FARMLAND BIRDS AND CROP PRODUCTION

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ABSTRACT

Farmland in Europe provides a vitally important habitat upon which numerous wildlife species depend. Such species, including birds, insects, and vascular plants, have suffered heavy population declines in the past 25 years. Loss of food source and habitats due to changes in farming practice are thought to be the cause of bird declines. A review of the indirect effects of pesticides shows that they are removing bird food sources and therefore probably contributing to the decline of bird populations. Grant schemes, farm advice and farming systems, such as integrated crop management, may be ways of addressing these wildlife declines. Improving the selectivity of pesticides could be a way of reducing impacts on food sources for wildlife with limited effects on crop production.

INTRODUCTION

The Royal Society for the Protection of Birds (RSPB) has been working on agricultural issues for over 10 years. We have a three pronged approach to tackling such subjects: research, policy and advice. Extensive research, based on sound science, has been carried out on species associated with farmland (such as cirl bunting, and skylark) and on agricultural habitats, for example set-aside. There is an agricultural adviser working on management information for RSPB Reserves and for farmers, and policy advisors working on such issues as Common Agricultural Policy reform, livestock subsidies, and arable farming issues such as pesticides. We have a rural economist working full-time on agricultural issues and have recently employed an agricultural colleges liaison officer who will be taking information and ideas to universities and colleges. Furthermore we also have agricultural specialists in our Scottish and Welsh headquarters and Conservation Officers in each of our 10 regional offices throughout the United Kingdom.

IMPORTANCE OF AGRICULTURE FOR BIRDS AND BIODIVERSITY

In 1994 BirdLife International published the first review of the conservation status of all birds in Europe. The aim was to identify species in need of conservation measures so that action could be targeted towards them. These species are known as Species of European Conservation Concern (SPECs).

SPECs were then categorised with regard to their European and global status. Species which have a small population or are substantially declining or are highly localised are said to have an Unfavourable Conservation Status. The analysis revealed that 195 species fall into that category. This represents 38% of European bird species (Tucker *et al.* 1994).

Lowland farmland consists of approximately 70 % of the land surface in the European Union. Of the 195 SPECs, 116 species (approximately 60 %) utilise lowland farmland for feeding and breeding, with a substantial number being highly dependent including seven species of global conservation concern. Assessment of the threats to the habitats shows that agricultural intensification affects 42 % of SPECs, the highest proportion. Pesticide use alone affects 24 % of the declining SPECs (Tucker *et al.* 1994).

In the UK the RSPB has identified 43 species that are directly threatened by agricultural improvement or abandonment (Taylor *et al.* 1990). The UK's leading non-governmental bird conservation organisations (RSPB, BirdLife International, Wildfowl and Wetlands Trust, The Game Conservancy Trust (GCT), British Trust For Ornithology (BTO), The Hawk and Owl Trust, Wildlife Trusts, and The National Trust) recently updated their Birds of Conservation Concern document. This document contains the agreed priorities for bird conservation following a review of the status of all bird species in the UK, Channel Islands and Isle of Man. The latest edition, which came out in April 1996, assigns priorities to 280 regularly occurring bird species and divides them up into three sections: red, green and amber. The red list species are of greatest conservation concern and contain 36 species of which there are 15 that depend on farmland habitats (grey partridge, quail, stone curlew, turtle dove, skylark, song thrush, spotted flycatcher, red-backed shrike, tree sparrow, linnet, twite, bullfinch, cirl bunting, reed bunting and corn bunting).

It might fairly be said, therefore, that intensive farming systems present the greatest threat to European birds, if not European biodiversity as a whole. Conversely it could also be said therefore that farmers and farming have the greatest opportunity to benefit European biodiversity.

BIODIVERSITY DECLINES ON FARMLAND IN THE UK

Birds are highly visible and widespread and are almost certainly the best researched and monitored taxon. Useful information is available on populations and distribution, including historical data for describing trends (Pain *et al.* 1997). Because of this fact and because birds are situated near the top of the food chain they are often used as indicators of health of an ecosystem. Most of the data available has come from monitoring under the BTO's Common Bird Census (CBC) and Breeding Bird Atlas.

Information from the CBC shows that over the past 25 years there have been dramatic declines in the numbers and range for most of our bird species associated with the UK's agricultural land (Evans *et al.* 1995) (Table 1). Recent reviews show that 86 % of farmland bird species are in decline compared with only 51 % of non farmland species (Fuller *et al.* 199X).

Table 1. Declines in farmland birds 1969-1994 (BTO)

Species	Decline in range (%)	Decline in population (%)
bullfinch	6.5	76
corn bunting	32.1	80
grey partridge	18.7	82
linnet	4.6	52
reed bunting	11.7	61
tree sparrow	19.6	89
turtle dove	24.9	77
skylark	1.6	58

However population declines are not just limited to birds. Other research shows equally dramatic population losses in other species groups. Research by GCT in its Sussex Study identified 700 species of arthropods in cereal crops and has shown that each year between 1972 and 1990 there has been a 4.2% population decline (with the exception of mites and springtails) (Aebischer 1991). The most desperate case is the decline of arable flowering plants. There are many plants that are becoming endangered as British species and a few are already extinct. For example the corn buttercup was widespread in the 1960's is now only found in 25 sites in the UK. Such species are at a loss as they are totally dependent on arable cultivation, especially during the spring, and therefore do not exist elsewhere.

Declines are occurring much faster in farmland bird species than declines of birds in other habitats, such as woodland. Therefore it would suggest that changes in farming practice that have occurred over the past 25 years are perhaps the major factor in causing farmland species to decline. This fact is backed up by the recorded population fall in other species groups that rely on farmland as a habitat.

CAUSES OF BIRD DECLINES

Intensification of agricultural practices has lead to a series of changes in the farmed landscape. However the impacts of these changes on bird ecology are very complex and will vary depending on the species. Broadly, however, they can be simplified into three main areas:

Loss of winter food: for part of the year many farmland birds eat weed seed and spilt grain. Stubbles remaining over the winter as a preparation for a spring sown crop provided a great source of this food. As a result of intensification most cereal drilling times have switched from the spring to the autumn removing stubbles from the landscape. It is also highly probable that any stubbles that do remain, including as a result of set-aside, are generally diminished in their value, because of the increased use in herbicide on the preceding crop reducing broad leaved weed populations (Evans *et al.* 1995).

Loss of food for chicks: most young birds of farmland species are raised on invertebrates. The GCT Sussex Study showed declining populations of insects which is thought to have occurred as a result of the increased use of broad spectrum insecticides, which directly remove insects, and the use of herbicides which remove insect food and habitats. GCT showed that increased herbicide use reduced the availability of saw-fly larvae which had a direct consequence on grey partridge chick mortality (Evans *et al.* 1995).

Loss of nesting sites: much of the farmed landscape has been rationalised and has lead to the loss of features such as hedgerows, uncultivated field margins, small woodlands and patches of scrub all of which provided nesting sites for many farmland birds. The crops themselves also provided nesting sites for birds such as the skylark, however winter sown cereals mature too quickly and become too dense for such birds to establish a nesting site (Evans *et al* 1995).

Overall the general specialisation of farming into either animal production or crop production has exacerbated the situation. Many birds require the habitat mosaic of grassland and arable land, and features such as undersown crops, associated with a mixed farming system, can also help insect diversity (Potts 1997).

To summarise, the most important changes that have occurred in farming in terms of bird populations are believed to be: the loss of mixed farming, the switch from spring to autumn sown crops (loss of winter stubbles), and the increased use of agrochemicals.

INDIRECT EFFECTS OF PESTICIDES ON BIRDS

A report, entitled "A Review of the Indirect Effects of Pesticides" produced by a consortium including, RSPB, Oxford University, BirdLife International, Butterfly Conservation, The Institute of Terrestrial Ecology, and Plantlife was recently submitted to the Department of the Environment, the Joint Nature Conservation Committee and English Nature*. This report highlighted the fact that the concerns from the increased use of pesticides over the past 25 - 30 or so years has changed from the implications of direct or toxic effects to the indirect effects. The "indirect effects" being the removal of components of the food chain thus denying sources of food for birds.

The review looks at three possible indirect effects of pesticides on birds:

1 Insecticides reducing the abundance of summer food during the breeding season;

2 Herbicides reducing the number of host plants, thus reducing the abundance of invertebrates which depend on them;

3 Herbicides reducing the abundance of weeds and seeds, which represents a food source birds in winter.

The review examined the diet of lowland farmland birds, finding that in general there were no major differences in the diets between declining and increasing species, but there were some indications of some insect groups (Lepidoptera, Coleoptera and Orthoptera) featuring more prominently in the diet of declining species.

* This document is shortly to be published by the Joint Nature Conservation Committee

The study then analysed trends in abundance of food of farmland birds, examining evidence from Rothamsted Insect Survey, the Butterfly Monitoring Scheme, the Atlas of the British Flora and BSBI surveys, and the GCT's Sussex Study. The findings for invertebrates were of general decline over the past 20-30 years, with most groups declining or remaining stable. The data for plants was less clear with some individual plant species declining dramatically but in general weed abundance did not change. However there was also some evidence of a general increase in grass weeds relative to broad-leaved species.

The study examined evidence of short term declines in both target and non-target species after pesticide applications and found that some reductions may last for weeks or months which potentially could have serious implications for birds. Many of the plant and invertebrate species found to be declining immediately after an application are known to be eaten by farmland birds. Although there have been other changes in farming practice that could have caused long term declines, the known short term effects seem to indicate that pesticide usage could be highly important in influencing abundance of bird food. The review also found strong temporal correlations between trends in pesticide use (% crop area sprayed) and the periods of rapid decline of many of the declining species of birds.

The most clear evidence studied within the review is the work on grey partridge by GCT. This study has been running continuously for the past 30 years and has considered aspects such as cropping patterns, predation and pesticides in the decline of this game bird. This study provides convincing evidence that partridge chick survival has been reduced by the indirect effects of herbicides and broad spectrum insecticides, thereby leading to a decline in breeding bird population density. Manipulation of pesticide usage alone has been shown to result in significant improvements in chick survival. Whilst there is no conclusive evidence, such as this, for other farmland species the similarity in ecology and pattern of recorded population declines means that for these other species indirect effects cannot be ruled out.

We admit that reports' findings are not conclusive and suggest the need for further research examining the other factors of agricultural change, the need for improved monitoring schemes and improved understanding of the ecology of individual bird species, much of which is on-going. The report ends by recommending that in the absence of full evidence we should exhibit caution when determining policy, but that support should be given to measures aimed at reducing pesticide inputs, improving application methods and the development of more-target specific products.

SOLUTIONS TO THE CAUSES OF BIODIVERSITY DECLINES

The RSPB has no desire to turn back the clock in terms of agricultural production. Although the farming systems of, for example pre World War II, seem very attractive, they would of course be uneconomic and although they would provide ample habitats for wildlife would do little to feed the millions of contemporary consumers, who primarily desire cheap wholesome food.

The RSPB has long advocated schemes where farmers are paid to carry out certain environmental management operations. These schemes now fall under the EU Agri-environment Regulation 2078/92. However up until recently schemes such as

Environmentally Sensitive Areas and Countryside Stewardship did not address the issues of declining arable wildlife directly. They recognised and supported management or creation of species rich grassland and non-farmed features such as ponds, hedgerows and woodlands, but did not acknowledge the centre of the crop as an important habitat.

However ESA schemes in certain parts of the country now pay farmers to leave stubbles over the winter and the CSS has payments for grass margins and beetle banks which can help increase arthropod populations in arable fields. Recently English Nature, The GCT and RSPB submitted a paper entitled "A Proposal for an Arable Incentive Option" to the MAFF Arable Working Group, part of the National Agri-Environment Forum. The proposal contains a number of new prescription ideas that have been shown to be effective at supporting arable wildlife such as paying farmers to undersow spring crops, planting wildbird cover crops and Game Conservancy Conservation Headlands.

The proposal also contains some cross-compliance conditions particularly in relation to pesticide use; for example a prescribed herbicide regime should be used in the preceding crop to a winter stubble in order that the remaining stubble will be rich in broad leaved weeds; in cereal crops on farms within the scheme, only aphicide can be used for insect control. It is hoped that we will learn in spring 1997 whether the Government intend to implement this scheme as a pilot project.

Bodies such as the Farming and Wildlife Advisory Group have helped arable wildlife through on-farm advisory services, showing farmers how they can combine profitable crop production and wildlife-rich farmland. However, the market and consumers may also be moving to benefit the farmed environment. Over the past few years, and particularly in the light of modern day crises such as BSE, the consumer is beginning to place new demands on the farmer. The consumer now wants safe and clean food and appears to want this food to be produced in a biodiversity-friendly environment. Of course they still demand that it should be cheap.

As a response to this initiatives are beginning to emerge from supermarkets and other processors and food buyers, from farming organisations and to a certain extent agrochemical manufacturers and their trade organisations such as the British Agrochemical Association. I will group all these initiatives under the general phrase Integrated Crop Management (ICM), however I realise there appear to be many other names for broadly the same approach (Integrated Farming Systems, Integrated Pest Control and so on).

ICM will no doubt benefit much of the farmed environment in terms of pollution and energy use, but we are currently unsure how integrated crop management will help with issues such as the decline of mixed farming systems or with encouraging more spring sown cropping. However in the area of pesticide usage and selection there are potentially great benefits for arable wildlife.

ISSUE FOR THE FUTURE: PEST TARGETING

The RSPB has done little work in the past 10 years on pesticide issues, and any thinking on this subject is currently being developed and brought up-to-date, but the area that most interests us is the use of highly specific, targeted products. This we believe may possibly be an area which could help to find a balance in the continuing dilemma between the need for increasing agricultural production and the need to supply habitats for wildlife. We hope that this talk will stimulate thoughts or lead to help in pursuing new ideas.

RSPB and others are currently involved in research projects that are studying the detailed ecology of the bird species about which we are concerned, to date only GCT work on the grey partridge has produced such information, but on-going RSPB work on skylark will offer more information soon. Such studies will begin to unravel the actual needs of birds, particularly in terms of food sources. Once we can begin to get an idea of the actual requirements for birds we can then begin to see which are the most critical factors, or determine which insects and weeds for example are important for farmland birds.

We assume that these food sources do not include major agricultural pests (this seems a fair assumption in the light of bird declines). The indirect effects review showed that grass weeds, generally the most detrimental cereal weeds, are less important for birds than broad leaved weeds (further research will be required to determine the most important broad leaved weeds). Therefore positive selection of such species could become an opportunity for tomorrows farming systems. In this system major pest species, those which compete significantly with the crop causing yield losses, can be specifically targeted leaving potential food sources and insect habitats in the ecosystem. This would of course also apply to the so called aphid predating "beneficial insects" and to insects that provide bird food sources. We are unaware of any such research in this area and would be interested in any available information.

We are aware that currently on the market there are highly selective products available. However it is apparent to us that economics, which of course have a weightier part to play in the decision making of the farmer or agronomist, are not necessarily in favour of these more advanced chemicals. This is obviously regrettable and is actively encouraging farmers to have a greater impact on the environment than they actually need to.

We are currently examining ways in which this factor could be overcome such as the cross compliance measures in the Arable Incentive Option, which could be applied to a wider farming support payment system. Other options could be through economic disincentives such as taxation of pesticides based on environmental performance. We would be highly interested in finding or developing ways to classify pesticides in terms of their environmental impacts for the latter process or to aid choice and stimulate technological improvement.

An area that appears to be running in a direction diametrically opposite to the development of targeted pesticides, on which we have little information at this stage is the development of genetically modified crops which are unaffected by broad spectrum products, 'Roundup Ready' maize is an example. For European agriculture this would, if it became widespread for arable crops, spell tragedy for all of the species I have so far mentioned in this paper and thousands of others.

We realise the importance of a profitable rural economy and a thriving agriculture, but the farmland ecosystem in the UK and Europe is thousands of years old, nature has evolved with it and many species are dependent on it for their survival (something that agriculture in the new world may not be able to claim). It is vitally important, for our future generations, that any technological developments take this fact into account.

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MICROBIAL INSECTICIDES AND PATENT LAW

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ABSTRACT

Current patent law in the UK provides for patent protection for inventions employing or consisting of microbes. In order for any invention to be patentable it must be new, inventive, capable of industrial application, and not excluded under the Patents Act. Exclusions under the Patents Act which have caused difficulties for patents in respect of biotechnological inventions are those prohibiting patents for immoral inventions and for plant and animal varieties. Any patent application must contain a description of the invention. In the case of patents for micro-organisms this requirement is met by the depositing of samples of the microbe with an authorised depository. Employers should be aware of laboratory practices now required in order to file "first to invent" patent applications in the USA. There is now a second EU draft directive on the patenting of biotechnological inventions.

INTRODUCTION

The law impinges on the development and marketing of microbial insecticides and other products of biotechnology in order to protect the manufacturer, the public and the environment. The investment of the manufacturer in biotechnology is protected by patents and other intellectual property rights. The manufacturer's workforce, the public and the environment are protected by health, safety and environmental law (including for example the regulations on the contained use and deliberate release of genetically modified organisms, the new EU regulation on novel foods and drugs/veterinary products legislation). This paper concentrates on the protection of microbial insecticides by patents, and considers some aspects of patent law which are peculiar to biotechnological inventions in general.

APPLICATIONS FOR PATENTS

Inventors have three routes available to apply for patent protection: 1. A national application to the UK (or an overseas) patent office, 2. An application to the European Patent Office "EPO", and 3. An international application under the Patent Cooperation Treaty "PCT".

A national application will, if successful, result in the grant of a patent for the state in which the application is filed only. In the UK the main legislation dealing with patents is the Patents Act 1977 and the Patents Rules made pursuant to the Act.

Applications for a European Patent may be made to the EPO, designating a number of member states of the European Patent Convention "EPC" (which extend beyond the European Union). Applications for European Patents may also be made to the UK Patent Office. If a European Patent is granted it must then be registered in each of the designated states and must be translated for most countries. A European Patent is, in effect, a bundle of national patents but has the advantage that only one application is made.

For an international application made under the PCT, a single application is made to the applicant's national patent office. The application is converted into a number of national applications later and there are then local filing costs and translations to be made. The main advantage for the applicant in filing a PCT application is that the costs of local filings and translations are delayed. There are around seventy PCT states which can be designated.

For many years there has been discussion about the possibility of creating a European Union Patent where a single patent would provide protection throughout the Union but to date this has not been achieved.

Whichever route is used the principles of patent law are very similar.

MICROBIAL INSECTICIDES AND THE REQUIREMENTS OF PATENT LAW

Are microbial insecticides patentable? Under the UK Patents Act, the answer is yes provided certain conditions are met. The conditions are that (a) the invention is new, (b) it involves an inventive step, (c) it is capable of industrial application and (d) it is not excluded by one of a number of exclusions under the Act. The conditions in a, b and c apply to all patents and not just those in respect of biotechnological inventions. However, there are some exclusions in the Act which either apply specifically to some biotechnological inventions or have been used to object to the granting of patents for particular biotechnological inventions, The immorality argument has been used by environmental pressure groups in attempts to block patents in the Plant Genetic Systems (1) and Oncomouse (2) cases, which are discussed in more detail below. There are other exclusions applying to plant and animal varieties, which specifically affect biotechnological inventions.

IS THE INVENTION NEW?

At the outset it is important to establish that the invention is new. An invention will be regarded as new if it does not form part of the "state of the art". If an invention has been made available to the public (whether in the UK or elsewhere) by written or oral description, by use or in any other way then it will be regarded as being part of the state of the art and, therefore, not patentable. The date for judging whether an invention is novel for a European Patent is the date of application to the Patent Office (in the USA it is the date of invention itself). It is important therefore not to disclose the invention to the public in any way (including at a conference), other than under obligations of confidence, before the patent is filed.

Old inventions might still be patentable if the claims in the patent are for a new use. For example, consider a compound which is known to act as a plant growth regulator. If the same compound was later found to act as a pesticide on plants then this represents a use for a new purpose which might be patentable if all the other conditions of patentability are met.

INVENTIVE STEP?

The subject of the patent must have an inventive step. The Act provides that, in order to be patentable, the invention must not be obvious to a person skilled in the art; it must be more than just novel and must exhibit some element which makes it inventive or innovative. A person skilled in the art is regarded as one who has a wide knowledge of the relevant science but does not have inventive skills of his/her own. He or she is deemed to know the state of the art but not information included in earlier patent applications which have not yet been published.

It will be a question of fact and degree whether or not the invention is obvious. An invention may be very simple (for example cat's eyes in roadways) without being obvious. Some of the facts which will be considered include, for example, whether the invention was cheap to make and fulfilled a need but had not been thought of before (3) and, where a patent is being attacked as invalid, whether the invention had been an obvious commercial success where attempts by others to invent a solution to a problem had failed (4).

However, commercial success as an indicator of inventiveness must be treated with caution as lack of success could be attributable to things which do not relate to obviousness.

INDUSTRIAL APPLICATION?

An invention must be industrially applicable in order to benefit from patent protection. Under the Patents Act (subject to some exceptions) an invention is taken to be capable of industrial application "if it can be made or used in any kind of industry, including agriculture". The industrial applicability test is normally the least difficult of the conditions to meet.

IS THE INVENTION EXCLUDED FROM BEING PATENTABLE?

The EPC sets out a number of exclusions which prevent certain works becoming patentable. For example, discoveries, scientific theories and mathematical models are not patentable. In the UK, computer programs on their own are not patentable (but they may be patentable if they form an integral part of a piece of computer hardware, and they may be protected by copyright law).

The exclusions which most affect biotechnological inventions are those set out in Article 53 of the EPC which says:

"European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to "order public" or morality, provided that the exploitation shall not be deemed to be so contrary because it is prohibited by law or regulation in some or all contracting states;

(b) plant or animal varieties or essentially biological process for the production of plants or animals; this provision does not apply to micro-biological processes or the products thereof."

Article 53, which is reflected in Section 3 of the UK Patents Act, has created problems for the patenting of biotechnological inventions. In 1988 a patent was granted in the USA for a mouse which had been genetically engineered to be susceptible to cancer; now known as the Harvard Mouse or Oncomouse. A patent for Oncomouse was granted by the EPO in 1992. The argument that the patent was immoral was rejected at that time. However, in 1993 a coalition of animal welfare groups filed an opposition to the patent based on the immorality argument again. Harvard filed a reply in 1994 and the hearing of the opposition proceedings started in November 1995. After three days at the hearing no decision had been arrived at and the opposition proceedings continued in writing. No decision had been made by the end of January 1997.

Article 53(b) does not exclude the patenting of plants and animals as such but only excludes the patenting of plant and animal varieties. The rationale behind the exclusion on plant varieties is that other forms of protection for plant varieties exist (for example under the Plant Varieties and Seeds Act in the UK). However, there is no equivalent system of animal variety protection.

In 1995 the EPO made a ruling concerning genetically engineered plants. Plant Genetic Systems of Belgium and Biogen Inc of Massachusetts owned a patent granted in 1990 covering an invention to create herbicide-resistant plants through genetic engineering. Greenpeace mounted a challenge to the patent on the basis that it was, among other things, contrary to morality and was for a plant variety. The EPO rejected the morality argument. Technical Board of Appeal decided that the claims to the plants were made, in effect, for plant varieties and were therefore invalid. The EPO allowed claims to the gene conferring herbicide-resistance and for the techniques used in introducing the gene into plants but not for the plants themselves or the seeds from which they were produced. The President of the EPO referred the question to the Enlarged Board of Appeal. The Enlarged Board decided that there was no conflict with earlier Board decisions on patenting varieties, including those in the Oncomouse case and held the referral inadmissible. This leaves some uncertainty for plant patents. The Enlarged Board in its decision said that the claim for the genetically engineered plants "was held to be contrary to Article 53(b) EPC, not because the claim embraces known plant varieties..., but because the claimed genetic modification of a plant itself makes the modified or transformed plant a new plant variety". This case was a set-back for patents in plant biotechnology but it remains possible that claims to genetically engineered plants will be acceptable so long as it can be shown that the engineered plants are not new plant varieties.

The Plant Genetic Systems and Oncomouse cases illustrate some of the problems facing potential patentees of biotechnological inventions. There are also more general objections from those opposing "patents on life", Opponents claim that, among other things, biotech patents, inhibit research and prevent genetic resources from being freely used by everyone. Industry argues that a patent only gives the patentee a right to prevent others exploiting the invention for a limited period (20 years) and is required in order to ensure that research costs are recouped. It argues that questions of morality should be dealt with outside the area of patent law. Applicants for patents in respect of biotechnological inventions will need to be aware of the likely objections. Although the EPC's exclusion of plant and animal varieties from patentability is not likely to cause difficulties for developers of microbial insecticides some of the other objections, including those based on morality, might.

MICRO-ORGANISMS AND THE PRINCIPLES OF PATENTING

How are the principles of patenting applied to micro-organisms? Can a natural, newly discovered micro-organism be patented? Mere discoveries are not patentable. However, if a substance, or a microbe, must first be isolated from its environment in order to use it then the process for isolating it may be patentable. Furthermore, if the substance or microbe can be properly characterised by structure, the isolation process or other features and it is new in that it was not previously recognised then it may be patentable. The discovery of the production of a new substance by a micro-organism may be patentable. It is difficult to patent a naturally occurring microbe *per se*, because of the argument that it is not novel, unless an additional feature applies (for example, a process of isolation). Microbial cultures of naturally occurring organisms are, for this reason, often patented as biologically pure cultures.

If the microbe is genetically modified by laboratory methods or is an isolated mutant then it will be easier to demonstrate novelty and to get patent protection. DNA and gene vectors may also be patented provided the principles of patent law are complied with.

It is clear that the EPC does not prevent the patenting of micro-organisms so long as all the other conditions for patentability are met. In the USA, until 1980, the Patent Office refused claims to living things on the grounds that they were not patentable subject matter. However, in 1980, in the well known Chakrabarty case, the US Supreme Court granted a patent for a new strain of bacteria produced by bacterial recombination. The bacteria had the ability to feed on and disperse oil slicks but did not produce a product as such. Therefore, it was important to obtain a patent for the organisms themselves in that case. In the UK, the Patent Office had already granted a patent for the same organism in 1976. Patents have been granted for inventions involving microbes since that time.

THE PATENTING OF MICRO-ORGANISMS AND THE BUDAPEST TREATY

Any patent application must contain a specification, that is, a description sufficient to allow a person skilled in the art to understand and work the invention. It is almost impossible to define a micro-organism solely in writing and, even if it was, such a description does not effectively make the invention public on expiry of the patent (which it must be). The answer to this problem has been to accept a deposition of a sample of the organism in a recognised culture collection as an alternative, or in addition to a description. The culture of the organism is then maintained and, on request, samples are supplied to the public.

The 1997 Budapest Treaty (6) on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Protection (the "Treaty") lists a number of international depositary authorities at which all nationals of the signatories to the Treaty may deposit strains of micro-organisms in the knowledge that they will have satisfied the disclosure requirements of their patent application. In November 1996 thirty eight states were party to the Treaty including the UK.

The Treaty provides that the deposit of the microorganism with any "International Depository Authority" is sufficient to comply with the applicant's obligations to provide a description of the invention. An International Depository Authority is an institution which provides for the receipt, acceptance and storage of micro-organisms and the furnishing of samples, which has acquired recognition by virtue of a written communication addressed to the Director General of the World Intellectual Property Organisation "WIPO" by the Contracting State on the territory where the depositary is located (or by an inter-governmental industrial property organisation). The communication must contain a declaration that the institution will comply with certain requirements (for example, with regard to staff and facilities) set out in the Treaty. In November 1996 there were 29 Depository Authorities, seven of which were in the UK.

The advantage of the Treaty to an applicant is that if he is applying for patents in several Contracting States he will only be required to make one deposit of the organism (so reducing costs and administration), at one Depository. The Treaty is designed to create a uniform system of deposit throughout the Contracting States.

Regulations made under the Treaty set out, among other things, rules on the making of a deposit (eg stipulating a statement to be produced by the depositor including details of culture conditions and properties of the organism) acceptance procedures (including rights of the depository to reject the sample if it is not technically in a position to maintain the organism under the terms of the Treaty), receipts (stipulating contents of the receipt), storage of the micro-organisms, viability testing (to be carried out at least at reasonable intervals), furnishing of samples (including those supplied to industrial property offices, the depositor himself and other parties legally entitled) and fees.

A problem with the Treaty is that most developed countries publish patent applications early (18 months from the priority date) and regard the deposit as available to the public from the date of publication. Under the EPC, for example, the deposited material is available to any person from the date of publication. Samples of the microorganism then become available to the public before the applicant is sure he will obtain patent protection. However, under the EPC a depositor may require that, up to the grant of the patent, or where applicable, for 20 years from the date of filing if the application has been refused or withdrawn, samples will only be provided to an expert nominated by the person requesting them. The expert must undertake not to make the samples available to any third party and to use the material for experimental purposes only, until the patent is either refused or withdrawn or has expired. In the USA samples are not released until the patent has been granted; a system which provides greater protection for the applicant.

The differences between deposit and sample systems can create difficulties because competitors will seek samples from states where restrictions are weakest. Some states still have troublesome deposit rules. Companies might prefer to keep microbes secret, particularly those used for processes which are to be patented, rather than depositing them for patent applications. However, with microbial insecticides and other microbes intended for release into the environment, secrecy is unlikely to be an option. In practice it is now rare to make a deposit with an application for a patent involving microbes. The main reason for this is that where patents describe inventions which employ genetic engineering, the description can often be adequately set out in writing. Where newly isolated microbes are being patented, a deposit is still likely to be required.

In 1988 the EU produced a draft Directive on the patenting of biotechnological inventions (7). The Directive was the subject of much debate and pressure from industry and environment groups until on 1st March 1995 it was rejected by the European Parliament. A second draft has now been produced (8) and the debate has begun again. Some argue that a Directive is not required because patents for biotechnological inventions can be obtained under existing law. One of the arguments in favour of a Directive is that without it EU law on the patenting of biotechnological inventions is not harmonised and individual states can annul patents in their own territories granted through the EPO.

The EU Directive, if it becomes law, will harmonise EU law and will affect the activities of the EPO (even though the EPO is not an EU body) because Article 2(2) of the EPC states that "The European patent shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that State.....". The EU Directive deals with the deposit of micro-organisms under the Budapest Treaty and will ensure future uniformity throughout the EU States. It provides that where biological material cannot be described in the patent application then the material must be deposited with a recognised depository institution which includes at least those recognised under the Budapest Treaty. The draft Directive provides that samples of the materials will be provided:-

(a) up to the first publication of the patent application, only to those persons who are authorised under national patent law;

(b) between the first publication of the application and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert; and

(c) after the patent has been granted, and notwithstanding subsequent revocation or cancellation of the patent, to anyone requesting it.

The recipient of the samples will be obliged to undertake, for the term of the patent, not to make them available to third parties and only to use them for experimental purposes (unless the patent holder waives the undertaking). The Directive provides that, at the applicant's request, where an application is refused or withdrawn, samples will only be provided to independent experts for 20 years from the date of filing (and the same undertakings regarding third parties and experimental use will then apply).

The Directive deals with other aspects of patenting in biotechnology. It confirms that a mere discovery will not be patentable. The Directive describes an invention as a technical solution to a technical problem. The draft excludes germ line therapy on humans from patentability and provides a farmer's privilege which will allow farmers to use purchased patented propagating materials and livestock to replenish stock on their own farms. However, it is unlikely that the Directive will introduce material changes to the law on patenting of micro-organisms other than those relating to deposits.

EMPLOYMENT POLICIES AND GATT

The UK Patents Act provides that (as between employees and employers) rights arising in inventions created by employees under their normal employment duties will vest in their employers. Employers should ensure their employees are given guidance on the protection of intellectual property rights. In particular, employees should be made aware of the need for strict confidentiality, before and after the term of their employment, to avoid bringing inventions into the public domain, so destroying the opportunity to obtain patent protection.

In almost all countries in the world, apart from the USA, a patent is granted to the first applicant to file an application in respect of an invention. If two inventors develop the same invention then the first to file will take priority. In the USA patents are granted to the applicant who is first to invent, and proof of the date of invention is required by way of laboratory notebooks and similar records. In the USA the date for judging whether an invention is novel or not is the date of the invention, rather than the date of filing. The "first to invent" system appears fairer but can lead to disputes between two inventors (a procedure known as "interference"). The "first to file" system is easier to administer.

Until recently inventors resident outside the USA found great difficulty in succeeding in interference actions in the USA because US law prevented them using knowledge arising outside the USA to establish the invention date. However, on 1st January 1996 it became possible for the date of invention to be proved by records made in any country which is a member of the World Trade Organisation, including the UK. The change arises from the General Agreement on Tariffs and Trade "GATT". In order to benefit from this right, employees of UK research groups and companies must keep accurate records of their research findings. For example, the pages of laboratory notebooks should be dated and countersigned (if possible by an independent signatory), they should be hard bound (not loose leaf) and no gaps should be left which might permit additions at a later date. Gels, X-ray films and other trace records should be fixed to notebooks and dated. Failure to comply with such procedures could jeopardise patent applications in the USA. The full standards are set down by the US Patent Office and courts. Companies and research bodies in doubt should seek advice.

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