RESEARCH PAPER

New Biotechnology • Volume 27, Number 5 • November 2010

Review

The private sector's role in public sector genetically engineered crop projects

Ingo Potrykus[1,2]

[1] Plant Sciences, ETH Zürich, Switzerland
[2] Humanitarian Golden Rice Board, Switzerland

There is widespread interest within academia to work on public good genetically engineered (GE) projects to the benefit of the poor, especially to use GE-technology to contribute to food security. Not a single product from this work has reached the market. The major cause is GE-regulation, which prevents use of the technology for public good beyond proof-of-concept (Potrykus, I. (2010) *Lessons from the Humanitarian Golden Rice project: Regulation prevents development of public good GE-products* (these Proceedings)). There is, however, another key problem responsible for the lack of deployment of public good GE-plants: the public sector is incompetent and disinterested for work beyond proof-of-concept, and has neither capability nor funding to develop GE-plant products and introduce them to growers and consumers. The private sector has the expertise for both and in the right circumstances can be ready to support the public sector in public good enterprises. Public–private-partnerships are the best solution so far, to advance exploitation of GE-technology to the benefit of the poor. Public–private-partnerships are viable, however, only, if there is mutual interest from the private sector and initiative and funding from the public sector.

Contents

Background

The following observations are exclusively based on our experience with our public good project on 'Golden Rice' [1,2]. The conclusions are, however, probably applicable to all public sector GE-projects with an altruistic objective. As the private sector has an important role to play, it is appropriate to present at least one case study of a successful public–private-partnership, to illustrate the key role of the private sector for public good projects, of which neither the public nor the media are aware.

Golden Rice represents an almost unique case in as far as it is the only public good project from the public sector, which has been advanced beyond the proof-of-concept phase, across all hurdles from intellectual property (IP) rights, to product development and GE-regulation, and to a state close to deployment [2]. There is only one precedent of deployment of a public sector GE-product, which is the case of the virus-resistant Papaya [3]. This case is, however, not comparable, because it passed the regulatory hurdles before extreme precautionary regulation was established to block all public good GE-plant deployment.

The Golden Rice project was initiated in 1990 in response to the wish of rice breeders of the International Rice Research Institute

E-mail address: ingo@potrykus.ch.

1871-6784/$ - see front matter doi:10.1016/j.nbt.2010.07.006

(IRRI), Philippines, to produce vitamin A-rice (yellow rice), because of the severe problems of vitamin A-malnutrition in rice-dependent poor populations. Because there was no chance to reach this goal with traditional breeding techniques, it became a challenge for genetic engineering technology. Together with my colleague Dr (now Prof.) Peter Beyer, from the University of Freiburg, Germany, the author was motivated to take up this challenge and to use genetic engineering technology, in a public good project, to the benefit of the vitamin A-deficient and rice-dependent poor in developing countries. The author knows of many scientists around the globe which work in the arena of GE-plants with similar motivations.

The task of engineering the biochemical pathway for pro-vitamin A into rice endosperm was (correctly) considered almost impossible by the scientific community at the time. Thanks to longer term funding from public sources and philanthropic foundations, the complementary expertise of our two teams, and good fortune, proof-of-concept results were established in Spring 1999. They were presented to the public on the day of the author's retirement, 31st March 1999, and published, with some delay, in Summer 2000 [4].

Proof-of-concept and publication are normally the endpoints of the engagement of public sector scientists, although much of their work is financed with the argument that it will contribute to the solution of humanitarian problems. However, practical problems are not solved by proof-of-concept and publication. Solutions require subsequent product development, regulatory approval and product deployment for use, tasks generally not considered appropriate for an academic environment and readily left to 'someone else'. For public good GE-plant product development and deregulation there is, however, no one else to take over. The private sector must recover its investment from commercial products. International organisations with a mandate for food security or micro-nutrient malnutrition (e.g. WHO, FAO and UNIDO) stay away from GE-projects.

As we were determined to ensure an impact from our work, we had to develop it ourselves. When proof-of-concept was established, this was also the end of any financial support from the public sector. Financial support in academia is for scientific novelty. There was (and is) no mechanism in the public domain for support in either product development or deregulation, for the simple fact that no scientific novelty can be expected. Fortunately, visionary organisations (The Rockefeller Foundation and USAID) supported some initial work, but all this would not have rescued the transition into the product development phase and the extension into the deregulation phase, as not only were funds a problem, but expertise was absent. The public sector International Rice Research Institute (IRRI), Philippines, volunteered to take responsibility for variety development. But IRRI had no experience with GM-product development and was initially as naive as the inventors in this respect. In that situation 'Golden Rice' was very much in danger of remaining an academic exercise – unless something unusual would happen. The unusual approach we finally took was to search for support for the humanitarian project in the private sector.

How the private sector rescued the public good project

During the ten-year phase of proof-of-concept work, IP rights did not play a restrictive role. On the contrary, patenting enables inventors to publish their discoveries, which in turn enables the scientific community to use this information, which otherwise would remain secret. Appreciating this aspect of patents, we applied for patents on our invention of Golden Rice.

However, this free situation for basic research changes dramatically, when working towards practical application. As common for academic scientists, we had no idea which and how many patented inventions we had been using in the course of our work. A study commissioned by the Rockefeller Foundation revealed that more than 70 patents were involved in Golden Rice [4]. As our concept was to provide Golden Rice to subsistence farmers free of charge, this meant that we would need free licences for those 70 patents. Such a complex problem was beyond the capacity of public scientists and their institutions.

Peter Beyer and I realised that we needed professional help to address this problem. At the time we thought that this was the only problem standing between our invention and our vision of adoption of Golden Rice to contribute to Vitamin A Deficiency alleviation. We decided to approach the private sector for assistance, and entered into discussions with a relevant company, but were finding the attitude of the individual we were dealing with less than helpful.

Shortly after this realisation occurred, Zeneca's head of licensing, Dr Dubock[1] approached us with an interest in commercial rights to our invention. (Zeneca has since 2001 been merged as part of Syngenta, and is so referenced henceforward.) We explained our perceived problem with IP. Dr Dubock realised that we had no commercial interests and understood fully our interest in humanitarian applications. Dr Dubock proposed and negotiated with us a contractual basis for our collaboration. His vision complemented ours, was consistent with Syngenta's needs, and became the basis for a fruitful public–private-partnership which laid the foundations for the progress with our humanitarian project. *Without that public–private-partnership, Golden Rice would probably have remained a scientific curiosity*.

We licensed our rights in our invention to Syngenta which added further technologies and obligations (including donating technology improvements to us) and licensed them back to us for carefully and precisely defined humanitarian applications, including the defined right to sublicense further for the same defined humanitarian purpose. Syngenta retained the commercial exploitation rights.

One of the first tasks of Syngenta was to address the perceived problem of IP for the humanitarian project. The initially worrying analysis had considered only the situation in the USA; it turned out, almost irrelevant to our developing country targets. Thanks to the support from Syngenta's patent lawyers (which reduced the 70 general IPs to a handful of patents which may be important), the bargaining skills of our partner Dr Dubock and the good will of private sector patent holders, this problem was solved within less than half a year. We learned that there is good will in the private sector to grant free licences for public good projects, as long as this does not compete with commercial plans, does not lead to liability problems and the relationships are clearly defined in written form. *Without the cooperation of the private sector we would, probably not have been able to resolve the IP mass and the project would have ended at this stage*.

[1] Dr Adrian Dubock, has fortunately remained strongly associated with the project to this day, even after his retirement from Syngenta.

Dr Dubock proposed how we could develop a network of licensed public sector institutional collaborators (the Golden Rice Network) in countries where vitamin A deficiency (VAD) was a problem, and proposed and helped us set up a novel governance and strategy body, the Golden Rice Humanitarian Board (see http://www.goldenrice.org) providing multidisciplinary expertise, and taking all the strategic decisions which has guided Golden Rice close to its delivery to the target population. As a result of the mutual obligations and rights so created, and the collaborative structures put in place, Syngenta and the inventors had from then on access to all the missing knowhow and in-kind support for product development and deregulation for 'the humanitarian project'. *Without the advice and the experience of the private sector there would be no defined collaborative structure nor Humanitarian Board for the strategic guidance of the project*.

A scientific breakthrough is a necessary first step for a product. Application to the benefit of the poor, however, requires many more to follow. In the area of GE-plants, the public sector is totally unprepared, naïve and incompetent for any further step along those lines. In the philosophical world view of academia, there is no room for any support along those lines, neither with regard to financial support, nor with regard to recognition, motivation, publication or any other reward for scientists motivated to step out of the ivory tower.

The Golden Rice project was rescued because the private sector invested its know-how, its personnel and its laboratory facilities to advance the development of transgenic events along the lines of established regulatory requirements. It also invested hundreds of experiments into the search for events producing so much pro-vitamin A that half a cup full of Golden Rice a day would protect from malnutrition. All this was, of course, not done to advance the humanitarian project, but to promote a commercial project. However, according to the license terms offered by Syngenta and accepted by us, improvements made by Syngenta were to be licensed to the Humanitarian Golden Rice project. When the commercial project was abandoned as being too small, Syngenta donated all their materials and the rights to use their related data to the Humanitarian project. They were even persuaded by Dr Dubock to spend a further $1.0m+ after the commercial project was terminated to bring the research to 'donatable form' and to pay for the first field trials in the USA in 2004. Again, we learned that the private sector could be far more generous than expected if it did not have to concern itself with liability problems and there was no other conflict with its commercial strategies. *Without the contribution from the private sector it would have been difficult to arrive at a product with the present high level of expression*.

Once agronomically optimised Golden Rice varieties are registered for use and authorised for distribution to farmers, this is not yet the end of the story. Effective intervention requires careful preparation of nationally adjusted social marketing for which prior marketing research for a humanitarian project has to be organised. This again is a very complex field of activities requiring a different set of expertises, and into which the project is entering just now to have everything necessary ready, as soon as the varieties have been registered for use and seed material has been multiplied (best done again by the private sector) for distribution. Members from academia, who have not developed and registered a product, nor been involved with product launch for use, have not the slightest idea of how small the academic contribution is to the solution of a practical problem. *Without the advice and the experience of the private sector there would be no marketing research and social marketing and the putative success for Golden Rice would be totally unpredictable*.

These were only a few examples from the history of the Humanitarian Golden Rice project, which demonstrate how much a public sector project, despite the best intentions, might have failed, had not the private sector and visionary funders supported it throughout. Public good projects fall, beyond any doubt, within the responsibility of the public sector. In the case of Golden Rice the public sector completely failed to honour its responsibility. And it turned out that the public sector was totally incompetent for such a task anyway. Without support and expertise from the private sector this altruistic project would probably have failed. If the public sector sometime, hopefully, decides to honour its responsibility for public good GE-projects, the best it can do is to aim at public–private-partnerships, with a clear definition of the respective interests. There is lot of room for clearly defined, mutually respectful partnership, where commercial competition is not a problem – and where liability problems for the private sector can be avoided.

Fortunately there is progress with regard to the public sectors capacity for GMO product development and deregulation. To develop a GMO product, guide it through the regulatory hurdles, and deliver it as seed to the needy require expertise in numerous areas of which members of academia have not the slightest idea. The Golden Rice Network [1] involves numerous scientists in public sector rice institutions in developing countries such as The Philippines, India, Bangladesh, Vietnam, Indonesia and China which play an important role in breeding the Golden Rice trait into locally preferred rice varieties. The International Rice Research Institute (IRRI), Philippines [5], has taken a lead within the CGIAR system [6] and has, with recruitment from the private sector and funding from USAID and subsequently the Rockefeller Foundation, built the capacity to handle GE-variety development, interaction with regulatory authorities, as well as supporting the planning for social marketing, and IP management – again exploiting the capacity and experience of the private sector. We gratefully acknowledge that IRRI now has taken the lead, under the legally defined strategic guidance of the Golden Rice Humanitarian Board – in which key IRRI staff participate – to complete the task. IRRI could teach other CGIAR institutes how to manage GE events beyond the proof-of-concept phase. It should, however, not be overlooked that this is not typical public sector activity. It is dependent on philanthropy and one government – the US – which appreciates the potential of GE crops for development. There is no support from the donor countries of the CGIAR system (mostly European countries) for any GE-related activity – except for superfluous 'biosafety research' (see respective contributions in these proceedings). On the contrary, there is impressive and generous support from these donor countries for anti-GE activities (see A Apel, these proceedings).

Acknowledgement

The author is grateful to Dr A. Dubock for editing the language of this manuscript.

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