Legal issues in bioinformatics

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Abstract

This paper is a review of legal issues in the discipline of bioinformatics. It covers the intellectual property rights (IPR) protection available to databases (together with their contents) and software. Legal problem areas that are unique to the discipline are then discussed. The paper concludes with a summary of the IPR position and recommendations that have been made for resolution of problem areas.

This paper has been written and compiled by the author as a review of current legal issues in bioinformatics and is not intended to be exhaustive. If any issue referred to in the paper is to be relied on, appropriate specific professional advice should be sought.

INTRODUCTION

Bioinformatics is the use of computers to handle, and interpret, biological information. In the last decade there have been significant technological advances in both the disciplines of computer science and molecular biology, resulting in both large-scale generation and more accurate interpretation of biological information. The information is contained in databases and interpreted using specialised software with a view to elucidating gene (through the discipline of genomics) and protein (through the discipline of proteomics) structure and function.

Increasing funds are being poured into bioinformatics in the hope of advancing the partnership of the information and life sciences. Most bioinformatics companies started off as database providers but now, as the discipline matures, there is a growth in companies mining the data and also those involved with compatibility issues (bioportal companies).

One of the greatest, if not the greatest, paradoxes that faces the discipline is the contemporaneously opposing needs for open accessibility of the software and databases constituting the backbone of the discipline against the increasing requirement to enforce intellectual property rights (IPRs) in the technology. This paper first looks at what those IPRs are. Secondly it addresses problems that have arisen in the application of the rights to the discipline. The paper concludes by considering recommendations for resolution of the discipline-specific issues, focusing on the need for multifaceted solutions reflecting the multidisciplinary nature of bioinformatics.

Problem areas in general in bioinformatics together with recommendations and conclusions for their resolution are also contained within many of the reports and workshops cited in the paper. The paper focuses predominantly on those areas that the author views as most significant from a legal perspective. The paper also aims to bring together information relating to IPR issues in bioinformatics. A detailed discussion of issues such as economics, management, public policy and ethical issues are outside the scope of the paper.

INTELLECTUAL PROPERTY RIGHTS AND BIOINFORMATICS

This section of the paper looks at IPRs in the biological molecules comprising the databases (proteins, genes and expressed sequence tags – ESTs – the fragment of the genome that is expressed by the organism), the databases themselves and associated software.

Bioinformatics databases are used in conjunction with software packages to carry out protein sequence analysis. There are many types of database[1] but for routine protein sequence analysis primary, secondary and composite databases are the

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Databases

ones of most importance. Primary databases comprise nucleic acid or protein sequence data and composite databases comprise a variety of different primary sources and are useful because they dispense with the need to utilise other resources. Secondary databases contain what is termed pattern data which are diagnostic signatures for protein families. These signatures encode the most highly conserved features of multiply aligned sequences which are often crucial to the structure or function of the protein.

There is a vast array of bioinformatics software programs,[1] many of which are used in sequence analysis in various ways. Some programs offer service integration via the intranet, others integrate facilities for database searching, motif recognition and structure visualisation.

Commercial value
Protection

Commercial value is realised in bioinformatics through the exploitation (often by way of licence arrangements) of IPRs in the biological molecules, databases and software. For example in the case of proprietary databases one company may give another exclusive access for a consideration and may also request royalties on resultant product sales. Both public domain and proprietary or commercial databases benefit from IPR protection. The difference between the two relates in IPR terms to the extent of permitted use, accessibility and enforcement of the IPRs. Bioinformatics databases may be considered to occur at many points along a public–commercial continuum with some databases essentially falling part in and part out of the public domain.[1] The terms of licences granted will often depend on whether the user is academic or commercial.

Tables 1 and 2 provide an overview summary of the intellectual property position in both the EU and the USA.

Databases

In Europe legal protection is given to databases by the European Directive on The Legal Protection of Databases (96/9) which was adopted by the Community on 27th March, 1996.[2,3] The Directive provides two main forms of protection for databases.

Table 1: Summary diagram of IPR protection in bioinformatics in the EU

	Copyright	Database rights	Patents
Software	Protection available	Not applicable	Patentability depends on whether it makes technical contribution to the art
Databases	Available to protect structure and form	Available for contents as *sui generis* right	Unclear
Biological molecules*	Yes. If amount to 'literary work' and recorded in writing. In the case of ESTs must not be too short to amount to 'literary works'	Not applicable	Criteria for patentability becoming quite restrictive Demonstration of functionality required

*Proteins and nucleic acids (including ESTs).

Table 2: Summary diagram of IPR protection in bioinformatics in the USA

	Copyright	Database rights	Patents
Software	Protection available	Not applicable	US has more liberal approach than EPO† to patentability of software programs and business methods and screening inventions
Databases	Protection available	Not applicable	Possibly – guidelines USPTO‡ followed
Biological molecules*	Yes in accordance with US copyright law	Not applicable	Criteria for patentability becoming quite restrictive Demonstration of utility required

*Proteins and nucleic acids (including ESTs).
†European Patent Office.
‡US Patent and Trademark Office.

The first is the structure and form of the database given by way of copyright protection, and the second is the contents (given by way of the so-called *sui generis* right).

Copyright

Copyright protection in databases is available to natural or legal persons of third countries and parties to the Berne Convention or World Trade Organization (WTO) TRIPs Agreement (except for a shorter term of protection – 50 years after the death of the author compared with 70 years under Directive 93/98 EEC). Copyright protection is available in the database irrespective of whether the individual components of the database (eg the individual gene sequences) attract copyright.

Copyright protects both database producers and the owners of the data that database producers may wish to use.[4] The main drawback with copyright protection to date has, however, been that the contents of a database may be copied and rearranged electronically without the authorisation of the maker ('investor') to produce a database of identical content which does not infringe any copyright in the arrangement of the database. The *sui generis* right addresses this deficiency in the copyright laws.

Sui generis

This is available in respect of databases involving a substantial investment in obtaining verification or presentation of contents. It is conferred on the investor of the database for 15 years but this can be extended into a new term when substantial new investment has occurred. If the right subsists in a database, then its maker will have the right to prevent 'extraction' (transfer to another medium) and/or 're-utilisation' (for the purpose of creating rival databases or other 'downstream' products) of the whole or of a substantial part of the contents of the database. The *sui generis* protection is available only to makers who are nationals of EU member states or have their habitual residence in the Community, or companies formed in accordance with the law of a member state and having their registered office, central administration or principal place or business within the Community. Notwithstanding this, under Article 11(3), reciprocal agreements may be concluded with third countries that offer comparable protection to EU nationals/residents.[2,3,5] Structures can be adopted using EU-based independent contractors and appropriate contractual arrangements to enable US-based companies to qualify for database rights.[5]

The Directive aims to protect investment and encourage the development of databases. It is, however, subject first to other legislation governing availability of information and second competition laws. Critics of the Directive claim that it actually prevents access to information. This topic has been widely debated in the USA where there are no distinct IPRs protecting databases and reliance is placed on copyright protection (in conjunction with state misappropriation, contract and trade secret law). The fact that the laws in the EU and USA are at present so different can have a significant impact and even an exclusion effect on EU–US collaboration. The EU may be affected by being excluded from collaborations with non-EU countries. The IPR system can in this way create unintentional effects. Because of these difficulties a complex database such as the genome database is not necessarily well covered by database law.[6]

Both copyright and the *sui generis* rights discussed above are automatic, unlike patents where filing is a legal necessity. The USA provides for the registration of copyright but these provisions are not a prerequisite for copyright, only an aid to enforcement. However, the extent of rights, the overlap of *sui generis* database and copyright law and the ownership and enforcement of these rights are highly complex.[6] In some cases a series of inter-dependent rights may have to be addressed analogous to the concept of 'dependent patents'.

One cannot leave the topic of IPRs in databases without considering the issue of patent protection both in Europe and in the USA. In looking at bioinformatics

databases the questions one might reasonable ask are, first, 'is the method for constructing a sequence database or data structure patentable?', and second, 'are the individual biological molecules patentable?'

Data structures

The position in the EU regarding bioinformatics method patents (including databases) is considered in detail in the next section on bioinformatics software. In the USA[7] data structures *per se* are not patentable but a computer or CD-ROM/floppy disk encoded with a data structure is patentable. This is laid down in Guidelines (1996) of the United States Patent and Trademark Office (USPTO).[8]

Patents

Two key cases on this point are *re Warmerdam* and *re Lowry* and where there is inconsistency between these and the guidelines the judicial decisions will be followed.[9,10] It seems to be a moot point whether a US court would consider a method for constructing a sequence database or data structure, using existing sequence information to be patentable.[7]

Biological molecules

As far as individual biological molecules (proteins and nucleic acids) are concerned,[11–14] the position in the EU is governed by the EU Directive 98/44/EC on the legal protection of biotechnological inventions[15] which came into force on 30th July, 1998. Subsequently on 1st September, 1999, the Administrative Council of the EPO introduced further new rules. The EPO has introduced amendments to the European Patent Convention (EPC) (Rule 23 Implementing Regulations to Part II EPC) which largely reflect those of the Directive in relation to the patentability of biotechnological inventions. The Directive is now used as a supplementary means of interpretation by the EPO. Under the Directive an element isolated from the human body or otherwise produced by means of a technical process can constitute a patentable invention provided that industrial application is disclosed in the patent application.

Many patent applications have been filed in the field of genomics/functional genomics claiming the output from large-scale DNA sequencing projects. The most useful information on criteria for patentability of these applications is now the trilateral web site of the USPTO, Japanese Patent Office (JPO) and EPO. An extensive discussion paper on the ethics of patenting DNA (Nuffield Council on Bioethics) is also highly relevant in this context.[16] This explains the different uses to which DNA sequences can ultimately be put and the relative merits of patent grant in each case. It is intended that the guide be used by patent offices and courts alike.

With respect to such applications currently pending at the EPO, where there is only putative function assigned to the sequence the Examining Division are likely reject them for lack of inventive step. The Examining Division is also using the introduction of the new rule 23e(3) (EPC Implementing Regulations) as a way of applying Article 57 EPC to biological molecules in a manner not previously seen.[17] The result is that the EPO is now applying an even higher threshold for industrial application in relation to biotechnological inventions than for other inventions.[12–14]

As a result far greater emphasis is being placed on demonstrable function for biological molecules than has been the case in the past and new tests for patentability of such molecules are being developed. Notably, there have been changes of emphasis with regard to Articles 56 (inventive step), 57 (industrial application) and 83 (sufficiency) EPC.[14,17,18]

The US Patent Office also attempted to create a more formal structure for examinations of certain types of biotechnology invention by revising the Examiners' Utility Guidelines for assessing compliance with utility and written description requirements.[19] Under these new guidelines utility now needs to be substantial as well as credible and specific.

With respect to the patentability of biological molecules found within these databases other important issues have

emerged such as the concept of 'reach through'. This is the term given to the method of using the identification of one target molecule to secure patent claims on more lucrative downstream products with a greater commercial value.[14,20]

Software

Software

Software programs (whether patentable or not) are regarded as literary works by copyright law and, if they are original, attract copyright protection as soon as they are written or fixed in permanent form. This protection applies to source code, object code, micro-code and preparatory design materials.[21] Different copyrights may reside in a single program and two or more authors may be entitled to the single copyright in a program.[3] The individual algorithms making up the source code in many bioinformatics suites are, however, not protected, with the result that they can be reused to develop a similar product without copyright breach.

Patents

Copyright

The current UK law relating to copyright is found in the Copyright, Designs and Patent Act 1988. This now implements the EU Directive on the Legal Protection of Computer Programs adopted in 1991 and the 1996 Directive on the Legal Protection of Databases.[22] Also of relevance is the EU Copyright Directive (2001/29/EC) – a directive on the harmonisation of certain aspects of copyright and related rights in the Information Society. This latter Directive harmonises rights in certain key areas, to cater for the needs of the Internet and e-commerce, and digital technology in general and its implementation in the UK may result in a substantial overhaul to the Copyright, Designs and Patents Act (CDPA) 1988.[23] Generally, international harmonisation of copyright law has been achieved under the Berne Convention and the main benefit of this is that the copyright of an author resident in one signatory state will be enforced in any other state.

Although much sequence analysis software is actually in the public domain (some packages are freely available over the Internet) companies prefer to purchase commercial licences for these packages (eg because of the need for support).[1]

These analytical packages should also be considered in the light of patent protection. Considerable discussion continues to take place concerning the role of the patent system in respect of software-related inventions but the trend throughout the world is to accept that software should be brought within the ambit of the patent system. Although Article 52(2) EPC and UK law excludes from patentability 'methods of doing business . . . and programs for computers' (the latter only applying to computers *as such*) last year (2002) the European Commission published a proposal for discussion for a Directive on the patentability of software inventions.[24,25]

The new proposal defines a new class of inventions entitled 'computer implemented inventions' and then sets out the conditions under which they are patentable. The main focus is on whether an invention involves a technical inventive step or makes a non-obvious technical contribution to the state of the art. The contribution is assessed by comparing the invention as a whole against the state of the art.[26]

An example of a technical method in the bioinformatics field[27] would be 'a computer-based method and program for identifying multiple polypeptides as functionally linked'. An example of a non-technical method would be 'a computer-based method and program for determining the evolutionary distance of proteins on the basis of a conditional probability calculation'.

There is no reason why a bioinformatics method, eg screening method inventions which generate technical information, should not meet the 'technical effect' standard applied by the EPO in relation to software inventions. Claire Baldock, European Patent Attorney, pointed out in her paper 'Biotechnology and gene patenting'[14] that it is also encouraging that for international

applications recently filed the EPO is issuing search reports. However, although there are a considerable number of applications pending, nothing has yet been granted. She explains that it is likely that the inventive step requirements will be the toughest hurdle for these applications at the EPO.

Another exclusion from patentability in Article 52(2) EPC and in UK law is methods for performing mental acts. Under UK law the position is that merely carrying out exercises that notionally could be done mentally, but much faster by a computer, is not enough to overcome the mental act exclusion. Many bioinformatics methods are merely methods of data comparison and could therefore under UK law attract objections on these grounds.[14,28]

Financing

Databases

In the USA[7] much discussion has also taken place over the patentability of bioinformatics software programs where computer programs *per se* are non-patentable subject matter. In contrast, a general-purpose computer programmed to carry out a specific function pursuant to instructions from a computer program is patentable.[29] The USPTO and US courts have generally been more accepting of these applications than the EPO.

Ownership

Hultquist *et al.*[7] point out in their paper that in the USA the availability under the Guidelines of patent protection for a computer-readable medium encoded with a computer program gives rise to a potential overlap between patentable subject matter and copyrightable subject matter. As the scope and term of protection afforded by copyright and patent law are substantially different, obtainment of both types of protection therefore maximises the strength of the inventor(s) or author(s) proprietary rights in such computer program. The Guidelines also provide for patents to be granted in respect of computer-based processes or methods that involve pre- and post-computer activity or are limited to a practical application. These criteria also cover a broad spectrum of bioinformatics-based activity. The USPTO has also reacted favourably to applications for screening methods which resemble business method patents which were granted to 'dotcom' companies.[20]

Over the next few years the Commission will be looking to the fallout from the USA's more liberal approach with respect to the patentability of software and business methods.[30]

LEGAL PROBLEM AREAS FOR BIOINFORMATICS

Public and private funding of databases

The financing of bioinformatics databases is inextricably linked with proprietary interest and ownership in them.[31] In the first stages of development the databases are usually financed with R&D funds.[32] This is of course justified in the early stages of development. However, later on maintenance issues become important and databases need to be seen as products. It is in the later stages of development and maturity that financing needs to be considered further and many databases of necessity switch to becoming commercial enterprises. With commercialisation comes the need for enforcing intellectual property protection. The need to patent, for example, then restricts what can be done with the working data.

The funding and ownership issues are also tied closely with accessibility issues. In the early days of bioinformatics it was always assumed that the data would be made freely available and that this was both desirable and necessary to help the research community as a whole make the best use of the data and to facilitate innovation and discovery.[33] In Europe, for access to the results of others, researchers rely almost totally on publicly available data and do not have funding for access to increasingly important IPR-protected private databases and software.

Many scenarios and arrangements are encountered in looking at database funding. These range from basic research-funded collaborations, university–public research organisation collaborations,

Collaborations

industry–university collaborations and open source collaborations. All of these raise their own set of legal and commercial issues. Problems arise as a result of the different regimes and value systems between industry and academia and the competing goals of IPR protection and freedom of access. This is further complicated by the nature of Internet collaborations. In international bioinformatics collaborations many legal rights come into complex interplay and in some cases harmonisation of those rights is lacking. Case studies have indicated that funding arrangements do in fact influence the decision as to whether or not to enforce or use IPR to obtain revenue from the use of database (or interlinked databases).[6]

One notable problem is that database protection laws are largely aimed at large data compilations rather than at multiple integrated (and evolving) databases with variable formats. There is also concern that the need to 'fix' short-term funding problems may at the same time create long-term unwanted IPR effects for bioinformatics Internet collaborations.[6]

Public/private partnerships

It has been suggested[33] that in such cases, partnership between public and private sectors might offer opportunities for sustainability. However, these relationships take time to develop. Thus, a mechanism for providing appropriate levels of continuing funding from public sources might facilitate such marriages and consequently offer a better future for bioinformatics databases.

Lack of clarity about ownership of bioinformatics databases and related software during their evolution

Ownership

A key issue in deciding whether a database can entertain a commercial relationship is legal ownership.[33] This was addressed in detail in the BTSF Workshop 'Building and Owning Biotechnology Databases'. It is pointed out that this is rarely a clear-cut issue. In many cases there is a complex trail of ownership. To date, too few databases have secured the necessary clarity on ownership. This in turn means that insufficient guarantees can be given to any third-party investor. Most academic institutions now claim (as supported by the position under CPDA 1988) that the products and IPR developed by their staff belong to that institution and the majority of staff contracts have rules and regulations as to what can be developed and on what conditions.[34]

In many cases the curator of the database might well have moved institution, been joined along the way by different staff, who are often transient short-stay, post-doctorate personnel and dependent on external grants for support. These changes might also have taken place during a time when attitudes concerning ownership were far looser. In some cases there are many people who claim at least part-ownership in a database product.[34] If researchers move institution and the IPR is vested in their original institution, there is no 'production champion' left in the original laboratory and no one to continue the work and see it through patent procurement.[35]

Questions of ownership are also convoluted because the EU Directive does not readily cater for the complexity of biological databases. It is generally accepted that the raw or primary databases, such as the nucleotide sequence data banks, should remain in the public domain. The storage and release of data in these databases is governed by a series of decisions, known as 'The Bermuda Principles', which, in this respect, state that all such data should be left in the public domain. Where IPR rights are asserted, as we have seen above the EU Directive lays down clear guidelines as to what rights an owner of a database or the data can confer on others. There are concerns, however, that the Directive restricts the 'fair use' of databases (see below).

Another interesting phenomenon seen in bioinformatics is data mining, where database users link databases together and slice through the different databases, collecting relevant pieces from different

inputs. There is no legal problem in doing this if all the rights attaching the contributory databases are honoured. The resultant product produced from such data mining may attract IPRs in their own right but great care is needed from the compiler not to abuse the rights of the contributory database owners.[34] The ownership problems faced by some bioinformatics databases are not dissimilar to problems and issues faced by the whole Internet infrastructure.[36,37]

Copyright

Copyright complexity issues

Complexity

Much debate has arisen over the suitability or applicability of international IPRs to the discipline. It is a cause of concern amongst bioinformatics professionals that the proliferation of IPRs (in terms of numbers and types through extensions, *sui generis* creations, lowering of standards and increased propensities to acquire IPRs) are not necessarily conducive to more basic research as well as to some types of research collaborations. This creates a need for neat and complementary IP approaches, eg creation of weak, open or free (in some cases), IPR regime with lower transaction costs but sustained incentive effects. Copyright laws were not created nor are they tailor-made for Internet research collaborations as is the case with software and biotechnology generally. We have also seen that the extent of rights, the overlap of database and copyright law and the ownership and enforcement of these rights are complicated.[38,39]

In considering specific copyright issues that arise it is helpful to look in detail at the origins of data in bioinformatics databases. Analogies have been drawn between databases and journals. Journals are collections of validated articles and most journal publishers request that authors transfer the copyright of their articles to the journal on acceptance. The rationale is that a journal can protect the integrity of an article better than an individual. In the same way it has been suggested that database producers should follow these arguments as increasingly the content comes from a variety of sources.[34]

Some databases store material as 3D computer-generated images and the same 'image' might have been published in 2D form as a photograph in a journal. Both 2D and 3D forms can be copyrighted and in these circumstances there is a need for flexibility and cooperation between the author, the database and other organisations (eg journals and with the institution where the work is carried out) to clarify the rights position.[34]

A database has to ensure that, if it later wishes to charge for access to, or usage of, its materials, it has the rights to do so and has the copyright needed to allow a fee to be recovered without litigation ensuing. We have seen that in the specific field of data mining great care is needed from the data compiler not to abuse contributing copyrights.

Overprotection

Overprotection issues

As we have seen there are significant differences between the EU and the US IPR regimes. As a result of the EU Database Directive, the EU now has a more protective/restrictive regime when considering databases.[40]

As a consequence of the Directive accessibility of sources of scientific and technological information has become more limited and expensive. Some believe[40] that the EU has adopted an over-protective regime which may lead to a monopolistic dominance of sole producers over a wide range of information goods. This has arisen because of the time-lag between technological advance and implementation of complementary IPR provisions to such new technology.[41]

Undermining of sequence patent grant by use of Internet for database searching

The issue has been raised as to whether patentability of proprietary sequences may be jeopardised by the performance of a database search on a public server.[1] It has been said that such disclosure (which may

amount to publication of the sequence) could potentially prejudice a subsequent patent proposal and therefore limit the subsequent utility of the sequence in a commercial environment.

Looking at a partially analogous situation, the Chartered Institute of Patent Agents (CIPA) took counsel's advice on whether the sending of an e-mail from client to patent agent could invalidate a patent application.[42] The opinion made it clear that provided e-mail communication is made in confidence, any interceptor is not free in equity to use the information by reason of that duty of confidence. (However, as with the inceptor of a client–patent agent e-mail sent over a public network such as the Internet, an offence might well be being committed under S1 of the Regulation of Investigatory Powers Act 2000). However, the position with using proprietary sequences to search databases is somewhat different in that there is no implied duty of confidence.

Confidence

The issue becomes whether an inceptor of the proprietary sequence is entitled in law and equity to make use of it – clearly this is not the case with information transmitted between client and patent agent but perhaps it is less clear in the scenario outlined above.

RECOMMENDATIONS FOR RESOLUTION OF THE PROBLEM AREAS

Categorisation of databases in an international context

It was recommended at a meeting on Financing Biotechnology Databases that the field of bioinformatics would benefit greatly from a more concrete framework to guide and support database producers through the life of their database.[43]

Negotiation

The recommendations emerging from the meeting suggested that databases fall into three categories. First, there is a central core of databases which are fundamental to international biological and biotechnological research and development.[44] There needs to be agreement at international level on how a policy will be achieved and sustained to secure public funding for these databases to ensure access and quality are maintained.

Categorisation

Secondly, it has been suggested that there is a second group of databases that can be successfully sustained through normal market processes. There needs to be agreement at international policy level on the exclusion of databases in this sector from core public funding.

There is then a third group of databases that are too small or that have too small a user community to be commercially viable, and that are not part of the core group for sustained public funding. In these cases, it is suggested that partnership between the public and private sectors may offer opportunities for sustainability.[45]

To assist in the success of databases, database funding management must override individual project lifetimes. It is important (as stated in the recommendations to the EC Working Paper 'IPR Aspects of Internet Collaborations') that public disclosure as practised in open science has to be complementary to the proprietary IPR regime of R&D in promoting high rates of innovation over the long run and thus raising levels of productivity and product quality. Both parts of the system must be kept in balance in the interest of long-term economic growth.[46,47]

Early discussion and negotiation and timely contracts

Too few databases have resolved the ownership position.[48] Nevertheless, a legal framework (albeit with the flaws and issues highlighted) to claim and secure IPRs is in place and, while it has perhaps come too late for some biotechnology databases, it is clear that any database producer should deal with the IPR situation before starting the product.[48]

Such discussion and negotiation will usually have to take place at several levels, between academics and their

employer institutions, and technology transfer offices and between the various collaborating institutions (and their technology transfer offices). Mark Seely points out in his article on 'Copyright and the publishing world'[48] that any database producer should in the first instance assume that the other party (or perhaps their employer or government) has copyright in the material, assume that using the material (or parts thereof) would not be fair use/fair dealing/ personal use and seek permission to incorporate the material. In some cases it may be desirable to consider joint ownership, but in others a suitable licensing arrangement may be more suitable. If any third party has a claim to exploit anything developed, early discussion can mean lack of controversy later. A database compiler is responsible for the content of that database. It is their responsibility to ensure that the content they use is copyright-cleared. A chain of copyright-clearance is often required.

Copyright

Content

'Model' contracts

Contractual difficulties can arise at the academia–industry interface where perhaps usage of a database or its contents has been based on an academic licence and then the academics want to use the results obtained in relation to a commercial enterprise (eg a university spin-out company).

In considering the issue of early discussion and negotiation the relevant bargaining power of the parties to the negotiations needs to be looked at. Less experienced and less powerful partners in negotiations do need coordination and support. This might involve, for example, the formation of networks (clubs, cooperatives) of universities and research institutes which can act as one party in negotiations with industry.[49]

One of the problems to emerge from the Fifth Framework Programme[35,49] and that often results in discussion about IPRs too late, is that many researchers feel that IPR is an issue separate from the scientific process, or one that interferes with it, and that when it must be addressed, it is a subject entirely for lawyers at the end of the project. Another issue highlighted is that researchers need funds to do the necessary work but to persuade the funding body it is necessary to secure positive peer review of a proposed early scientific publication, which might be self-defeating for patent purposes. In the USA and Canada (and some other countries), where there is a 'grace period' provision in patent law (whereby patent filing can validly proceed within 12 months following publication by the inventor), many academic scientists have benefited from this in terms of the relative timing of funding, publication and patenting.[35]

Awareness, education, training and helpdesk activities need to concentrate on the strategic use of IPRs at all stages of the research process.[50]

The various types and models of contractual arrangements seen in bioinformatics are considered below.

The use of 'model' contracts

The main category of database used in publicly funded collaboration projects is an open science model creating an 'IPR-free' zone where IPR rights are relinquished by potential stakeholders.[50] This 'IPR-free' database is vulnerable to IPR usage in general, and can thus be threatened (eg when one or a few of the participants uses the collective information and converts it into private domain information). But IPRs are established and enforced in bioinformatics for many reasons including the intention to commercialise an invention, the need to defend against a rival's patent position and the need to trade cross-licences.[50,51]

A range of model contracts such as those of the EU Framework Programme supplemented by consortium agreements are useful in forming collaborations.[50,52]

Certain IPR management tools and strategies developed by industry and public research organisations have also been successful in facilitating collaborations, eg the formation of 'clubs' or 'co-ops' or new organisations of similar interest groups.[50]

EU

IPR

'Model' contract

In the EC working paper 'IPR Aspects of Internet Collaborations', consideration is given to the issue of model contracts.[53] For EU-funded projects these are currently governed by the RTD Model Contract (Community Research and Technological Development Model Contract) under the Fifth Framework Programme. IPR provisions for existing EU model contract structures for collaborations are based on (a) the fraction of EU funding provided; (b) prescribed conditions on access and ownership; and (c) on the assumption that particular research parts can be associated with particular partners.

These model contract types are not well adapted for Internet collaborations with large shared databases. In their place discussion has taken place as to alternative types of model contract which should be looked at.[54]

It has been suggested that these alternative optional model contracts should be left to parties to choose from in a decentralised manner[53] and that annual reviews should be undertaken with renegotiation points and options to switch models, according to progress and stage-shifts in the collaboration.[55]

The European Commission's Sixth Framework Programme and its associated model contract provisions may well address some of the outstanding issues. Certainly Article 22 (Protection of Knowledge) of the draft rules of participation (which contain the IPR provisions for all projects) gives more flexibility than previously as to how knowledge is protected and also the types of open cooperations which often occur in bioinformatics basic research.

As we have seen, the issue arising for many databases later in their development is further funding for support of the database, which may initially have been funded for example under an EU grant with associated model contract terms and conditions applying.[56] This means that, for example, to secure continuing funds for a database that originally emerged from a research project funded by the European Commission, the project must be reinvented, with different aims and objectives and with a different name.[33] This, of course, has implications in terms of complexity of IP issues. For example, the parties to the first EU contract may not be the same as the parties to the follow-up contract which will create the need for cross-licences and complicate further exploitation issues in relation to the database. Furthermore some parties to either EU contract may have separate collaborations with third parties.

Commercial in-licensing for database searching

As we have seen, patent jeopardy issues may occur with the use of the Internet for database searching. Such security issues often provide the incentive for companies to license packages wherever possible and bring them in-house. Figure 1 illustrates the various licensing scenarios that may be encountered in bioinformatics research.

Multifaceted solutions

From the above analysis of the legal issues in bioinformatics it is clear that the problems the discipline faces generally must be addressed from all angles. The conclusion of the Workshop report[35] on 'Managing IPR in a knowledge-based economy – Bioinformatics and the influence of public policy' states *inter alia* that

> 'Apart from its inherent value to science, bioinformatics may be used to discover end products of value to health care and the industries which invest heavily in developing marketable products. In the course of such development IPR is itself a tool, designed to protect innovators from illegitimate appropriation of their work so that they may undertake the risk and cost of developing research discoveries towards a commercial end product with some feeling of security from unfair competition on the part of those who have not themselves laboured to produce this harvest.'

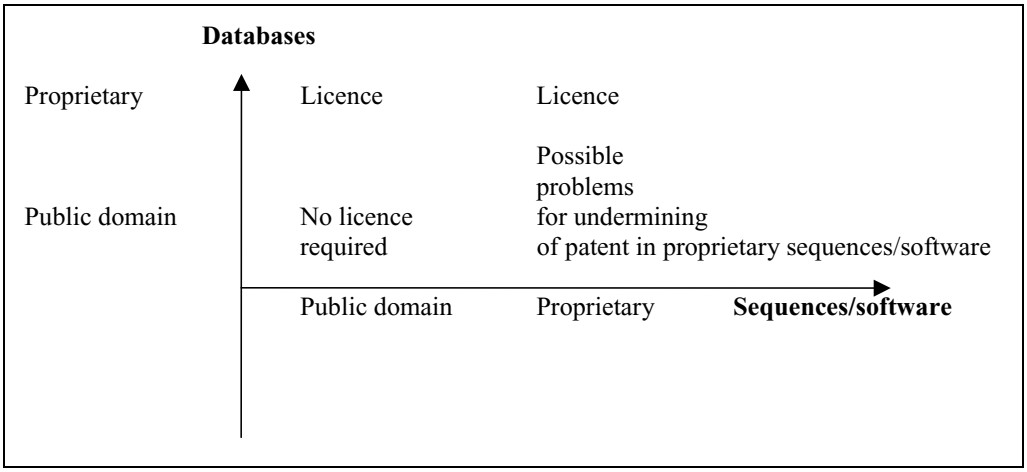

Figure 1: Diagram illustrating licences required for using search software to search bioinformatics databases. *Public domain databases do generally have some form of public licence attached to them

Databases

Guidelines

Biological molecules

IPR

The importance of IPRs to bioinformatics is self-evident. Primary, secondary and composite databases may be protected by the database right in the EU, by copyright in the EU and USA and also in limited circumstances under patent law. It is encouraging to see the practices of the EPO and USPTO converging in relation to patents on biological molecules. Even if these molecules do not have the required level of functionality specified and cannot therefore be patented, they may be protected by copyright. In relation to software inventions, the Commission's proposal for a Software Patenting Directive moves away from the current more liberal USPTO approach.[20] Notwithstanding this, many screening inventions may have the necessary level of technical contributions to be entitled to patent protection under the proposed Directive.[20] Interestingly technical solutions are beginning to emerge which aim to manage the rights attached to digital information. Work is being planned to develop and implement 'Electronic Copyright Management Systems – ECMS' for various application fields. Such systems are likely to include 'automatic licensing systems' as well as the means to identify protected information and their usage rights and conditions.[57] The digital environment presents unprecedented possibilities for controlling access and use of information through technological protection measures conditional access and on-line contracts.[58]

A number of approaches have been proposed in the Workshop Report[35] to address the wider commercial and policy problems, in the form of guidelines to researchers and industry and policy changes for funding organisations. These guidelines suggest *inter alia* that EU member states need to consider the funding imbalance between the USA and EU in bioinformatics and the use of IPR in this context.

IPR awareness training is needed for both research and technology transfer offices. (The nature of the implementation of IPR awareness also depend on the goals of the research involved.) It is further suggested that employment contract conditions on IPR ownership need to be reviewed and adapted to the more mobile university workforce and that international collaborative research also needs to take account of different legal systems in the EU and USA (eg concerning the grace period and patent filing connected with publications). In this respect, it will take time to achieve international harmony of all IP rights.

The EU needs to be an attractive location for large pharmaceutical

industries and it is suggested in the guidelines that government regulations and legislation need review to see if research is being driven out of the EU and what influence IPR plays on this.

Finally, and as identified in the Working Paper,[53] bioinformatics involves a huge and growing IPR assembly problem, in that, increasingly, many pieces of IPR need to be assembled to produce modern 'products' such as databases. IPR assembly creates large transaction costs and even hold-up situations where key IPR holders can block further progress. The pharmaceutical industry is faced with rapid escalation of costs and problems with royalty and licence fee stacking, which could discourage companies from following promising but expensive lines of medical development.[35] There are several options for coping with the IPR assembly problem, such as improving technology market mechanisms, IP pooling, schemes for collecting and clearing IPRs, licensing incentives (eg through tax deduction) reducing the proliferation of IPRs (without essentially reducing incentives) and improving dispute resolution.[53]

References and notes

1. Attwood, T. K. and Parry-Smith, D. J. (1999), 'Introduction to Bioinformatics', Prentice Hall, Harlow. Attwood, T. K., private communications on the issue of proprietary/public databases. An example of a database falling part in and part out of the public domain would be the SWISS-PROT database.
2. Byrne, N. (1999), 'Biotechnology and the European Community's Database Directive', *J. Comm. Biotechnol.*, Vol. 6(1), pp. 25–29 for a detailed analysis of the Directive. The Directive was implemented on 1st January, 1998, in the UK and must be applied retrospectively to databases created prior to that date, provided that on that date any such database satisfies the substantive criteria for protection (Article 14). A database is defined as a collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means (Article 1(2)).
3. Byrne, N. (2001), 'Legal protection for inventions, designs and other information', *J. Comm. Biotechnol.*, Vol. 8(2), pp. 124–130.
4. The essentials of copyright protection in databases are as follows:

   - Fixation – creators or producers have rights under copyright law from the moment a writing is 'fixed' in a tangible medium.
   - Reproduction – copyright law gives the creator the right to set the terms and conditions for the reproduction of the work (including the right to make it widely available for anyone to copy without charge).
   - Attribution and integrity – creators also have the right, under copyright law and under moral rights, to be identified as creators and to ensure the integrity of the result of reproduction of the work.
   - Subsidiary rights – creators have the right to create and control the creation of subsidiary and derivative works and to license or authorise others to use the work (or parts thereof).
   - Transfer and licences – creators can transfer their rights or license those rights (or parts thereof) without limitation and, in most countries the transferee steps into the shoes of the creator.
   - Employers/governments – some creators do not have copyright in their works, as in some countries the rights of employees are automatically (or by written agreement) transferred to their employers. US governmental works are public domain, with no copyright and UK Crown copyright works differently, with the choice of creator or institution regarding transfer or copyright being obtained by the government.

   (Abbreviated from Seely, M., 'Copyright and the publishing world', in 'Building and Owning Biotechnology Databases' (a BTSF Workshop held at Purmerend, The Netherlands, 22–23rd September, 1998), Franklin, J., Ed., Chapter 12 – 'What every database builder should know'.
5. Coleman, L. (1998), 'Directive 96/9/EC of the European Parliament and of the Council of 11 March on Legal Protection of Databases', in 'Building and Owning Biotechnology Databases' (a BTSF Workshop held at Purmerend, The Netherlands, 22–23rd September). For a detailed discussion of measures US companies can take to protect databases, see Nettleton, E. and Obhi, H. (2002), 'Can US companies protect their databases in Europe with Database Right?' (see

Bristows web site, URL: http://www.bristows.com).

6. IPR (Intellectual Property Rights) Aspects of Internet Collaborations – European Commission Working Paper (Fifth Framework Programme), p. 16 Database Law – The Database Directive and Copyright Law. (Prepared by Ove Granstrand in conjunction with Dominique Foray and Paul David *et al*.) Contact Frederick.Marcus@cec.eu.int. See p. 22 (Steinmueller, E.), p. 24 (David, P. A.), p. 25 (Kamperman-Sanders, A.).
7. Hultquist, S. J., Harrison, R. and Yang, Y. (July 2002), 'Patenting bioinformatic inventions: Emerging trends in the United States', *Nature Biotechnol.*, Vol. 20(7), p. 743.
8. Examinations Guidelines for Computer-related Inventions 61 Fed Reg 7478 (1996).
9. *Re Warmerdam* (31 USPQ 2d 1754 (Fed Cir. 1994)).
10. *Re Lowry* (32 USPQ 2d 1031 (Fed Cir. 1994)).
11. For an analysis of the overall landscape of biotechnology patent developments in Europe see Broadhurst, T. (2002), 'Biotechnology patent developments in Europe: An overview', *Nature Biotechnol.*, Vol. 20, p. 309–310.
12. Baldock, C. (2001), 'Developments in Biotechnology and Gene Patenting', Cambridge IP Law School, September (Boult Wade Tennant).
13. Baldock, C. (2001), 'Biological Molecules – Has the EPO Moved the Goal Posts?', CIPA Biotechnology Seminar, November (Boult Wade Tennant).
14. Baldock, C. (2002), 'Biotechnology and Gene Patenting', Cambridge IP Law Summer School, September (Boult Wade Tennant), cbaldock@boult.com.
15. *Official Journal* of the European Communities, 1998, L213/13.
16. In 1998 the three offices started a comparative study of their biotechnology patent practices, given the title of Trilateral Project 3b. The first report (URL: http://www.european-patent-office.org/tws.sr-3-b3b.htm) was published in April 1999 with updates in June and November 2000 respectively. For a discussion of the ethical issues surrounding the patenting of DNA see 'The Ethics of Patenting DNA – A Discussion Paper', Nuffield Council on Bioethics, July 2002.
17. Article 57 EPC provides that: 'An invention shall be considered capable of an industrial application if it can be *made* or *used* in any kind of industry including agriculture'. To date this has been an Article with little effect as most products were viewed as meeting the requirement. The new rule 23e(3) which reads as follows: 'The industrial applications of a sequence or a partial sequence of a gene must be disclosed in the patent application' has allowed the EPO to find the previous interpretation of Article 57 unsustainable. Now a use must be given and in future two types of invention should be recognised – those where the invention resides in the mode of production and those where the invention resides in the usefulness of the product.[14] The June 2000 update of the Trilateral report included two additional conclusions. First, all nucleic acid molecule-related inventions, including full-length cDNAs and single nucleotide polymorphisms (SNPs), without an indication of function or specific, substantial and credible utility do not satisfy the industrial applicability, enablement or written description requirements and second isolated and purified nucleic acid molecule-related inventions, including full-length cDNAs and SNPs, of which function or specific, substantial and credible utility is disclosed, which satisfy the industrial applicability, enablement, definiteness and written description requirements would be patentable. The expression 'specific, substantial and credible utility' comes from the new US Utility Guidelines which set out the criteria for meeting this test. For example, a 'substantial' utility is one which defines a 'real world' use as opposed to a 'throw-away' use.[14] Claire Baldock points out in her paper 'Biotechnology and gene patenting' that the question in relation to many sequences which applicants want to know is 'is an assignment of functions to a nucleic acid or protein which has made by virtue of the homology of the sequence with a known sequence appearing in a database, but without any experimental verification sufficient for the purpose of Article 57?' The USPTO, EPO and Japanese Patent Office (JPO) attempted to answer this in the third report (November 2000). This is entitled 'Nucleic acid molecule related inventions whose functions are inferred based on homology search'. However, uncertainties are still raised because there is conflicting advice given on the extent to which biological function needs to have been demonstrated. For a more detailed discussion of these issues see Baldock.[14]
18. Article 83 addresses the issue of sufficiency – 'The European Patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art'. Claire Baldock points out in her paper 'Biotechnology and gene patenting' that 'the EPO now applies the same test to see whether a claimed molecule meets the requirements of Article 83 as it does with Article 57 the proposed use of the molecule and the extent to which it can be substantiated are all important'.
19. The guidelines were finally published in the Federal Register on 5th January, 2001 (URL: http://www.uspto.gov/web/offices/com/speeches).

20. Wilson, A. (2002), 'Patents in the bioinformatics field: Releasing the gene genie', (see Bristows web site, URL: http://www.bristows.com).

21. Moore, G. and Wilson, A. (2002), 'Bioinformatics – The IT Industry Pulls on its Genes' (see Bristows web site URL: http://www.bristows.com).

22. Lloyd, I. (2000), 'Legal Aspects of the Information Society', Butterworths, London, Chapter 7, p. 132.

23. Heide, T. (2002), 'UK Copyright Directorate Launches Consultation on EU Copyright Directive' (see Bristows web site URL: http://www.bristows.com).

24. Burnside, A. (2002), 'EU Review – a review and commentary on recent decisions relating to licensing in the European Union Commission Proposal on Software Patents', *Les Nouvelles J. Licensing Exec. Soc.*, Vol. xxxvii(2), pp. 69–74.

25. A previous proposal in the summer of 2000 to reform the European Patent Convention (EPC) to remove the express prohibition on inventions for computer programs 'as such' was rejected in a Diplomatic Conference in November 2000. In the meantime, the Boards of Appeal of the EPO have further considered the patentability of software inventions — see ref 24.

26. This aspect of the proposal accords with the case law of the Boards of Appeal of the EPO. Most relevant are the decisions of the Technical Board of Appeal in T208/84, T26/86, T0769/92 and T1173/97, each representing increasing liberalisation with respect to patenting software inventions. Certain aspects of the proposal do not follow the EPO's approach. This is because the EPO maintains a distinction between inventions that are potentially patentable (patentable subject matter) and the tests for novelty and inventive step. These are amalgamated in the proposal. According to the Commission (and in contrast to recent EPO decisions), programs in isolation from the computer on which they are to be run or even programs recorded on a carrier should not be patentable. This conflict could be important, as the EPO (which is not bound by the Directive) may grant a European patent under the EPC which might later be held to be invalid in national courts under the Directive (see Burnside[24]).

27. Yeats, S. (2002), 'Patenting of 3 D Protein Crystal Structures and Bioinformatic Methods', Presentation at Cambridge IP Law Summer School (EPO – Munich).

28. In *Raytheon Co.*'s application (Raytheon Co.'s application 1993 RPC, 427) the invention as claimed related to a computer-based method of identifying unknown ships. The court concluded that the comparison of the two images was merely a mental process and that carrying it out by computer more quickly did not make it less so. In *Fujitsu Ltd*'s application (Fujitsu Ltd's application 1997 RPC, 608(CA)), again it was concluded that a claim to a computer-based method and apparatus for creating synthetic crystal structure images involved merely a mental act which could be carried out without a computer.

29. *Re Alappat* 33 F. 3d. 1526, at 1545 (Fed Cir. 1994).

30. Batteson, A. (2002), 'EU Software Patents Directive: A Missed Opportunity?', *In House Lawyer*, April (see Bristows web site, URL: http://www.bristows.com).

31. Franklin, J. (1997), 'Introduction', in Financing Biotechnology Databases, a workshop organised by the Biotechnology Information Strategic Forum, with support from DGXII of the Commission of the European Communities, Purmerend, The Netherlands, May.

32. The public financial contributions from the National Institutes of Health (NIH) in the USA in this area are several times that of Europe, more coherent and also include direct support for database infrastructure — see ref 35.

33. As current funding rules preclude support beyond the term of the research project, it is inevitable that many such databases will fold, and the scientific community will waste enormous amounts of time and money. Many specialist databases are either too small or have too small a user community to be commercially viable. Ellis, L. B. M. and Attwood, T. K. (2001), 'Molecular biology databases: today and tomorrow', *Drug Discovery Today*, Vol. 6(10), pp. 509–513; Pool, R. and Esnayra, J. (2000), 'Bioinformatics: Converting Data to Knowledge – Workshop Summary', National Academy Press; Powerledge, T. (2001), 'Changing the rules?', *EMBO Rep.*, Vol. 2, pp. 171–172.

34. Building and Owning Biotechnology Databases (a BTSF Workshop held at Purmerend, The Netherlands, 22–23rd September, 1998), Chapter 10 Discussion. (Facilitators: Jim Gilmore, Simon Jones and Jack Franklin) See also reference 35, section 'Analysis, problems and policy options'.

35. Workshop report on 'Managing IPR in a knowledge-based economy – Bioinformatics and the influence of public policy', European Commission Working Paper (Fifth Framework Programme) produced for the European Commission Research Directorate General Directorate B – European Research Area: Structural Aspects. Based on a Workshop held in Brussels, Belgium on 11–12th September, 2001 (Eur 20066), prepared by Crespi. S. *et al.*; Crespi, R. S., 'Bioinformatics, IPR and Public Policy', p. 19.

36. Wishart, A. (2002) 'Is the internet facing

collapse?', *The Times*, June 21; Wishart, A. and Bochsler, R. (2002), 'Leaving Reality Behind – The Battle for the Soul of the Internet', Fourth Estate.

37. The operation and running of the Internet itself is currently under discussion. Wishart explains in his article for *The Times* that it still bears many of the hallmarks of its inception by academics in the 1960s and much of its structure remains based on informal agreements. Key components underpinning the Internet include the A-root file (which encapsulates the Internet's address book/ domain name system) and the B-servers (the 13 computers that channel domain information from the A-root to Internet users). The organisation charged with running the Internet is ICANN (Internet Corporation for Assigned Names and Numbers). However the legal constitution and nature of ICANN is under continuous discussion, eg should it be public or private or part of each? The issues are further complicated by the fact that here is no contract in place between ICANN and those who run the B-servers (unpaid volunteers who are support financially by the academic institutions and corporations they work for).
38. IPR (Intellectual Property Rights) Aspects of Internet Collaborations – European Commission Working Paper (Fifth Framework Programme), p. 10 General problem areas and p. 16 Database Law – The Database Directive and copyright law.
39. Governments have of course in the past found that particular technologies raise certain fundamental risks to creators or involve Catch-22s for industries involved. Seely, M. (1998), 'Copyright and the Publishing World', Building and Owning Biotechnology Databases (a BTSF Workshop held at Purmerend, The Netherlands, 22–23rd September), Chapter 2.
40. IPR (Intellectual Property Rights) Aspects of Internet Collaborations – European Commission Working Paper (Fifth Framework Programme); Cowan, R. and Harison, E., 'The EU Database Directive: Did Europe Adopt an Over-Protective Regime?', p. 26.
41. An eloquent article on the subject of overprotection has been written by Uhlir in connection with proposed US Database IPR legislation. The grounds for his objections to the creation of a property right in databases *inter alia* are as follows:

    - questionable constitutionality;
    - not enough requirements to make data available for research, education and other public-interest users on fair and equitable terms;
    - an incomplete exception for publicly funded government data;
    - no protection of value-adding user rights in derivative works, either in the same or in distant markets.

    Uhlir believes that 'as scientists and their employing institutions become more accustomed to a new legal regime that encourages the commercial exploitation of their own research data sets, the cooperative culture that has become the hallmark of so many fields of science (eg bioinformatics) will be undermined'. Uhlir does, however, support new US legislation that would be specifically targeted at prohibiting commercial data piracy, based on unfair competition law but rejects any attempt to create an exclusive property right in building blocks of knowledge. Uhlir, P. F. (1998), 'Potential impacts on research from proposed US database IPR legislation', 'Building and Owning Biotechnology Databases' (a BTSF Workshop held at Purmerend, The Netherlands, 22–23rd September), Chapter 9, p. 25.
42. Onslow, R. (2002), 'In the matter of the Patents Act 1977 and disclosure by e-mail', *CIPA J.*, February, pp. 83–85.
43. 'Financing Biotechnology Databases', a workshop organised by the Biotechnology Information Strategic Forum, with support from DGXII of the Commission of the European Communities, Purmerend, The Netherlands, May, 'Introduction' and Chapter 5 – Recommendations.
44. The Bermuda principle clearly recommends that certain forms of database should remain in the public domain. (URL: http:// www.ornl.gov/hgmis/research/ bermuda.html).
45. Along with categorisation of the databases themselves come the issues of quality control and standardisation of databases. A stable environment to plan and work on bioinformatics and the surrounding biotechnology information strategies is needed. To ensure a sustainable income from users, the database needs to deliver wanted services at acceptable quality and price levels. Therefore its operation should be governed by quality-management procedures. 'Biotechnology Information – Access, storage, validation and security', a workshop organised by the Biotechnology Information Strategic Forum, with support from DGXII of the Commission of the European Communities, CAB International, Wallingford, UK, October 1996, 'Discussion – conclusion and recommendations'.
46. Given the central role of the EC it has been suggested that it should (perhaps in conjunction with other funding agencies) publish guidelines for the establishment and privatisation of such services, so that the biotechnology market is not taken by surprise

when a 'free' service starts to make commercial demands and public money is not wasted financing databases which cannot be sustained when the public subsidy ends.

47. The role of central institutes such as NCBI (National Centre for Biotechnology Information) and EBI (European Bioinformatics Institute) is vital. These services benefit from international cooperation and mutual data exchange to which successful collaboration bear witness (eg the highly successful EMBL/GenBank/DDBJ). Ellis, L. B. M. and Attwood, T. K. (2001), 'Molecular biology databases today and tomorrow', *Drug Discovery Today*, Vol. 6(10), pp. 509–513.

48. Building and Owning Biotechnology Databases (a BTSF Workshop held at Purmerend, The Netherlands, 22–23rd September, 1998), Chapter 2 Seely, M., Copyright and the publishing world, Chapter 10 Discussion and Chapter 12 What every database builder should know.

49. IPR (Intellectual Property Rights) Aspects of Internet Collaborations – European Commission Working Paper (Fifth Framework Programme), p. 5 Recommendations; Foray, D., 'A preliminary note on the IPR. Aspects of integrated Internet collaboration: Be prepared to cope with a large variety of problematics', p. 20.

50. IPR (Intellectual Property Rights) Aspects of Internet Collaborations – European Commission Working Paper (Fifth Framework Programme); see 'Problems' and Ryckaert, V. 'The need for a unified IP terminology'.

51. Since most companies and universities have explicit policies with regard to the securing of IPRs, the EC will need to take these motives into account even when there is little or no evidence for their public or private benefit — see ref 50.

52. However, it has been said that surveys from the USA and anecdotal evidence from Europe and Japan suggest that partners, especially from industry, are reluctant to contribute their best knowledge and researchers to a project. This reluctance arises from the differences in perceived exploitation goals and value of resources of the partners and will worsen from a common obligation to pool knowledge and rights (eg) to contribute to central databases. Therefore, flexibility in the use of IPR protection may be essential in forming a wide range of collaborations as well as for commercially exploiting the results. IPR (Intellectual Property Rights) Aspects of Internet Collaborations – European Commission Working Paper (Fifth Framework Programme). 'Problems' p. 4.

53. IPR (Intellectual Property Rights) Aspects of Internet Collaborations – European Commission Working Paper (Fifth Framework Programme), p. 3 'Problems', p. 11 'Main themes of the Workshop discussions: Issues, problems and recommendations 3.20A – Recommendations for model contracts'.

54. In this regard it has been suggested that the ideas of Electronic Copyright Management Systems could be used in this context. Schemes for licensing in and out (back and forth) should be worked out in advance for interfacing the open and closed parts of the hybrid IP regime. Since collaboration proceeds in stages, a stage-specific mix of open/closed regimes should be envisaged with controlled stage shifts. At a late stage a model contract for equity partnership should also be made available.

55. One supporter of the use of model contracts has been the company Alcatel. Alcatel has had good experience establishing a 'model consortium agreement', the so-called 'unified consortium agreement (UCA)' for FP5 projects. Alcatel had worked on the basis of bilateral contracts with research institutes/ universities. Distribution is made between two types of results: Type A – owned by the company solely; Type B – jointly owned with research institute. Alcatel has successfully applied this scheme and therefore are strong supporters of the use of model contracts. De Moor, A. (1998), 'Participation of industry in the framework programme and contracts with universities on a bilateral basis', IPR (Intellectual Property Rights) Aspects of Internet Collaborations – European Commission Working Paper (Fifth Framework Programme),

56. A case in point is European Bioinformatics Institute (EBI). In 1999, following the publication of a new rule disqualifying the support of core funding and operational costs of infrastructure from the EC's Fifth Framework (FP5), the EC rejected the EBI's application for funds to support core facilities.

57. Gonthier, D. (1998), 'DG INFSO Copyright Protection and Privacy with ECMS: Electronic Copyright Management System', IPR (Intellectual Property Rights) Aspects of Internet Collaborations – European Commission Working Paper (Fifth Framework Programme).

58. Kamperman Sanders, A. (1998), 'Databases – Some considerations', IPR (Intellectual Property Rights) Aspects of Internet Collaborations – European Commission Working Paper (Fifth Framework Programme).