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ICDC LEGAL UPDATE

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From ICDC's desk in Penang...

This Legal Update focuses on patents on human milk components. Formula companies use such patents to claim ownership over processes and substances they copy from breastmilk. Patents are one of the sources for claims companies use to promote their products. Therefore, ICDC thought it was useful to look into some of the intricacies to better understand how patents impact on the Code. There are 2,000 patents and applications in the US Patent office alone.

But first, a short overview of the first half of 2013.

Africa

In February, ICDC joined IBFAN Africa to conduct a Code implementation course for UNICEF in Addis Ababa, Ethiopia. 35 participants from various government agencies including Food Medicine, Health Care Administration and Control Authority (FMHACA) were trained. ICDC is hopeful that FMHACA will take the lead in implementing the Code in the country as there is as yet no effective national measure and violations are rampant amidst fast economic development in the country.

ICDC's Legal Advisor, Yeong Joo Kean with participants and other trainers including David Clark of UNICEF and Joyce Chanetsa of IBFAN Africa.

In Bulawayo, Joo Kean introduces Zimbabwean environmental health officers to a forgotten law.

Ehtiopia was followed by Zimbabwe in March. The country has a strong law adopted in the 90s but political strife and economic meltdown have set back past achievements. ICDC welcomed the opportunity to support IBFAN Africa in their attempt to resuscitate the Zimbabwean law and is grateful to UNCEF for making the trip possible.

Asia-Pacific

In April, ICDC participated in a regional advocacy workshop to develop stronger policies and laws on infant and young child feeding in Hanoi, Vietnam. In a plenary session, Joo Kean made a presentation on the status of the Code in ASEAN countries and beyond drawing attention to how the Code is coming under attack in a region which is experiencing the highest growth in terms of baby food sales. The workshop, which was hosted by the Government of Vietnam, attracted participants from 14 countries.

ICDC's Director and Legal Advisor with government delegates from Brunei and Malaysia.

In May, Annelies attended the World Health Assembly as usual.

North America

At the invitation of INFACT Canada, ICDC was able to conduct a Code training in Toronto, Canada in June. The training attracted 30 health professionals from across Canada and the US. It received excellent feedback and opened opportunities for North-South cooperation and exchange of ideas and information.

A first for ICDC — Code training in an industrialised country. The line-up of facilitators minus Annelies.

Happy reading! Raja Razak, Publication Support

IN THIS ISSUE

Legal Update wishes to acknowledge the contribution of Valerie McClain for writing the main article and Alison Linnecar for her editorial assistance.

Patents & the Code: where do they clash?

Manufacturers of infant and baby milks, like Nestlé, use patented components of breastmilk to expand and protect their infant nutrition business.

- Can a corporation or an institution claim ownership and monopolize substances from human milk?
  Yes, they can! A recent US Supreme Court decision allows cDNA (complementary DNA) to be patented.
- How are these patents influencing the baby milk industry's advertising of infant formula?
  Managers consider patents and patent applications as effective marketing tools as they allow for all kinds of nutrition, health and functional claims.
- How does using patents as marketing tool impact the International Code of Marketing of Breastmilk Substitutes (BMS)?
  The Code and resolutions prohibit such claims.

There is a petition demanding that Nestlé stop patenting human milk components.
Consider signing on.
http://www.ipetitions.com/petition/nestle-stop-patenting-human-milk-components/

Brief history of US patents on human milk components

The first patent on human milk was filed in 1981 and involved isolating and culturing human mammary epithelial cells. In1985, a cell line derived from breast surgery and human milk was patented. The HMEC (Human Milk Epithelial Cell) cell line was immortal and could divide indefinitely; the patent #4808532 is owned by the US government and used by the biotech research community and industry. Subsequent patents had commercial interests and usually involved genetically engineered human milk components. Human lactoferrin showed early commercial promise as it has the unique ability to deprive bacteria of iron, thus stopping the growth of bacteria. This activity in human milk is believed to partly account for the reason that breastfed infants were healthier than formula fed infants.

Cow's milk has little or no lactoferrin, and efforts to extract this component have been difficult and expensive. Breastmilk and particularly colostrum has very high concentrations. Scientists believed that human lactoferrin could be used as an alternative to antibiotics. *"In addition to its antimicrobial properties, [human lactoferrin] has anti-inflammatory, detoxicant, antioxidant and anti-cancer activities"*, (Goldman et al., 2010).

The commercial promise of lactoferrin is wide-ranging: as an antibiotic, a nutrient additive in the infant formula and food industry, or a supplement used in body-building (in colostrum and whey supplements). Other human milk components have been studied, genetically engineered and patented, such as human milk oligosaccharides, prebiotics and probiotics.

Genetic engineering techniques

There are various ways to genetically engineer human lactoferrin: cell culture, animals or plants.

In 1987, a patent entitled, "Lactoferrin as a dietary ingredient promoting the growth of the gastrointestinal tract," was filed in Europe, Australia, and the USA. The Green movement in Europe called it the "Pharm Woman Patent" and described it as "as a patent on humans that would gain monopoly rights to the production of drugs in women's breasts." The protest campaigns led the European Patent Office to refuse the patent, but it was approved in the US and Australia. A US company, under the Baylor Licensing Group, manufactured recombinant human lactoferrin through cell culture in which the host cell may be Aspergillus awamori niger, a fungus. They have over 70 patents on human lactoferrin, and have had clinical trials on its use in wound healing and diabetic foot sores.

Early attempts using animals began around 1990, when researchers at GenPharm International (now part of Bristol Myers Squibb–Mead Johnson) inserted the gene from human lactoferrin (patent #5545806) into a cow embryo cell. Their research partner, Pharming of the Netherlands, used the work to create Herman the Bull, a transgenic animal who had the gene for human lactoferrin (patent #6140552). Herman was created through complex genetic engineering that inserted the human gene lactoferrin into an embryonal bovine cell. The transformed cell was transplanted into a cow. It was hoped that the calf that resulted from this genetic engineering would be female, but Herman was a bull and the only calf that survived. He sired about 55 calves who also carried the human gene lactoferrin and lived on a secluded Dutch farm behind tall steel fences.

The intention of this genetic engineering experiment with human lactoferrin was for use as an additive to infant formula. When this became public knowledge, outrage was great and much pressure was created to force the companies to abandon the project. It was suspected that the entire herd was moved to secret farms in New Zealand, Finland and possibly other places.


Huge posters protesting Herman were widely spread in Holland.

Genetically modifying plants to produce lactoferrin also took place. Ventria Bioscience, a US biotech, used rice to produce human lactoferrin. The spliced genes from human lactoferrin and lysozyme could be placed into other plants, such as barley, wheat, maize, oats, rye and sorghum or

millet (patent #6991824). Their experimental rice plants in California became the focus of Greenpeace protests. In 2006, Ventria was denounced in Peru for experiments on infants with a rice-based oral rehydration solution. The clinical trials with the genetically engineered product (not approved for consumption in Peru) created a public uproar and became subject to a criminal investigation.

Infant formula patents and marketing

Like the pharmaceutical industry, the nutrition industry values patents because they can be used to protect a marketing strategy and boost product sales. The table below shows three examples of how BMS manufacturers are using patents of breastmilk components to create powerful marketing messages targeting mothers and caregivers:

Product **Company**	***Good Start Protect Plus*** **Gerber/Nestle**	***Similac Advance*** **Abbott**	***Enfamil Newborn*** **Mead Johnson**
Added Component	Probiotics *Bifidus BL.*	Besides Docosahexaenoic acid (DHA)/Arachidonic acid (ARA) for brain and eye development, this formula has added Lutein to support eye health.	Prebiotics
Manufacturer's Patents	The patent "Infant formula with probiotics," (#8377430) that states, "For the benefit of infants that will not be completely breast fed, there is a continuing need to develop infant formulae which will replicate human milk as far as possible, both in terms of its nutritional and its bioactive properties;"	The Abbott patent "Infant formulas containing docosahexaenoic acid and lutein" (patent #7829126) states that "lutein concentrations in infant formula must be much higher than the lutein concentration found in breast milk in order to achieve the same plasma lutein concentrations found in breast fed infants..." An older patent "Methods and compositions for brightening the color of thermally processed nutritionals" (patent #6811801), declares that, "the addition of lutein compounds to thermally processed nutritionals brightens the nutritional resulting in a more appealing color"	"Method for stimulating the functional attributes of human milk oligosaccharides in formula-fed infants," (patent #8277863) states that there are disadvantages to prebiotics added to infant formula; "< they do not produce a SCFA (single chain fatty acid) profile that is similar to that of a breast-fed infant;" Prebiotics can cause excess gas, abdominal distension, bloating and diarrhea. The patent is an attempt to resolve this problem by using polydextrose (PDX) to slow the rate of fermentation caused by prebiotics, which would eliminate the problem of excess gas, diarrhea, etc.
Marketing Message	"Specially made with Nutrients Found in Breastmilk" "Advanced Immune Support" "Comfort proteins® ADVANTAGE" Easy to Digest Brain and Eye DHA & ARA Probiotic *Bifidus BL*™ is a Nestle trademark. Only Good Start formula begins with 100% whey proteins broken down to be easy to digest. Our special blend of antioxidant vitamins C, E, zinc, vitamin A and probiotic cultures, like those naturally found in breastmilk.	"Closer Than Ever to Breast Milk;" "designed with breastmilk in mind;" Similac® has EarlyShield In addition to having DHA/ARA, Similac has Lutein, an important nutrient babies can get from breastmilk and Similac. It's especially helpful now, during this critical time of your baby's brain and eye development.	Enfamil's label states, "Experts recommend breastfeeding," and "Experts recommend vitamin D;" Enfamil Newborn has, "an easy-to-digest protein blend patterned after breast milk;" *Natural Defense Dual Prebiotics Blend*™ is a Mead Johnson trademark.
Questions we should ask	A number of researchers have cultured *Lactobacilli* and *Bifidobacteria* from human milk. Yet, the Nestle patent makes claim to a variety of bacteria from a variety of sources. What bacteria are they using and how are these bacteria replicating the properties of human milk?	The FDA considers lutein a dye. But now Abbott is adding it into infant formula because it is found in breastmilk. Is the use of lutein in formula justified because it makes it look brighter? Is lutein, the manufactured product the same as the human milk component? No, certainly not.	How does polydextrose, a synthetic glucose product used in the food industry as a bulking agent make this a product "patterned after early breast milk?" It is not a substance found in human milk. And side effects of polydextrose in foods can be bloating, excess gas, and diarrhea. What is the real intent of adding this ingredient?

A patent enables its holder to achieve a unique position, e.g. to control resources, eliminate competition for the period of the patent or longer (20 years but can be extended), deny consumers true choice, and limit research.

Patents involving infant formula are usually based on human milk components—lactoferrin, oligosaccharides, prebiotics and probiotics—and enable the manufacturer to claim his product has unique qualities. Such claims are forbidden by subsequent WHA resolutions which clarify and extend the International Code.

Infant formula with genetically-engineered patented components is often promoted as "closer to breastmilk" (the ideal) or "the only formula with..."

Not only is this kind of advertising misleading to mothers, who may believe that the product is equivalent to breastmilk, but it also violates the Code's Article 9 on labelling—no pictures or text that idealise the use of formula, no terms like "humanized", or similar.

Most claims are banned by the Code and resolutions

The examples highlight significant issues:

- The infant formula nutrition claims are based on the inclusion of one or more ingredients that are similar to, or the same, as those found in human milk. Manufacturers cleverly link the patent-protected nutritional claims to infant health claims—that the formula protects infants from diseases, increases infants' intelligence, or improves infants' eyesight.
- In most cases manufacturers cite research to support their claims, but any researcher knows that with the limitations in study design, making a health claim requires results from many studies, not just one or two. (Only a few years ago, lycopene was hyped as the prevention and cure for prostate cancer, now it is recognized to have no measurable effect.) The research needs to be independent too, but Nestlé studies are by researchers linked to the Nestlé Nutrition Institute. Abbott and Mead Johnson also support research around the globe and are increasingly linked to milk banks, which is ominous.
- Claims idealize the product by implying it is similar to breastmilk, or even better than breastmilk. (Idealize is defined by the Oxford English Dictionary, *"to regard or represent as perfect or better than in reality"*) Words such as *"humanized, maternalized,"* or similar terms are banned by the Code and by the recently amended EU Directive. Pictures or text that can idealize formula products are also banned.
- Manufacturers brand their claims using logos or symbols. Gerber/Nestle has the Comfort proteins ADVANTAGE and the benefits logos.

Abbott has branded their health claims using the #1 Brand fed in Hospitals and the Early Shield logo while Mead Johnson uses the Triple Health-Guard Immune System and the #1 Brand recommended by Pediatricians.

These logos mislead parents into believing that the formulas contain ingredients that protect infants from disease or boost their development. And messages such as *"#1 Brand recommended by Pediatricians"* suggest approval from healthcare professionals and hence the best choice for their infant.

- Claims are prohibited under WHA resolution 63.23 [2010], which says: Member States are urged to *"end inappropriate promotion of food for infants and young children and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for, in relevant Codex Alimentarius standards or national legislation;"* So, unless there is a recognised and recorded health benefit, e.g. calcium helps build bones, claims are NOT allowed on food for children. ■

Human Milk Patents Pending

Human milk components and their gene constructs are being patented. Currently, there are some 2,000 patents and applications in the US Patent & Trademark Office. The patenting of human milk [with its need for secrecy and profit] will no doubt result in less protection and less promotion of breastfeeding.

Valerie W. McClain
http://vwmcclain.blogspot.com/

See also an earlier document by ICDC, called *Outrageous Claims*. http://www.ibfan.org/art/333-1.pdf

Law in El Salvador

The National Assembly of El Salvador finally (after 20 years) adopted a Law on Breastfeeding, on 26 June 2013.

In 2007, ICDC and UNICEF held a regional Code training in San Salvador urging the host country to move ahead on a law. The final text was based on the proposal put forward by CALMA (Centre for Breastfeeding Support, the IBFAN member in El Salvador).

Members of the National Assembly and the public applauding the historic vote in El Salvador.