

LEGAL PROTECTION OF INNOVATIVE USES OF COMPUTERS IN R&D: A Review

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INTRODUCTION

Intellectual Property Rights

Intellectual property rights are used to describe the legal instruments for protecting innovation. Although there are often differences in the laws governing these rights in different countries, almost all countries recognize the basic types of intellectual property that are summarized in Table 29.1 [4]. Member states of the World Trade Organisation have all committed to introducing these rights [5]. Of these rights, the most important in the application of computers to pharmaceutical research and development are patents, copyrights, and database rights.

What are intellectual property rights?

Intellectual property rights are like any other property right. They allow creators, or owners, of patents, trademarks or copyrighted works to benefit from their own work or investment in a creation. These rights are outlined in Article 27 of the Universal Declaration of Human Rights, which provides for the right to benefit from the protection of moral and material interests resulting from authorship of scientific, literary or artistic productions.

The importance of intellectual property was first recognized in the Paris Convention for the Protection of Industrial Property (1883) and the Berne Convention for the Protection of Literary and Artistic Works (1886). Both treaties are administered by the World Intellectual Property Organization (WIPO).

Why promote and protect intellectual property?

There are several compelling reasons

- ❖ The progress and well-being of humanity rest on its capacity to create and invent new works in the areas of technology and culture.
- ❖ The legal protection of new creations encourages the commitment of additional resources for further innovation.
- ❖ The promotion and protection of intellectual property spurs economic growth, creates new jobs and industries, and enhances the quality and enjoyment of life.
- ❖ An efficient and equitable intellectual property system can help all countries to realize intellectual property's potential as a catalyst for economic development and social and cultural well-being.

- ❖ The intellectual property system helps strike a balance between the interests of innovators and the public interest, providing an environment in which creativity and invention can flourish, for the benefit of all.

Types of Intellectual Property Rights (IPR)

Type of IPR	Protects	Maximum Lifetime (generally—may vary from country to country)
Patent	Technical ideas	20 years from filing
Copyright	Literary works including computer programs	70 years from death of author or date of creation (in the case of joint works)
Database rights	Collection of data (only exists in the European Union and some other countries—the US is discussing the proposal)	70 years from the date of creation
Trade secrets	Secret nondisclosed information	Unlimited, as long as access is limited to a select group
Design	Aesthetic creation (generally not relevant in the pharmaceutical field)	Varies from country to country; 25 years in the European Union from application; 14 years in the United States from grant.
Trademarks	Brand name or sign designating a product	Unlimited, as long as the trademark remains in use

Patents

Patents are the most important and strongest type of intellectual property. Patents protect inventions or technical innovations. Patents do not protect new designs (these are protected by copyright or registered designs), nor do they protect new brand names (trademark protection). In the application of computers to pharmaceutical applications, both hardware inventions and software inventions can be protected by patents. The hardware might consist of a microarray, a processor, memory and a display device. The software would consist of the set of instructions processed in the processor for processing data obtained from the microarray and stored in the memory. Hardware inventions are clearly patentable, and, despite misgivings in some quarters [6], it is now generally recognized that software can be protected by patents. In the United States, the decision of the Court of Appeal in the so called “State Street” case [7] opened the way for much more far-reaching patent protection for computer-implemented inventions than had been previously granted. In that decision the Court stated that the sole test for determining

whether an innovation is patentable is whether a “useful, concrete, or tangible” result was obtained.

A general-purpose computer programmed for a special purpose is, however, not excluded from patentability as long as it produces a technical effect. The initial decision—often called the VICOM decision after the applicant for the patent—was followed by further decisions of the Boards of Appeal that opened the way for the patenting of inventions implemented by means of computers. The reasoning behind these decisions has often been adopted by courts in other countries (not only in Europe, but elsewhere). The German Supreme Court, for example, has explicitly stated that the application of computers in chemistry or biology is acceptable patentable subject matter [14].

Patents on Algorithms:

Whereas until recently much of the analysis of data in pharmaceutical research and development was carried out essentially by manual processes, the volume of data that is currently being generated means that increasingly sophisticated algorithms are being used to order, sort, and analyze the data. No patent office will allow the patenting of an algorithm per se without reference to its practical application. The European Patent Convention clearly states that scientific theories and mathematical methods are not to be regarded as being inventions [15]. As discussed above, the USPTO (Washington, DC) and the US courts are looking for a concrete, useful, and tangible result to justify the grant of a patent. When an application of the algorithm is involved, patent protection can be secured.

Patents on Human Interfaces:

Most computer programs for use in pharmaceutical research and development must interact with a human researcher. Given the amount of data that can be potentially provided to the researcher, efficient means are needed to present the data in a readily understood manner. In Europe such methods of presenting information are excluded from patent protection [18]. However, several decisions from the European Patent Office indicate that patents might be granted if the information presented is more than just “mere” data. For example, the European Patent Office granted a patent on a method for displaying one of a set of predetermined messages indicating a specific event that may occur in an input/output device of a word processing system.

Patents on Machine-Machine Interfaces:

Unlike patents on machine-human interfaces, patents are regularly granted in both the United States and in Europe on the interfaces to a computer program. Such patents can be extremely valuable as they can allow the creator of the computer program to limit the access to the computer program only to others to whom a license to use the interface has been granted. During the course of the debate on patents for computer-implemented inventions in the European Parliament an amendment was proposed that would, in effect, have prevented the enforcement of patents on interfaces [20]. As mentioned above, this proposal has been dropped, and thus there is currently no restriction on patenting such interfaces. As discussed below, copyright protection on interfaces is, however, limited. The use of patents on machine-machine interfaces can be illustrated by considering the example of a microarray. The data obtained by the microarray can be processed by any computer system running a suitable program. The data are transferred from the microarray to the computer system through an interface, and use of a

patented interface can be restricted only to the patent holder and its licensees.

Patents on Data Structures:

Much of the early interest in the application of computer programs to pharmaceutical research and development was focused on the construction of databases to record data generated by drug testing, high-throughput screening, or gene sequencing experiments. The experimental data in such early databases were often stored in a simple flat file structure. Subsequently, relational database structures were developed to allow the more efficient and significant analysis of the data stored therein. The structure of these databases can be protected by patents. It is unlikely, however, that a claim to a database structure per se without any reference to its application would be seen to be patentable because the structure by itself does not produce a useful, tangible, or concrete result. A patent application on the application of the database structure to a particular pharmaceutical problem would be more likely to be granted.

Why are patents necessary?

Patents provide incentives to individuals by recognizing their creativity and offering the possibility of material reward for their marketable inventions. These incentives encourage innovation, which in turn enhances the quality of human life.

What kind of protection do patents offer?

Patent protection means an invention cannot be commercially made, used, distributed or sold without the patent owner's consent. Patent rights are usually enforced in courts that, in most systems, hold the authority to stop patent infringement. Conversely, a court can also declare a patent invalid upon a successful challenge by a third party.

Patent Holders In India

- The list of top 10 patents holders in India comprises only pharmaceutical and bio-tech companies.
- In India, 184 patents are held by the Council of Scientific and Industrial Research, followed by 'Ranbaxy'
- While the top 10 patents holders across the world are IT companies, in India, no IT firm has patents

Youngest Patent-holder on wheelchair

Jaipur: Drawing inspiration from scientist Stephen Hawking, a wheelchair-bound nine-year-old boy here has invented a game of six-player circular chess. The boy, Hridayeshwar Singh Bhati has got the game's design patented in his name.

Copyright

Copyright is traditionally used to protect literary works or works of art from copying or from the making of so-called derivative works, that is, new works based on a protected work. More recently, protection under the copyright laws has been extended to software. In the United States, software is protected as a literary work [23] and registration of the copyright is carried out at the US Copyright Office (www.copyright.gov). Until 1991, the situation in Europe was more complicated as protection was granted under national laws rather than on an EU-wide basis. Council Directive 91/250/EEC on the Legal Protection of Computer Programs of 14 May 2001 [24] introduced a common protection within the member states of the EU under which software was to be protected as a literary work. No requirements other than original authorship of the software were to be required before protection would be granted. The EU did not introduce a registration system for the protection of computer software under copyright law. Most other major industrial countries have adopted similar rules, and in 2002 the World Intellectual Property Organisation (WIPO) Copyright Treaty of 1996 [25] entered into force for a number of countries, including Japan and the United States. Signatories to this treaty must ensure that computer programs are protected as literary works [26]. Compared to patent protection, copyright has a major disadvantage. Copyright only protects the so-called “expression” of the innovation, that is, the computer code, and protection does not extend to the innovation itself. In other words, the idea behind the program can be copied, as long as the code itself is not copied or adapted. Copyright protection can extend also to flow diagrams or pseudocode, and so these cannot be used to create a new (derived) program. Reverse engineering of computer code is also not allowed. However, in the European Union, use of reverse engineering is allowed if the intention is to obtain information about interfaces between computer programs [27].

What rights do copyright and related rights provide?

The creators of works protected by copyright, and their heirs and successors (generally referred to as “right holders”), have certain basic rights under copyright law. They hold the exclusive right to use or authorize others to use the work on agreed terms. The right holder(s) of a work can authorize or prohibit:

- Its reproduction in all forms, including print form and sound recording.
- Its public performance and communication to the public.
- Its broadcasting.
- Its translation into other languages; and its adaptation, such as from a novel to a screenplay for a film.

Many types of works protected under the laws of copyright and related rights require mass distribution, communication and financial investment for their successful dissemination (for example, publications, sound recordings and films). Hence, creators often transfer these rights to companies better able to develop and market the works, in return for compensation in the form of payments and/or royalties (compensation based on a percentage of revenues generated by the work). The economic rights relating to copyright are of limited duration – as provided for in the relevant WIPO treaties – beginning with the creation and fixation of the work, and lasting for not less than 50 years after the creator’s death. National laws may establish longer terms of protection. This term of protection enables both creators and their heirs and successors to

benefit financially for a reasonable period of time. Related rights enjoy shorter terms, normally 50 years after the performance; recording or broadcast has taken place. Copyright and the protection of performers also include moral rights, meaning the right to claim authorship of a work, and the right to oppose changes to the work that could harm the creator's reputation.

Protection of Databases:

In addition to the patenting of database structures (see 29.2.1), a database can be protected either by copyright protection or by so-called database rights. The extent to which information in the database can be protected by copyright varies widely depending on the country involved. In many countries, copyright protection is not available for information contained in databases. Other countries, such as Australia [28], consider that the arrangement and collection of the information may be so significant that copyright can be granted on the database. In contrast, the US Supreme Court in 1991 rejected the so-called "sweat of the brow" theory that previously had accorded copyright protection to informational compilations [29].

Trade Secrets:

Trade secret protection is probably the weakest of all intellectual property rights. The US Uniform Trade Secret Act defines a trade secret as information, including a formula, pattern, compilation, program device, method, technique, or process, that (1) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy [33].

Trade secrets (or "undisclosed information") are also protected under the TRIPS Agreement [34]. Despite this international agreement, there is a wide range of difference in the manner in which countries implement these provisions. Few countries, apart from the United States, have explicit provisions in their laws on the protection of trade secrets. In some countries, protection is only granted when a former employee takes confidential information to a new employer, whereas in other countries, protection is granted more widely. Unfortunately, once a trade secret is no longer a trade secret it can be freely used by anybody else who obtained the information fairly. The value of the trade secret is thus much more limited than, for example, patents or copyrights. Trade secret protection can play a significant role in the protection of computer software. If the code is only released in object form and the source code is not readily available, then the source code—so long as it is only known to a limited group of programmers—remains covered by trade secret protection. As long as it is not published, any disclosure of the code would be considered to be an infringement of the creators' trade secrets. Data on the efficacy of new drugs, as long as their origination requires considerable effort, are also protected under the TRIPS Agreement [35]. The regulatory authorities are required to keep the information supplied confidential.

What kinds of trademarks can be registered?

Trademarks may be one or a combination of words, letters and numerals. They may consist of drawings, symbols or three dimensional signs, such as the shape and packaging of goods. In some countries, non-traditional marks may be registered for distinguishing features such as

holograms, motion, color and non-visible signs (sound, smell or taste).

Trademark	Proprietor	Observation
BAJAJ	Bajaj electrical limited	The use of a family name Bajaj by defendants was held to be an act of passing off. The goodwill and reputation
GLAXO	Glaxo India Ltd.	Glaxo is an invented word. By original adoption, registration,
NIVEA	Beiersdorf	Nivea is a recognized product of high quality and has international reputation and recognition. These are marks where the line between the goods and the name is blurred.
PHILIPS	Philips NV, Netherlands	Is a household mark and has acquired enviable reputation in India and throughout the world.
Dr.Reddy in respect of pharmaceutical products	Dr.Reddy Laboratories	Trademark Dr.Reddy, in spite of not being registered, has acquired considerable trade reputation and goodwill in the community dealing with drugs and pharmaceuticals not only in India, but abroad also.

ENFORCEMENT OF RIGHTS

Obtaining IP protection is only the first step. The intellectual property rights obtained are only useful if they can be exploited and—ultimately—unauthorized users of the rights can be stopped from exploiting them. This presents a fairly unique problem in the computer science field. IP rights are essentially national rights. They are only valid in the country in which they are granted or registered. A valid US patent is only valid in the United States, a Canadian copyright only valid in Canada. Even a so-called European patent is, in effect, a bundle of national patents valid in various European countries. This raises a problem in a situation in which, for example, the user of a computer program is in one country and the server is in another country. Courts in both the United States and the United Kingdom have had to deal with this issue in patent infringements unrelated to pharmaceutical science.

CONCLUSION

The use of computers in developing new pharmaceutical products is nowadays commonplace, and a number of tools and databases have been developed to improve their use. Although intellectual property rights have to date rarely been the subject of court cases, protection is available and the courts are prepared to enforce these rights, even in an international context.

REFERENCES

1. Sean Ekins Computer Application In Pharmaceutical Research And Development, Published by John Wiley & Sons. 2006. 703-713.
2. Toner B. Bioinformatics patents remain a rarity in IP-heavy biopharmaceutical industry. GenomeWeb, 4 July 2001 (<http://www.genomeweb.com>).
3. Patent Applications generally remain unpublished for 18 months after their first filing.
4. Steinberg D. New PTO Unit examines Bioinformatics Application. The Scientist 27 November 2000;200:14(23);8.
5. Adapted from Robert Harrison, Protecting innovation in bioinformatics and insilico biology. Biodrugs 2003;17(4):227–31.
6. TRIPS Agreement (Agreement on Trade Related Aspects of Intellectual Property). Available at URL http://www.wto.int/english/docs_e/legal_e/27-trips_01_e.htm.
7. Nichols R. The age of software patents. Computer April 1999:25–31.
8. State Street Bank & Trust Co. Inc. v. Signature Financial Group 149 F.3d 1368 (Fed Cir Jul 23, 1998).
9. Proposal for a Directive of the European Parliament and of the Council on the patentability of Computer-Implemented Inventions, COM (2002) 92 final. Available from URL http://europa.eu.int/comm/internal_market/en/indprop/comp/com02-92en.pdf.
10. Bodini S. EU software patent law is dead managing intellectual property. Weekly News, 11 July 2005. Accessible at <http://www.managingip.com/?Page=9&PUBID=198&ISS=17456&SID=524170&SM=ALL&SearchStr=computerimplemented%20inventions>.
11. European Patent Office Press Release. European Patent Office continues to advocate harmonisation in the field of CII patents, 6 July 2005. Accessible at http://www.european-patent-office.org/news/pressrel/2005_07_06_e.htm.
12. Programs for Computers in Guidelines for Examination in the European Patent Office, Part C, Chapter IV, Nr. 53, European Patent Office, October 2001. Available at URL <http://www.european-patent office.org/legal/guidelines/e/index.htm>.
13. European Patent Convention, Art 52 (2). Available from URL <http://www. european-patent-office.org/legal/epc/e/ar52.html#A52>.
14. Decision T0208/84 of 15 July 1986 “Computer-related Invention/VICOM.” OJ EPO 1987:14–23.
15. Decision X ZB 16/00 Suche Fehlerhafter Zeichenketten, 17 October 2001. Available from URL <http://www.bundesgerichtshof.de>.
16. European Patent Convention, Art. 52 (2) (a). Available from URL <http://www. european-patent-office.org/legal/epc/e/ar52.html#A52>.
17. Smith TF, Waterman MS. Identification of common molecular subsequences. J Mol Biol 1981;147:195–7.

18. Art. 53 (2) (d) European Patent Convention. Available at URL <http://www.european-patent-office.org/legal/epc/e/ar53.html#A53>.
19. T0115/85 “Computer-related Invention/IBM.” OJ EPO 1990:30–4.
20. European Parliament Committee on Legal Affairs Recommendation for Second Reading on the Council common position for adopting a directive of the European Parliament and of the Council on the patentability of computerimplemented inventions. Document Number 11979/1/2004—C6-0058/2005— 2002/0047(COD).
21. In re Lowry, 31 USPQ 2d 1301 (Fed Circ 1994).
22. Decision T1194/97–3.5.2 of 15 March 2001. “Data Structure Product/PHILIPS” OJ EPO December 2000: 515–573.
23. Copyright Directive EU Official Journal L 122, 17 May 1991 42–46.
24. Art. 4 WIPO Copyright Treaty. Available from URL http://www.wipo.int/treaties/en/ip/wct/trtdocs_wo033.html#P56_5626.
25. Telstra Corporation Limited v. Desktop Marketing Systems Pty Ltd [2001] FXA 612 (15 May 2001).
26. Feist Publications v. Rural Telephone Service Corp., 499 US 340 (1991).
27. OJ European Union No. L77, 27 March 1996, 20. (the “Database Directive”).
28. NTP v Research in Motion, US Court of Appeals for the Federal Circuit, 03-1615. Available at URL <http://www.fedcir.gov/opinions/03-1615.pdf>.
29. Art. 39 (2). Available at URL http://www.wto.int/english/docs_e/legal_e/27-trips_04d_e.htm#7.
30. Menashe Business Mercantile v William Hill Organisation 2002 EWCA Civ 1702. Available at URL http://www.hmccourts-service.gov.uk/judgmentsfiles/j1398/menashe_v_william_hill.htm.