Prometheus, Vol. 23, No. 3, September 2005

Japonica Rice: Intellectual Property, Scientific Publishing and Data-sharing[1]

MATTHEW RIMMER

Abstract *This article examines a series of controversies within the life sciences over data sharing. Part 1 focuses upon the agricultural biotechnology firm Syngenta publishing data on the rice genome in the journal* Science*, and considers proposals to reform scientific publishing and funding to encourage data sharing. Part 2 examines the relationship between intellectual property rights and scientific publishing, in particular copyright protection of databases, and evaluates the declaration of the Human Genome Organisation that genomic databases should be global public goods. Part 3 looks at varying opinions on the information function of patent law, and then considers the proposals of Patrinos and Drell to provide incentives for private corporations to release data into the public domain.*

Keywords: Intellectual property rights; genomics; scientific publishing; data sharing; rice and staple crops; food security; copyright law; scientific databases; patent law; research exemption.

Introduction

Henry Oldenburg founded the *Philosophical Transactions of the Royal Society of London* in 1665 with the aim of establishing a public registry of ideas that would ensure the rapid evolution of scientific knowledge.[2] Historian Jean-Claude Guédon comments:

> In particular, [the *Philosophical Transactions*] introduced clarity and transparency in the process of establishing innovative claims in natural philosophy, and, as a result, it began to play a role not unlike that of a patent office for scientific ideas. The purpose was to tame and police 'scientific paternity' and priority controversies and intellectual polemics so as to make this potentially unpleasant spectacle disappear from the public eye. If scientific disputes could be handled in a quiet, orderly, and civil manner, Oldenburg and others calculated, natural philosophers would stand to gain a better, more dignified,

Prometheus ISSN 0810-9028 print/ISSN 1470-1030 online © 2005 Taylor & Francis
http://www.tandf.co.uk/journals
DOI: 10.1080/08109020500235180

> public image. At the same time, the presence of a public registry of scientific innovations would help create internal rules of behavior leading to a well structured, hierarchical society.[3]

Thus the journal encouraged the scientist to disclose knowledge that might otherwise have remained secret in return for the public credit and kudos associated with being recognised as the author of scientific publications.

This ethos of open disclosure is now under threat from modern commercial developments. In February 2001, *Nature* and *Science* published papers reporting the sequence of the 3.2 billion base pair human genome. The *Nature* paper was written by the publicly-funded International Human Genome Sequencing Consortium.[4] The *Science* paper was by the private company, Celera Genomics, led by Craig Venter.[5] The public consortium deposited its sequence material in GenBank as soon as was possible. However, Celera Genomics posted its data on its own website on publication, and limited free access to 1 million base pairs per day. Academic researchers requesting the entire sequence are required to sign a licensing agreement; private sector researchers had to pay a licence fee.

In April 2002, *Science* published two papers reporting the draft genome sequence for two subspecies of rice, *Oryza sativa*—one by the Beijing Genomics Institute, and the other by Syngenta International, a private company.[6] Like Celera Genomics, Syngenta International placed limitations on data access by developing licence-based services and relying on copyright and patent protection. These constraints resulted in criticisms directed at *Science* and the private companies that such limits violate norms of standard scientific practice rooted in openness and unrestricted access to all data underlying a publication in the open literature.

In considering the debate over scientific publishing and the disclosure of data, this article draws upon a mixture of methodologies including the history of science,[7] the sociology of science,[8] and the legal discourse on intellectual property.[9] This article draws in particular upon the theoretical insights of the sociologist, Mario Biagioli, who explores the shifting, protean meaning of authorship in a number of contexts including scientific publishing, copyright law, and patent law.[10] He comments upon the similarities and the disjunctures between the various frameworks:

> As with copyright, the patent system may provide scientists with an authorship venue, but not with scientific authorship. Scientists can patent useful processes stemming from their research, but scientific authorship is defined in terms of the truth of scientific claims, not of their possible usefulness in the market. In sum, according to definitions of intellectual property, a scientist *qua* scientist is, literally, a nonauthor. While novel claims are the objects rewarded by both intellectual property and the reward system of science, the 'unit of credit' is dramatically different in these two economies. A new, dramatic discovery that may warrant a Nobel Prize cannot be translated, in and of itself, into a patent or a copyright. Likewise, a scientist's copyrights and patents will not earn him or her such an award. It seems, then, that scientific authorship is not 'independent' from the logic of the market, but that its definition is complementary to that of market-based authorship as articulated through the copyright or patent systems.[11]

There is, therefore, a need to consider the impact of copyright law and patent law upon scientific authorship, publishing, and data sharing.

With Biagioli's views in mind, this article canvasses policy options that would ensure greater access, and open and free scientific communication. Part 1 focuses upon the Syngenta controversy and the similar debate in relation to the human genome project.[12] This part also focuses upon proposals to reform scientific publishing and data sharing. Part 2 examines the relationship between copyright law and scientific publishing. It considers the protection of scientific databases under copyright law and evaluates the declaration of the Human Genome Organisation that genomic databases should be global public goods. Part 3 looks at opinions on the information function of patent law and then examines proposals, in particular those by Patrinos and Drell, to provide incentives for private corporations to release data into the public domain.

Part 1. Syngenta and the Rice Genome: Scientific Publishing and Data Sharing

There was much competition between public and private researchers to sequence the rice genome in 2002.[13] In April, the Beijing Genomics Institute published a rough draft sequence of indicia rice variety 93-11. In the same month, the private company Syngenta published a draft sequence of japonica variety *Nipponbare*. Both draft sequences were obtained by a whole-genome shotgun sequence approach. In November, two members of the International Rice Genome Sequencing Project published high quality phase-3 sequences of chromosome 1 and chromosome 4 respectively. Both sequences were obtained by a clone-by-clone strategy. On 18 December, the International Rice Genome Sequencing Project announced the completion of a high-quality draft with at least phase-2 sequences of the 12 rice chromosomes.

The International Rice Genome Sequencing Project

The International Rice Genome Sequencing Project, established in 1997 to obtain a high quality, publicly available, map-based sequence of the rice genome,[14] comprises ten members: Japan, the United States, China, Taiwan, Korea, India, Thailand, France, Brazil, and the United Kingdom. It subscribed to the policy of immediate sequence release and published the rice genome in public databases in daily increments. It has adopted a 'clone-by-clone' approach whereby every clone sequenced can be associated with a specific position on the genetic map. The accuracy standard is less than one error in 10,000 bases, with the rice genome composed of about 400 million bases.

With rice being the most important cereal crop for half of the world's population,[15] the Project stressed the immense social benefits to be derived from the rice genome sequence:

> Plant breeders are able to identify and to map traits for yield, disease resistance, and tolerance to environmental stress. DNA sequence of rice that is tied to the genetic map facilitates the identification of genes governing those traits. Pinpointing the crucial genes will expedite transfer of beneficial traits into locally adapted elite lines and will permit plant breeders to search for useful allelic variants. In fact, publicly available sequence information has been used to discover genes that are responsible for controlling flowering time. This permits plant breeders to grow higher yielding rice strains in areas with different day lengths.[16]

The rice genome sequence has implications for other cereal crops because the arrangement of genes on the chromosomes is similar in all cereals, including corn, wheat, barley, rye, sorghum, oats, and millet.

The Project was aided by contributions from private corporations. In 2000, Monsanto produced a draft of a rice genome in support of its ongoing internal research programmes in genomics and crop improvement.[17] In April of the same year, Monsanto announced that the draft sequence data would be made available at no charge to the Project and to other registered public researchers. Monsanto claimed it did this to benefit the Project in reaching its primary objective sooner—the production of a complete and finished sequence of the genome of the Japanese rice variety Nipponbare—and was part of its pledge to support developing countries.[18] Through such a philanthropic act, Monsanto sought to dispel negative public perceptions of the company as 'the poster-villain for the anti-biotechnology movement'.[19] It also obtained incidental commercial benefits from keeping the material in the public domain as it could potentially thwart commercial rivals from exclusively exploiting such matter. Novartis also supported the physical mapping of the rice genome; that is, the ordering of the DNA fragments that are used for the sequencing.

Syngenta's Publication of the Rice Genome

Syngenta is a Swiss agricultural company created in November 2000 by the merger of the agricultural divisions of AstraZeneca and Novartis.[20] On 1 February 2001, the company's genomic research centre, Torrey Mesa Research Institute, announced that it had sequenced more than 99% of the rice genome in collaboration with Myriad Genetics.[21] The Institute's scientists published their first major analysis of the rice genome in *Science* in April 2002.[22] The journal permitted Syngenta to keep the data on a private database.[23] This broke the 20-year convention within genomics research of placing data in GenBank (or a similar public database) as a condition of academic publication.

Donald Kennedy, editor-in-chief of *Science*, who previously agreed to publish the human genome sequence subject to the conditions of Celera Genomics,[24] has played a crucial role in the controversy over standards in publishing and the disclosure of data. As Jean-Claude Guédon comments: 'Among scientists, those who manage to play an active editorial role in the publication process enjoy a special and rather powerful role, that of "gatekeeper"'.[25]

Kennedy defended the Syngenta decision on the grounds that it was upholding the spirit of the convention, as academic users could still gain free access to the data. It was, he maintained, a creative way to marry the conflicting interests of private investment and open research. He sought to rebut the arguments of some scientists who argued that this decision would compromise accepted community standards[26] by contending that the public benefit of releasing the findings from trade secret status outweighed the access costs for private researchers on 'terms essentially identical to those we allowed for the human genome sequence'.[27] In his view, not only will the privileged elite of the research community benefit from the publication, but also agricultural scientists, plant breeders, and Third World farmers.

Kennedy does not believe that such compromises will necessarily arise in the future:

> I cannot envision another likely exception. But given the volume of high quality, high-throughput basic research now being done in proprietary places,

> the scientific community needs, over time, to rethink the community standards it applies to sharing of data and materials associated with scientific publication.[28]

For Syngenta, there were two benefits to publication: it enabled the company to open its data to more people, and it benefited from having its work scrutinised by the peer review process.[29] Undoubtedly, Syngenta was keen to publish its work in *Science* because it sought prestige, kudos and respectability, benefits described by the French sociologist Bourdieu as 'social capital'.[30] As Guédon notes, a scientific journal not only serves as a registry of scientific information, it also operates as a label or a brand by which a scientist is identified: it delivers audiences and creates visibility much as prime time television does.[31] However, Syngenta did not merely desire symbolic gains; social capital was also helpful to cantilever its commercial objectives.

Critics maintained that such an arrangement could create a situation where data became distributed between different databases, each with different rules of access and use. A letter of protest from 20 eminent scientists, sent to the editorial advisers of *Science*, stressed that the withholding of publication-related data was 'a serious threat to genomics research'.[32] One of the letter's key authors, Michael Ashburner, from the Department of Genetics at the University of Cambridge, acknowledged Syngenta's right to protect its data, but objected to its cynical commercial use of a very respectable magazine without adhering to the norms of its community: 'Syngenta should be honest and take out a paid advertisement'.[33] Moreover, he was scathing in his condemnation of what the Syngenta deal actually offered researchers:

> Offering you data in tiddly bits of 100 kb from a 400 Mb genome is stupid. If you want to know how many genes of a particular class are in the rice genome, you couldn't do it—not unless you sell your soul to Syngenta. Doing comparative genomics on the other cereals with this sequence is going to be very difficult. People, if they've got any sense, will either work on the *indica* sequence (from the Beijing Genomics Institute) or they'll wait for the public sequence to come out of Japan.[34]

He concluded that *Science* was being short sighted and claimed the rival journal *Nature* had now become the magazine of choice for researchers to make their genomic announcements.[35]

Reconciliation

In May 2002, an agreement was announced that the Syngenta data would be shared with the International Rice Genome Sequencing Project. Under the agreement, two of the Project members, the National Institute of Agrobiological Sciences and the Institute for Genomic Research, would have access to the assembled sequence, the underlying sequence files, and chromosome assignment information. Access would also be given, on a confidential basis, to individual member laboratories that had signed the transfer agreement, and once the quality of the sequence had met the Project's standards, it would be released to public databases.[36] On 7 June 2002, the transfer was completed. Although the laboratories must initially keep the data confidential, the Project can then use such information in their sequencing efforts. This agreement is similar to the one reached with Monsanto.

Five months later, on 4 December 2002, Syngenta announced its intention to close the Torrey Mesa Research Institute, opened just four years earlier. The Institute led the company's efforts to sequence the rice genome.[37] The closure, effected by February 2003,[38] was part of a restructuring that brought together Syngenta and Diversa, a San Diego-based biotech company that focuses on isolating genes from microbes in extreme environments. Despite assertions by Steven Briggs, the Institute's CEO, that the new partnership was an extremely exciting opportunity,[39] many saw the closure as part of an industry-wide reduction in research funding.[40] In the meantime, on 18 December 2002, the International Rice Genome Sequencing Project announced the completion and free public availability in public databases such as GenBank, EMBL and DDBJ of a high quality draft sequence of the rice genome.[41]

It remains a mystery why Syngenta decided to change its policies on the release of the rice genome data. Perhaps the private company was keen to emulate Craig Venter of Celera Genomics and Francis Collins of the public consortium, who made a joint announcement on the completion of the human genome. Possibly Syngenta was disappointed by its rice genome database subscription sales and wished to abandon the information provider business model in favour of patent exploitation. Undoubtedly, the case study demonstrates that biotechnology companies are not monolithic, homogeneous entities. They contain much internal debate and division over appropriate policies for intellectual property rights, scientific publishing, and data-sharing.

Sharing Publication-related Data and Materials

The conflicts over the human genome and the rice genome are symptomatic of a wider problem of scientists and researchers withholding data in academic genetics. Empirical research undertaken by Eric Campbell and his collaborators from the Institute of Health Policy at Massachusetts General Hospital suggests that the problem is widespread.[42] Their results reveal that 47% of geneticists had at least one of their requests for additional information, data or materials about published research refused, with 10% of all post-publication requests for additional information denied. Campbell explored the motivations behind this withholding of data. He found that a large number of scientists lacked the time and resources needed to produce and share information. A significant number of researchers commented upon the need to protect the commercial value of intellectual property. Campbell found that withholding information undermined relationships between scientific peers, and detracted from scientific communication and progress.

A number of academic societies and scientific associations have undertaken similar investigations into scientific publishing and data-sharing. In 2001, the National Academies established the Committee on Responsibilities of Authorship in the Biological Sciences to study issues related to sharing publication-related data and materials.[43] The Committee's chairman, Thomas Cech, prefaced the Committee's report with the following:

> In general, the committee held to *a uniform principle for sharing integral data and materials expeditiously*, or UPSIDE. The upside of UPSIDE is two-fold: it keeps science honest and it fosters the progress of science. Both are worth nurturing and protecting.[44]

Cech was anxious that restrictions on access to scientific data would have an adverse impact on scientific research and communication. Furthermore, he was concerned that embargoes upon scientific data could result in scientific dishonesty, fraud and malpractice, because of a lack of peer review and scrutiny.[45] The Committee articulated a uniform principle for sharing integral data and materials expeditiously.[46] It observed:

> The act of publishing is a *quid pro quo* in which authors receive credit and acknowledgment in exchange for disclosure of their scientific findings. An author's obligation is not only to release data and materials to enable others to verify or replicate published findings (as journals already implicitly or explicitly require) but also to provide them in a form on which other scientists can build with further research.[47]

The Committee was convinced that most arguments for making exceptions to standards could not be rationalised without sacrificing the integrity of the principles of publication. It believed that exceptions unfairly penalised the community, which would otherwise have had access to the information. Furthermore, granting a special exception to certain categories or particular researchers was considered to be problematic. The Committee observed that exceptions are likely to weaken the effectiveness of the scientific process over the long term. Cech concluded the Committee's final report with a defence of open and shared publication in the tradition established by Oldenburg. He stressed that: 'Community standards, like the principles articulated in this report, are really only valuable to the extent that they are upheld by the scientific journals and honoured by the community'.[48]

In 2003, the National Institute of Health (NIH) in the United States released its final statement on sharing research data.[49] In its funding guidelines, it emphasised 'that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health'.[50] The funding agency stipulated that investigators seeking $500,000 or more in any single year should include a data sharing plan or state why data sharing is not possible.[51] In certain circumstances, the funding agency can request such plans for applications seeking less than $500,000. The NIH is willing to provide additional funding for preparing data for sharing and archiving.

In recognising that the value of data depends on its timeliness, the NIH expects data sharing to occur 'no later than the acceptance for publication of the main findings from the final dataset'.[52] The NIH resisted arguments that it was legitimate to delay the sharing of data because of proprietary concerns related to intellectual property. In its view, a publication delay of between 30 and 60 days was a reasonable period in which to allow a party to seek and exercise intellectual property rights.[53] As to the use of proprietary data in respect of collaborations between the public and private sectors, the NIH stated that applicants should identify any restrictions and propose how data will be shared.[54]

In 2003, the Royal Society in the United Kingdom released its report, *Keeping Science Open: The Effects of Intellectual Property on the Conduct of Science*.[55] The Society's Vice-President, John Enderby, argued that the UK's current intellectual property system encouraged a gold rush mentality, which restricts the free flow of scientific information and has damaging effects on both science and society.[56] The Royal Society was concerned that '[m]onopolies can develop where scientific information is protected by copyright, but are even more likely where a dominant position

has been achieved using patents or database rights'.[57] The report noted that current database rights, which were designed to protect media and commercial interests, were damaging scientific research. It contended that these rights rewarded the database creator rather than the data creator, although in science the latter provides the more costly and time-consuming contribution. Moreover, if publicly-funded research is contained in a commercial company's database, it can result in the user paying for the information twice—through taxes, and then to access a private database. The Royal Society recommended that 'unresolvable concerns over data access and monopoly rights in the private sector' be addressed by the Office of Fair Trading.[58] It reiterated in its conclusion: 'Competition law is an overriding remedy, but it is best if restraints are such that it need not be applied'.[59]

More recently, the Society participated in the United Kingdom House of Commons Science and Technology Committee inquiry into scientific publishing.[60] It recommended that 'Learned Societies have liberal copyright policies and make their publications available at as low a cost as is reasonably feasible and that scientists, wherever practicable, publish in journals with liberal access policies'.[61] Such inquiries emphasise the need to come to grips with the underlying commercial imperatives of genomics companies and fully consider the legal mechanisms underlying the control of scientific data, most particularly copyright and patent law.

Part 2. Philosophical Transactions: Copyright Law and Scientific Publishing

There has been growing interest in the use of copyright law to protect the products of biotechnology, particularly genetic databases.[62] In its annual report for 2002, Syngenta stressed the commercial benefits arising from the rice genome sequence at the same time as providing reassurance that the information would be shared with the International Rice Genome Sequencing Project. Briggs of the Torrey Mesa Research Institute observed, though, that such information would not be in the public domain.

> Think of it like a book or a movie. It's available to you, you can get the book, you can watch the movie; but it isn't in the public domain, you've got to go pay for it. Somebody owns it, and provides access to it. But we're not charging people for access to it for non-commercial uses. So to academics and so forth it's available without charge. But what we require is that if a commercial invention is made from the collaboration, that Syngenta has an option to consider a licence for it.[63]

Adrian Dubock, Syngenta's Head of Ventures and Licensing, speculated about some future collaboration with the International Rice Genome Sequencing Project, but having achieved results six months ahead of schedule, also said that 'we've a time advantage created with commercial money and we're looking for a reward'.[64]

The Torrey Mesa Research Institute does provide several levels of access to its scientific data on the rice genome. Academic users can access the data through the Institute website or on CD, under Free Public Access agreements.[65] Users must acknowledge the Institute, Syngenta and *Science* (should individual scientific results from using the data be published in a scientific journal or thesis), and must

otherwise recognise the Institute's copyright in the data.[66] Commercial entities can access the data under a Material Transfer Agreement, which similarly notes that the Institute retains copyright, and that the data are to be used solely for academic (non-profit) research purposes unless the user obtains a licence to use the material for commercial purposes.[67] Other clauses provide that the material shall not be shared with other researchers, deposited in a database, merged with any other data, or transferred to any third party. The Institute also established protocols for collaborations such as gene mapping, expression profiling, proteomics and metabolic profiling. The terms of the two-year collaboration agreements ensure that the Institute retains ownership of copyright data and patented inventions, and will share any benefits arising from commercial research from applications of the rice genome.

Some researchers have expressed reservations about these contracts. Rod Wing, Director of the Clemson University Genomics Institute, observed:

> Anybody should be concerned. The concept of owning the most important food crop in the world raises serious ethical issues there that need to be addressed. I think it's inevitable that some genes, no matter what, will end up being patented. And my understanding is that Syngenta is going to try to patent every single thing they can. I had this thought yesterday—a dream—that a genome like rice should be considered a national park, where it's a resource for the world. In Asia, rice is like a religion, so to own a religion is impossible. We're going to press on as hard as we can to get rice into the public domain as soon as possible.[68]

Mike Gale, Head of the Comparative Genetics Unit at the John Innes Centre in Norwich, England maintains that rice shares its major genes with the other cereals.[69] He believes that Syngenta's work is of little use if it cannot be shared because of exacting contractual arrangements.[70]

Copyright Database Protection

Syngenta asserts that it has copyright protection over the database of the rice genome.[71] Similarly, the business statement of Celera Genomics concludes that it depends upon copyright protection of its databases even though copyright law currently provides uncertain protection regarding copying and resale of factual data.[72]

In Australia, it is possible to obtain general copyright protection of databases under the 'sweat of the brow' doctrine. In *Telstra* v *Desktop Marketing Systems*, the Federal Court, on the basis of English precedents which suggest that only skill and labour are required to obtain copyright protection, held that there was originality in the directories created through Telstra obtaining and listing the data.[73] Because of insufficient prospects of success, the High Court declined to grant special leave to Desktop Marketing Systems to appeal.[74] Justice Hayne stated that *Feist* did not represent the law in the United Kingdom or Australia and further held that the meaning of originality had been definitively settled in Australia in a number of previous precedents of the High Court.[75] This decision is a surprising one, especially given the policy debate over the level of originality.

In the United States, there is some doubt as to copyright protection of databases. In *Feist Publications Inc* v. *Rural Telephone Service Inc*, the United States

Supreme Court held that a telephone directory lacked sufficient originality to be protected as a copyright work.[76] Justice O'Connor emphasised the need for a work to have a 'creative spark':

> To be sure, the requisite level of creativity is extremely low; even a slight amount will suffice. The vast majority of works make the grade quite easily, as they possess some creative spark, 'no matter how crude, humble or obvious' it might be. Originality does not signify novelty; a work may be original even though it closely resembles other works so long as the similarity is fortuitous, not the result of copying.[77]

The Court criticised the 'sweat of the brow' doctrine under which copyright is seen as a reward for the hard work that went into compiling facts. It found that a telephone directory, which contained only factual information, such as phone numbers, addresses, and names listed in alphabetical order, lacked the requisite originality because the respondent had not selected, coordinated, or arranged the facts in any original way.

Since 1996, several *sui generis* database protection bills have been introduced into the United States Congress.[78] Congress is currently debating two bills.[79] The first, the *Database and Collections of Information Misappropriation Bill 2004* (HR 3261), seeks to prohibit the misappropriation of certain databases by making it illegal to take a 'quantitatively substantial' part of the information in a database and make it commercially available in the same market without the authorisation of the database owner. However, following amendment and approval by the House Judiciary Committee, the Bill received an unfavourable response from the House Energy and Commerce Committee. The second Bill, the *Consumer Access to Information Bill 2004* (HR 3872), put forward as an alternative regime, narrowly defines the definition of misappropriation of a database and calls for Federal Trade Commission oversight and enforcement while denying private parties the right to sue. Both the House Judiciary Committee, and the House Energy and Commerce Committee support this Bill. There remains staunch opposition from public domain groups, scientific organisations and libraries, who question the need for legislative protection of databases.[80]

In *American Geophysical Union* v. *Texaco Inc*, Justice Jacobs concludes that there is a need to reinterpret copyright law and the defence of fair use in the light of its impact on scientific practice:

> Since the copyright laws seek to stimulate *creativity* we should consider the incentives chiefly from the perspective of the authors and scientists. It has been recognized by this Court that in the scientific community, 'what is valuable [to the authors] is recognition because it so often influences professional advancement and academic tenure'. From their point of view, then, what is truly important is the wide dissemination of their works to their colleagues … Nowhere in the case law is there support for the proposition that the monopoly granted by copyright is designed to ensure the holder a maximum economic return; rather, the law's purpose is to balance competing interests—assuring the author a *fair* return, while permitting creative uses that build upon the author's work.[81]

To promote the public interest, there is a need to override contracts and material transfer agreements which place undue restrictions on access to scientific data. If

companies cannot obtain copyright protection over scientific databases, there would be less incentive for private companies to monopolise essential scientific information.

European Database Directive

The *European Database Directive* provides 15 years of protection for the contents of a database and each significant update, and permits database owners to prevent the use of substantial parts of a database. 'As the United States has not yet enacted corresponding domestic legislation, US companies engaged in the biological data business might consider setting up their databases in Europe if they want to be eligible for this type of supplementary protection',[82] but as Bernt Hugenholtz reports, '… five years after the adoption of the Database Directive the contours of the new database right remain obscure'.[83]

The Directive, which is currently under review, has a number of critics. The Royal Society of the United Kingdom argues that it is inappropriate for scientific data and recommends it be repealed or substantially amended.[84] Similarly, the ethics committee of the Human Genome Organisation (HUGO) has challenged the Directive. Its recent statement on genomic databases adopts the principle that genomic databases be considered global public goods, and calls for all genetic information in databases to be freely accessible in perpetuity.[85] The committee acknowledges both the potential global good arising from genetic research and the scientific and clinical uses of genomic databases, as well as the 'potential for conflicts between the free flow of information that is crucial to research advances and the legitimate rights to return from research expenditure'.[86]

Recognising that some very valuable databases are already in private hands, such as the human genetic sequence produced by Celera Genomics and the rice genome sequence held by Syngenta, the HUGO committee hopes to forestall a situation in which databases are commonly privatised. 'The impetus should be to give people knowledge rather than gaining money', says one committee member.[87] A compromise would be a subscription website, run by the government or a university, with a token fee for access. Contributors could receive a portion of the fees based on how often their data were accessed—much like royalties paid for songs played on the radio.

Although HUGO's statement is at this stage aspirational, the committee is recommending concrete change by lobbying the European Union to allow greater access so as to reflect the principles set out in the TRIPS Agreement.[88] Under the *European Database Directive*, if a private genetic database holds information that can be used to treat a disease such as severe acute respiratory syndrome (SARS) or HIV, but withholds it from the research community, it would be difficult to force the owners to allow access.[89] Bovenberg argues that one way to implement HUGO's statement would be to amend EU database law so that compulsory licensing would allow access to databases under certain conditions, such as a public health emergency.[90]

Greenbaum and Gerstein have called for the development of a universal legal framework.[91] Specifically, they advocate legislation narrow in scope and broad in academic exemptions: 'This legislation ought to promote research—through compulsory licensing and limiting technological safeguards—as well as promoting database creation through simply and uniformly protecting investment in databases'.[92] Suspicious of the increasing reliance upon technological protection

measures to protect databases, they propose that it be mandatory that databases adhere to interoperability principles and limit technological protections as a prerequisite to attaining *sui generis* protection.

In 1996, the World Intellectual Property Organisation (WIPO) proposed a draft treaty dealing with database protection.[93] However, it was not adopted at that time. In 2004, at the 11th Session of WIPO's Standing Committee on Copyright Law and Related Rights, the protection of non-original databases was reconsidered. The European Union supported the development of a treaty; the United States thought that the topic should remain on the agenda, but there remained vigorous opposition from influential developing countries, such as India and Brazil, as well as from non-government organisations, such as the Civil Society Coalition and the Union for the Public Domain.[94]

Whatever the jurisdiction, biotechnology industry companies will have to establish that databases are original works in the face of allegations that they draw upon public databases.[95] However, Bovenberg foresees complications:

> More confusing in this respect and a potential legal battleground is the fact that DNA sequence databases are typically made of the contributions of multiple contributors; it took the results of a collaboration involving 20 groups from the United States, the United Kingdom, Japan, France, Germany and China to produce a draft sequence of the human genome. Both the collection of raw sequence data and the annotations or proposals for the functions of the genes in the database often represent substantial pieces of research in themselves. Even those created by commercial genomics companies are the result of the combination and extension of a mix of commercial and non-profit databases.[96]

However, the hurdle of originality is not an insurmountable one. Even under the *Feist* test, only a modicum of creativity is required. As long as Syngenta and other biotechnology companies add sufficient value to the information, they should be assured of copyright protection for their genetic information.

Part 3. The Times They Are A Changin': Patent Law and the Patrinos/Drell Proposal

The controversies over scientific publishing call into question whether patent law serves to help the free flow of scientific information. Some commentators focus on the public benefits that flow from the grant of patents. Sherman and Bently emphasise the information function of the patent system: '… patents act as incentives to individuals or organisations to disclose information that may have otherwise remained secret'.[97] Others doubt whether patent law serves to circulate information. Macdonald comments that patent owners are strategic players who seek to minimise disclosure of patent information:

> In the virtual world, the patent can represent—can be—almost anything—an entitlement, an encapsulation of information, an insurance, a currency, an advertisement, a weapon, a status symbol, a reward, a signal. In this world, there is no pressure from patent owners to have their property treated more like tangible property; the less tangible the better.[98]

Eisenberg explores the potential negative impact of patent rights in the field of biotechnological research: 'By providing such broad exclusive rights, patent law

may aggravate pre-existing conflict between scientific norms and the reward structure of science'.[99] She believes that the key values that have produced an ethos of science—what Merton defines as universalism, communism, disinterestedness, and organised scepticism—will be threatened.

Syngenta would contest that this is not the case, arguing that patent protection stimulates innovation and openness in scientific research and allows for technology transfer to developing countries. The company articulates its position on intellectual property on its website:

> Patents are essential to encourage innovation and openness in scientific research. Denial of intellectual property rights should not be used as a means to regulate or restrict scientific research. This would discourage transparency, stifle investment in technological advances and confine knowledge. There is no case for treating biotechnology inventions differently to any other invention. Syngenta provides patented technology royalty-free to benefit subsistence farmers in developing nations, on a case-by-case basis, through agreements with research institutions.[100]

Since its formation, Syngenta has taken out nearly 300 patents. The company has been quite willing to enforce its patents against its competitors.[101]

Its collaborator on the rice genome project, Myriad Genetics, explains its intentions in relation to access to information and the rice genome:

> Myriad and TMRI will seek patent protection for inventions relating to specific gene uses that result from this project. In some cases, these inventions will include the composition of a gene. The sequence generated by this project will be made available to researchers via a genome technology access agreement. Myriad and Syngenta will seek patent protection for particular uses of selected genes. Neither Myriad or Syngenta will seek a patent on the rice genome.[102]

In 2004, Syngenta lodged a provisional patent application in respect of identification and characterisation of the plant genes.[103] The abstract notes: 'The present invention relates to nucleic acid molecules obtainable from the rice genome that encode protein products that are involved in the development and timing of flower formation in plants and which can be used to modulate flower development, architecture and flowering time'. There was much protest about the breadth of the claims contained in this patent—in particular, the general application to plants and flowers.[104] Reportedly, the company has agreed to let this particular patent lapse after pressure from environmental groups.[105]

Non-government organisations are hostile towards patent protection for rice and other crops. The ETC Group,[106] which campaigns on agricultural and environmental issues, argued that '[a]ny attempt to privatise the genetic blueprint of the world's most important food crop is a threat to food security'.[107] Moreover, it alleges that Syngenta could use material transfer agreements to gain 'first rights to any commercial results and/or prohibit the sharing of resulting materials with third parties'.[108] The ETC Group awarded Syngenta a Captain Hook Award for Biopiracy in 2002 for the worst anti-food security.[109] It argued that patents on staple food crops jeopardise the ability of the poor to feed their families. Such sentiments have also been expressed by some members of the scientific community: 'Any attempt by a private company to assert its rights over a plant as fundamental to humanity as rice is wholly wrong and completely immoral'.[110]

Timed Release of Information

On 6 June 2002, Patrinos and Drell from the United States Department of Energy weighed into the debate, arguing that release of biological data policies should reflect the realities of private research and commerce.[111] The authors take issue with the complaints about the publication of the human genome and the rice genome in *Science*, and put forward a number of alternative approaches.

First, Patrinos and Drell argue that scientific information published in a scientific journal could be released on a timer 'to permit a set duration for commercial exploitation (including filing of patent applications) on inventions derived from the data'.[112] As with a provisional patent in the US, where one year is allowed before conversion to a utility patent application (thus allowing additional research to clarify the invention's value whilst keeping the early priority date), one year might be reasonable for such a timer.[113] The responsibility for implementing this scheme could rest with the journal or with a respected non-profit foundation which, after consultation with GenBank (or other public repository), could provide access to the necessary files after the timer expires. The authors conclude that '[t]his role might be uncomfortable for journals and trustees, so it is important to explore fully a mechanism that all sides would have confidence in'.[114] They note, though, that additional concerns could arise if the data had implications for national or international security.

Similarly, Pesko, in *Genome Biology*, defends the decision made by Kennedy and *Science* not to require the deposit of the rice genome sequence in GenBank.[115] He argues that such a system of publishing reflects the dual purpose of the patent regime 'to allow the world to use the fruits of creativity and research as well as to provide exclusivity of profit for the originators'.[116] He argues that some mechanism must be found to get important genomic information out into the community, and that the Syngenta licensing model is one means of doing so. He adds: 'It would be easy to add a requirement for GenBank deposition as well, after some waiting period (six months, perhaps, or a year) that would allow the companies in question to allow for some small measure of control over the results of their efforts'.[117] Pesko concludes: 'Like all compromises, Kennedy's decision displeased many people, but even though his rice policy goes against the grain, it contains a kernel of the wisdom we need to deal with the complex and changing world that genomics has given us'.[118]

Experimental Use Exemption

Second, Patrinos and Drell, concerned that the experimental use exemption under US patent law has been narrowly interpreted, support the development of an experimental research use exemption so as to 'permit the advancement of science using new technologies—such as PCR (polymerase chain reaction) or expressed sequence tag (EST) sequences as probes—without fear that the inventor of the technology would "reach through" to claim intellectual property rights on new discoveries and thus discourage the original research'.[119] Such protection 'would not extend to the use of someone else's patented technology for an economic return, only for fundamental research intended for open publication and dissemination'.[120]

Such a proposal has some academic support.[121] The defence of fair use in copyright law would provide a useful model.[122] Essentially, fair use turns on the

degree to which the infringer has added substantial value to the original work and 'transformed' it in some way.[123] As Gitter notes: 'Such an exemption is appropriate for biotechnology research, especially research relating to homologous DNA sequences, since later inventions often contribute significant information about a particular sequence's function, thereby transforming scientists' understanding of that sequence'.[124] However, a fair-dealing style defence to patent law remains controversial amongst patent holders.

In the recent case of *Madey* v *Duke University*, the United States Court of Appeals for the Federal Circuit denied that the experimental use defence inoculated uses that were solely for research, academic or experimental purposes.[125] It held that the defence was very narrow and was limited to actions performed for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.[126] The Court stressed that the defence did not immunise any commercial use or conduct that is in keeping with the alleged infringer's legitimate business. Accordingly, Duke University could not rely upon the defence because the projects 'further the institution's business objectives, including educating and enlightening students and faculty'.[127] The United States Supreme Court refused to hear an appeal.

The decision of the Court of Appeals has been widely criticised. Eisenberg notes that 'it eviscerated [the experimental use defence] to the point that it is essentially useless to research universities'.[128] She comments that the 'seemingly disingenuous opinion … neither conforms to the implications of precedent nor explains the reasons for steering the law in a different direction but pretends that prior courts never meant to give research science special treatment'.[129] Eisenberg concludes that the defence 'could have evolved on a case-by-case basis as a tool for mediating between the private interests of patent owners and the public interest in unfettered scientific progress, but the Federal Circuit has shown no appetite for such a nuanced role'.[130]

The Federal Trade Commission was also critical of the decision because it 'has a potential to upset the equilibrium regarding research uses of patented inventions and may heighten any problems raised by uncertainty over the reach of the experimental use defense'.[131] In its workshops, the Commission considered three scenarios in relation to the scope of the exemption. One involved research on a patented invention to see how or if it works. Panellists generally supported a research exemption for this purpose. A second scenario involved research to improve a patented invention, either creating a blocking situation (in which both the initial and the follow-on innovator need licences to use the other's invention) or designing around the initial patent. Panellists expressed a range of views—from support through uncertainty and doubt—about whether this research should be exempted. Third, there is the possibility of using a patented item as a research tool to create an unrelated product. Panellists generally voiced objections to exempting patented items produced for use by researchers. There remains great debate over the nature and scope of the defence of experimental use not only in the United States, but also in the European Union and Australia.[132]

Public/Private Collaboration

Third, Patrinos and Drell support greater private/public sector collaboration to encourage a relaxation of restrictions upon scientific data. Collaboration could include personnel exchange programmes, such as academic scientists working in a

private laboratory or a university department offering adjunct appointments to private-sector scientists. Another option might be direct funding of academic research by the private sector.

> Whatever the specifics, the benefits are in both directions: academic expertise and legitimacy would become more available to companies; private-sector research would become more accessible to academic scientists. Ideally, this becomes a 'win–win' situation for both sectors. Although such interactions have been common in other disciplines, the practice in biology is limited.[133]

The authors cite a number of precedents for successful public–private collaboration. First, the Keck Graduate Institute in California has graduate students conducting company-sponsored research under confidentiality agreements in exchange for publication rights. Second, the SNP Consortium involved a partnership on single-base-pair variants useful for trait mapping, which placed into the public domain valuable genomic sequence information. Third, the IMAGE Consortium is involved in complementary DNA sequences representing expressed human genes. Of the latter, they conclude: 'The commercial partners became valued contributors, having made the assessment that the value of restricting the data was less than the expected benefits of making them freely available'.[134] However, they acknowledge that such a plan is not without hazards, given the unpredictability of some commercial ventures and the long-term sustenance needs of databases.

Role of Scientific Journals

Finally, the authors note that scientific journals will have to act as gatekeepers and trustees of data:

> Whatever policy or policies are promulgated by scientific communities, it is the journals that, as a practical matter, must enforce them. The tradeoff has always been between the prestige of publishing in *Nature*, *Science* or other high-profile journals in exchange for openness and unrestricted access to the relevant data. What expectations of the journal review process are reasonable? In an era when the source data for a publication might be the complete multi-million base-pair sequence for an organism, which is obviously beyond the capacity of any journal to print, access must be via websites and the Internet.[135]

Reviewers would be temporary trustees of the data under review for publication; as fiduciaries, they would be required to respect the information as confidential. The authors argue that the academic scientific community should be willing to forgo the principle of universal free access in return for the publication of data. Otherwise, 'an increasing fraction of the 60% or so of genomics research that is conducted in the private sector will remain unavailable to academic and government scientists. In our view, that is too high a price to pay'.[136]

Patrinos urges people to recognise the importance of the emerging biotechnology industry and avoid adopting a set of 'feel-good' data-release policies that could cut the academic world off from some of the most exciting research now being done.[137] He argued instead for a 'trench-by-trench' campaign, accommodating the rules of publishing to the circumstances of the author.[138] Noting that private investment in research is increasing, Patrinos also warns that agencies such as the

Department of Energy and NHGRI may have less clout than before, thus making it difficult to enforce the rules you would like us to enforce.[139] Patrinos and Dell conclude:

> Science has never been the exclusive province of the academic world … Private-sector science has its legitimate interests. The burden of argument is on the academic sector to attract and justify greater openness on the part of private-sector science by stating clearly what benefits this will bring to companies. Above all, it requires openness to new approaches, bereft of fundamentalism, regarding access to data that governments did not fund and cannot claim to own.[140]

This position has received a mixed response. Kennedy welcomed the commentary on data access by Patrinos and Drell,[141] but sought to make a number of corrections of the collaboration with Celera Genomics. The editors of *Nature* were rather more circumspect about the merits of the proposal, stressing 'that restricted access to data that we publish is in general inappropriate particularly where public projects and databases exist' but encouraging the research community to consider and respond to the proposals.[142] The response by O'Malley and colleagues is that '[s]uch reasoning may be the start of a slippery slope leading to different standards and treatment for privately funded, profit-making science'.[143]

Conclusion

The controversies over the publication and data sharing of the human genome and the rice genome have generated calls for a reform of scientific norms, copyright standards, and patent law. There has been the development of an open access movement in opposition to the 'walled gardens' of commercial publishers, such as *Science*.[144] There has been a concerted push to establish a 'scientific commons'.[145] Such efforts represent an effort to defend traditional scientific values of open access and publication in the new digital environment. As Cech observes:

> The data generated by modern science may be increasingly diverse and complex and present novel challenges, but the power of the principles first established by Henry Oldenburg and the Philosophical Treatises of the Royal Society in 1665 remain undiminished. The rewards of publication counterbalance inclinations to secrecy. Oldenburg's simple idea created an ethic of open disclosure of scientific results that has lasted for centuries and served to move science forward.[146]

Proposals favouring open access, such as those made by the United States National Academies of Science, could be reinforced by reforms to copyright law to allow greater access to scientific information. As Justice Jacobs observed in *American Geophysical Union* v *Texaco Inc*, copyright law should promote the primary public interest in the free flow and exchange of scientific information amongst researchers and sciences.[147] There are concerns that the patent system fails to promote the circulation of information. To address this problem, patent applicants should be encouraged to release data quickly and fully into the public domain. This very problem was noted by Justice Binnie of the Canadian Supreme Court, who stressed

'the public interest in avoiding cluttering the public domain with useless patents and granting monopoly rights in exchange for speculation or misinformation'.[148] Under patent law, there must also be access to a broad defence of experimental use to facilitate scientific research. Such reforms would help foster greater international communication and collaboration in the life sciences.

Notes and References

1. Matthew Rimmer, BA (Hons)/LLB (Hons) (ANU), PhD (UNSW), is a Senior Lecturer at ACIPA, the Faculty of Law, the Australian National University. The author is grateful to Brad Sherman, Kathy Bowrey, Stuart MacDonald and the referees for their comments on earlier drafts of this paper. He is indebted to Elsa Gilchrist and Katrina Gunn for their research assistance. This project has been supported by an ARC Discovery Grant (Gene Patents in Australia: Options for Reform) and an ARC Linkage Grant (The Protection of Botanical Innovations).
2. J. Guédon, 'In Oldenburg's long shadow: librarians, research scientists, publishers, and the control of scientific publishing', in *Creating The Digital Future*, Université de Montréal, May 2001, http://www.arl.org/arl/proceedings/138/guedon.html.
3. *Ibid.*
4. The International Human Genome Sequencing Consortium, 'Initial sequencing and analysis of the human genome', *Nature*, 409, 2001, pp. 860–921.
5. J. C. Venter *et al.*, 'The sequence of the human genome', *Science*, 16 February 2001, pp. 1301–4.
6. J. Yu *et al.*, 'A draft sequence of the rice genome (*Orryza Sativa* L. ssp *Sativa*)', *Science*, 5 April 2002, pp. 79–92; and S. J. Goff, 'A draft sequence of the rice genome (*Oryza sativa* L. ssp. *japonica*)', *Science*, 296, 2002, pp. 92–100.
7. S. Smith Hughes, 'Making dollars out of DNA: the first major patent in biotechnology and the commercialization of molecular biology, 1974–1980', *Isis*, 92, 2001, pp. 541–75; Robert Cook-Deegan, *The Gene Wars: Science, Politics and the Human Genome*, Norton, New York and London, 1994; Paul Rabinow, *Making PCR: A Story of Biotechnology*, University of Chicago Press, Chicago, 1996; Paul Rabinow, *French DNA: Trouble in Purgatory*, University of Chicago Press, Chicago, 1998; and Donna Haraway, *Modest Witness: Feminism and Technoscience*, Routledge, New York, 1997.
8. Mario Biagioli (ed.), *The Science Studies Reader*, Routledge, New York, 1999; and Mario Biagioli and Peter Galison (eds), *Scientific Authorship: Credit and Intellectual Property in Science*, Routledge, New York, 2003.
9. M. Heller and R. Eisenberg, 'Can patents deter innovation? The anticommons in biomedical research', *Science*, 280, 1 May 1998, pp. 698–701; and David Magnus, Arthur Caplan and Glenn McGee (eds), *Who Owns Life?*, Prometheus Books, New York, 2002.
10. M. Biagioli, 'Rights or rewards? Changing frameworks of scientific authorship', in Biagioli and Galison (eds), *op. cit.*, pp. 253–81; and M. Biagioli, 'Aporias of scientific authorship: credit and responsibility in contemporary biomedicine', in Biagioli (ed.), *op. cit.*, pp. 12–30.
11. Biagioli (ed.), *op. cit.*, pp. 13–4.
12. See John Sulston and Georgina Ferry, *The Common Thread: A Story of Science, Politics, Ethics and the Human Genome*, Bantam Press, London, 2002.
13. T. Sasaki and R. Sederoff, 'Genome studies and molecular genetics: the rice genome and comparative genomics of higher plants', *Current Opinion in Plant Biology*, 6, 2003, pp. 97–100.
14. International Rice Genome Sequencing Project, 'International rice genome sequencing project response to publication of draft sequences of the rice genome', 28 March 2002, http://demeter.bio.bnl.gov/March28.html.
15. *Ibid.*
16. *Ibid.*
17. The sequence data was produced primarily in the laboratories of Leroy Hood at the University of Washington in Seattle, under contract for Monsanto.

18. Monsanto, 'Commitments to our stakeholders: support for rice genome sequencing', http://www.monsanto.com/monsanto/layout/our_pledge/rice_genmo.asp.
19. Mark Winston, *Travels in the Genetically Modified Zone*, Scribe Publications, Melbourne, 2002, p. 214.
20. *Ibid*, p. 49.
21. Syngenta, 'Researchers complete rice genome map: groundbreaking discovery points to better cereal crops', 1 January 2001, http://www.syngenta.com/en/media.
22. Goff, *op. cit.*
23. P. Moore, 'Publication with a pinch of privatisation', *The Scientist.com*, 4 April 2002.
24. 'Accessing the celera human genome sequence', http://www.sciencemag.org/feature/data/announcement/gsp.shl.
25. Guédon, *op. cit.*
26. D. Kennedy, 'The importance of rice', *Science*, 5 April 2002, p. 13, http://www.sciencemag.org/cgi/content/summary/296/5565/13. See also J. Amos, 'Genome dispute touches rice', *BBC News*, 4 April 2002, http://news.bbc.co.uk/1/hi/sci/tech/1910889.stm.
27. *Ibid.*
28. Moore, *op. cit.*
29. D. Butler, 'Geneticists get steamed up over public access to rice genome', *Nature*, 14 March 2002, pp. 111–2.
30. P. Bourdieu, 'The specificity of the scientific field and the social conditions of the progress of reason', *Social Science Information*, 14, 6, 1975, pp. 19–47.
31. Guédon, *op. cit.*
32. E. Marshall, 'A deal for the rice genome', *Science*, 296, 5 April 2002, p. 34.
33. Amos, *op. cit.*
34. *Ibid.*
35. *Ibid.*
36. 'International rice genome sequencing project–Syngenta rice genome announcement release', 23 May 2002, http://www.nias.affric.go.jp/pressrelease/2002/20020523/announcement.html; and 'Completion of the rice genome sequence announced', 18 December 2002, http://rgp.dna.affrc.go.jp/Dec_18NEWS.html.
37. G. Vogel, 'Retreat from Torrey Mesa: a chill wind in ag. research', *Science*, 298, 13 December 2002, p. 2106.
38. 'Diversa and Syngenta complete transactions announced in December', 20 February 2003, http://www.diversa.com/presrele/2003/view_release.asp?id=20030220.
39. Vogel, *op. cit.*
40. *Ibid.*
41. 'Completion of the rice genome sequence', 18 December 2002, http://rgp.dna.affrc.go.jp/Dec_18NEWS.html.
42. E. Campbell *et al.*, 'Data withholding in academic genetics: evidence from a national survey', *Journal of the American Medical Association*, 287, 4, 23 January 2002, pp. 473–80.
43. Committee on Responsibilities of Authorship in the Biological Sciences, *Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences*, National Academies Press, Washington, DC, 2003.
44. *Ibid*, p. vii.
45. For a discussion of scientific fraud, see Marcel La Follette, *Stealing into Print: Fraud, Plagiarism and Misconduct in Scientific Publishing*, University of California Press, Berkeley, 1992.
46. Committee on Responsibilities of Authorship in the Biological Sciences, *op. cit.*, p. 2.
47. *Ibid.*
48. *Ibid*, p. 43.
49. National Institutes of Health, 'Final NIH statement on sharing research data', 26 February 2003, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.
50. *Ibid.*
51. *Ibid.*

52. National Institutes of Health, 'Frequently asked questions on data sharing', 5 March 2003, http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm.
53. *Ibid.*
54. *Ibid.*
55. The Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science*, Royal Society, London, April 2003a, http://www.royalsoc.ac.uk/files/statfiles/document-221.pdf.
56. The Royal Society, 'Gold rush mentality. Damaging science and delaying development of medicines', 14 April 2003b, http://www.royalsoc.ac.uk/files.
57. The Royal Society, 2003a, *op. cit.*, p. 30.
58. *Ibid*, p. 24.
59. *Ibid*, p. 30.
60. Science and Technology Committee Hearings, *Scientific Publications*, House of Commons, 1 March 2004, 8 March 2004, 21 April 2004 and 5 May 2004.
61. The Royal Society, *Royal Society Response to the House of Commons Science and Technology Committee into Scientific Publications*, February 2004, http://www.royalsoc.ac.uk/files/statfiles/document-252.pdf.
62. J. Silva, 'Copyright protection of biotechnological works: into the dustbin of history', *Boston College Intellectual Property and Technology Forum*, 28 January 2000; S. Coke, 'Copyright and gene technology', *Journal of Law and Medicine*, 10, 2002, p. 97; Rebecca Eisenberg, 'Molecules v. information: should patents protect both?', *Boston University Journal of Science and Technology Law*, 8, 2002, pp. 190–217; M. Rimmer, 'Beyond blue gene: intellectual property and bioinformatics', *IIC*, 34, 1, 2003, pp. 31–49; and Scott McBride, 'Bioinformatics and intellectual property', *Berkley Technology Law Journal*, 17, 2003, p. 1331.
63. Steve Briggs of the Torrey Mesa Research Institute quoted in R. Walgate, 'Syngenta claims ownership of rice—but will give data away', *The Scientist.com*, 1 February 2001, http://www.biomedcentral.com/news/20010201/05.
64. *Ibid.*
65. P. Brickley, 'A scrap over sequences—take two', *The Scientist.com*, 13 May 2002, http://www.the-scientist.com/yr2002/may/prof_020513.html.
66. Syngenta, 'Summary of terms of rice genome access agreements', http://www.tmri.org/en/partnership/summary.aspx.
67. *Ibid.*
68. Walgate, *op. cit.*
69. *Ibid.*
70. *Ibid.*
71. Syngenta, 'Summary of terms of rice genome access agreements'.
72. PE Corporation, *Annual Report*, 2000, p. 52.
73. *Desktop Marketing Systems Pty Ltd* v *Telstra Corporation Limited* (2002) 55 IPR 1; for commentary, see S. Gosnell, 'Feeling rather "sweaty" down under … but would we be better off with a northerly change? An Australian perspective on the legal protection of compilations of information', *The University of New South Wales Law Journal*, 26, 3, 2003, p.639; and B. Fitzgerald and C. Bartlett, 'Database protection under Australian copyright law: Desktop Marketing Systems Pty Ltd v Telstra Corporation Limited [2002] FCAFC 112', *Southern Cross University Law Review*, 7, 2003, p. 308.
74. *Desktop Marketing Systems Pty Ltd* v *Telstra Corporation Limited*, 20 June 2003, High Court special leave application, http://www.austlii.edu.au/au/other/hca/transcripts/2002/M85/1.html.
75. *Sands and McDougall Proprietary Ltd* v *Robinson* (1917) 23 CLR 49; *Victoria Park Racing and Recreation Grounds Company Limited* v *Taylor and Others* (1937) HCA 45; *Computer Edge Pty Ltd* v *Apple Computer Inc* (1986) 161 CLR 171; and *Data Access Corporation* v *Powerflex Services Pty Ltd* (1999) 45 IPR 353.
76. *Feist Publications* v *Rural Telephone Service Inc* (1991) 113 L. Ed. 2d 358.
77. *Ibid.*

78. Mark Davison, *The Legal Protection of Databases*, Cambridge University Press, New York, 2003.
79. J. Band, 'The database debate in the 108th US Congress: the saga continues', *European Intellectual Property Review*, 27, 6, 2005, pp. 205–12.
80. C. Doctorow, 'Database protection in the United States of America', http://www.eff.org/IP/WIPO/20040607_database_protection.pdf.
81. *American Geophysical Union* v. *Texaco, Inc.* (1994) 60 F.3d 913 [133]–[135].
82. J. Bovenberg, 'Should genomics companies set up database in Europe? The EU Database Protective Directive revisited', *European Intellectual Property Review*, 23, 8, 2001, p. 361.
83. B. Hugenholtz, 'The new database right: early case law from Europe', paper presented at *Ninth Annual Conference on International IP Law and Policy*, Fordham University School of Law, New York, 19–20 April 2001.
84. The Royal Society, 2003a, *op. cit.*, p. 27.
85. H. Pearson, 'Database free for all: human genome organisation calls for open-access sequence repositories', *Nature*, 30 April 2003, http://www.nature.com/nsu/030428/030428-10.html.
86. HUGO Ethics Committee, *Statement on Human Genetic Databases*, December 2002, http://www.hugo-international.org/Statement_on_Human_Genomic_Databases.htm; and H. Thorsteinsdottir, A. Daar, R. Smith and P. Singer, 'Genomics—a global public good?', *Lancet*, 15 March 2003, pp. 891–2.
87. Pearson, *op. cit.*
88. *Ibid.*
89. M. Rimmer, 'The race to patent the SARS virus: the TRIPS agreement and access to essential medicines', *Melbourne Journal of International Law*, 5, 2, October 2004, pp. 335–74; and M. Rimmer, 'The Jean Chretien pledge to Africa act: patent law and humanitarian aid', *Expert Opinion on Therapeutic Patents*, 15, 7 July 2005, pp. 889–909.
90. J. Bovenberg, 'Access to essential databases', *Human Genome Meeting*, Cancun, Mexico, 27–30 April 2003.
91. D. Grenbaum and M. Gerstein, 'A universal legal framework as a prerequisite for database interoperability', *Nature Biotechnology*, 21, 9, 2003, pp. 979–82.
92. *Ibid*, p. 982.
93. World Intellectual Property Organization, 'Basic proposal for the substantive provisions of the treaty on intellectual property in respect of databases', December 1996, http://www.wipo.int/documents/en/diplconf/6dc_sta.htm.
94. Union for the Public Domain, '11th meeting of the WIPO Standing Committee on Copyright and Related Rights', 7 June 2004, http://www.public-domain.org/?q=node/view/39.
95. Tim Hubbard from the Sanger Centre claims that Celera Genomics sought to hijack the public Human Genome Project. He alleges that the genome assembled in the private domain was based on what came out in the public domain. Of course, Celera Genomics denies such claims. The leader of the bioinformatics project, Gene Myers, points out that the firm was able to map Drosphilia without any assistance from the Human Genome Project.
96. Bovenberg, 2001, *op. cit.*, p. 361.
97. Brad Sherman and Lionel Bently, 'Introduction to patent law', in *Intellectual Property Law*, Oxford University Press, Oxford, 2001, Chapter 14.
98. S. Macdonald, 'When means become ends: considering the impact of patent strategy on innovation', *Information Economics and Policy*, 16, 1, 2004, pp. 135–58.
99. R. Eisenberg, 'Proprietary rights and the norms of science in biotechnology research', *Yale Law Review*, 97, 1987, p. 177.
100. Syngenta, 'Position statements: patents', http://www.syngenta.com/en/about_syngenta/our_views.aspx.
101. Syngenta, 'Syngenta files suit to enforce biotechnology patents', 26 July 2002, http://www.syngenta.com/en/media/article.asp?article_id=234.
102. Myriad Genomics, 'Rice genome: frequently asked questions', 2003, http://www.myriad.com/research/rgfaq.html#ai.
103. PCT Patent Application PCT/EP02/06968 (WO/03000904).

104. P. Oldham, 'Global trends in intellectual property claims: genomics, proteomics, and biotechnology', 2004, http://www.cesagen.lancs.ac.uk/resources/docs/genomics-final.doc; and ETC Group, 'Syngenta claims multi-genome monopoly', 10 January 2005, http://www.etcgroup.org/article.asp?newsid=494.
105. ETC Group, 'Syngenta to let Mega-Genome patent lapse: "Daisy-Cutter" patent busted', 14 February 2005, http://www.etcgroup.org/article.asp?newsid=502.
106. The ETC Group is the action group on erosion, technology, and concentration, http://www.etcgroup.org/. It was formerly called the Rural Advancement Foundation International.
107. A. Salleh, 'Rice genome—very early days', *ABC Science*, 5 April 2002, http://www.abc.net.au/science/news/stories/s521385.htm.
108. *Ibid.*
109. *Ibid.*
110. G. Vince, 'Rice genome access a growing concern', *New Scientist*, 19 March 2002; and M. Ashburner, 'Whose cells are they anyway?', *Open Democracy*, 25 October 2001, http://www.opendemocracy.net/debates/article-9-79-409.jsp.
111. A. Patrinos and D. Drell, '"The times they are a-changin": policies on release of biological data should reflect reality, to the benefit of all', *Nature*, 417, 6 June 2002, pp. 589–90.
112. *Ibid.*
113. *Ibid.*
114. *Ibid.*
115. G. Pesko, 'Grain of truth', *Genome Biology*, 3, 5, 25 April 2002, http://genomebiology.com/2002/3/5/comment/1007.
116. *Ibid.*
117. *Ibid.*
118. *Ibid.*
119. Patrinos and Drell, *op. cit.*
120. *Ibid.*
121. D. Gitter, 'International conflicts over patenting human DNA sequences in the United States and the European Union: an argument for compulsory licensing and a fair use exemption', *New York University Law Review*, 76, 2001, p. 1623.
122. M. O'Rourke, 'Toward a doctrine of fair use in patent law', *Columbia Law Review*, 100, 5, 2000, p. 1177.
123. *Campbell* v *Acuff-Rose Music* (1994) 127 L Ed 2d 500.
124. Gitter, *op. cit.*
125. *Madey* v *Duke University* (2002) 307 F.3d 1351.
126. *Ibid.*
127. *Ibid.*
128. R. Eisenberg, 'Patent swords and shields', *Science*, 299, 14 February 2003, pp. 1018–9.
129. *Ibid.*
130. *Ibid.*
131. Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, A Report by the Federal Trade Commission, October 2003, p. 37, http://www.ftc.gov/os/2003/10/innovationrpt.pdf.
132. For a comprehensive account of the policy debate over the patent defence of experimental use, see M. Rimmer, 'The freedom to tinker: patent law and experimental use', *Expert Opinion on Therapeutic Patents*, 15, 2, February 2005, pp. 167–200.
133. Patrinos and Drell, *op. cit.*
134. *Ibid.*
135. *Ibid.*
136. *Ibid.*
137. E. Marshall, 'Clear-cut publication rules prove elusive', *Science*, 295, 1 March 2002, p. 1625.
138. *Ibid.*
139. *Ibid.*
140. Patrinos and Drell, *op. cit.*

141. D. Kennedy, 'Science's policy on access to private data', *Nature*, 417, 20 June 2002, p. 788.
142. Opinion, 'Genomics and taxonomy for all', *Nature*, 417, 6 June 2002, p. 573.
143. M. O'Malley, A. Roger and F. Doolittle, 'Can commercial protection be good for research?', *Nature*, 419, 12 September 2002, p. 111.
144. D. Hunter, 'Walled gardens', *Washington and Lee Law Review*, 62, 2005.
145. http://sciencecommons.org/.
146. Committee on Responsibilities of Authorship in the Biological Sciences, *op. cit.*, p. 43.
147. *American Geophysical Union* v. *Texaco, Inc.* (1994) 60 F.3d 913.
148. *Apotex* v *Wellcome Foundation Ltd* [2002] SCC 77, http://www.canlii.org/ca/cas/scc/2002/2002scc77.html.