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Update on Trojan Trade Reps, Golden Rice, and the Search for Higher Ground

"Golden" *Goosed*?

The Golden Rice AstraZeneca saga is a case study in public science's failure to understand and address patent issues. In justifying their surrender of Vitamin A enriched GM rice to the giant corporation, the researchers claim they couldn't navigate the 70+ intellectual and tangible property conflicts that could potentially scuttle their work. There are likely no more than 11 - and possibly as few as 4, patent conflicts and one outstanding tangible property issue. A public sector group - including the people Golden Rice is intended to help - should meet to debate all the options and alternatives. The contract and the events surrounding it should be investigated.

When shareholders confirm this week that the agricultural divisions of AstraZeneca and Novartis will indeed merge under the new name, "Syngenta," they will probably be talking more about their market prospects for GM crops in the North than about the needs of poor farmers and malnourished consumers in the South. More of the discussion will be about the opportunities created with the coming together of the two enterprises' Terminator and Traitor patents than about Vitamin A deficiency in Asia. But, according to RAFI's Research Director, Hope Shand, "Syngenta had better be giving some serious thought to its deal on Golden Rice - and quickly, or they could have a major embarrassment on their hands."

Laying a not-so-Golden Egg: "The deal struck by Potrykus and Beyer (the Swiss and German scientists who developed Golden Rice) with AstraZeneca was totally unnecessary," Shand insists. "It should be thoroughly investigated by the public institutions who funded the research." News that Golden Rice, a GM rice containing Vitamin A enrichment genes, was showing promise first surfaced in January. By April, however, the financial backers of the research - including the Rockefeller Foundation, the Swiss Federal Institute of Technology, and the European Union - were letting it be known that commercialization of the work in countries with Vitamin A deficiency (VAD) could run afoul of between 70 and 105 patents, licenses, and Material Transfer Agreements (MTAs – agreements governing technical property such as germplasm) controlled by more than 30 public and private institutes. Their alarm appears to have been kindled by a study the Rockefeller Foundation commissioned from ISAAA (International Service for the Acquisition of Agri-biotech Applications – a bio-broker with offices in the UK, USA, and the Caribbean). The patent search was conducted on behalf of the International Rice Research Institute (IRRI) in the Philippines, spurred by concerns that if it adopted Golden Rice it might be sued by other patent-holders. Despite their shock as to the number of potential intellectual property conflicts, the donors were stunned on May 16th when the two researchers independently signed a deal with AstraZeneca turning over the future development of Golden Rice to the Gene Giant. The agreement was negotiated through another biotech bargainer, Greenovations, which is a spin-off of the University of Frieburg where one of the inventors has his lab. In return for exclusive monopoly control of Golden Rice in the North and in sales to larger farmers in the South, AstraZeneca agreed to make the technology freely available to the South's poor farmers. At the time, Beyer and Potrykus told the media that the dizzying muddle of conflicting intellectual property claims necessitated the deal. Aside from clearing away intellectual property hurdles, AstraZeneca will also undertake additional research related to the environmental and health issues surrounding Golden Rice before releasing seeds to the market, they suggest, sometime around 2003. At the time of the deal, some of the donors were actively exploring public sector avenues for completing this work in Australia, Asia, and Europe. All of the donors were apparently aware that the inventors were considering commercial options but did not expect an agreement to be reached unilaterally or so quickly. Their public sector efforts came to an abrupt halt. Nine years and millions of dollars of public funding were surrendered to a multinational corporation.

The media continued to talk of the gaggles of patents and haggles of licensing from May through August. On August 3rd, Monsanto, which had jettisoned its own rice programme some months earlier, garnered cheap publicity by proclaiming that its warehouse of rice-related patents would be licensed *gratis* to the Golden Rice project. The next day, Potrykus told the *Washington Post*, "I consider the Monsanto offer important because I can now use this case to tell other companies, 'Look, Monsanto is giving me a free license. Won't you do the same?' It's an important first example." It now appears that only one Monsanto patent is a factor in most countries in the South that have high levels of Vitamin A deficiency.

Potrykus' comments beg the question*: **Why didn't the public researchers, backed by their donors, attempt to clear possible patent constraints before striking a deal with AstraZeneca?***

At the beginning of September, AstraZeneca let it be known that as few as four patents and two MTAs might have to be negotiated. RAFI now understands that only one MTA continues to be a problem.

Counting Eggs Before They Hatch: At the beginning of October, RAFI received a copy of ISAAA's IP audit on Golden Rice. The ISAAA study identifies 70 patents and 16 technical property constraints (MTAs and other licenses) that could have implications for Golden Rice commercialization. RAFI's review of the claims indicates that no more than 11 patents potentially complicate the completion of the project. RAFI's analysis focuses on the 60 countries that are designated by the World Health Organization (WHO) as having clinical or severe levels of Vitamin A deficiency.

- Although there are technically 70 patents, many of the same patents are replicated with different codes in the United States and the European Patent Office. In fact, there are only 44 patents applicable in any one country.
- Of the 44 patents, 26 are for process claims. These patents are not applicable if the product using the process is made in a country where the patent does not apply.
- Of the 60 countries that suffer the most serious levels of VAD, 35 countries recognize no patents related to Golden Rice.
- Of the 25 VAD countries where Golden Rice patents have been recognized, only a dozen patents are actually relevant.
- Of the 12 patents that are recognized in VAD countries, 7 patents are held by four Gene Giants (AstraZeneca –1; Aventis – 2; Monsanto – 1; and DuPont – 3 though the 3 DuPont claims are all identical). One patent – recognized only in Mexico (of the VAD countries) is held by Yissum Research & Development Co. – a biotech company spin-off of the Hebrew University of Jerusalem. The remaining 4 patents are held by four public sector institutions (University of Maryland; Centre National – France; National Research Council of Canada; University of California).
- But, only 12 countries have VAD *and* consume rice in sufficient quantity to make them potential targets for introducing Golden Rice. Of these 12 countries, 6 have no patent conflicts for the production of Golden Rice.
- At most, 11 patents can be considered a constraint to the project.

In sorting out the ownership conundrum, three points become clear. First, only a very small percentage of the patents are relevant for the poor countries suffering the most from Vitamin A deficiency. Second, only a few patents held by the private sector actually conflict with the further development of Golden Rice for the South. Of the four companies with patents, two – Monsanto and Astra Zeneca – have already agreed to royalty free licensing, leaving only two other major players, Aventis and Dupont to agree to the same. Third, the abuse of MTAs as a market weapon to frustrate scientific advances has been underestimated and is in urgent need of examination.

Trojan Trade Reps? "The researchers appear to have surrendered a decade of public funding to the commercial and PR interests of the biotech industry," notes Julie Delahanty of RAFI, "The threat of a plethora of industry patents that had no relevance to the development of Golden Rice turned the project into a "Trojan Trade Rep" for northern industry's campaign to impose their IP rules on the world." Even though poor countries have every legal right to utilize any technology not patented within their territories

- pressure from industry seems to have convinced public science - and its funders - that they had to negotiate access to all the patents in order to develop Golden Rice.

RAFI believes that a number of questions need to be answered in order for the public to have confidence in any ongoing research related to Golden Rice:

- What were the terms and conditions of the contract with AstraZeneca? Were there other related arrangements between any of the parties involved in Golden Rice research and funding?
- What was the substance of the initial report made by ISAAA on Golden Rice prior to the publication of its later document in September? How many conflicts did it identify and what was its advice? Why didn't ISAAA researchers give a more accurate and transparent IP audit – taking into account the rather limited number of IP constraints for most poor countries?
- What is the commercial potential for Golden Rice in the North and among larger farmers in the South? In other words, what market was surrendered to AstraZeneca?

Action Needed: RAFI, along with many other civil society organizations, is increasingly skeptical about the public health and environmental safety aspects of any GM crop. A great deal more research will be needed in these areas as well as a full examination of the socio-economic impact and other alternatives, before Golden Rice can be considered. RAFI believes that there are other more cost-effective strategies for addressing micronutrient deficiencies in the South that not only meet human needs but also promote - not restrict - biological diversity. RAFI also believes that the technological and public relations disaster surrounding GM seeds is continuing into biotech's second and third generations. As a Generation Three product, Golden Rice requires forensic scrutiny since it is aimed directly at poor consumers - in the centre of genetic diversity of the world's most important food crop.

RAFI recommends three initiatives:

1. The public sector funders who supported this research should form a consortium to conduct an immediate investigation of the events leading up to the contract with AstraZeneca.
2. The funders, in cooperation with the Consultative Group on International Agricultural Research (CGIAR) should discuss mechanisms that could allow the issue of public scientific research and intellectual property conflicts to be addressed to the Office of the High Commissioner for Human Rights in the United Nations and the International Court of Justice.
3. The consortium of donors should invite concerned organizations - especially organizational representatives of the poor farmers and consumers who are the focus of Golden Rice research - to meet and discuss not only Golden Rice but the wider issue of meeting the micro-nutrient needs of malnourished peoples. Hopefully, such a meeting would lead to a renewed and collective commitment to address this issue. Whether or not Golden Rice is seen as part of the problem or part of the solution would be for the meeting to decide. Astra Zeneca (now Syngenta) should immediately surrender its exclusive rights to the public sector, if this meeting asks it to do so. The company should also assure the public that its own intellectual property claims will not interfere with the research or its final commercialization - if the work should eventually be acceptable for marketing.

Searching for Higher Ground: RAFI will continue to follow this issue closely in the months ahead. "We don't want to suggest that patent conflicts are not a major problem. They are." Hope Shand concludes. "But the only clear intellectual property claim right now comes from ISAAA which has applied for a trademark on the name Golden Rice." "The clear conclusion," Julie Delahanty adds, "is that the public sector has not been facing up to the complex issues and moral dilemmas associated with intellectual property. It's time they got their head out of the sand and looked around before it's too late."

(For further background, see RAFI Genotypes *On Golden Pawns*, June 20, 2000, RAFI News Release "*Patent Evils Threaten Public Goods*," September 7, 2000, and RAFI Occasional Paper, *In Search of Higher Ground*, September 7, 2000, all available at http://www.rafi.org). RAFI will soon be publishing a *Communiqué* on the Golden Rice deal that will be posted on our website.

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RAFI (The Rural Advancement Foundation International) is an international civil society organization based in Canada. RAFI is dedicated to the conservation and sustainable use of biodiversity, and to the socially responsible development of technologies useful to rural societies. RAFI is concerned about the loss of agricultural biodiversity, and the impact of intellectual property on farmers and food security.