prices more meaningfully.[91]

Increased competition in the absence of the patent might also encourage producers to seek cheaper production strategies or less costly variations of the Plumpy'nut formula.[92] Because the Plumpy'nut patent is sufficiently broad to cover multiple RUTF formulas, it may be restricting research on cheaper RUTF recipes,[93] such as ones using substitutes for milk powder, a

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[90] *Id.* at 36-37; Goldsmith, *supra* note 78, at 21.

[91] The recent entry of Tabatchnick Fine Foods and Challenge Dairy in the U.S. market may be instructive. While not constituting generic competition, the presence of these substitute products could theoretically drive prices down, particularly if the products remain in the public domain and are produced widely by several competitors. At present, however, UNICEF reports price quotes from Tabatchnick and Challenge similar to Nutriset's. *See* UNICEF/WHO, SOURCES AND PRICES OF SELECTED MEDICINES FOR CHILDREN, INCLUDING THERAPEUTIC FOOD, DIETARY VITAMIN AND MINERAL SUPPLEMENTATION 25, 62 (2d ed. April 2010), *available at* www.unicef.org/supply/files/SOURCES_AND_PRICES_2010(1).pdf.

[92] At least one Nutriset licensee, Valid Nutrition, reports that it is developing cheaper formulations of RUTF that are in the process of being clinically tested. Valid Nutrition reports that these products fall under intellectual property that Valid Nutrition has released into the public domain. If Valid Nutrition's product is successful, this could significantly improve access to RUTF. Valid Nutrition – Announcement, Oct. 15, 2010, *available at* http://validnutrition.org/images/stories/valid%20site_images/news_pdf/VN%20statement%20re%20Nutriset.pdf.

[93] The degree to which the Plumpy'nut patent blocks experimentation under the patent in any given country will depend on that country's experimental use laws. While some countries have more permissive laws exempting from infringement certain kinds of research practicing the subject matter of a patent, the common law experimental use exemption in the United States is extraordinarily narrow. *See* Kevin Iles, *A Comparative Analysis of the Impact of Experimental Use Exemptions in Patent Law on Incentives to Innovate*, 4 NW. J. TECH. & INTELL. PROP. 61, 67 (2005). Since the Federal Circuit's 2002 decision in *Madey v. Duke University*, experimental use in the United States constitutes infringement if "the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." 307 F.3d 1351, 1362 (Fed. Cir. 2002). There is a separate statutory exception when the alleged infringer practices the patent "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. 271(e)(1) (2006). Thus the U.S. patent, at

particularly expensive ingredient. Nutriset's incentives for pursuing cheaper formulas are questionable, given the advantage it gains from its patent monopoly.[94] Additionally, the patent may have a chilling effect and prevent producers with bona fide non-infringing substitute products from effectively entering the market and bringing down prices through substitute competition. For example, Tabatchnick Fine Foods has reported that although it has developed an RUTF that it claims does not infringe the Plumpy'nut patent, buyers are reluctant to purchase from Tabatchnick for fear of becoming embroiled in a patent dispute.[95]

III. The Relative Importance of Patent Incentives for Innovation in the Field of Therapeutic Food

Despite the above-identified access obstacles, the classic argument in favor of exclusive patent rights would counter that without patent protection, therapeutic food innovation would simply not occur.[96] Patent protection is generally justified by the theory that a limited patent monopoly is necessary to guarantee innovators the opportunity to recoup the research and development ("R&D") and commercialization costs involved in bringing their inventions to market.[97] The public pays the price of a temporary monopoly in exchange for the marginal increase in innovation that would not come about absent the patent incentives.

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minimum, significantly restricts experimentation under the Plumpy'nut patent absent Nutriset's consent.

[94] *Cf.* Iles, *supra* note 93, at 64.

[95] David Bois, *Tabatchnick is Nutty for Butta*, TONIC, Aug. 27, 2010, http://www.tonic.com/article/tabatchnick-fine-foods-humanitarian-aid-nutty-butta.

[96] Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev.1575, 1580 (2003).

[97] F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE & ECONOMIC PERFORMANCE 440 (2d ed. 1980).

The incentives provided by exclusive patent rights are not equally vital for innovation in all industries, however.[98] Professors Dan Burk and Mark Lemley argue that patent incentives are particularly important in fields where the ratio of R&D costs to imitation costs is high, such as in the pharmaceutical industry.[99] If an innovation requires significant up-front R&D costs during its initial development but is relatively cheap to imitate, then the developer will be unable to recoup her R&D costs because the quick entry of competitors into the market will drive prices down toward marginal cost within a short period of time. However, if R&D costs are sufficiently low or imitation costs sufficiently high, then the patent monopoly might be less necessary. Additional factors affecting the importance of patent incentives across industries include the availability of alternative incentives to innovate and the existence of ex ante subsidies to support R&D.[100]

Cumulatively, these factors suggest that therapeutic food is not a field where patent protection is crucial to spurring innovation. The R&D costs of therapeutic food are far lower than that of, for example, pharmaceuticals, for which the importance of patent incentives has been demonstrated. While a new drug can cost up to $800 million in R&D and take many years to develop,[101] it is highly unlikely that Plumpy'nut's R&D costs were comparable. RUTF is relatively straightforward to produce. The ingredients are basic food products, and RUTF production requires no expensive equipment. Indeed, RUTF preparation essentially involves mixing the various ingredients together in a bowl with an electric mixer at specified, varying

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[98] MICHAEL BLAKENEY, INTELLECTUAL PROPERTY RIGHTS AND FOOD SECURITY 214 (2009). For example, studies show that patents are particularly important for innovation in the pharmaceutical and chemistry industries, but far less so in other fields. Burk & Lemley, *supra* note 96, at 1589 & n.37; Chien, *supra* note 23, at 865.
[99] Burk & Lemley, *supra* note 96, at 1585.
[100] SCHERER, *supra* note 97, at 443; Burk & Lemley, *supra* note 96, at 1586-87.
[101] Burk & Lemley, *supra* note 96, at 1616.

speeds.[102] Clinical trials of Plumpy'nut appear to have been carried out predominantly by university researchers and Briend, the product's developer who is associated with IRD. While Nutriset donated the Plumpy'nut for these trials, the studies were otherwise funded by a combination of public and private grants.[103] The regulatory approval process in any given country is also likely less expensive than for pharmaceuticals, though manufacturers must conduct basic quality assurance to ensure a lack of contamination.[104]

There are also strong alternate incentives to innovate and substantial ex ante research subsidies available for therapeutic food. Humanitarian food production is not a field that has historically been characterized by a lot of patent activity; neither F100 nor Oral Rehydration Therapy, two key prior treatments, was ever patented.[105] Briend, Plumpy'nut's inventor, was a pediatric nutritionist who reportedly was inspired to develop the product based on his experience working in famine-affected areas and his frustration with the then-available treatments.[106] Briend has also renounced all ownership rights of the Plumpy'nut patent, belying any suggestion that he was motivated by the possibility of obtaining patent rights.[107] While the patent incentive was arguably necessary for securing Nutriset's help in commercializing the product, there is significant alternate funding available in this field, given its humanitarian nature. For example, Edesia, Nutriset's U.S. partner, recently received a $2 million grant from USAID for the

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[102] Manary, *supra* note 6, at S85.
[103] *See, e.g.*, Diop et al., *supra* note 29, at 302; Manary et al., *supra* note 36, at 561; M.J. Ndekha et al., *Home-Based Therapy with Ready-To-Use Therapeutic Food Is of Benefit to Malnourished, HIV-infected Malawian Children*, 94 ACTA PEDIATRICA 222, 225 (2005); Sandige et al., *supra* note 87, at 141.
[104] *See* GIORGIA PAIELLA, UNICEF TECHNICAL REQUIREMENTS FOR RUTF PRODUCTS (2010), *available at* http://www.unicef.org/supply/files/Technical_Requirements_for_RUTF_Products.pdf.
[105] Enserink, *supra* note 26, at 38.
[106] Rice, *supra* note 5.
[107] *Id.*

production of RUTF.[108] Moreover, other producers are entering the RUTF field without seeking patents, again suggesting that innovation might take place irrespective of the patent incentives.[109]

IV. The Prospect of Using Compulsory Licensing to Ensure Access to Therapeutic Food

If Nutriset's U.S. patent is upheld, the question arises as to whether an attempt should be made to circumvent Nutriset's current patent monopoly to facilitate broader access to RUTF. The projected lesser importance of patent incentives in the therapeutic food industry, coupled with the access obstacles identified in Part II, supports such action. In this Part, I explore the prospect of using compulsory licensing, which has received the bulk of the attention among access tools in the medicines context,[110] to allow generic production of RUTF. Compulsory licensing has long been a feature of patent systems, used as a remedy for patent abuses and in other cases where limiting the patentee's monopoly power is perceived to be in the public interest.[111] The right to its use, especially in relation to the public health, has also been affirmed in international agreements among WTO Members.[112]

Compulsory licensing could play an important role in remedying several of the access obstacles identified in Part II. Compulsory licensing would allow for the introduction of new manufacturers in the event of supply shortages even if Nutriset were unwilling to license new

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[108] *Edesia Wins $2 Million USAID Grant to Prevent Malnutrition*, PR NEWSWIRE, Feb. 24, 2010, http://www.prnewswire.com/news-releases/edesia-wins-2-million-usaid-grant-to-prevent-malnutrition-85189652.html.

[109] *See supra* note 91. Tabatchnick Fine Foods has filed a patent application for its RUTF formula, which is currently pending, but claims that the patent will be "open source" and that Tabatchnick would allow others to produce the product. *Making Peanut Butter Gets Stickier*, *supra* note 73.

[110] Kapczynski, *supra* note 74, at 1588.

[111] Abbott, *supra* note 18, at 326; Jerome H. Reichman & Catherine Hasenzahl, Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA 1 (June 2003), *available at* http://ictsd.org/i/publications/11764/.

[112] Doha Declaration, *supra* note 20, para. 5(b).

suppliers; such a technique could be crucial if, for example, countries were experiencing unexpected increases in demand akin to those that led to UNICEF stock-outs in 2008. Compulsory licensing could also play a role in bringing down prices, though price reductions on the pharmaceutical scale should not be expected due to the role played by ingredient cost in current RUTF pricing.

However, as I demonstrate below, the current international treaty regime governing the intellectual property obligations of WTO members sharply limits the ability of the United States, and indeed any WTO country, to use compulsory licensing to export RUTF to countries suffering from nutrition crises. In Sections IV.A and B, I provide a brief overview of the restrictions on compulsory licensing imposed by the TRIPS Agreement, including the current provisions limiting compulsory licenses for export. In Section IV.C, I argue for amending the existing regime to more broadly enable export of therapeutic food under a compulsory license, and I explore the feasibility and desirability of such action.

A. Compulsory Licensing under TRIPS

Countries that are Members of the WTO are limited by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") in how and under what circumstances their national laws can allow for the issuance of compulsory licenses.[113] Nearly every country in

[113] The TRIPS Agreement requires WTO Members to adopt specified minimum standards of intellectual property protection. With regard to patents, the Agreement requires, *inter alia*, that patents be available for products and processes in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. TRIPS, *supra* note 25, art. 27. The patent holder is guaranteed exclusive rights to prevent third parties from making, using, offering for sale, selling, or importing the invention covered by the patent without her consent. *Id.* art. 28. Patents must also provide protection to the patentee for a minimum of twenty years from the filing date of the patent. *Id.* art. 33.

which Plumpy'nut is patented is a WTO Member,[114] so we must look to TRIPS for the outward bounds of countries' freedom to use compulsory licensing as an access tool for RUTF. While TRIPS does not use the phrase "compulsory licensing," it is widely agreed that Article 31 of TRIPS, which governs "other use[115] of the subject matter of a patent without the authorization of the right holder,"[116] delineates Members' obligations with regard to compulsory licensing.[117]

Article 31 lays out a series of limitations on the conditions under which WTO Member countries' domestic laws can provide for compulsory licensing. While Article 31 leaves it up to each country to determine the grounds on which compulsory licenses may be issued,[118] each license must be considered on its "individual merits."[119] Licenses must be non-exclusive and non-assignable,[120] and the "scope and duration" of the license must be limited to "the purpose for which it was authorized."[121] Crucially, the license must also be issued "predominantly for the supply of the domestic market of the Member authorizing such use."[122]

There are two procedural routes that license applicants may take. In the absence of a "national emergency," "other circumstances of extreme urgency," or "public non-commercial use," the applicant must first attempt to obtain voluntary authorization from the patentee on

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[114] Of the countries identified in Part I, only Sudan is not currently a WTO member. *Members and Observers*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Nov. 26, 2010).
[115] "Other use" refers to uses other than those governed by Article 30 of the agreement, which allows for "limited exceptions to the exclusive rights conferred by a patent" meeting certain enumerated conditions. TRIPS, *supra* note 25, art. 30, art. 31 n.7.
[116] TRIPS, *supra* note 25, art. 31.
[117] *See, e.g.*, Abbott, *supra* note 18, at 319.
[118] *Id.* Countries' freedom to determine the grounds for issuing compulsory licenses was reaffirmed by the Doha Declaration. Doha Declaration, *supra* note 20, para. 5(b).
[119] TRIPS, *supra* note 25, art. 31(a).
[120] *Id.* art. 31(d)-(e).
[121] *Id.* art. 31(c).
[122] *Id.* art. 31(f).

"reasonable commercial terms and conditions."[123] A license may only be issued if these negotiations do not yield a voluntary license within a "reasonable period of time."[124] The prior negotiation requirement can be waived by a Member in cases of national emergency, extreme urgency, or public non-commercial use; however, the patentee must be notified of the use as soon as reasonably practicable.[125] In each case, the patentee must be paid "adequate remuneration . . . taking into account the economic value of the authorization."[126] Countries must have a judicial review or other independent review mechanism available to review the validity of decisions to grant a license and to review decisions relating to remuneration.[127]

Within these guidelines, countries where the Plumpy'nut patent is in force are free to enact legislation enabling the issuance of compulsory licenses for the production of RUTF or to issue compulsory licenses if implementing legislation is already in place. Under Article 31(f), however, such licenses must be predominantly for the supply of the domestic market. This provision poses a significant obstacle to the prospect of U.S. RUTF production under a compulsory license if Nutriset's U.S. patent is upheld. RUTF is highly unlikely to be widely consumed, if at all, in the domestic market in the United States, so any compulsory license issued would likely be predominantly (if not exclusively) for export. Article 31(f) thus effectively precludes U.S. production of RUTF under a compulsory license; the same is true for other developed WTO countries seeking to export RUTF.

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[123] *Id.* art. 31(b).
[124] *Id.*
[125] *Id.*
[126] *Id.* art. 31(h).
[127] *Id.* art. 31(i)-(j). There are additional guidelines specific to licenses issued to remedy anticompetitive practices, licenses for semi-conductor technology, and licenses issued to allow the exploitation of a patent that cannot be exploited without infringing a pre-existing patent. *Id.* art. 31(c), (k) & (l).

One response to this would be that any increased production of RUTF under compulsory licensing will simply have to take place in the countries where RUTF is needed domestically.[128] However, as discussed above, reliance on local manufacturing is risky, given the emergency circumstances under which Plumpy'nut is often needed. Countries experiencing drought, natural disasters, or civil unrest are vulnerable to having their local production facilities incapacitated even if a compulsory license for domestic production were to be issued.[129] Additionally, many of the African countries in which Plumpy'nut is patented are designated Least Developed Countries (LDCs) by the United Nations.[130] A country with extremely poor infrastructure is likely to be less capable of suddenly scaling up production during emergencies than a country like the United States, even if the emergency is not industry-disabling. Countries outside of those where the product is needed may also generally be capable of cheaper production, such that production for export could play a significant role in driving down prices and allowing more expansive coverage of children suffering from severe acute malnutrition.

These factors weigh strongly in favor of having compulsory licensing for RUTF export more broadly available as an option for ensuring access. Although in the absence of compulsory licensing Plumpy'nut could still be produced generically for export in countries where Plumpy'nut is off-patent,[131] the patent severely limits potential suppliers. Moreover, while

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[128] If Nutriset follows through on widely and openly licensing its product in the developing countries where Plumpy'nut is patented, domestic compulsory licensing might actually be moot for Plumpy'nut, except in Mozambique and Niger, where Nutriset has granted exclusive licenses. *See supra* notes 49-53 and accompanying text.

[129] Further empirical work would be needed to identify how often such circumstances in fact disrupt local production.

[130] *Least Developed Countries: Country Profiles*, UN-OHRLLS, http://www.unohrlls.org/en/ldc/related/62 (last visited Nov. 26, 2010).

[131] Countries where Plumpy'nut is not patented are of course not barred from producing and exporting the product. However, if Plumpy'nut is under patent in the importing country, then the importing country would still need to issue a compulsory license or have an exhaustion-of-rights

Plumpy'nut in particular may not be patented in some potential exporting countries, there is no guarantee that holders of patents for new therapeutic food products developed in the future would similarly refrain from patenting in countries capable of mass production and export.[132]

B. Article 31(f) and the Export of Pharmaceuticals under Compulsory Licensing

In the medicines context, Article 31(f) was criticized as foreclosing the use of compulsory licensing for countries with insufficient or no domestic pharmaceutical manufacturing capacity.[133] The first step toward identifying a solution to this problem emerged in the Declaration on the TRIPS Agreement and Public Health ("the Doha Declaration") adopted at the 4th WTO Ministerial Conference in Doha in 2001.[134] The Doha Declaration generally affirmed that TRIPS should be interpreted and implemented "in a manner supportive of WTO

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regime allowing parallel imports. Under TRIPS, countries are free to determine their own rules for exhaustion of intellectual property rights. TRIPS, *supra* note 25, art. 6; *see* UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 106-07 (2005).

[132] For example, Plumpy'nut is not patented in India, a country that has played an important role in the production of generic medicines. Enserink, *supra* note 26, at 38. Although at first India strongly resisted RUTF, even prohibiting UNICEF from importing the product into the country, there are now several Indian RUTF producers, including a recently added member of Nutriset's PlumpyField network. *Id.*; MEMBERS OF THE NETWORK, PLUMPYFIELD, *supra* note 72, at 1. It is unclear whether Nutriset never sought patent protection in India or whether it was simply unable to obtain a patent. Since the adoption of TRIPS, India (like every other WTO Member) has been forced to amend its patent laws to make food, along with pharmaceuticals, patentable subject matter. *See* Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 547 (2007). It may be, however, that other features of Indian patent law make it relatively difficult to obtain patents on therapeutic food products. *Cf.* Kapczynski, *supra* note 74 (identifying features of India's current patent laws likely to curtail the number of pharmaceutical patents granted and increase competition in the pharmaceutical sector). If Plumpy'nut is not patented in India for this reason, the same factors that hindered the patentability of Plumpy'nut could also affect the likelihood that therapeutic food patents will be granted in India in the future, perhaps ensuring a continued supply of generic therapeutic food products. A complete examination of the patentability of therapeutic food in India is beyond the scope of this paper.

[133] *See* Duncan Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?*, 7 J. Int'l Econ. L. 73, 78 (2004).

[134] *Id.* at 81.

Members' right to protect public health,"[135] and in light of this recognition, reaffirmed that Members "ha[ve] the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[136] The Declaration also specifically recognized the obstacle posed by Article 31(f) for "Members with insufficient or no manufacturing capacities in the pharmaceutical sector," and it instructed the TRIPS Council to find "an expeditious solution to this problem."[137]

That solution came in the form of the Decision of the General Council of 30 August 2003 ("the August 30 Decision"),[138] which has been incorporated as an amendment to the TRIPS Agreement as Article 31*bis*, subject to ratification in accordance with WTO rules.[139] The August 30 Decision allows for a waiver of Article 31(f) "to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export" to Members who are least-developed countries or who otherwise establish that they have no or insufficient manufacturing capacity for the product to be exported.[140] Under the Decision, both the importing and exporting countries must issue compulsory licenses,[141] and both countries must notify the TRIPS Council of their intention to use the mechanism created by the Decision, as well as provide certain other

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[135] Doha Declaration, *supra* note 20, para. 4.
[136] *Id.* para. 5(b).
[137] *Id.* para. 6.
[138] Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of 30 August 2003, IP/C/W/405 (Sept. 1, 2003) [hereinafter August 30 Decision], *available at* http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.
[139] INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 473 n.1 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 2d ed. 2008). Thirty-one members, including the United States, have accepted the amendment thus far. *Members Accepting Amendment of the TRIPS Agreement*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.
[140] August 30 Decision, *supra* note 138, para. 2.
[141] *Id.* paras. 2(a)(iii), 2(b).

assurances.[142] Measures must be taken by all Members, including the exporting and importing countries, to prevent the diversion of products exported under the mechanism to other territories.[143] The Decision also waives Article 31(h) for the importing country, such that only the exporting country is responsible for paying adequate remuneration to the patent holder.[144]

While the August 30 Decision may address the export problem for countries with insufficient pharmaceutical production capacity, it is unlikely to be of much use for compulsory licensing of RUTF. The Decision limits the waiver to compulsory licenses issued for the production of "pharmaceutical products."[145] Pharmaceutical products are defined, for the purposes of the Decision, as "any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the [Doha] Declaration."[146] While the Decision specifies that this includes "active ingredients necessary for [the product's] manufacture and diagnostic kits needed for its use,"[147] it would be a stretch to argue that RUTF is a product or process of the "pharmaceutical sector." RUTF is produced predominantly by organizations that manufacture nutritional products or by food companies.[148] In accordance with the Vienna Convention on the Law of Treaties, TRIPS must be interpreted "in accordance with the ordinary meaning to be given to

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[142] *Id.* paras. 2(a), 2(c).
[143] *Id.* paras. 2(b)(ii), 4 & 5.
[144] *Id.* para. 3.
[145] *Id.* para. 2.
[146] *Id.* para. 1.
[147] *Id.*
[148] Nutriset and its PlumpyField network produce nutritional supplements and RUTF for combating malnutrition, as does Valid Nutrition. NUTRISET, http://www.nutriset.fr/en/homepage-nutriset.html; VALID NUTRITION, http://validnutrition.org. Tabatchnick Fine Foods and Challenge Dairy are both food companies. CHALLENGE DAIRY, http://www.challengedairy.com; Tabatchnick, http://www.tabatchnick.com.

[its] terms . . . in their context and in the light of its object and purpose."[149] The Oxford English Dictionary defines "pharmaceutical" as "of, relating to, or engaged in pharmacy; used in pharmacy, of the nature of a medicinal drug; of or relating to the manufacture, use, or sale of medicinal drugs."[150] The Doha Declaration's emphasis on providing "access to medicines" and discussion of epidemics such as AIDS, tuberculosis, and malaria further supports a reading limiting "pharmaceutical sector" to drugs, rather than therapeutic food. Examples provided in the Decision of best practices for clearly marking products to be exported under the Decision identify practices of pharmaceutical companies like Bristol Myers Squibb, Novartis, Merck, and Pfizer.[151] As such, it appears that even after the adoption of the August 30 Decision, TRIPS largely prevents Members from issuing compulsory licenses for the export of RUTF.[152]

C. Making Compulsory Licensing Available for the Export of RUTF

The August 30 Decision's limitation of the Article 31(f) waiver to products of the pharmaceutical sector should be reconsidered. The rationale behind the waiver applies with equal force in the RUTF context and would be consistent with the spirit of both the Doha

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[149] Vienna Convention on the Law of Treaties art. 31(1), May 23, 1969, 8 I.L.M. 679 (1980).
[150] OXFORD ENGLISH DICTIONARY, http://dictionary.oed.com. "Pharmacy" is also defined in relation to medicinal drugs. *See id.*
[151] August 30 Decision, *supra* note 138, Annex.
[152] When Members were negotiating a solution to the Article 31(f) problem with respect to pharmaceuticals, some countries and NGOs suggested that a solution could be devised under Article 30 of TRIPS, which provides for "limited exceptions" to the exclusive rights conferred by a patent, rather than Article 31. Abbott, *supra* note 18, at 338-39. During the negotiations, the United States strongly argued for a narrow reading of Article 30; it is thus unlikely that the United States, in looking to export RUTF covered by the U.S. Plumpy'nut patent, would do so under Article 30. *See* Matthews, *supra* note 133, at 89. The August 30 Decision specifies that it is adopted "without prejudice" to Members' other rights and flexibilities under TRIPS, so Members still could conceivably attempt to export RUTF under compulsory license based on Article 30. August 30 Decision, *supra* note 138, para. 9. However, Members are likely to be wary of proceeding in the face of significant legal uncertainty, especially since a decision by the WTO Dispute Settlement Panel on the meaning of Article 30 in relation to the Canadian Patent Act is considered to have cast doubt on the legality of using Article 30 in this manner. Abbott, *supra* note 18, at 338; Matthews, *supra* note 133, at 90.

Declaration and TRIPS itself. The process laid out in the August 30 Decision is already under reconsideration by the TRIPS Council in response to criticisms that the process is unduly burdensome administratively;[153] when the Decision is again revisited at the next Council meeting, the Council should also examine the possibility of extending the export waiver to other patented inventions used for the treatment of severe public health problems that cannot be effectively provided domestically, including RUTF.[154]

The first several paragraphs of the August 30 Decision lay out the justification for the Article 31(f) waiver. The Decision takes note of the Doha Declaration and, in particular, the difficulties faced by WTO Members lacking pharmaceutical manufacturing capacity in making effective use of compulsory licensing.[155] The Decision also recognizes the "importance of a rapid response" for countries seeking to obtain pharmaceutical supplies, and it finds that these factors collectively create "exceptional circumstances" justifying a waiver of Article 31(f).[156]

This rationale applies to the export of RUTF as well. Although a general lack of manufacturing capacity is of less concern given the relative simplicity of RUTF production,

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[153] *TRIPS Council Holds In-Depth Review of "Para 6" System*, TWN THIRD WORLD NETWORK, Oct. 29, 2010, http://www.twnside.org.sg/title2/wto.info/2010/twninfo101102.htm. Critics contend that the mechanism established by the Decision is too complicated for it to be of much use. The mechanism has thus far been used only once, by Canada and Rwanda, for the export of an HIV antiretroviral drug. *Id.* Even if the current system is imperfect, the option of compulsory licensing for the export of RUTF should be available; any additional proposals for modifications to the procedural aspects of the mechanism are beyond the scope of this paper.

[154] A proposed extension to the Article 31(f) waiver raises the question of whether the extension should specifically cover therapeutic food or instead broadly encompass any technology needed to address the serious public health problems faced by developing countries. A broader definition would be preferable, because the provision should be flexible enough to cover future-arising technologies key to public health treatment. This is the approach that was adopted in the implementation of the August 30 Decision in choosing not to limit the applicable scope of diseases under the waiver. *See infra* notes 161-163. The mechanism could still require importing countries to demonstrate that they lack sufficient production capacity in the sector in question at the time the license is needed.

[155] August 30 Decision, *supra* note 138, preamble.

[156] *Id.*

countries may be unable to make use of compulsory licensing domestically either because the same emergency conditions that led to the nutritional crisis have impacted production or because the nutritional crisis requires response on a scale beyond the capacity of the country where the product is needed. The importance of rapidity of response is also crucial in the RUTF context, given the serious health complications—and eventual death—that result from delays in treating severe acute malnutrition.

Including products like RUTF within the scope of the Article 31(f) waiver would also be consistent with both the Doha Declaration[157] and TRIPS. Although the Doha Declaration, like the August 30 Decision, places particular emphasis on pharmaceutical products, it recognizes generally "the gravity of the public health problems afflicting many developing and least-developed countries"[158] and reaffirms Members' freedom to independently determine the grounds upon which compulsory licenses may be granted.[159] Article 8 of TRIPS, which lays out "Principles" of the TRIPS Agreement, emphasizes that Members may "adopt measures necessary to protect public health and *nutrition*" if such provisions are otherwise consistent with the rest of the Agreement.[160]

There are several objections that might be lodged against this proposal, the first of which is its feasibility. Indeed, expanding the scope of the Article 31(f) waiver is unlikely to be easy. During the WTO Members' negotiations leading up to the adoption of the August 30 Decision,

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[157] Commentators differ on the precise legal status of the Doha Declaration. *See* UNCTAD-ICTSD, *supra* note 131, at 718 n.38 (taking the position that the Declaration is legally binding); Matthews, *supra* note 133, at 82-83 (noting that while some commentators argue that the Decision constitutes "subsequent practice in application of the treaty" to be used in interpreting the treaty under the Vienna Convention, others caution that the precise legal status of the Declaration remains uncertain).
[158] Doha Declaration, *supra* note 20, para. 1.
[159] *Id.* para. 5(b).
[160] TRIPS, *supra* note 25, art. 8 (emphasis added).

the United States took the position that the waiver should be limited to pharmaceutical products targeting the diseases identified in paragraph 1 of the Doha Declaration: HIV/AIDS, tuberculosis, and malaria.[161] The United States also argued that the solution should be limited to medicines and should not include diagnostic kits.[162] The United States' insistence on the scope-of-diseases issue held up negotiations for several months, although it eventually conceded and the final draft of the Decision contained no limitation on the scope of diseases to which the waiver could be applied.[163]

Although the United States' position ultimately did not prevail, the United States might be expected to put up similar resistance against any attempt to expand the Article 31(f) waiver beyond pharmaceutical products to other patented products needed for the treatment of serious health problems. Whether the United States would be successful at blocking such an addition is difficult to predict. Professor Frederick Abbott suggests that the United States failed to limit the scope of diseases in the August 30 Decision—in the face of a common opposing position adopted by the developing countries—because (1) its arguments were not adequately supported by the text of the Doha Declaration; (2) it was unable to persuade the other WTO Members of the risk of eroding future R&D; and (3) it did not gain the support of the European Union, in part because the interests of the pharmaceutical industry were less paramount to European countries without significant pharmaceutical production.[164]

Applying this framework to the current proposal, the United States would be correct to maintain that the Doha Declaration specifically calls for a solution with respect to countries lacking manufacturing capacity in the *pharmaceutical* sector; any arguments that the scope of the

[161] Abbott, *supra* note 18, at 327-28.
[162] Matthews, *supra* note 133, at 86-87.
[163] Abbott, *supra* note 18, at 328-31.
[164] Abbott, *supra* note 18, at 324, 332.

Article 31(f) waiver should be expanded beyond pharmaceuticals would thus have to be grounded in the spirit and overall rationale of the Declaration and the TRIPS Agreement. As to the interests of the negotiating parties, there is no evidence that the European Union or any other developed country has a particular interest in preventing the erosion of revenue from RUTF or other therapeutic food patents; though Nutriset is based in France, it is not a major national industry. In fact, even the United States has no clear vested interest in protecting revenues for RUTF patents in particular, though the United States might still be expected to oppose broadening compulsory licensing for precedential reasons. Since at present the United States is largely closed out of the RUTF market by Nutriset, there is even perhaps a chance that it would take a contrary position here, if, for example, there were strong lobbying from the peanut or dairy industries, whose materials would be used as raw products in RUTF production.

A second objection pertains to the desirability of using compulsory licensing for facilitating RUTF access at all. Critics contend that the loss of patent rents resulting from compulsory licensing will reduce incentives for further innovation and dissuade foreign companies from investing in the territory issuing the license.[165] The extent to which either of these effects will result when compulsory licenses are issued in a particular industry or country is ultimately an empirical question. Several existing studies cast doubt on the contention that compulsory licensing generally reduces innovation,[166] and there is evidence that the influence of

[165] Jerome H. Reichman, Symposium, Pharmaceutical Innovation: Law & the Public's Health, Comment, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. & ETHICS 247, 253-54 (2009).

[166] *See, e.g.*, Chien, *supra* note 23, at 879-80. Colleen Chien, based on a literature review of prior studies and an independent analysis of six compulsory licenses issued by the FTC to remedy antitrust violations in the United States, found that in most cases, compulsory licensing in the pharmaceutical industry did not affect future innovation. *Id.* at 891-92. Chien tentatively concluded that a negative impact on innovation is likely only when compulsory licenses are

patent protection on foreign direct investment varies with several other factors, including a country's overall level of development or economic climate, the industry in question, and the type of investment under consideration.[167] Without attempting to resolve these ongoing debates, it seems likely that, given the evidence presented in Part III regarding the lesser importance of patent rents for creating incentives in the therapeutic food industry, any reductions in innovation or investment occasioned by compulsory licensing in other industries should be less expected in the RUTF context. Additionally, Nutriset has created PlumpyField partners in countries where it does not have patents on Plumpy'nut at all, demonstrating that the existence of strong patent protection has not been deemed a prerequisite by Nutriset in deciding where to invest and transfer its technology.[168]

Finally, it might be objected that the use of compulsory licenses for export would simply be unlikely—and thus not a very useful access tool—even if the Article 31(f) waiver were extended, given low political will in potential exporting countries like the United States. Indeed, the United States' negotiating position in attempting to restrict the scope of the August 30 Decision, along with its failure thus far to pass legislation implementing the Decision,[169] raises doubts about whether the United States would ever issue a compulsory license for the export of

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issued predictably (i.e., the compulsory licenses apply to future innovation) in significant markets. *Id.* at 887, 892.

[167] Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 AM. BUS. L.J. 283, 299-300 (2008); Carlos A. Primo Braga & Carsten Fink, *The Economic Justification for the Grant of Intellectual Property Rights: Patterns of Convergence and Conflict*, 72 CHI.-KENT. L. REV. 439, 454-55 (1996)

[168] Nutriset has PlumpyField partners in Ethiopia and India, neither of which are countries where Plumpy'nut has been patented. *See* MEMBERS OF THE NETWORK, PLUMPYFIELD, *supra* note 72.

[169] Legislation was proposed in 2006 but never made it out of committee. *See Life-Saving Medicines Export Act of 2006*, GOVTRACK.US, http://www.govtrack.us/congress/bill.xpd?bill=s109-3175.

RUTF.[170] Even if the United States does not play this role, however, several other countries have shown the willingness to step in. Canada, Norway, the Netherlands, Switzerland, and India have all passed legislation implementing the August 30 Decision,[171] and Canada has used the Decision's mechanism to export antiretrovirals to Rwanda under a compulsory license.[172] Finally, even if compulsory licenses for exporting RUTF were issued infrequently, the availability of the tool could play a key role in negotiating with patent holders to obtain more favorable prices or additional voluntary licenses.[173]

Conclusion

The patenting of ready-to-use therapeutic food provides a new stage for examining familiar tensions between intellectual property rights and access to humanitarian goods. As in other contexts, the Plumpy'nut case demonstrates that patenting of therapeutic food is limiting access to this life-saving product. Given the probable lesser importance of strong exclusive patent rights in the therapeutic food industry, solutions should be sought to improve access, even at the expense of weakening patentees' right to exclude.

Compulsory licensing could play an important role in expanding access by introducing additional suppliers to open up supply bottlenecks and driving down prices through generic competition, even if such reductions are modest relative to those generated by generic competition in other industries. Because RUTF is a product often needed in crisis situations,

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[170] The United States has also attempted to restrict countries' use of compulsory licensing beyond the limitations of TRIPS through bilateral and regional trade agreements. *See* Carlos Correa, *Implications of Bilateral Free Trade Agreements on Access to Medicines*, 84 BULL. WORLD HEALTH ORGAN. 399 (2006). Countries' obligations under these agreements may further limit countries' abilities to use compulsory licensing for the export of RUTF.

[171] Abbott, *supra* note 18, at 337-38.

[172] *See supra* note 153.

[173] *See* Matthews, *supra* note 133, at 81 (noting that recent experiences in Brazil and the United States demonstrate that "the mere threat of compulsory licenses may often be as, if not more, effective in achieving public policy objectives than actual use").

including nutrition crises caused by natural and human-induced disasters, compulsory licensing for export must be made available, to ensure a reliable supplier base in the case that domestic production is disrupted or incapable of meeting sudden emergency surges in demand.

While the availability of compulsory licensing for exporting RUTF, whether for actual production or as a negotiating tool, would be a vital safeguard, other access approaches should be pursued as well. Such approaches could include the creation of entities to engage in open R&D for future products and aggressive pursuit of additional voluntary licenses from Nutriset for the production of products covered by the Plumpy'nut patent. Nutriset has arguably already shown itself to be responsive to public pressure. Nutriset's announcement of its new royalty-free open licensing policy for developing countries in October 2010 and the addition around that time to the Nutriset website of a page attempting to clarify "[a]n inappropriate confusion between Nutriset and the pharmaceutical industry"[174] regarding access to healthcare products show Nutriset's sensitivity to public criticism over access to RUTF. Both of these developments came on the heels of the Mama Cares/Breedlove lawsuit and rising attention in the media of the access obstacles posed by the Plumpy'nut patent.[175]

These alternative approaches could be particularly useful where compulsory licenses are likely to be less so. For instance, compulsory licensing has the disadvantage of requiring top-down action in both the importing and exporting country, if Plumpy'nut is patented in both. In addition to standard problems of political will, this could be especially problematic if the RUTF is needed in the importing country during a period of political conflict, when humanitarian aid groups may be operating independent of government cooperation. Negotiation of creatively

[174] *See supra* note 81.
[175] *See, e.g.*, Rice, *supra* note 5.

structured voluntary licenses with researchers could also be particularly useful in expanding experimentation for new, cheaper RUTF formulas under the Plumpy'nut patent.

While prior experience with RUTF has uncovered access obstacles, the RUTF field may be on the cusp of change. Valid Nutrition, one of Nutriset's licensees, reports to be in the process of testing a new, cheaper RUTF formula that it claims would be released into the public domain. Tabatchnick Fine Foods and Challenge Dairy are now marketing alternate RUTF products in the United States, neither of which is under patent, at least at present.[176] If these products prove to be effective and remain in the public domain,[177] their availability could significantly add to supply and generate far more competition, hopefully driving down prices. The proliferation of alternative RUTF products might also suggest that, because of the relative simplicity of RUTF composition relative to pharmaceuticals, this is a field where non-infringing substitute products are likely to arise more swiftly and improve access organically. Whether the same would be true of future therapeutic food products beyond RUTF is an open question. Given the stakes, all avenues should continue to be pursued to achieve maximal access for children suffering from severe acute malnutrition.

[176] As noted *supra*, Tabatchnick has filed a patent application but maintains that the patent will be open to the public.

[177] This would also depend in part on whether Nutriset filed infringement proceedings against either of the U.S. producers and the outcomes of any such proceedings.