Golden Rice and Trojan Trade Reps: A Case Study in the Public Sector’s Mismanagement of Intellectual Property

**Issue:** Genetically modified, Vitamin A fortified rice (dubbed “Golden Rice” for its yellowish tinge contributed by beta-carotene) was developed by public sector researchers in an effort to address a significant nutrient deficiency afflicting the South’s poor. In May 2000, millions of dollars and 10 years worth of publicly funded research on Golden Rice was “donated” to multinational Gene Giant AstraZeneca (now Syngenta). The inventors handed over the technology when faced with the complexity and expense of negotiating licenses for an estimated 70-105 patents which they believed blocked commercial release of Golden Rice technology. In reality, the patents were not insurmountable obstacles for poor countries. RAFI’s analysis of patent claims identifies a maximum of 11 patents that could potentially complicate the release of Golden Rice in countries with the highest levels of Vitamin A deficiency.

**Impact:** The take-over of Golden Rice by AstraZeneca is a case study in public science’s failure to understand and address patent issues. Public sector institutions were misled and failed to explore alternatives. Golden Rice scientists and donors surrendered a decade of public funding to the commercial and PR interests of the biotech industry. The threat of scores of industry patents that had little actual relevance to the development of Golden Rice turned the project into a “Trojan Trade Rep” for industry patent hegemony around the world.

**Players:** The public sector inventors of Golden Rice, through patent broker Greenovation, gave UK-based AstraZeneca (Syngenta) exclusive commercial rights to Golden Rice in the North, and when used by large and medium-scale farmers in the South. In return, AstraZeneca pledges to make Golden Rice freely available to poor farmers, and to give regulatory, advisory, and research assistance in helping to make the controversial technology available to developing countries. Monsanto (now a wholly-owned subsidiary of Pharmacia) also pledges to give royalty-free licenses on its technologies to the developers of Golden Rice. The major donors for the genetically modified, Golden Rice technology include the Rockefeller Foundation (who funded the research from 1991-2002), the Swiss Federal Institute of Technology (1993–1996), the European Union under a European Community Biotech Programme (1996-2000) and the Swiss Federal Institute of Technology (1993-1996).

**Policies:** 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. If requested by the public sector group, AstraZeneca (Syngenta) should relinquish its rights to the exclusive license of this product and release it to this group. Even if all the intellectual property issues are resolved, there are serious obstacles to the deployment of genetically modified Golden Rice. The human health, environmental and socio-economic impacts and risks of GM rice have yet to be determined.
Background

Vitamin A deficiency is one of the world’s major nutritional problems. More than 100 million children, especially in Africa and Asia, do not get enough Vitamin A, and it is the leading cause of blindness in the South. An estimated two million children die each year indirectly as a result of persistent Vitamin A deficiency.

In January 2000 a report published in Science announced the successful engineering of beta-carotene-enhanced rice in the laboratory using a complex array of three genes. The report was hailed as a technologic tour de force. But whether or not Golden Rice is safe, effective or even an appropriate technology to address malnutrition in the South is the subject of enormous controversy worldwide. One controversy centres on whether or not the best (including safest and least expensive) solution to Vitamin A deficiency is through genetic modification of the world’s most vital food crop. The second controversy – the subject of this RAFI Communiqué – surrounds control and ownership of the technology and the confusing role of private patents related to public goods.

From the ‘get-go’, the prospect of genetically modified rice with enriched Vitamin A was a Red Flag to embittered GMO opponents and a Flag of Convenience for the embattled biotech industry.

Red Flag: Critics are concerned that the advent of Golden Rice’s ‘quick fix’ for Vitamin A deficiency could kneecap other low-tech and more cost-effective initiatives, among them, to re-introduce the many vitamin-rich food plants that were once cheap and available. Rather than nurture a strategy that encourages biodiversity, Golden Rice could promote monocultures and genetic uniformity.

Especially worrisome, given the huge per capita consumption of rice among the poor, is the risk that changes in the nutrient or toxicant content of rice could have serious consequences. Some worry that children could over-dose on vitamin A. This concern may be somewhat premature since, current formulations of Golden Rice provide only 10% of the daily Vitamin A requirements. Even assuming that the technology is eventually able to provide 100% of vitamin A requirements, it will do so only where people consume very large quantities of rice (between 110 and 180 kg per year). However, possible nutrient changes in the rice and the possibility that the Vitamin A content may increase are real concerns that have not yet been adequately addressed.

Then, of course, there are the GMO issues. Can the technology be proven safe for people? As a GMO to be released in the genetic heartland of the crop most important to the world’s poorest people, will it be safe in the environment? Finally, will Golden Rice be palatable and/or culturally acceptable to those for whom it is intended?

Those developing the rice speculate that vitamin A rice could be in farmers’ fields as early as 2003. Such a schedule for introduction would not leave sufficient time to undertake the socio-economic, human health and ecological impact studies necessary to ensure everyone’s wellbeing. Vitamin A rice targets vulnerable people within the centre of genetic diversity of the crop. For all of these reasons, RAFI concludes that the initiative demands intense forensic scrutiny.

Flag of Convenience: The inventors of Golden Rice are motivated primarily by humanitarian concerns; their goal is to deliver the technology free-of-charge to resource-poor farmers in the South. But the importance of the rice’s commercial success to the biotech industry cannot be underestimated. Golden Rice is the first serious product of biotech’s long-awaited ‘Generation Three’ portending actual - or at least perceived - benefits to consumers. The beleaguered Gene Giants - reeling from GM seed pollution debacles in Europe and the more recent GM-contaminated taco shell scandal in America - are trumpeting the rice as proof positive that genetic engineering can feed the hungry and meet human needs. Golden Rice is the “GMO success story” that the biotech industry desperately needs to counter the biotech backlash.

Golden Rice Research and Proprietary Science:

Over the past decade the scientists who developed Golden Rice, led by Ingo Potrykus of the Swiss Federal Institute of Technology in Zurich and Peter Beyer of the University of Freiburg (Germany), unavoidably utilized a host of proprietary technologies in their Vitamin A rice research. The researchers and their donors became increasingly concerned that release of Golden Rice could be restricted by a complex web of patents and tangible property constraints. Early estimates on the number of possible patent constraints ranged from 70-105. The time, expense and complexity of negotiating licenses, the researchers feared, could present insurmountable obstacles to both the commercial and humanitarian distribution of Golden Rice. Their alarm appears to have been kindled by a study commissioned by the Rockefeller Foundation, prepared by the

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International Service for the Acquisition of Agri-biotech Applications (ISAAA) - a non-profit group that specializes in tracking patents and negotiating "freedom to operate" technology transfer deals. ISAAA conducted a patent audit related to Golden Rice 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 intellectual property (IP) holders.

The potential legal complexities of negotiating dozens of patent licenses led Potrykus and Beyer to strike a deal with Greenovation (a university spin-off biotech company based in Freiburg, Germany) and AstraZeneca. The researchers, through Greenovation, approached a number of enterprises in the hopes of finding a private sector partner. In a surprise announcement on 16 May, AstraZeneca announced that it would collaborate with Golden Rice researchers to make Vitamin A rice available free-of-charge for humanitarian purposes in the developing world. The deal gives Zeneca exclusive commercial rights to Golden Rice in the North, and among medium and large-scale farmers in the South (farmers selling over $10,000 worth of Golden Rice). Zeneca licensed non-commercial rights to Golden Rice back to the inventors, and also agreed to provide regulatory, advisory and research expertise to assist in making Golden Rice available in resource-poor countries. (It should be noted, however, that Gene Giants have no experience in making GM seeds available to poor farmers – who are not generally their customers.)

Sanctimoniously promising to make the technology freely available to poor farmers in the South, AstraZeneca captured years of public investment and enormous public relations at minimum cost. Although no one can predict whether consumers will ultimately accept GM rice in the North, some observers believe that the market for nutritionally-enhanced rice is considerable. Hadyn St Parry, Zeneca’s general manager told the Financial Times, "Golden rice contains the anti-oxidant beta-carotene, and anti-oxidants have been shown to play a role in the fight against cancer and coronary disease…we see it doing particularly well in Japan as a functional food." If Golden Rice becomes commercially viable, it could help gain acceptability for other GM products with huge markets and potential profits.

On August 3, Monsanto basked in the glow of Golden Rice and positive PR by announcing that it would grant royalty-free licenses on all of the company’s technologies related to Vitamin A rice as a means of hastening its free delivery to the developing world.

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.”

Potrykus’ comments beg the question: Why didn’t the public researchers, backed by their donors and public sector institutions, attempt to clear possible patent constraints before striking a deal with AstraZeneca or any other multinational enterprise?

### ISAAA’s IP Audit and RAFI’s Rice Count

In September 2000 ISAAA released a briefing paper entitled, “The Intellectual and Technical Property Components of pro-Vitamin A Rice (GoldenRice™): A Preliminary Freedom-to-Operate Review.” ISAAA’s study identifies 70 patents and 16 tangible property constraints (Material Transfer Agreements-MTAs, licences, agreements, etc.) that could have implications for the commercialization of Golden Rice. By contrast, RAFI’s review of the patent claims identifies a maximum of 11 patents that could potentially complicate the completion of the Golden Rice project in countries with the highest levels of Vitamin A deficiency. Countries where the patents are non-applicable have every right under international law to use the technologies without reference to the patent-holders overseas.

### Monsanto and Golden Rice: Giving up IP or Gaining PR?

RAFI contacted Monsanto in August after the company made its pledge to give away royalty-free licenses on all of its technologies related to Golden Rice. RAFI asked Monsanto to provide a list of the most relevant patents owned by Monsanto related to Vitamin A rice technology. Monsanto’s Gary Barton responded: “There is no single ‘list’ of patent numbers to provide…we don’t know specifically which of our dozens (if not hundreds of technologies may find application by individual scientists)...” The ISAAA audit uncovered 5 Monsanto patents related to Golden Rice. RAFI’s analysis indicates that just one of Monsanto’s patents is recognized in poor countries suffering the highest levels of Vitamin A deficiency.

RAFI used ISAAA’s list of 70 possible patents related to Golden Rice as the basis for its analysis. It is beyond the scope of RAFI’s research to confirm or reject the validity of these patents (in terms of whether or not and how they relate to GoldenRice technology). However, based on ISAAA’s analysis, the intellectual property situation includes the following (see Table 3 and Figure 1):

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*ISAFI Communique, September/October, 2000*
Although there are technically 70 patents, many of the same patents are replicated with different numbers in the United States and the European Patent Offices. 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 Vitamin A deficiency (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 (see Table 1).

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).

There are 16 tangible property (MTA's, licenses, documents and agreements ) relevant to GoldenRice. Little is known about what the constraints really are – since most are confidential. The sources of tangible property include: IRRI (for Taipei 309 variety), Promega; Stratagene; Novartis (2); Monsanto (2); Washington State Univ. (2); Kirin (3); Rutgers University; Clontech; Bio-Rad Corp. (2).

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 (see Table 2).

At most, 11 patents can be considered a constraint to the project.

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Table 2 - Countries with Clinical or Severe VAD that also are high consumers of rice (110-180 kg per capita rice consumption per year)*

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For more information see table 3.
*Though according to the WHO, China has only moderate levels of VAD, we have included it here since as a high rice consuming country, it would be a likely target for introduction of Golden Rice.
Table 3 - Golden Rice-Related Patents Recognized by Countries with Highest Levels of Vitamin A Deficiency in the South

<table>
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<tr>
<th>Countries with Clinical or Severe Vitamin A Deficiency (WHO, 1997)</th>
<th>Countries with high rice consumption (110–180 kg per year) indicating likelihood that Golden Rice might be applicable.</th>
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* = OAPI countries (l’Organisation Africaine de la Propriété Intellectuelle/ African Intellectual Property Organization)
** = ARIPO Countries (African Regional Intellectual Property Office)
† Though according to the WHO, China has only moderate levels of VAD, we have included it here since as a high rice consuming country, it is likely that China would be considered an important target for Golden Rice technology. A number of other countries with high rice consumption might be expected also to have significant VAD, however, no VAD data are available according to WHO. These countries include: Gambia, Guinea, Guinea Bissau, Madagascar, and Sierra Leone.

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 AstraZeneca - have already agreed to royalty-free licensing, leaving only two other major players, Aventis and DuPont to agree to the same. Third, the potential 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 ISAAA report states clearly that its “Freedom to Operate” opinion “is not aimed at commenting on any institution’s current IP/TP (technical property) strategy, but on providing relevant information to make sound policy and strategy decisions.” ISAAA concludes that it will be up to developing countries that wish to benefit from Golden Rice to make choices on the best options to follow. In reviewing options for policymakers, ISAAA considers the possibility that developing countries might choose to ignore all intellectual property and tangible property constraints on Golden Rice. However, ISAAA essentially dismisses this option when it later explains:

“This option eliminates all need to ascertain who are the IP/TP rights owners/assignees but it flies in the face of current international treaties signed by the majority of developing countries and widely accepted national laws in virtually every country of the world.”

Though ISAAA acknowledges that there are few patent restrictions in some countries, the authors ultimately conclude: “All in all, widespread release of the current version of GoldenRice™ will require significant licensing activity if it is to legitimately become available to the world, either commercially or for humanitarian purposes.” (emphasis added)

In RAFI’s opinion, ISAAA paints a distorted and incomplete picture of the international IP situation. In reviewing policy options related to genetic resources and IP, the Crucible Group concluded earlier this year: “Despite concerted efforts to achieve harmony and consistency across national and regional borders, IP as it applies to life forms remains steeped in a climate of controversy and uncertainty.”

There is increasing awareness about the inequities surrounding control and ownership of biological products and processes, and growing consensus that intellectual property requires urgent societal review. In August, the United Nations Sub-Commission on the Promotion and Protection of Human Rights recognized that conflicts exist between the IP regimes embodied in the World Trade Organizations’ Trade-Related Aspects of Intellectual Property (TRIPs), on the one hand, and the human rights of poor people to have access to new technologies.

Intellectual property negotiations relating to life forms were a controversial topic during the last round of GATT negotiations (1986-1994). Some developing country members favored excluding all biological diversity-related inventions from IP laws. The compromise text that prevailed, Article 27.3(b), states that plants and animals as well as essentially biological processes may be excluded from patentability. Protection for plant varieties must be provided either by patents and/or by an effective **sui generis** system. It was agreed that the controversial text, Article 27.3(b) would be reviewed in 1999 – one year before developing countries were obliged to implement the provision. The deadline for implementation in the South has come and gone, and a substantive review of Article 27.3b has not been concluded. Numerous developing countries have made proposals for the review or re-negotiation of TRIPs as regards biodiversity and associated knowledge. According to GRAIN, as of March, 2000, 76 WTO members in the South were still lacking IP protection for plant varieties, and 47 developing countries could be targets for dispute proceedings on grounds of non-compliance with TRIPs Article 27.3(b). Clearly, there is confusion, uncertainty and indecision surrounding the implementation of WTO/TRIPs. To imply, as ISAAA does, that IP is widely accepted by virtually all countries is misleading and inaccurate.

**Conclusion**

In RAFI’s opinion, Golden Rice researchers prematurely surrendered publicly-funded research to the private sector without fully considering other options. In signing over rights to AstraZeneca, the public sector capitulated to
U.S. and European patent regimes, which, in most cases, are not valid in countries where poor people suffer the highest incidence of Vitamin A deficiency.

The precedent is dangerous and disturbing. Does this example signal a future where the international public sector will capitulate to the supremacy of patent law? Does it mean that if, and when, biotech has a role to play in meeting the health and nutrition needs of the South’s poor, the terms and conditions will be based on the sanctity of patent law instead of the needs of the South’s poor – or against the needs and wishes of the South’s poor? In the transfer of GM technology to the South, will the rights of poor people to new technologies be trampled by IP hegemony? Will the terms and conditions for technology transfer always be determined by the Gene Giants?

The big issues and questions still remain. Is Golden Rice necessary or safe? Will Generation Three biotech products make any real contribution to the poor, or will these products merely provide ‘safe cover’ and positive PR for the Gene Giants? How can public research be protected from predatory patents and patenters? Most important: is there an unspoken ‘understanding’ within the international public sector that U.S. patent law is ‘Pax Romana’ and must be respected and enforced around the world?

The AstraZeneca deal was a mistake. Rather than dodge or submit to intellectual property pressures, public science must confront its problems openly and directly. Will they do what neither the U.S. Government nor the WTO have succeeded in doing, and force a global patent regime on the poor - or will they honour existing international law and uphold the rights of poor countries? Will they accept the problems inherent in MTAs and pass the risks onto the poor, or will they address them? Will their solution always be to subsidize the corporations and acquiesce to IP by surrendering their publicly-funded research rather than to defend public goods?

Publicly funded Golden Rice research has already been “appropriated” by the private sector. By kowtowing to multinationals (for fear of infringing their exclusive monopoly patents), public sector researchers have surrendered public goods they didn’t need to surrender. Patents are causing chaos; and international public institutes are being railroaded into becoming “Trojan Trade Representatives” – upholding and defending U.S. and European patent regimes that are not legally recognized by the majority of countries where Vitamin A deficiency is a serious problem.

**Action Needed:**

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. AstraZeneca (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.

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**Additional Resources**


Other civil society organizations have prepared extensive critiques on various aspects of Golden Rice's promise and perils. The following sources compiled by GRAIN offer additional background and perspectives on Golden Rice:

*RAFI Communique, September/October, 2000*


Florianne Koechlin, “Golden Rice: The Big Illusion?” No Control on Life! Mail-Out No. 74, Blueridge Insitute, February 2000. (Also in German.) http://www.blauen-institut.ch/Pages/P_MailOut/pMailOut.html

Golden Rice was exclusively licensed to Zeneca Agrochemicals, a subsidiary of AstraZeneca. Zeneca recently merged with the seed and agrochemical division of Novartis, to form Syngenta. The new company becomes the world’s largest agrochemical corporation and a major developer of GM seeds. Syngenta is jointly owned by Novartis and AstraZeneca.

Zeneca contributed to research through the EU carotenoid research project, but did not provide cash funding for Golden Rice research.


According to ISAAA, tangible or technical property (TP) refers to property such as computer software, germplasm and the biological materials and derivatives thereof, and related information. TP related to Golden Rice includes Material Transfer Agreements (MTAs) and use licenses. MTAs are legal agreements, usually a letter, accompanying the transfer of a proprietary technology. Standard MTAs often limit the use of the proprietary technology to research, restrict transfer to third parties, require that new inventions are reported, and ownership is based on inventorship.

ISAAA has filed for a US Trademark for the words “Golden Rice” and “Golden Rice,” to “ensure that the name GoldenRice remains in the public domain for the benefit of resource-poor farmers.”

Personal email communication from Gary F. Barton of Monsanto to Hope Shand of RAFI, 16 August 2000.


Crucible II Group, Seeding Solutions. Volume 1. Policy Options for Genetic Resources: People, Plants and Patents Revisited, Co-published by the International Development Research Centre, the International Plant Genetic Resources Institute, and the Dag Hammarskjold Foundation, 2000, p. 105.

WTO TRIPs obligates developing countries to adopt minimum standards for intellectual property and a mechanism for their enforcement.

Developing countries were given until 2000 to pass laws in this direction, and least developed countries (LDCs) have until 2006.

GRAIN, “For a full review of TRIPs 27.3(b): An update on where developing countries stand with the push to patent life at WTO. March, 2000. http://www.grain.org