CHAPTER

22

Ethics and Legal Protection of Uses of Computer Applications in Pharmaceutical Research

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22.1 COMPUTERS IN PHARMACEUTICAL RESEARCH: LEGAL PERSPECTIVE

The use of computers and information technologies are endless and countless in today's society. In fact, almost all the fields of sciences are dependent on computers. The incorporation of computer-based technologies in health care professions generally helps in improving the efficiency and quality of patient care with the involvement of other tools, devices, and methods built into the computers (Marckmann and Goodman 2006; Goodman and Miller, 2001). Specifically, in pharmaceutical research, computer technology acts as a valuable vehicle to deliver research outputs. In addition, there is a growing knowledge and use of computational techniques in drug design and discovery research, where the computer acts as an essential tool for the generation, processing, and analyzing of data (Kapetanovic, 2008; Balakumar et al., 2017). Despite their numerous benefits, computer technologies are posting unanticipated problems: legal, social, and ethical issues that are continuously rising to the individual and the professional level.

Every step of pharmaceutical formulation development requires the use of computers, such as to analyze the data for drug content, entrapment efficiency, or dissolution studies (Maheshwari et al., 2015; Rahul et al., 2017). It was James Moor's article "what is computer ethics" that had made a marked point in the history of computer ethics; he proposed an idea of how policies should be formulated to use these technologies (Moor, 1985). Moor's efforts were highly influential but however, the importance and validity of his concepts support the previous period where computer was considered as a machine that crunches numbers or acts as a big calculator. Today's the computer is quite different from those displayed in the 19th century; its superior role, as a tool that is elemental to operate tasks in the workplace and as a communication medium can never be disregarded. Because computer technology has changed substantially, one might have thought that also conceptions and issues of ethics accordingly evolved. This is however not the case, as soon as personal computers spread in the 1980s, certain questions began to be raised, such as whether it is acceptable to copy proprietary software programs from one computer to another, as well as many other questions including intellectual property that were added to the list of issues drawing the attention of computer ethicists (Tavani, 2001).

22.2 PHILOSOPHY OF ETHICAL USE OF COMPUTER APPLICATIONS IN PHARMACEUTICAL RESEARCH

The word "Ethical use of computer" literally means the proper, right, socially appropriate behaviors of using computer machines and related technologies. These are basically sets of rules that establish the boundaries of generally accepted behavior while dealing with computers. The perception of the ethical quality of an act is mostly based on

relatively precise values and norms that are accepted by the cultural or social group and are easily applicable. This is what ethics as the discipline of moral philosophy does. Although there is a notable body of literature considering the moral aspects of technology, the field of computer ethics has not yet made up itself as a renowned philosophical topic and the awareness of philosophers about its value and challenges is low. Although computers have existed in homes and workplaces since the 1970s (Floridi, 1999), during that time the only ethical worries were related to the spontaneity of the personal information exchange and storage in huge databases, both privately and in the public sphere. It is therefore not surprising that, as yet, less effort has been made to explore the correlation between this area and more advanced fields of applied ethics.

According to Matthew and Richard's general observations, until 1985 there had been no literature produced under the name of "computer ethics" and the progress in the library went very slowly, in that only 42 items (articles to book chapters and monographs) were listed from the years 1985 to 2004 under the *philosopher's index*. Among the 42 mentioned articles, about 12 papers focused on the status of computer ethics in the pantheon of philosophy (McGowan and McGowan, 2006). The absence of philosophers input into the literature of computer ethics shows clearly that they have no deep intrinsic interest on the subject. One of the reasons that has been suggested is that technology is less likely to grow and develop in the philosophical field, in other words, they are unmindful of the issues that technology could pose ethically. Also, professional philosophers might not comprehend much about what could be the issues that face the philosophers' community exactly. Other justifications would be the debate on the uniqueness of the questions raised by computer ethics to the philosophers. Some supporters believe that the use of computers have created a variety of unique and new ethical issues that are connected directly and only to the computer technologies (Maner, 1996).

Deborah Johnson described the issue of computer technology as a new species of existing generic moral issues. On the other edge of the spectrum are the proponents who strongly believe that there is nothing special or new regarding ethical issues of computer and claim that crimes and privacy violence remain the same whether it is related to the use of computers or not. Also, traditionalists believe that the unique matter of computer ethics is overstated and that traditional ethical theories can be applied to the moral problems of the computer as well (Tavani, 2001). All these attempts have been made about computer ethics along with other theories in order to justify it as a definite subdiscipline of applied ethics. Some philosophers agree that computer ethics combines many principle characteristics of business ethics and medical ethics which are in turn branches of applied ethics and were considered as perfect templates for computer ethics (Wong, 2000). Philosophers have not yet resolved and/or categorized "the uniqueness of questions" related to computer ethics, the field remains flexible and dynamic, and the rules of computer ethics will eventually be applied either generally or for pharmaceutical research (McGowan and McGowan, 2006).

22.3 CODES OF CONDUCT PERTINENT TO THE USE OF COMPUTER APPLICATIONS IN PHARMACEUTICAL RESEARCH

Computer technologies play a crucial role in the society; as a communication tool, a source of entertainment, a governmental medium, and as an information system in

industry, research, and medicine. It is, therefore, necessary to ensure that this diverse use of technology could not harm human values but in fact protects and advances them (Dodig-Crnkovic, 2004). Every society has got different rules of ethics which have been founded consequent to consensus in that society and are often translated into laws regarding computer crimes and computer fraud. Table 22.1 lists the 10 commandments of computer ethics that have been outlined by the computer ethics institute (Barquin, 1992).

TABLE 22.1 Ten Commandments of Computer Ethics

1.	Thou shalt not use a computer to harm other people
2.	Thou shalt not interfere with other people's computer work
3.	Thou shalt not snoop around in other people's files
4.	Thou shalt not use a computer to steal
5.	Thou shalt not use a computer to bear false witness
6.	Thou shalt not use or copy software for which you have not paid
7.	Thou shalt not use other people's computer resources without authorization
8.	Thou shalt not appropriate other people's intellectual output
9.	Thou shalt think about the social consequences of the program you write
10.	Thou shalt use a computer in ways that show consideration and respect

To conduct an ethically acceptable research, pharmaceutical researchers have certain obligations and responsibilities towards their profession and must avoid ethical misconducts while following their research career with the help of computers. A list of the 10 most serious unethical behaviors that are prohibited in scientific research shown in Table 22.2 have been obtained from the survey of Martinson and his colleagues, as a result of data collected from a questionnaire of mid-career scientist of the United States to report their own behaviors (Martinson, et al., 2005). With the application of the computer in pharmaceutical research, different sorts of ethical problems were raised by the researchers in the implementation of their research. Professional organizations in science and engineering, such as the Association for Computing Machinery (ACM), adopted their own codes of professional conduct which provide guidelines of ethical codes for professional scientists and engineers. Table 22.3 shows a list of some organizations that have developed codes of conduct along with their corresponding websites. Some are highly different in their content, because of their specific devotion and origins, but the chief idea and the general ethical values they express are parallel (Dodig-Crnkovic, 2006).

22.4 INTELLECTUAL PROPERTY RIGHTS RELEVANT TO COMPUTER APPLICATIONS IN PHARMACEUTICAL RESEARCH

Intellectual property rights (IPRs) refer to the privileges given to the inventor, creator, or an organization to protect their innovation for their exclusive rights of use for a certain

TABLE 22.2 The 10 Most Serious Unethical Behaviors of Researchers

1.	Falsifying or "cooking" research data
2.	Ignoring major aspects of human–subject requirements
3.	Not properly disclosing involvement in firms whose products are based on one's own research
4.	Relationships with students, research subjects, or clients that may be interpreted as questionable
5.	Using another's ideas without obtaining permission or giving due credit
6.	Unauthorized use of confidential information in connection with one's own research
7.	Failing to present data that contradict one's own previous research
8.	Circumventing certain minor aspects of human-subject requirements
9.	Overlooking others' use of flawed data or questionable interpretation of data
10.	Changing the design, methodology, or results of a study in response to pressure from a funding source (Martinson et al., 2005)

TABLE 22.3 Computing Societies with Codes of Conduct

Professional societies	Web sites
IEEE Code of Ethics	www.ieee.org/about/whatis/code.html
ACM Code of Ethics and Professional Conduct	http://www.acm.org/constitution/code.html
Responsible Conduct In Research	http://www.nap.edu/readingroom/books/obas
Codes of Ethics for Engineering	http://www.iit.edu/departments/csep/PublicWWW/codes/engineer.html
Curriculum Guidelines for Undergraduate Degree Programs in Software Engineering	http://sites.computer.org/ccse/
American Society of Civil Engineers Code of Ethics	http://www.asce.org/inside/codeofethics.cfm
Software Engineering Code Of Ethics And Professional Practice	http://www.computer.org/tab/seprof/code.htm
Ethics in Computing "site map"	http://legacy.eos.ncsu.edu/eos/info/computer_ethics/
Codes of Ethics Online	http://www.iit.edu/departments/csep/PublicWWW/codes/

periods of time (Prabu, et al., 2012). Their importance arises from the encouragement and the financial aid they give to stimulate creativity in the fields of technology and modern sciences. The laws of IPR were first introduced in 1883 in the Paris Convention for the Protection of Industrial Property. Several countries became members of the Paris convention and they set unions and arrangements for the protection of the international

trademarks. Three years later, another convention was set up in Berne to protect international copyrights which included the literary and artistic world. Both of which are administered by the World Intellectual Property Organization (WIPO) which was established in 1967. In 1977, the World Trade Organization (WTO) was composed which became an important international organization for the understanding and development of IPRs (Prabu, et al., 2017). Since most of the countries are assembled under the WTO organization, they recognize almost all the types of intellectual property listed in Table 22.4, despite the variations in the law that governs these rights (Harrison, 2003). In the applications of computers to pharmaceutical research, the most significant rights are patents, copyrights, and database rights.

TABLE 22.4 Types of Intellectual Property

Types of intellectual property rights	Protects	Maximum lifetime of protection (generally may vary in some countries)
Patent	Technical ideas	20 years from filing
Trade secret	"Secret" technical or commercial information	Unlimited until the information becomes public
Copyright	Literary works, including computer programs and works of art	70 years from the death of the author or from the date of creation for a joint work
Database rights	Collections of information (only exists in the European Union and a few other countries)	15 years from the date of creation
Design	Esthetic creation	Varies from country to country
Trademark	Brand name or sign designating a product	Unlimited as long as the trademark remains used

22.5 PATENTS APPLICABLE TO COMPUTER APPLICATION

Patents are the rights given for inventions that fulfill the rule of global novelty and nonobviousness (i.e., have inventive steps in comparison with previous art). Patency can give exclusive rights to products and processes for a limited period of time and prevents others from selling, importing, using, and making them. The patentee can implement his rights of exclusivity on marketing of his patent invention either by himself or with the help of a third party to which it should be licensed (Prabu, et al., 2017). In computer applications toward the pharmaceutical research, the most patentable tools considered are the hardware and software. Microarray, UV spectrophotometer, electronic microscope, and PCR machine are examples of hardware used in pharmaceutical research that are patentable. The patency of hardware was undoubtedly recognized a long time ago. On the other hand, the software was legally defenseless until the 1960s and was distinguished as incidental programs that were customized for certain hardware to operate.

The advent of profitable application of software and operating systems from international trademarks, such as Apple and Microsoft, to be packed and sold to the market, has led to a distinct separation between hardware and software and their protection became a central concern (Avram, 2014). The software patentability issue was first investigated by the US Supreme Court under several circumstances in the cases of *Diamond v. Diehr*, *Parker v. Frook*, and *Gottschalk v. Benson* that has changed the patent history (Bowman, 1996). Accordingly, the federal circuit then outlined the limits of patentable applications with regard to computer-aided process that enhanced the operational productivity and denied the patentability of mathematical algorithms. Following the US software patentability lead, a number of European countries and Japan applied the patency of software (Bakels and Hugenholtz, 2002). Software such as that of docking, chemical structure drawing, data processing, and statistics are examples of patentable software in pharmaceutical research (Fig. 22.1).

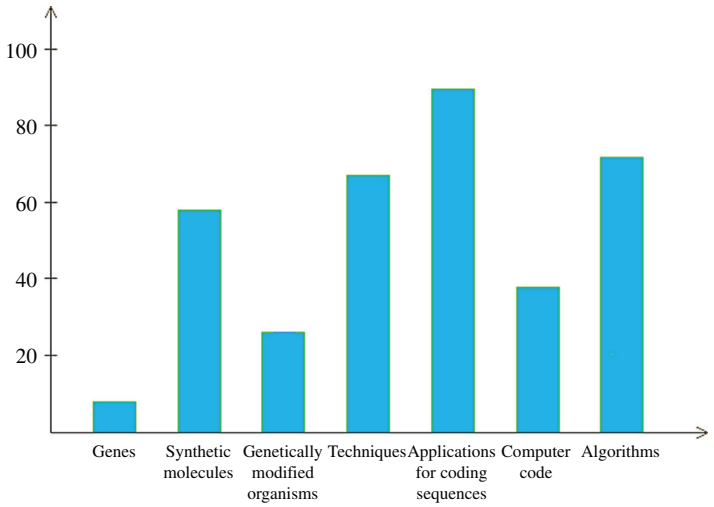

FIGURE 22.1 A chart showing different aspects and the relative number of respondents to each aspect.

22.5.1 Patents on Algorithms of Computer Applications

Algorithms refer to series of steps of either logical or arithmetic bases that are carried out by stored and loaded numbers. Courts used to consider algorithms as patent-ineligible abstract ideas. Arguments arose by some commentators regarding the idea that many software innovations, as well as algorithms, have the right to be protected by patents (Pai, 2007). Previously and until recent times, manual processes were essentially being carried out to analyze data obtained during the processes of research and development of pharmaceuticals. Highly sophisticated algorithms are being increasingly applied to generate a considerably large volume of data, and such algorithms are basically used for the purposes of data ordering, sorting, and analysis. Such arguments were based on the fact that humans are the ones who do the selection and combination of the mathematical operations

required to design a software, which means in other words that algorithms are not naturally occurring. The Federal Circuit have given a number of inconsistent decisions about the eligibility of patents for computer software or algorithms (Harrison, 2006).

In 1981, the *Diamond v. Diehr* case established the software patents' basis in the world. The court discussed the patents of mathematical-based computer processes that are used in the production of cured products from raw synthetic rubber. The patent was not given by the US Patent and Trademark Office (USPTO) which considered such operations as an unpatentable subject matter. On the other hand, the Court of Appeals have stated that the involvement of a computer does not simply make the patentable invention an unpatentable one. Furthermore, the US supreme court has spoken and ended up with a decision that a process or a machine working on the basis of mathematical algorithms with a software component as a whole is considered to be patent-eligible (Yang, 2012).

22.5.2 Patents on Human Interfaces

It is well known that most of the computational programs intended to be applied during pharmaceutical research and development procedures necessitate the interaction with a human researcher who has the potential to represent the resulting data into readily understood information. Such a procedure is not considered to have patent protection in Europe (Harrison, 2006). Certainly, specific cases were discussed by the European Patent Office and it was noted that patent protection might be given only if the information represented by the researcher indicated specific events occurring in a certain device or system. Conversely, the United States are noted to be less restrictive in patents issuing; therefore, patents given by the US might be rejected in Europe (Rana and Bakshi, 2017).

22.5.3 Patents on Machine–Machine Interfaces

Regularly, the United States and Europe are shown to provide patents on the computer program's interfaces. Patents given were shown to have the value of allowing computer programmer creators to have the right to allow only those who have licenses to access to the program (Rana and Bakshi, 2017). Patents granted for machine–machine interfaces can be clarified by giving a microarray as an example. A microarray provides data that are able to be processed by any suitable computational program. Data are supposed to be transferred through an interface to the computer system, and if patented interfaces were used, that means only patent holders and those having a license are able to use such interface (Harrison, 2006).

22.5.4 Patents on Data Structures

Recently, there has been increasing interest regarding the inclusion of databases as a part of pharmaceutical research and development to record the data resulting from the high-throughput screening, drug testing, as well as the experiments done for gene sequencing (Rana and Bakshi, 2017). The structure of these databases has been shown to be patentable if they produce concrete, useful, and tangible results. For example, patents

were granted in the United States for novel relational and hierarchical data structures (Harrison, 2006). Computer scientists have been sincerely making efforts to analyze these data structures to successfully find more efficient ways to use them in practice. In spite of the efforts done, no authoritative definition for data structure has resulted. Unfortunately, the courts have completely failed in the appreciation the nature of data structures and hence, in the determination of whether data structures are patentable or not.

22.6 ETHICAL ISSUES: PRIVACY, LIABILITY, OWNERSHIP, AND POWER

22.6.1 Privacy

Due to the wide spreading of information technologies and the use of computers, an alteration regarding the way people think about privacy has been noticed. The nature and also the scale of interference into the privacy have changed after the use of computers, which in turn has necessitated a rethinking about new ethics for the use of computer applications (McGowan and McGowan, 2006). Privacy issues are taken into consideration in several scientific areas (i.e., biological research) which describes the application of mining techniques in healthcare studies and the improvement of the healthcare delivery (Wahlstrom et al., 2006). The privacy right can be considered as an individual's rights in the determination of manner, scope, and the nature of information representing themselves. In the medical health perspective, although it might be harmful to people surrounding patients of fatal diseases, patients also have the right of privacy to protect their medical record from being released to the public (McGowan and McGowan, 2006).

22.6.2 Liability

Liability refers to the legal responsibility of an entity that extends beyond contract or criminal law (Warren et al., 2005). Liability and computer use generally comprise a number of topics as shown in Fig. 22.2. Little interest regarding computer ethics was shown to be given by liability topics. In some cases, less importance is given to legal liability in philosophy as compared to jurisprudence for example. Due to the communication between both the programmer and the researcher, data of high precision, as well as high accuracy, are usually involved in the research process. For example, in the pharmaceutical industry, there is a high dependency on the accuracy of data recorded which in turn is shown to influence liability. People who are involved in the pharmaceutical industry, in addition to those who are not, are typically discussing about the best way to provide visible research to a drug's potential users (McGowan and McGowan, 2006).

Despite the private guidelines regarding the health information of patients, this information comes under the patient's responsibility who in turn are free to ensure the confidentiality, privacy, and the safety of such information. Due to the increased demand from patients to get the accessibility to their genomic results, it should be noted that patients' portals will not serve as unauthorized entry that would make it easier for unauthorized individuals to have the accessibility to their genomic results

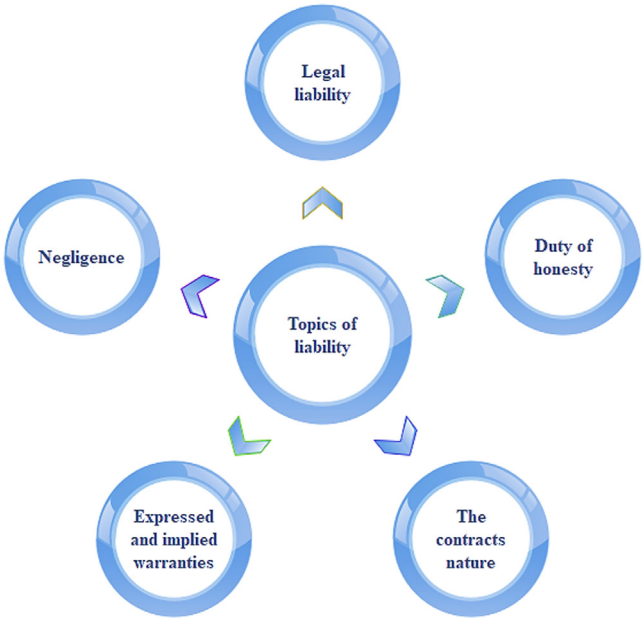

FIGURE 22.2 Different topics of liability related to computer use.

(Hazin et al., 2013). Eli Lilly and Company, have announced public research that enables people to view the company's work and have their own judgments regarding the drug's efficacy (McGowan and McGowan, 2006). Patients' laboratory results, radiographic images, clinical notes, and provider-to-provider correspondence are collected and have been increasing over the years. This bulk of data might result in an information overload, which in turn requires a new liability for reliable documentation access. (Sittig and Singh, 2011)

22.6.3 Ownership

One of the most critical questions that surrounds computers is how to regard software. The courts have faced difficulties to answer this question. Yet, different devices have applied for the encapsulation and resolving of the question regarded software's ownership (McGowan and McGowan, 2006). Due to the considerable enhancement in the convenience and accessibility of higher education and research (HER) data, ethical questions have arisen regarding the protected health information (PHI) ownership and clinicians in preventing and informing patients of the potential for privacy breaches. Generally, few patients are shown to be concerned with the considerable increase in the risk of unauthorized PHI disclosures. For example, patients' databases are sold as de-identified copies to pharmaceutical companies, health services researchers, and medical device makers by HER vendors (Sittig and Singh, 2011).

22.6.4 Power

The issue of power has been identified as a crucial aspect for computer ethics development. The revolution of computers has entered two recognizable stages, which are the introduction and the permeation stages (McGowan and McGowan, 2006). Moor (2001) announced that the revolution of computers is now going through a third stage, namely, the power stage. As Moor believes that the power stage will basically focus on how computers affect human lives in the political, sociable, and legal areas, during this stage, several serious questions associated with the social, political, legal, and ethical aspects are expected to arise on a large scale. Although many people are nowadays dependent on the new technology, the lack of definite control of this stage is as yet a critical issue. The increase in the computational power is shown to allow pharmaceutical researchers, for example, to test a large number of compounds to determine their expected potential (Petrova, 2013; Balakumar et al., 2017). A special concern regarding the use of computers in pharmaceutical research programs is the way computers may eliminate groups or show embedded biases (McGowan and McGowan, 2006). Policy vacuums have arisen during the first two stages of the computer revolution, but it is now expected to be most acute during the power stage, since various novel computer applications will be possible and many users will be capable of manipulating computer technology and many others will be manipulated by this technology, which will reveal a group of computer ethics issues as well (Moor, 2001).

22.7 COPYRIGHTS APPLICABLE TO COMPUTER APPLICATIONS

Copyrights law is one of the key branches of IP laws which offer legal protection for literary and artistic works (expression of ideas). To satisfy the rules for copyrightability, a work has to be original and must be recorded in a material form (e.g., on a computer disk, in writing, sound recording, or in a printed form) (Rana and Bakshi, 2017). A very recent incorporation under copyright laws is the protection of software. In the United States, the protection of software is considered a literary work and the registration process is made under the US Copyright Office (www.copyright.gov) (Harrison, 2006). In Europe, the condition was, however, more sophisticated until the early 1990s, where protection of software was established under national law rather than on an EU-wide basis. The decision of granting software copyrightability protection under literary works has been made on the Council Directive 91/250/EEC of "Legal protection of computer programs" on May 14, 2001. The same rules have been adopted by other industrial countries, and in 2002 a number of countries including the United States and Japan signed the WIPO copyright treaty of 1995 to ensure that software are protected as literary works.

In comparison to patent protection, copyright has shown an observable disadvantage regarding the protection of software, that is, copyrights only protect what is so-called expression of innovation, i.e., the computer code, but it does not cover the innovation itself. More clearly, individuals can copy the idea of the program but not the code itself. Moreover, protection by copyright can cover the pseudocode or flow diagrams, which cannot be used as the basis to create a new derivative of the same program. Also, copyright

protection does not allow the reverse engineering of the code. However, in the European Union, it is allowable to apply reverse engineering regarding the interfaces between computer programs (Harrison, 2006).

22.8 PROTECTION OF DATABASES

In addition to the previously mentioned section regarding database structures patency, it should also be noted that databases can also have copyright protection or in other words "database rights." Various extents of copyright protection of database information are found which depend on the country where they are involved. Many countries do not provide copyright protection for database information (Rana and Bakshi, 2017). In 2001, the Federal court granted Australia and some other countries the copyright protection to database information (Telstra Corporation Limited, 2001). Such countries rely on the assumption that the arranging and collecting of information might be highly significant. In spite of this assumption, the US Supreme Court had rejected the theory of "sweat of the brow" that grants copyright protection to database information.

22.9 CONCLUSION

Due to the continuous spreading of the new technology and the use of computers in almost all aspects of an individual's life, much interest has been recently given toward the computer as an important tool generally in all aspects of life and more specifically in pharmaceutical research. Therefore, the need for computer ethics to control the way the new technology is affecting individuals and societies has arisen. Various philosophies have been released in past and recent times that were mainly concerned with the ethical use of computer applications in pharmaceutical research. An ethically acceptable pharmaceutical research relies on certain obligations and responsibilities which necessitate the avoidance of ethical misconducts. Some scientific researchers have been noticed to behave unethically, which is prohibited in the scientific research laws. Another important issue that has been recently the focus of courts around the world is the patentability of computer applications, including patents granted to computer algorithms, human interfaces, machine–machine interfaces, and data structures. Ethical issues are specified and discussed by the legal authorities, and such issues included the privacy, liability, ownership, and the power of computer applications. Recent emerging terms, namely the copyrights and their protection for computer and software, have also been an issue of interest for many stakeholders around the world.

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ABBREVIATIONS

ACM	association for computing machinery
HER	higher education and research
IP	intellectual property

IPRs intellectual property rights
PCR polymerase chain reaction
PHI protected health information
USPTO United States Patent and Trademark Office
UV ultraviolet
WIPO World Intellectual Property Organization
WTO World Trade Organization

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Further Reading

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