# Occasional Paper Series

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## RAFI Challenges W.R. Grace (Agracetus) "Species Patent" on Soybeans at European Patent Office


*Synopsis*: For eighteen years RAFI has opposed the application of intellectual property rights to living organisms. In the 1970s and 80s, RAFI campaigned worldwide against the introduction of Plant Breeders Rights legislation, warning that it would open the door to ever-wider monopoly control over the world's food supply. As predicted, increasingly monopolistic and far-reaching intellectual property protection is now being granted to private corporations over living organisms: microorganisms (including human viruses), plants, animals, even human genes and cell lines. Increasingly, these monopolies take the form of patents. *RAFI Communiques* and *Occasional Papers* have analysed the implications of these trends - for the public interest worldwide, for public sector research, and for the South in North/South relations.

In March 1994, The European Patent Office granted an extraordinarily broad patent to Agracetus Corporation, a subsidiary of W.R. Grace, one of the largest food corporations in the world. The patent is the first of its kind on a food crop. It covers all transgenic soybean varieties and seeds (regardless of the genes used) and all methods of transformation. ("Transgenic" means it has been genetically engineered with a gene from another species.)

In April 1994 RAFI announced it would challenge this patent in Europe. In October, RAFI retained the Canadian Environmental Law Association to oppose granting of this patent in Canada. On December 1, 1994, with the support of 18 organizations worldwide, RAFI lodged Notice of Opposition with the European Patent Office (EPO) in Munich, calling on the EPO to revoke the Agracetus soybean patent on moral and technical grounds. This *RAFI Occasional Paper* includes the news releases which RAFI has issued about this patent challenge, and reproduces the complete text of RAFI's *Notice of Opposition to the European Parliament*.



**The Rural Advancement Foundation International (RAFI) is an international non-governmental organization which conducts research on agricultural biodiversity, biotechnology, and intellectual property. RAFI Occasional Papers are published irregularly, to disseminate RAFI research and work-in-progress, and they are available from all RAFI offices. We encourage readers to copy and distribute our material, and request only that RAFI be credited when RAFI publications are used. COST Per Issue: U.S.$10, Canadian $12, Australian $12**

**RAFI** (Rural Advancement Foundation International)

## FOOD PATENT CHALLENGED

### Second "Species" Patent Granted On Major Crop
### This Time In Europe - For Transgenic Soybeans
### Industry, Governments "Out Of Control" In Race To Monopolize Life Forms Warns
### Rural Advancement Foundation International

For Immediate Release: Wednesday, 30 March 1994

A legal challenge is being mounted against a "species" patent on the world's soybean crop. The Rural Advancement Foundation International (RAFI) today announced that it is contesting a patent issued on March 2, 1994 in the European Community to W.R. Grace (the world's largest specialty chemical company) that is tantamount to an exclusive monopoly on the world's $27 billion soybean crop. RAFI will appeal under Article 99, Section 1 of the European Patent Convention, requesting that patent examiners reconsider and reject the species patent. According to RAFI, the species patent should be revoked because it sets a precedent permitting monopoly patents over food crops. Pat Roy Mooney, RAFI's Executive Director, states in a letter to the European Patent Office, "*This is a clear threat to world food security*." RAFI also believes that W.R. Grace has not contributed a fundamental invention warranting the sweeping scope of the patent claim.

This is the second patent on a crop species ever granted. The first, approved by the U.S. Patent and Trademark Office in October, 1992 was for all transgenic cotton. The patent-holder was also W.R. Grace's biotech subsidiary, Agracetus. In announcing the patent challenge, Pat Mooney said, "*If this patent on the soybean species is allowed to stand, it will guillotine all high-tech research on one of the world's most important crops. It will also give Grace the green light to pursue similar species patents on rice, maize, groundnuts, and beans - all crops in which the company is doing gene transfer work.*"

RAFI has contacted a number of national and international organizations to enlist their support in a campaign against the Grace patent. Among those most concerned is Dr. Geoffrey Hawtin, Director-General of the International Plant Genetic Resources Institute in Rome, Italy. "*The granting of patents covering all genetically engineered varieties of a species, irrespective of the genes concerned or how they were transferred, puts in the hands of a single inventor the possibility to control what we grow on our farms and in our gardens. At a stroke of a pen the research of countless farmers and scientists has potentially been negated in a single, legal act of economic high jack.*" Dr. Hawtin's institute is the lead agency addressing intellectual property issues for the Consultative Group on International Agricultural Research (CGIAR) - the world's largest consortium of institutes of international crop research.

Over the weekend, the Board of the Jessie Smith Noyes Foundation in New York City made a grant of U.S.$50,000 to help RAFI fight the patent. "*Board members were shocked that a patent could be applied to an entire crop species*", Foundation President, Stephen Viederman said, "*This is an outrageous example of bio-piracy.*"

Hope Shand, RAFI's Research Director, notes that "*We campaigned against the cotton patent and, in mid-February, the Government of India rescinded Grace's claim.*" RAFI is now working with groups in other major cotton exporting countries to challenge the species claim in their jurisdictions. "*Now that a food crop is involved, people are really scared and angry,*" Shand says.

Agracetus is also applying for patents on transgenic rice, groundnuts (peanuts), maize (corn), and beans. W.R. Grace also has a patent pending on genetic transformation of livestock (based on work

conducted at the company's wholly-owned subsidiary, American Breeders Service). RAFI is releasing a **RAFI Communique** today to advise farmers' organizations and governments of the new and potential species patents and their implications for farmers and food security.

"*Grace is employing a patented gene bombardment technology that allows the company to transfer genes from one species into another. Every time they bombard a different crop species they claim they have the sole right to use any form of biotechnology on any germplasm of that species. It's a bit like allowing the inventor of the microscope to patent everything he could see that had not been seen before*," says Mooney. " *It's really quite ridiculous - but the kind of thing we have come to expect when industry tries to patent living plants and animals. The patent system in Europe and the United States is out of control*."

The Rural Advancement Foundation International (RAFI) is a not-for-profit international nongovernmental policy research organization headquartered in Ottawa, Canada. RAFI-USA is based in Pittsboro, North Carolina. RAFI works with partner organizations in Africa, Asia, Latin America, Europe, and Australia. RAFI's financial support comes from the international development agencies of a number of governments as well as private foundations and churches. RAFI has been working in the field of agricultural genetic resources and biotechnology for 16 years.

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Ref: ocpapsoy.wp

**NGOs Challenge W.R. Grace's "Species" Patent on Soybeans at European Patent Office**
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**Rural Advancement Foundation International Says Patent on Food Crop is Technically Flawed and Morally Unacceptable**
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**Embargoed Until December 1, 1994**

The Rural Advancement Foundation International (RAFI) today filed opposition at the European Patent Office to W.R. Grace's controversial soybean "species" patent. The patent, #301,749 B1, issued on March 4, 1994, covers all forms of genetically engineered soybean plants and seeds - irrespective of the genes used or the transformation technique employed. (The patent was awarded to Agracetus Inc., a biotechnology company that is a wholly-owned subsidiary of W.R. Grace Co. of Boca Raton, Florida, USA).

"*A patent granting a single corporation monopoly control over genetic research on one of the world's most important food crops - soybeans - is a threat to world food security, and demonstrates that the patent system is recklessly out-of-control. The soybean patent is technically flawed and morally unacceptable - and it must be revoked*," said Patrick Mooney, RAFI's Executive Director.

RAFI's protest is supported by a wide range of non-governmental organizations (NGOs) worldwide, including international development NGOs, indigenous peoples' organizations, farm, and environmental organizations, from North and South. Groups supporting the opposition are listed on page six.

RAFI is asking the European Patent Office to revoke the W.R. Grace patent because it fails to meet standard criteria for patentability; it is neither novel, nor non-obvious. The notice of opposition filed by RAFI today states that W.R. Grace's broad patent claim is not substantiated by the information disclosed in the patent application, and that the use of their technology was obvious given previously reported breakthroughs by the company and other scientists.

RAFI also cites ethical and moral reasons for revocation of the patent, claiming that it is a threat to world food security. The patent gives W.R. Grace exclusive monopoly control of all genetically-engineered soybean varieties. Soybeans are one of the world's most important food crops, valued at U.S.$27,000 million annually. The patent allows the company to exclude others from using their technology, and to set conditions for access. Monopolization of this technology will undoubtedly affect the cost of high-tech research on soybeans, as well as the price of transgenic soybean seed, says RAFI. Under patent law, it is illegal for farmers to save transgenic soybean seed harvested on their land for re-planting.

The international non-governmental organizations (NGOs) protesting W.R. Grace's species patent believe that it has far-reaching affects beyond the European Community. Grace has also applied for a broad soybean patent in Canada and the United States, and has also received a sweeping patent for all genetically engineered soybeans in Australia.

In response to international controversy over their species-wide patents on soybeans and cotton, W.R. Grace has stated that it will allow free licensing of its patent to all government and academic researchers upon request. RAFI calls this offer "nothing more than a clever public relations gimmick for the purpose of deflecting criticism of their patent and clearing the way for additional broad patents to be issued in the future." RAFI points out that the offer of free licenses could change with time, and is not required or enforceable by law.

In addition to the European challenge, W.R. Grace's broad crop patents are under fire in the USA, Canada, India, and Australia. The company's patent on transgenic cotton is currently being challenged by the U.S. Department of Agriculture and another anonymous party in the United States. The government of India announced earlier this year that it intends to revoke the W.R. Grace cotton patent. The Canadian Environmental Law Association has filed an initial letter of protest on behalf of

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the Rural Advancement Foundation International challenging Grace's soybean application in Canada.

"*If the soybean patent is allowed to stand, the door will be wide open to yet broader patent claims on additional food and industrial crops, and in jurisdictions far more malleable than Europe*," said RAFI's Mooney.

RAFI is an international, non-governmental organization which conducts research on agricultural biodiversity, biotechnology, and intellectual property, headquartered in Ottawa, Canada.

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For additional comments/background on W.R. Grace's "species" patent:


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Ref: ocpapsoy.wp

**RAFI** (Rural Advancement Foundation International)

## NOTICE OF OPPOSITION
## AGAINST EUROPEAN PATENT NO 301,749

1. European Patent 301,749 B1 entitled "Particle-mediated transformation of soybean plants and lines" ('The Patent') was granted to Agracetus Inc. ('the Patentee') on 2 March 1994.

2. Opposition to the grant of this patent is hereby filed by Rural Advancement Foundation International (Canada) ('the Opponent'), a body organised under the Canada Corporations Act and situated at 71 Bank Street, Suite 504, Ottawa, Ontario, K1P 5N2 Canada. The following organisations associate themselves with and support this opposition:

**Action for Solidarity, Equality, Environment and Development (Australia)**
**Assesoria e Servicos a Projetos em Agricultura (AS-PTA) (Brazil)**
**Australian Genethics Network (Australia)**
**Canadian Environmental Law Association (Canada)**
**The Ecologist Magazine (UK)**
**Genetic Resources Action International (Spain)**
**Friends of the Earth (Australia)**
**Friends of the Earth (Brazil)**
**Indigenous Peoples Biodiversity Network (Canada)**
**The Maori Congress (New Zealand)**
**The Mataatua Declaration Association (New Zealand)**
**The Ngati Awa Tribal Ethics Committee (New Zealand)**
**Pesticide Action Network - Asia and the Pacific (Malaysia)**
**Seeds of Survival - Africa (Ethiopia)**
**Southeast Asia Regional Institute for Community Education (Philippines)**
**Third World Network (Malaysia)**
**World Council of Indigenous Peoples (Canada)**

3. The claims of the patent are 1-25. Claims 1-16 are to methods of making 'genetically transformed' soybean plants using a particle accelerator (gun). Claims 17-20 are to 'genetically transformed' soybean seeds, however produced. Claim 21 is to seed claimed in claim 17 obtainable by a method claimed in any of claims 1-16. Claim 24 is to a method of making 'a genetically transformed line of plants' (any plants, not just soybean plants) by the processes defined in claims 1-17, followed by growing the transformed plant to produce seed, self-pollinating the seed, growing it and assaying its progeny. Claim 25 is to applying this process to soybeans.

4. **The exploitation of the alleged invention claimed in claims 17-21 and 24 would be contrary to 'ordre public' or morality, or both**, and hence is not patentable within the terms of Article 53(a) EPC.

5. **The alleged invention claimed in each of claims 1-25 is not new** - and hence not patentable within the terms of Article 52(1) EPC - having regard to each of the following documents:

"Program and Absracts (sic) for an International Symposium 'Biotechnology in Plant Science: Relevance to Agriculture in the Eighties'" Ithaca, New York, published in 1985, at page 25, poster #28, lines 1-16;

"Science Notebook", page A12, *Washington Post*, 18 May 1987( col 1, lines 1-40);

"Shotgun's Blast May Create New Forms of Life", *New York Times*, 26 May 1987 (the whole article);

*Nature*, vol. 327, no 6117, 7-13 May 1987, Klein et al., pages 70-73 (the whole article) (cited in prosecution and referred to in the Patent at page 4 lines 27-30).

and is further not new having regard to the oral disclosure which took place at the Symposium to which the first document refers.

6. **The alleged invention claimed in each of claims 1-25 involves no inventive step** - and hence is not patentable within the terms of Article 52(1) EPC - in view of each of the documents listed in 5. above, taken singly or together.

7. **The alleged invention claimed in each of claims 1-25** having regard to the art cited in paragraph 5 above **is no more than a discovery** - and hence not patentable within the terms of Article 52(2)(a) EPC.

8. **The patent does not disclose the invention claimed in each of claims 1-13 and 17-25 in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art** - and hence is not patentable within the terms of Article 83 EPC.

9. **The subject-matter of the patent, as claimed in claims 17-21 and 24, extends beyond the content of the specification as filed**, which, as a matter of substance, is confined to the transformation of soya by the use of a gene gun.

10. **None of claims 17-21 and 24 are supported by the description**. It is not open to the Opponents to raise this point as a ground of opposition, but the failure of the Examiner properly to consider this matter in prosecution is so gross that the Opposition Board are obliged, or at least entitled, to consider and remedy the matter once it has been drawn to their attention.

11. The Opponents ask for revocation of the Patent

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Further discussion and explanation of the matters set forth in paragraphs 4-11 above is given below.

## 12. EXPLOITATION OF THE ALLEGED INVENTION IS CONTRARY TO 'ORDRE PUBLIC' AND MORALITY

The Opponent submits that exploitation of the invention the subject of the Patent is morally and ethically unacceptable because:

1) Such exploitation is a deterrent to innovation;
2) Such exploitation is a threat to world food security;
3) Such exploitation is fundamentally inequitable because it ignores the contributions of informal innovators and fails to compensate them;
4) Such exploitation jeopardises access to and exchange of genetic materials on a planetary scale.

The opponent opposes the patenting of life forms in general. In recent years corporations have used a patent system designed for machines and industrial inventions to gain exclusive monopoly over the very nature of life. It is important to point out that the patenting of life poses far-reaching ethical concerns for some people, as well as for whole countries and cultures.

### 12.1 Such Exploitation is a Deterrent to Innovation

The essential reason for the existence of a patent is to promote innovative research by conferring on the owner of an industrially applicable invention the right to exclude third parties from commercially using it for a period of time.

The normal method of exploiting an invention is to prohibit or restrict others from using it.

A patent granting exclusive monopoly control over all transgenic soybeans, irrespective of the genes conferred or how they were transferred, will act as a deterrent to future innovation in genetic engineering of soybeans. The patent issued by the EPO is so broad that instead of fostering innovation, it will retard innovation, especially by public researchers and by farmers, who run the risk

of litigation for non-commercial investigations or use of patented subject matter. Farmers could infringe the patent by saving soybean seed from their harvest for re-planting on their own land, for example.

The cost of licensing the Patentee's technology (so far not disclosed by Agracetus) could prove too costly for many researchers, thus limiting the opportunity to conduct high-technology soybean research and innovation to private corporations who can afford to purchase licenses.

The research exemption, guaranteed under patent law, is supposed to protect the right of scientific workers to use patented inventions without charge or prejudice for non-commercial investigations. Nevertheless, some researchers believe that the exemption has been weakened over time, and they fear litigation due to alleged infringement of patent law. Some researchers worry that patent courts could order an end to their investigations. The ambiguity that surrounds the research exemption will likely discourage research and innovation on transgenic soybeans because of the exceptionally broad patent granted to Agracetus covering all transgenic soybean varieties and seeds, and all methods of transformation. Agracetus has stated that it will allow free licensing of its transgenic soybean patent to all government or academic researchers upon request. But this offer is one that could be withdrawn at any time, and is not required or enforceable by law. The public simply cannot depend on the "benevolence" of a private corporation to insure that transgenic research and innovation is not restricted on soybean, one of the world's most important food crops. Agracetus's gesture of offering free licenses may be nothing more than a clever public relations gimmick for the purpose of deflecting criticism of their patent and to open the door so that additional broad patents will be issued in the future. Ultimately, there is no guarantee that licenses will be made freely available for this or any other patent. Exploitation of an invention of this breadth, either by refusing to allow others to make any use of it at all, or by granting licences only under conditions which might be highly restrictive (either of which would be a perfectly normal way of exploiting a patent) would, we submit, be clearly immoral, and would be universally recognised as such. The Patentee's offer of free licences is a tacit admission that to exploit this monopoly in a normal way would be abusive.

## 12.2 **Such Exploitation Threatens World Food Security**

Exclusive monopoly control over all transgenic forms of one of the world's most important food crops is contrary to the public interest, and a threat to world food security. Although soybean is a relatively minor crop in Europe (grown on approximately 1.1 million acres in Europe), it is one of the world's most important food crops--valued at approximately (US) $27,000 million per annum.

The danger arises that Agracetus may control the future development of soybean crops in a manner not in the public interest. The patent gives Agracetus the legal right to exploit the invention by excluding others from using it, and by setting conditions for access to it. Monopolisation of this technology would undoubtedly affect the price of transgenic soybean research and the price of commercial transgenic soybean seed, and could thus limit the distribution or availability of agronomically important improvements in the marketplace.

The patent on all transgenic soybeans issued by the EPO is limited to those nations who are signatories to the EPC, but the potential economic impacts of this patent reach far beyond Europe. For example, many nations maintain protection against the import of products that would infringe a patent. In the case of transgenic soybeans, signatory states to the EPC would be legally permitted to block imports of transgenic soybeans, or even products derived from transgenic soybeans (such as oil or animal feeds containing transgenic soya) if they originated in countries that fail to recognise the Patent. This type of restriction, strengthened by the recently enacted world trade agreement (GATT), could legally prohibit soybean-exporting nations from access to European markets.

## 12.3 **Such Exploitation Will Jeopardise Exchange of Germplasm and Information and Ongoing Negotiations for Equitable Conservation and Use of Genetic Resources**

The patenting of an entire agricultural species will likely hinder the free and full exchange of germplasm, and therefore threatens the future enhancement and productivity of agriculture, not only in Europe, but world-wide. The Patent jeopardises access and exchange of genetic materials on a planetary scale because it gives a single corporation exclusive monopoly control over all transgenic soybeans - regardless of the germplasm used or the transformation technique employed.

It is possible that some areas of the developing world will respond to the "species patent" and the growth of intellectual property on biological products and processes in the industrialised world by restricting access to genetic resources found in the developing world. The ultimate danger is that the exchange of genetic material and information which is so vital for global food security will be severely constricted, undermining efforts to conserve biological diversity and guarantee access to it. Access to exotic germplasm is vital for the ongoing maintenance and improvement of agriculture.

At the very time this Notice of Opposition is filed at the EPO, contracting parties to the Convention on Biological Diversity will be meeting in the Bahamas to discuss equitable and sustainable means of conserving and using biological diversity. A species-wide patent on one of the world's most important food crops flies in the face of these negotiations. Genetic engineers at Agracetus have built on the accumulated success and knowledge of many generations of farmers and indigenous peoples. A species-wide claim on all transgenic soybeans fails to recognise or reward the contributions of "informal innovators" - generations of farmers, rural people and other plant breeders who are responsible for conserving, nurturing and using soybean germplasm. The Patent is a blatant example of the fundamental inequities of the patent system, and monopoly exploitation of an invention so broadly claimed is morally unacceptable.

## 12.4 **Conclusion**

The patent should be revoked because it sets a dangerous precedent. Its exploitation will permit exclusive monopoly control of all transgenic varieties of one of the world's most important agricultural species - soybeans. The Patent has far-reaching implications for farmers and rural societies in Europe and beyond. If the transgenic soybean patent is allowed to stand at the EPO, the door will be wide open to yet broader patent claims on additional food and industrial crops at the EPO, and in jurisdictions far more malleable than Europe.

## 13. **NOVELTY AND OBVIOUSNESS**

Claim 1 specifies making a genetically transformed soybean plant by a process comprising the following steps:

A: preparing a foreign gene with a coding region and regulatory sequences effective to express the coding region in soybean cells;

B: joining copies of the foreign gene to biologically inert carrier particles;

C: placing a regenerable soybean tissue on a target surface;

D: accelerating the particles at the target surface so that some of them lodge in cell tissue;

E: regenerating treated tissue into a whole plant;

F: verifying the existence of the foreign gene in the regenerated plant.

These features divide into those which are inherent in the use of the gene gun (B,C,D) and those which are inherent in any method of transforming plants (A,E,F). Each of the citations clearly shows the use of the gene gun, in which foreign genes are associated with metal particles (B) which are then fired at plant tissue (D) placed on target surfaces (C). Any plant transformation process, to work, must involve the use of a foreign gene with regulatory sequences effective to cause expression in the target plant (A); regenerate treated tissue to form a plant (E) (for which purpose it is logically rather than technically necessary to use regenerable tissue) and verify that the process has successfully produced a transformed plant containing the foreign gene (F).

There are only two points that the Patentee can hope to rely on in establishing that the claimed process is novel. Firstly he may say that the cited art does not mention using the process with soya. The Opponents say that the art (in particular the *New York Times* article, col 1, para 3) suggests using the process with crops generally: and hence with soya, which is one of the most important crops in the world. Secondly the Patentee may say that the cited art does not disclose that the process works: and hence their claim (which claims a process which works) is novel. The Opponent says that this is not a proper way to add novelty to a claim. Novelty must be given by specific technical features not found in the prior art - not simply by reciting success. It is clear that the workers in the prior art invented the same process for the same purpose, and expected it to work. ("Our microprojectiles have the important advantage that they can potentially penetrate almost any kind of cell, and they can transfer nucleic acid to many target cells extremely rapidly and efficiently "Dr Klein said. We plan tests of a lot of potential applications, and we have really high hopes for this procedure." *New York Times*, col. 4, 2nd paragraph). It has in fact worked very successfully on a wide range of crops. What merit has the Patentee, who is now claiming the right to exclude everyone (including the actual inventors of the process) not merely from using it with soya, but with all plants (claim 24)?

The art cited, it is submitted (with the possible exception of the Cornell abstract) would have been common general knowledge to those skilled in the art at the Patentees priority date. That the gene gun had been described in such widely circulated publications as the *Washington Post* and the *New York Times* indicates how much attention this development had attracted. *Nature* is a magazine of great authority and wide circulation, and would certainly have been read promptly by anyone with pretensions to skill in the art of plant transformation. Accordingly it is proper (should any need to be found to do so) to combine any of the cited art to render the alleged invention obvious.

The subclaims 2-16 all recite features which are known, conventional, inevitable or trivial. For example, claim 2 recites metal particles - anticipated by the tungsten particles mentioned in the prior art. Claim 3 suggests the particle are gold spheres, a trivial variant on tungsten. Claim 6 proposes the use of meristematic tissue, proposed in the Cornell reference. Claims 10-13 are absolutely routine in plant transformation. Claims 14 to 16 are to the use of specific plasmids. These claims are obvious. The person skilled in the art would expect the technology to work with these as with other genes. However, at least the scope of these claims is sufficiently narrow that (even if obvious) they present no significant obstacle to the use of the technology described.

Claims 17-19 and 21-23 claim the inevitable result of carrying out on soya the process disclosed in each of the cited documents. In saying this, it is assumed that the person repeating the process would have the objective of making stable genetically transformed plants (as the Patentee does) and would not be deterred by a few failures (as the Patentee will expect from anyone trying to repeat the process he describes). Claims 17-20 are to features conventional in plant transformation. The scope of claim 21 is indeterminate, but may not be different from that of claim 17 (it is a question of fact whether a product had been made by a particular process, but what tests are to be applied to determine whether such a product, in fact made by a different process, could have been made by the first process?).

Claim 24 partially repeats claim 1, with some differences. It is not to producing a genetically transformed soybean plant, but a 'line of plants' (any plants). It repeats features A through E of claim 1, adding the qualification of claim 6 to feature C. It modifies feature F: instead of detecting the transferred gene in the regenerated plant, this plant is first selfed and the seed lanted: the gene is then detected in the progeny. Feature F so modified is the natural and inevitable course any breeder would take to establish a line containing a desirable gene. Claim 24 is accordingly anticipated by each of the cited references. The limitation to soya in claim 25 merely reduces the scope of the claim to approximately that of claim 6.

There is a further objection to claims 17-21 and 24. They are to an obvious desideratum. The patentee admits this: "... genetic transformation of lines of soybean and other crop species is a desired objective because of the great agricultural value of the common crop plants and the potential to improve their value and productivity."(Patent, page 3, lines 42-44). Thus, to make transformed soya is a recognised problem. A specific solution of such a problem could well be inventive, and entitle the Patentee to claim this solution. The first to solve a recognised problem is NOT however entitled to claim ALL solutions to the problem - only the solution he has invented (if any). Claims like claim 17 pervert the purposes of the patent system.

14. Claims 1-25 are to a discovery, not an invention. They are to new knowledge, not a new product or process. The discovery made by the Patentee is that the process described in the cited art works as predicted to give products that the prior art predicted it could give. This is verification, not invention. Such work, if carried out by associates of those who actually devised the process and predicted that it would work, would not even qualify them for consideration as co-inventors. Support for the view that the contribution of the Patentees is mere verification is derived from their failure to specify any special feature invented (or even selected) by them as essential to make the gene gun work. Clearly there is no such feature.

15. If, contrary to what the Opponents argue above, the described processes and products are indeed unpredictable and inventive, then all claims are not described sufficiently to enable them to be carried out by a person skilled in the art. If prediction is this difficult, much more description is needed. The specification discloses the transformation of three varieties of soya using two types of regenerable tissue with a small number of gene constructs using the gene gun under a limited range of conditions. If a successful result is necessary to show that the prior art process is applicable to soya, it should be equally necessary to show that it is applicable under all the wide range of conditions which the Patentee claims. In particular, it is well recognised that varieties within a plant species differ in the ease with which they can be transformed and regenerated: such differences are at least as pronounced as corresponding differences between plant species. If (which is denied) the Opponent is wrong to say that what is disclosed is obvious, the claims should be at least limited to what is disclosed. If this is not obvious, on the basis that the prior art, though suggesting it, did not show it to work, why should the Patentee be entitled to claim what he has suggested, but not shown to work?

The term foreign gene is not clear. If foreign is taken to mean not normally contained in the soya genome then claim 16 cannot be reasonable - it will cover germplasm which spontaneously produces a mutated protein.

16. The disclosure of the specification, as a matter of substance and fact, is confined to the use of the gene gun to transform soya. Accordingly the subject-matter of claims 17-21 (relating to transformed soya produced by any method whatever) and 24 (relating to the use of the gene gun to transform any plant) claim matter extending beyond the content of the specification as filed.

Consider the title of the specification: "Particle-mediated transformation of soybean plants and lines". This extremely broad description is still too narrow to embrace the inventions claimed in 17-21 and 24. The same facts lead to the conclusion that these claims are not supported by the description. While the Opponents are not entitled to object on this latter ground, the Opposition Board, in the public interest, should take the point and act on it.

17. Opponents ask for oral proceedings, and for an award of costs.

by (name of lawyer)
25 November 1994

Authorised Representative before the European Patent Office
Agent for the Opponents.