

Therapeutic ready-to-use food (RUF) patent issues

MSF Access Campaign Briefing Note
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Persistent high rates of child mortality in sub-Saharan Africa and South Asia will not be reduced if malnutrition is not addressed more aggressively. This is a medical emergency. The research and development of ready-to-use food (RUF) for the treatment of malnutrition has revolutionized the ability to address this disease on a large scale. MSF is supporting the urgent scale-up of treatment programs through expanded funding and supply of RUF. This briefing note considers potential patent barriers to the scale-up of production and increased competition in the supply of RUF and proposes solutions to address these barriers.

Plumpy' nut patents

Nutriset, in cooperation with the Institut de Recherche pour le Developpment (IRD), both located in France, developed a new therapeutic RUF product which has become very well known under the brand name "Plumpy'nut".

Nutriset and IRD have obtained the grant of patents in many countries, both developed (e.g. Australia, Canada, Europe and the US) and developing, that run until at least 19 November 2018. In Africa, patents have been granted specifically in Benin, Burkina Faso, Cameroon, Central Africa, Chad, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Gambia, Ghana, Guinea, Guinea Bissau, Kenya, Lesotho, Malawi, Mali, Mauritania, Niger, Senegal, Sudan, Swaziland, Togo, Uganda, Zimbabwe. No patents have been found in India so far.

The scope of these patents covers not just Plumpy'nut per se but includes a wide range of food or nutritional supplement paste-based products (although there are defined limits in terms of classes of ingredient, water content and osmolality).

The fact that we have found these patents does not mean they are necessarily valid should they be challenged, for example, by a competitor company.

Plumpy'nut patents and competition

Apart from selling Plumpy'nut directly, the manufacturer Nutriset has offered two options for others to manufacture Plumpy'nut or Plumpy'nut-like products.

Under Nutriset's franchising system, franchisees benefit from Nutriset technical know-how and assistance, and can produce and sell "Plumpy'nut" just as Nutriset does. However, they also have to meet a number of terms and conditions such as "to respect and implement the know-how transferred by Nutriset, to buy the special preparation for the Plumpy'nut product® directly and only from Nutriset, or to respect the exclusivity territory fixed with Nutriset".

Nutriset has also offered another type of licence to bona fide NGOs wishing to manufacture the product for their own use but the total production is limited to 50 metric tonnes per year.

These agreements have significant advantages for producers that want know-how and support from Nutriset, but also include restrictions/limits to potential production scale-up. Many actors involved in the humanitarian nutrition field feel that producers should be able to produce

therapeutic RUF products under less stringent terms and conditions to foster more active competition.

Strategy to increase competition and production capacity

At a March 2007 meeting in Rome between the World Food Programme, UNICEF, MSF and a number of other actors in the humanitarian nutrition field, including producers, Nutriset proposed a new licensing option.

In this case, the licensed entity could produce a Plumpy'nut-like product, under a different brand-name, against the payment of a reasonable royalty to Nutriset for use of its patent. Nutriset would therefore not be responsible for the final product, but the terms and conditions of the license agreement would be sufficiently 'easy' to enable effective competition amongst Nutriset and other producers.

Although 'no patents' would be the ideal solution in the humanitarian nutrition field, the possibility exists here that patent holders could come to mutual agreements, to enable effective competition.

An agreement between Nutriset and Valid has been reached in December 2007 which allows Valid to produce and sell products under licence from Nutriset (See Valid Nutrition's June newsletter on their website: <http://www.validnutrition.org/index.php>) Valid Nutrition is an Irish Charity that produces and markets fortified nutritional pastes for the prevention and treatment of malnutrition. The production takes place in the countries where the products are needed, thereby stimulating local economies as well as providing life-saving products. However, no licence agreements have been reached with commercial producers. We urge Nutriset to offer and reach additional licence agreements.

We will monitor the developments regarding patents on therapeutic RUF products with a view to see whether the licence agreements will help to introduce additional producers, increase production capacity and bring prices down.

General principles for the management of nutrition patents

At the meeting in Rome, MSF Access Campaign also proposed 'general principles' to deal with IP issues in the humanitarian nutrition field. These encourage entities in this field not to file for patents but if and when they do, they seek to ensure, as an agreed 'norm', that any such patents will be made available to everyone else on 'easy' terms and conditions. These general principles are available at http://www.accessmed-msf.org/fileadmin/user_upload/medinnov_accesspatents/DraftRomePrinciplesIPand%20nut1.0.pdf

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