

## **[DRAFT] “Rome” General Principles**

Following constructive discussions at the Rome meeting (“Workshop on Ready To Use Food Production and Use”, Rome, Friday 2nd March 2007) the following [DRAFT] general principles are proposed. They should not be taken as reflecting the position or policy view of any given organisation present at the Rome meeting but are suggested by MSF/CAME simply as a means to stimulate further discussion about R&D and Intellectual Property issues in the humanitarian nutrition field. Comments are welcomed: Campaign for Access to Essential Medicines, Medecins Sans Frontieres, Rue de Lausanne 78, P.O. Box 116, CH-1211, Geneva 21, Switzerland

1. The need for humanitarian nutritional products is vast, specifically a high volume of quality products at the lowest possible cost.
2. This market is not “commercial” in an ordinary sense compared to, for example, the domestic nutrition market in Europe. The customers in this market tend to be international or national governmental or non-governmental agencies. The procurement activities of these agencies are directed at securing sufficient supplies from multiple competing sources to satisfy the volume, quality and cost conditions of (1) above.
3. There are comparatively few firms (whether for-profit or not-for-profit) traditionally serving this market and it is perhaps true to say, given the nature of humanitarian nutrition crises, that they are somewhat less prone to cut-throat competition than in some other market sectors.
4. Great benefit is derived from improvements in humanitarian nutritional products, so long as the improved products are readily able to be supplied to those in need (via agencies as appropriate).
5. The R&D necessary to bring about these improvements costs time and money. This R&D may be undertaken by the firms traditionally serving this market (although even in this case, international or national governmental or non-governmental agencies may play an important role in the eventual uptake of any new or improved humanitarian nutrition product given their role in carrying out large scale trials of such products). Firms must usually make a certain return on the capital they have invested in R&D activities (even if it is not necessarily as high a margin as in some other areas, given the humanitarian nature of the market as noted under (3) above) if they are to remain viably engaged in this market. Given the relatively small size of the firms traditionally serving this market, substantial R&D costs may be difficult to sustain. Once developed, improved or new humanitarian nutrition products may likely be fairly easily produced by other firms.
6. The humanitarian nutrition market is not characterised by a high degree of patent protection. There has traditionally been an open approach to important new humanitarian nutrition products, for example the F75 and F100 products. The Rome meeting strongly endorsed the continuation of this approach. Nevertheless, there is a possibility that firms or other entities may seek patent protection for a new or improved humanitarian nutrition invention.
7. Where such a patent has been granted, an attempt to exercise the patent monopoly right to prevent any other competitors from producing the new or improved product (involv-

ing legal and technical scrutiny of that patent to test for validity and infringement) will likely be inconsistent with (1) and (2) above. Public relations difficulties must also be expected in an attempt to enforce a monopoly position given the humanitarian nature of the market. Trade mark protection does not necessarily have such an impact. The fact that a new or improved product is sold under one brand name by one firm does not of itself prevent another firm selling the product under a different brand name.

8. One option to help resolve the tension that a patent covering new and improved products in the humanitarian nutrition area will cause is for the patent holder to engage in a voluntary patent licensing program. The “reasonableness” of the terms in such a patent licence must be considered in the context of the humanitarian nutrition field, as noted under (3) above, and it must be expected therefore that the licence would not contain any onerous restrictions. An example of such a patent licence arrangement was proposed at the Rome meeting, for further constructive discussion. Trade mark rights would be unaffected under such a patent licence and brand competition could still take place. Procurement activities under (2) above would thereby be enabled. Quality issues would of course have to be addressed as part of the procurement process. If there were a number of relevant patents owned by different parties it may be useful to consider placing them all into a “patent pool”, which could then be accessed by the patent owners and other third parties under one simple patent licence.

9. Another option would be for one or more international or national entities to offset the costs of a firm's R&D (e.g. 'buying out' the patent rights), where it was clear that that R&D activity had resulted in a new or improved product which ought to be able to be supplied by all the firms in the market.

10. Another option, which was strongly endorsed at the Rome meeting, would be to create a new international entity or collaboration to support or engage in open R&D in this area, sharing any resulting new or improved products with all. One example of this option would be a public R&D fund. A hybrid suggestion proposed at the Rome meeting draws on two of these preceding options to direct the royalty fee income from a patent licensing arrangement (under (9)) into such an R&D fund, although the fund could also be supported in a variety of other ways.

11. If the firms traditionally involved in the humanitarian nutrition market do agree some general principles of behaviour for the exercise of intellectual property and, more broadly, the carrying out of R&D it may be that, should others, including multinational companies, decide to enter this market, there could be substantial pressure on them to comply with these principles.