

# COMPULSORY LICENSING AND FOOD SECURITY

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## Introduction

The massive increases in food productivity in the 30 years between 1960 and 1990, which is described as the Green Revolution, was achieved by developing high-yielding crop varieties, combined with by massive increases in fertiliser and pesticide use. Reliance upon the chemically nurtured, high yielding crop varieties of the past is no longer economically or environmentally acceptable. To meet the food security needs of the next 30 years and to create wealth in poor communities, there is a need to increase agricultural productivity on the presently available land, while conserving the natural resource base.<sup>1</sup> A second Green Revolution is required which combines traditional agronomic wisdom with modern agricultural science.<sup>2</sup>

The modern biotechnological revolution has enabled the engineering of desirable genetic traits from useful local species. Genetic engineering has permitted the expeditious introduction of a wide range of desirable traits into plants. These include:

- pest control traits such as insect, virus and nematode resistance as well as herbicide tolerance; post-harvest traits such as delayed ripening of spoilage prone fruits;
- agronomic traits such as nitrogen fixation and utilisation, restricted branching, environmental stress tolerance,
- male and/or seed sterility for hybrid systems; and
- output traits such as plant colour and vitamin enrichment.

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<sup>1</sup> See G.Conway, *The Doubly Green Revolution- Food for All in the Twenty-First Century*, Harmondsworth: Penguin, 1997.

<sup>2</sup> See I. Serageldin and G.J.Persley, *Promethean Science.Agricultural Biotechnology, the Environment and the Poor*, Washington D.C.:Consulting Group for International Agricultural Research, 2000, 6.

The production of transgenic plants has become possible through the development of a number of enabling and transformation technologies, such as marker genes and plant transformation tools. These technologies have become the subject of patent and plant variety rights protection, as a consequence of intellectual property legislation and the favourable decisions of courts in the USA and Europe.

One consequence of the introduction of recombinant DNA technology to agriculture is the shift of agricultural research from the public to the private sector.<sup>3</sup> The expense of biotechnological research and the propensity of the corporations involved in this research to patent and therefore privatise their research results, has tended to lock out public agricultural research institutes from these innovations. Those institutes such as the CGIAR research centres are not in a very strong position, either to participate in this research or to appropriate its fruits. Added to the expense of research are the various transaction costs involved in creating and defending intellectual property rights. Although the CGIAR Centres have a decisively important role in agricultural research of relevance for farmers in poor countries, their research budgets are continuing to decline, particularly in times of financial instability.

The marketing of proprietary products in agricultural research has meant that Northern agricultural priorities and business plans have come to dominate innovation and the identification of food priorities. Hardly any of the newly engineered seeds which appear on the market “are designed to meet the food needs of the rural poor or to enhance the productivity of smallholder farmers”.<sup>4</sup> Almost entirely ignored by the private sector, because of the low return on investment, is research on the so-called orphan crops: rice, tropical maize, wheat, sorghum, millet, banana, cassava, groundnut, oilseed, potato, sweet potato, and soybean. Access to patented germplasm or to enabling technologies which could promote innovations in these areas has been beyond the means of public goods institutes and developing country agricultural researchers.

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<sup>3</sup> See P.G. Pardey and N. M. Beintema *Slow magic: Agricultural R&D a century After Mendel* Technical Report 36, Agricultural Science and Technology Indicators. Washington, D.C., International Food Policy Research Institute, 2001.

<sup>4</sup> Oxfam, *Rigged Rules and Double Standards: trade, globalisation and the fight against poverty* Oxford, Oxfam, 2002, 32.

A similar situation had obtained with vitally important pharmaceutical products, such as HIV AIDS drugs, where the domination of private corporations in research and development had meant that patented innovations were available only in the cash-rich markets of the north. As a step forward in dealing with the HIV AIDS health crisis, the international patent regime was modified to relax the compulsory licensing requirements. This chapter considers the possibility of compulsory licensing to address the food security crisis.

## **1. The International Compulsory Licensing Regime**

For private corporations in a market economy, a patent is an instrument of competition. It provides a limited monopoly (at least for 20 years) in those markets in which the patent owner or its licensees wish to compete and it allows a patent owner to lock out competitors from those markets in which it has a registered patent, but does not wish to compete. The potential for competitive abuse was recognised in the Paris Convention for the Protection of Industrial Property which in Article 5A.1 provides that a signatory “may legislate measures providing for the grant of compulsory licenses to prevent abuses of the exclusive rights conferred by the patent, for example for failure to work.” Article 5A.3 provides that a compulsory license “may not be applied for on the ground of failure to work or insufficient working before the expiration of three years from the date of application for the patent, or four years from the date of the grant of the patent whichever period expires last.” An exception to compulsory licensing is provided where “the patentee justifies his inaction by legitimate reasons.”

Notwithstanding the requirements of Article 5A of the Paris Convention, few countries introduced compulsory licensing regimes to deal with the non-working of patents. The TRIPS Agreement in Article 2 requires Members of the WTO to “comply with Articles 1 through 19” of the Paris Convention, but then in Article 31 provides for a comprehensive regime for the use “of the subject matter of a patent without the authorization of the right holder”. Article 31 (b) provides that such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. It also states that this requirement “may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of

public non-commercial use.” It may be strongly argued that the global situation of food insecurity, as it applies in the more vulnerable countries is a “situation of national emergency” or other circumstance “of extreme urgency”. Article 31 (c) provides that “the scope and duration of such use shall be limited to the purpose for which it was authorized.”

The key provision of Article 31 which was raised during the HIV AIDS debate was paragraph (f) which required that “any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”. The implication of this provision was that compulsory licensing would be permitted only to take advantage of a Member’s indigenous manufacturing capacity and not to license a foreign producer to supply the domestic market. Following extensive negotiations, paragraph (f) was waived to permit countries to licence overseas suppliers to satisfy domestic demand. This was obviously important for those countries without a domestic pharmaceutical manufacturing capacity. The question which this paper addresses is whether the international compulsory licensing regime is applicable to dealing with the preservation of food security.

## **2. Compulsory Licensing and Food Security under the TRIPS Agreement**

The TRIPS Agreement in Article 8.1 enunciates as a general principle that “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.” It is unclear what this provision adds to the compulsory licensing regime in Article 31 and what utility it may have in dealing with the food security crisis, particularly because of the qualification of the necessity for action taken to deal with matters of public health and nutrition to be consistent with the TRIPS Agreement.

One suggestion is that “emergency cases could trigger the application of a different test of ‘inconsistency’ (as provided for under Article 8.1)... in such a case, a suspension or an exclusion from patentability might be linked to and justified by a special emergency”.<sup>5</sup> This

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<sup>5</sup> Carlos. M. Correa, *Trade Related Aspects of Intellectual Property Rights. A Commentary on the TRIPS Agreement*, Oxford, Oxford University Press, 2007, 109.

interpretation is yet to be tested. The suspension of a patent over some DNA or over an enabling technology might assist a domestic agricultural researcher in using a relevant piece of biotechnology, but it would be difficult to suggest that the access to that patented technology was necessary to deal with the special emergency of food insecurity in the same way that anti-AIDS drugs were necessary to deal with the HIV AIDS epidemic.

The text of the Declaration on the TRIPS Agreement and Public Health at the time of the Doha conference in November 2001<sup>6</sup> indicated in the public health context the sorts of things which might fit within Article 8.1. Clause 4 of the Declaration stated that the declarants “while reiterating our commitment to the TRIPS Agreement” affirmed “that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.” To this end they reaffirmed “the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.” In clause 5 of the Declaration these flexibilities were identified as including:

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(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

In clause 6 it was recognized that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement and the Council for TRIPS was instructed to find an expeditious solution to this problem.

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<sup>6</sup> *The Doha Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/W/2,14 November 2001

After extensive negotiations<sup>7</sup> the General Council of the WTO by a Decision of 6 December 2005 adopted a Protocol for the amendment of the TRIPS Agreement which provided for the insertion of Article 31bis which relaxes the obligations of “an exporting Member under Article 31(f) for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.”

The tortuous negotiations towards this amendment and the detailed limitations on the waiver of Article 31 (f) illustrate the fact that similar negotiations to take account of the food security problem would be similarly tortuous and any waiver if it was capable of being achieved would probably be similarly circumscribed.

The Annex defines “pharmaceutical product” as those needed to address “HIV/AIDS, tuberculosis, malaria and other epidemics” referred to in clause 1 of the Doha Health Declaration. An “eligible importing Member” is defined as any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS that it will use the system in “the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.”

If this approach is to be followed in the case of agricultural patents, the case of national emergency would have to be made out. Alternatively, if the patent is to be used by a public agricultural research institute, this would fit within the case of “public non-commercial use”.

An example of the sort of thing which might be the subject of a compulsory licence is the patent secured on 7<sup>th</sup> June 1995 by the Regents of the University of California filed for a

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<sup>7</sup> SEE J. H.J.BOURGEOIS AND T.J. BURNS ‘IMPLEMENTING PARAGRAPH 6 OF THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH: THE WAIVER SOLUTION’, (2002) 5 JOURNAL OF WORLD INTELLECTUAL PROPERTY 835 ; E. NOEHRENBURG ‘TRIPS, THE DOHA DECLARATION AND PUBLIC HEALTH’, (2003) 6 JOURNAL OF WORLD INTELLECTUAL PROPERTY 379; C. M. CORREA, *IMPLEMENTATION OF THE WTO GENERAL COUNCIL DECISION ON PARAGRAPH 6 OF THE DOHA DECLARATION ON TRIPS AGREEMENT AND PUBLIC HEALTH*. GENEVA: WORLD HEALTH ORGANIZATION, 2004; P. DRAHOS, FOUR LESSONS FOR DEVELOPING COUNTRIES FROM THE TRADE NEGOTIATIONS OVER ACCESS TO MEDICINES, (2007) 28 LIVERPOOL LAW REVIEW 11.

process to enhance *Xanthomonas* resistance in plants.<sup>8</sup> This resistance is important for dealing with bacterial blight in rice, which has the effect of depleting the amount of rice for harvest.<sup>9</sup>

A further indication of difficulties likely to be faced in extending the TRIPS Article 31 (f) waiver to food security is the obligation under the Annex to the Protocol for the amendment of the TRIPS Agreement for the eligible importing Member is obliged to notify the Council for TRIPS of “the names and expected quantities of the product(s) needed and if a country other than a LDC that “it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product in question”. The compulsory licence issued by the exporting Member under the system must be subject to the conditions that: (i) only the amount necessary to meet the needs of the eligible importing Member may be manufactured under the licence; (ii) products produced under the licence shall be clearly identified as being produced under the system through specific labelling or marking; and (iii) before shipment begins, the licensee shall post on a website details of the quantities being supplied to each destination and the distinguishing features of the products. It is difficult to see how this kind of precision might be applied to the utilisation of agricultural patents.

Under the Annex eligible importing Members are obliged to “take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system.” Where the eligible importing Member is a developing country Member or a LDC developed country Members of the WTO “shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.”

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<sup>8</sup> U.S. patent 5,859,339.

<sup>9</sup> See WIPO/UNEP, *The Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge. Selected Case Studies*, WIPO: Geneva, 2001, 13.

### 3. Compulsory Licensing and Agricultural Research

An area where compulsory licensing has a significant contribution to make food security concerns agricultural research. The possibility established in *Pioneer Hi-Bred International Inc. v. J.E.M. Ag Supply Inc*<sup>10</sup> that plant varieties might be also patented, in those jurisdictions which permit double protection, has considerably circumscribed not only seed-saving, but also the scope of agricultural research. Plant variety protection legislation provides a broad exception from infringement for researchers in developing further varieties. The scope of the equivalent research exception in patent law scope was recently narrowed in *Madey v Duke University*.<sup>11</sup> Duke University's attempt to rely on the experimental use exception defence was rejected by the Federal Circuit Court as it held that the University's research activities were tainted by "business objectives" The narrowing of the experimental use defence in the USA is particularly problematic in the plant biotechnology research sector, where access to patented, university-owned germplasm is crucial for innovation in crops which will be made available to the agricultural sector.

In Europe Article 53(b) of the European Patent Convention (EPC) excludes plant varieties as such from patent protection. However, Article 4(1) para.2 of the European Biotechnology Directive permits the patentability of inventions concerning plants, where "the technical feasibility is not confined to a particular plant...variety". This qualification was addressed by the Technical Board of Appeal of the European Patent Office in *Novartis/Transgenic Plant*.<sup>12</sup> The patent application in that case concerned a patent containing claims to transgenic plants comprising in their genomes specific foreign genes, the expression of which resulted in the production of antipathologically active substances, and to methods of preparing such plants. The EPO had denied registration, supported by the Technical Board of Appeal, on the ground that art.53(b) denied the patentability of an invention which could embrace plant varieties. In its decision of 20 December 1999, the Enlarged Board of Appeal indicated that it would favour the application because, in substance, it did not involve a specific application for a plant variety. It observed that the claimed transgenic plants in the application before it were defined by certain characteristics

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<sup>10</sup> 200 F.3d 1374 (Fed. Cir. 2000), *cert. granted*, 148 L. Ed. 2d 954 (2001)

<sup>11</sup> 307 F.3d 1351 (Fed. Cir. 2002).

<sup>12</sup> [2000] *O.J. EPO* 511.

which allowed the plants to inhibit the growth of plant pathogens. No claim was made for anything resembling a plant variety.

To deal with the chilling impact of patent law upon plant variety research, the UK Parliament introduced the Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002.<sup>13</sup> These provide in Reg. 3(1) that “where a person cannot acquire or exploit plant breeders' rights or a Community plant variety right in a new variety without infringing a prior patent, he may apply in accordance with rules to the Comptroller General of Patents for a licence under the patent”. The applicant must provide particulars of the potential infringement and the fact that it has applied unsuccessfully to the proprietor of the prior patent concerned for a licence to use that patent to acquire or exploit plant breeders' rights or a Community plant variety right, and the new plant variety, which the applicant wishes to acquire or exploit “constitutes significant technical progress of considerable economic interest in relation to the invention protected by the patent.”

Where, having considered the application the Comptroller is satisfied of the above matters that a compulsory licence shall be granted to allow the use of the invention protected by the prior patent “in so far as the licence is necessary for the exploitation of the new plant variety on the conditions set out in regulation 7 and on such other terms as the controllers think fit.” Regulation 7 provides that a compulsory licence shall not be exclusive and shall entitle the proprietor of the patent concerned to an appropriate royalty, and entitle the proprietor of the patent concerned to a cross licence on reasonable terms to use the new plant variety.

Reciprocally, Regulation 11 provides that where a proprietor of a patent for a biotechnological invention cannot exploit a biotechnological invention protected by the patent without infringing prior plant breeders' rights, “he may apply in accordance with Breeders' regulations to the Controller of Plant Variety Rights for a licence and on such application shall pay the plant breeders' fee.” The application will be accompanied by particulars which seek to demonstrate that (a) the proprietor of the patent for a

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<sup>13</sup> These Regulations implement Article 12 of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (OJ No. L 213, 30.7.98, p. 13) and enable the Comptroller General of Patents, Designs and Trade Marks and the Controller of Plant Variety Rights, acting jointly, to grant non-exclusive compulsory licences and cross licences where the exploitation of a patent would infringe a plant variety right and vice versa.

biotechnological invention cannot exploit the biotechnological invention protected by the patent without infringing prior plant breeders' rights; (b) the proprietor of the patent has unsuccessfully applied to the holder of the prior plant breeders' rights for a licence; and (c) the biotechnological invention protected by the patent constitutes significant technical progress of considerable economic interest in relation to the plant variety protected by the prior plant breeders' rights.

#### 4. Ancillary Patent Policies

A range of patent policies, neighbouring on compulsory licensing have been identified as making a possible contribution to food security. In most common law countries, governments have the power of to take private property for a public purpose, even if the property owner objects. For example in the USA the Fifth Amendment to Constitution allows the government to take private property if the taking is for a public use and the owner is "justly compensated". Similarly, in the UK, there is a system of compulsory purchase, in Australia, compulsory acquisition and in Canada and South Africa, expropriation. For example, in the USA the Federal Government exercises its existing eminent domain authority under 28 U.S.C. § 1498. The eminent domain authority has been used primarily for military purposes, but its use was considered recently in a health context to make the anthrax drug "CIPRO" available more cheaply.<sup>14</sup> Eminent domain authority could be used to authorize the use of patented tools of biotechnology for developing country food-security purposes.<sup>15</sup>

Another option would be for governments to make available for developing country food-security purposes all tools of agricultural biotechnology developed by government agencies without the need for a license or other permission. For example, under the US Bayh-Dole Act the Government is granted a license in the inventions which it funds "[a]s necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement."<sup>16</sup> It has been pointed out that the Rome Declaration issued at the World Food

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<sup>14</sup> See Consumer Project on Technology, *Ciprofloxacin: the Dispute over Compulsory Licenses at <http://www.cptech.org/ip/health/cl/cipro>*, cited Michael R. Taylor & Jerry Cayford, 'Biotechnology Patents and African Food Security: Aligning America's Patent Policies and International Development Interests' 17 *Harvard Journal of Law & Technology* 323 at n.70.

<sup>15</sup> *Ibid.* 362.

<sup>16</sup> Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015-28 (1980) (codified as amended at 35 U.S.C. § 202(c)(4) (2000)).

Summit of 1996 and signed by the United States pledges “our actions and support to implement the World Food Summit Plan of Action.”<sup>17</sup> To date, the United States has not exercised its retained licenses on CRADA funded technology to advance the food security purposes of the World Food Summit. A similar policy approach could be taken in other countries where governments and public funding authorities, such as the European Commission, underwrite agricultural research.

## Conclusions

Patent protection is predicated upon a system in which inventions are disclosed in return for a limited monopoly during which the inventor can recoup research and development costs, through sale and licensing. Developing countries are not generally markets in which northern patent holders have much of a commercial interest, although occasionally, a patent will be filed to prevent the entry of a commercial rival. On the other hand, the filing of agricultural patents in industrialised countries will have the effect of preventing the sale in those countries of products containing patented material. This is relevant to the food security issue where agricultural products of interest to the north, such as sugar and coffee, are traded for the foreign revenues, which will allow the purchase of food crops.

Although agricultural research has tended to focus on crops of interest to cash rich markets, there is patented genetic material which may be of interest to agricultural researchers in the south. For example the “Golden Rice” project being undertaken by the International Rice Research Institute envisages the engineering of Vitamin D and some protein into rice. A freedom to operate study identified some 70 or so patents over genetic material held by various private corporations.<sup>18</sup> Many of these patents were quite distant from agricultural applications, for example the Japanese Tobacco Corporation held patents over various lysine gene sequences. These were required to facilitate the insertion of protein into

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<sup>17</sup> World Food Summit Plan of Action, Nov. 13–17, 1996, U.N. Doc. WFS 96/3 (1996), referred to *ibid*, at 364.

<sup>18</sup> Kryder, R. D., Kowalski, S. P. and Krattiger, A. F. 'The intellectual and technical property components of pro-vitamin A rice (Golden Rice™): A preliminary freedom-to-operate review', ISAAA Brief 20, Ithaca, NY. 2000.

the rice. A system of compulsory licensing or eminent domain acquisition could be used to make patents available in a public agricultural context.

The Golden Rice example illustrates another obstacle to agricultural research, namely thickets of multiple patents and cross licensing arrangements which hamper the access to patent rights.<sup>19</sup> Compulsory licenses and research exemptions may be used as a means of adjusting the balance between the private interests of the patent holder and the public interest as envisaged by Article 8(1) of the TRIPS Agreement.

The ideal of the international patent law regime would be a procedure to grant nonexclusive licenses to any requesting party for the use of any patented tool of biotechnology for developing country and LDC food security purposes. The royalty rate would reflect the extent of the value forgone by the patent holder. This will often be zero, given that a northern patent holder will often not contemplate commercializing its technology in developing country markets. Also, as the Golden Rice example illustrates, the patented technology will often be being used in a non-agricultural context. This compulsory licensing could significantly enhance food security without undercutting the profitability of the northern invention. invention incentives because the royalty provision would make the patent holder

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<sup>19</sup> See M. Blakeney, 'The Role of Competition in Biotechnological Patenting and Innovation', [2006/2007] 9 *Bio-Science Law Review* 95.