

Correlations on the protection of personal data and intellectual property rights in medical research

IULIAN GABRIEL POPESCU¹⁾, GABRIELA SEHEL²⁾, FLORIN GABRIEL LEAȘU²⁾, MARILENA MONICA ȚÂNȚU³⁾, BOGDAN-VIRGIL COTOI⁴⁾, LILIANA MARCELA ROGOZEA²⁾

¹⁾Department of Intellectual Property Law, Law School, University of Craiova, Romania

²⁾Department of Basic, Preventive and Clinical Sciences, Faculty of Medicine, "Transilvania" University of Brașov, Romania

³⁾Department of Nursing and Kinetotherapy, Faculty of Sciences, University of Pitești, Romania

⁴⁾Department of Family Medicine, University of Medicine and Pharmacy of Craiova, Romania

Abstract

Purpose: International regulations regarding the protection of individuals concerning the processing of personal data and the free movement of such data highlight the need for their systematization and customization, depending on the purpose for which they are collected and used. **Background:** Medical legislation is structured so that the constitutional right to healthcare is guaranteed and at the same time be protected by respecting the right to privacy with respect to identity, physiological state of the person and the way this, by health maneuvers, was restored. European Union (EU) legislation is more and more complex related to the patients' right and also to the *General Data Protection Regulation* (GDPR). After the Second World War, in all Europe the problem related to the human rights become a sensible one in all countries and become aware the importance of clear rules for protecting people, to develop and protect their rights. **Content:** The article presents the correlation between personal data and intellectual property right in the field of medical research, one of the most dynamic fields of scientific research both in the field of fundamental and applied research. Dissemination of medical information collected through scientific works is subject to the fact that progress in any field should be encouraged, in order to increase the quality of life while, at the same time, creating a balance between the interests of the researcher and the public interest and the interest of the academic community represented by any person in the situation of recourse to a medical service. **Conclusions:** In the context of the EU guidelines and implementation of GDPR starting to 2018, the medical research and the education of scientific researchers in the field has gone into a new stage of the ethical approach.

Keywords: privacy of patient data, intellectual property right, patient data protection, copyright protection.

Introduction

According to the *Universal Declaration of Human Rights*, every human being can take on all his rights and freedoms, having the right to life, liberty and security of his person. Starting from freedom of thought, we can say freedom of opinion and expression can be a way of spreading information and ideas, as well as the possibility to protect the rights of the authors who participated in the scientific work [1].

By summarizing, it can be concluded that by teaching and education, coupled with the dissemination of their results, respecting fundamental rights and freedoms, we can aspire to social progress and at the same time to improve living conditions and life itself.

The Romanian Constitution guarantees the freedom of expression of opinions, which may include scientific research, but at the same time, it cannot prejudice dignity, honor and right to the image of the person who generated this information [2].

Ethical dilemmas in medical research have often been systemic related with: individual human rights *versus* social rights, informed consent, medical communication, medical research using human subjects or using animal, biotechnology [3–6].

Intellectual property

Respecting the right to intellectual property in this millennium is paramount in reducing poverty and ensuring a fair access to human resources, being essential for the development of new technologies, as much the medical research has become increasingly complex [3, 7].

Respecting the right to intellectual property may also mean at the same time reducing developing or under-developed countries' access to new drugs, as long as they are placed under patent and therefore have a higher cost. On the other hand, these countries represent a great potential for the development of medical research, patients in these countries accepting much easier to participate in clinical trials.

In this context, it should be noted that *Doha WTO Ministerial Declaration on TRIPS and Public Health*, adopted on 14 November 2001, established that: "...intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices." (*WTO: World Trade Organization; TRIPS: Trade-Related Aspects of Intellectual Property Rights*) [7].

The adoption of the *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)* has impact also in medicine, and standards, sometimes

different, was developed in European Union (EU) and United States [8].

❏ Bioethics and intellectual property

Ethical dilemmas raised by intellectual property regimes must be correlated with individuals' and businesses' right to property on their findings but also with the need for altruism to ensure access to new discoveries for every patient [6].

Compromising the idea of autonomy of individuals both on the right to dispose of their accomplishments and to use them is one of the most complex issues, especially since the approach at the institutional level is different depending on the laws of each state.

One of the most important problems is related to the impact of globalization on the way in which the rules of intellectual property and, as shown by Samuel Adams in 2007: "globalization has both costs and benefits". And these "costs" must be appreciated not only economically, but also ethically [9].

❏ Protection of personal data in the medical field

According to Regulation (EU) of the European Parliament and of the Council of Europe No. 679/2016 [10] on the protection of personal data, both the information on the individual, the data on the collection method and the data related to their data are explicitly defined.

(a) Personal data refers to any identifiable person who can provide information about the health status of the person concerned. The data gathered in the preparation of the personal medical record, as well as the data on the medical conduct and the patient's placements, by issuing a diagnosis, in a target group are not exempted.

All this information is accompanied by data about the physician, information that may also constitute personal data. It can be said that a particularity in the medical field is the existence of information regarding both the target person (the patient) and the data operator (the treating physician).

(b) The data operator is represented by any natural or legal person who can determine the purpose for which such processing is carried out and at the same time determine the means of processing the processing. Another particularity in the medical field is represented, at this stage, by the possibility of collaboration of the treating physician with physicians from related specialties that contribute to the completion of a diagnosis, as well as specialized personnel who participate in it and who can access the personal data of the patient.

Access to the medicine it is saw like a global priority, according with *Intellectual Property Rights* (IPR) and the sustainability to the medical progress [11].

As Carlos Correa mentions: "...Article 39.3 of the TRIPS Agreement requires Members to protect test data submitted for the marketing approval of pharmaceuticals and chemical products for agriculture. Such data normally relate to the results of tests about quality, safety, and efficacy of new compounds." [8].

Developing a set of rules in these fields could be useful for medical professionals, lawyers or different

stakeholders, which are not directly involved in these subjects.

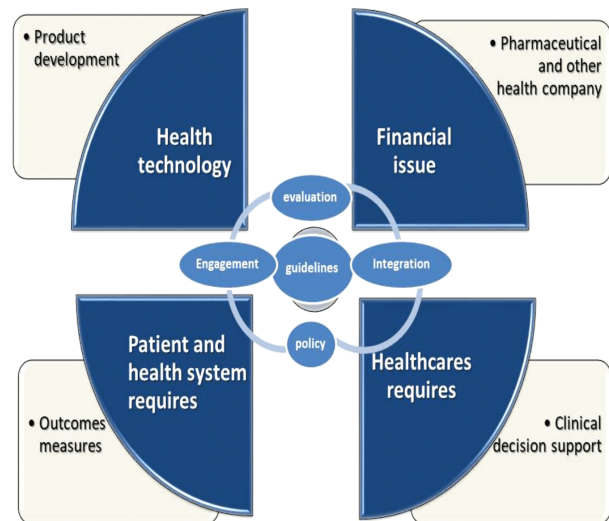


Figure 1 – Actors in sharing data and using intellectual property in medicine.

It can be considered that the physician/physician can meet the quality of personal data operator in a direct, primary, patient/patient relationship, as required by the *General Data Protection Regulation* (GDPR).

Processing with regard to organizing, structuring, retrieving, consulting, or disclosing through the dissemination of results may be operations performed on personal data.

Any data processing can only be performed if the person has given his consent for processing. However, the agreement (informed consent for the medical act) should be delimited by the data processing agreement, but which, through its complexity, also includes medical information.

It should be emphasized that in the medical field the consent of the patient is not required in the following cases:

- (a) in order to protect the life of the person concerned,
- (b) when the operator is bound by law,
- (c) in order to carry out national assessments (National Health Insurance House, Ministry of Health, public health institutions as well as authorities with responsibilities in the field of public order, national security and justice),
- (d) when the processing is done solely for scientific purposes.

"Pseudonymization is the processing of personal data in such a way that it can no longer be attributed to a particular data subject without the use of additional information, provided that such additional information is stored separately and is subject to technical measures and organizational arrangements to ensure that such personal data are not allocated to an identified or identifiable natural person." [12, 13].

By associating the data presented with the possibility of their dissemination through scientific papers, some aspects related to both medical ethics and, implicitly, anonymization of the patient's personal data or groups of patients with a certain symptomatology and who have received medical treatment.

☞ Medical education, intellectual property law and personal data protection

Medical education implies, through its own curriculum, intervention in this situation and of students, which raises the same issues related to patient data protection, and imposes a confidentiality protocol for them [14, 15].

Students must receive a curriculum in which aspects of intellectual property and data protection to be clearly presented so as to avoid the risk of violation of general rules, no matter if it is about the medical students, nursing students, the kinesiotherapy students or those who are concerned with the development of medical devices [16].

It became also important that together with ethics committees in medical facilities or universities to create those reflexes to create the conditions upgrading laws, knowing that “Law will always, therefore, lag behind science.” [17].



Figure 2 – Medical education and intellectual property.
NGO: Nongovernmental organizations.

Given the importance of biomedical research conducted in medical clinics, it is very important for students and resident doctors in these structures to have models on the conduct of research, including in terms of patient compliance and intellectual property rights.

According with Joris Heus: “The prime reason that should motivate researchers to be engaged in the development of IPR is that it is very rewarding to see a technology, originating from their own lab, developed into a final product that ultimately benefits patients.” [18].

The main topics identified by Heus were highlighted in Figure 3.

☞ Intellectual property law and personal data protection in medical research

Copyright is a legal institution similar to others, which essentially comprises all literary, artistic or scientific works and is governed by legal norms. Each author has such work within legal limits but may at some point be subject to the limitation of the exclusive property right over time. Copyright-related rights and *sui generis* rights are those rights whose existence is determined by the existence of copyright presenting both similarities and differences with copyright being legally and distinctly regulated [19, 20].

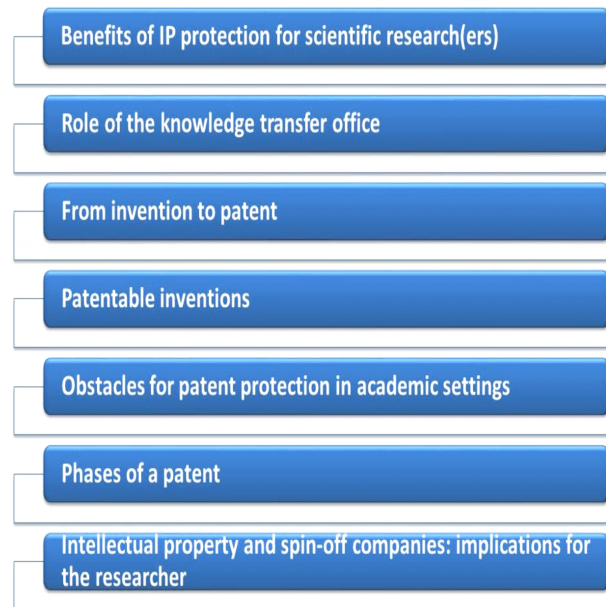


Figure 3 – Topics in medical education and intellectual property (IP) [18].

Original works are all works of intellectual creation in the literary, scientific or artistic field, irrespective of the way of creation, the form of expression, the destination or the value of the work. These include scientific, written or oral works (communications, studies, university courses, school textbooks, projects and scientific papers) [20, 21].

Scientific research can take various forms, being in most cases subject to deontological and life protection rules. Any work done on a patient from the clinical examination and reaching, through several stages, to surgery is accompanied by his written consent. In the case of minors, the consent of parents, guardian or legal representative is required.

Clinical trials require a statistical evaluation that does not require the principle consent of the patient(s) involved, some researchers considering that trials are public goods [22].

Decisional transparency in trials is not optional but even mandatory, but transfers and anonymity of data are essential processes, any data transfer must be subject to the rules on data protection [23].

The way the results are disseminated impose, in order to highlight a certain symptomatology or to highlight the partial or final result, making photographic images.

These are performed at both the body and intra-operative segments. Patient consent in this situation is mandatory. Face-up images that can directly refer to a person can be anonymized, but there are situations where the relevant presentation of the results of an intervention implies full exposure, thus making a parallel between the initial and the final situation. A problem arises in this situation regarding the protection of the patient's data and the author's right of the doctor, whose intervention, considered “premiere” (invention, innovation) modified, with the consent of the patient, his physiognomy. It starts from the idea that the technique is the operator subject to intellectual property law, or is it a good that helps protect and improve life?

Romanian Law on Copyright and Related Rights [20] provides that copyright on a scientific work as well as

other works of intellectual creation is recognized and guaranteed. This right is related to the person of the author and has moral and patrimonial attributes. We must maintain that treatment methods, including techniques developed on the basis of research and their own results with a direct impact on life as well as diagnostic methods, can be recognized by publishing them in specialized journals or by presenting them at conferences and congresses and international, but cannot be patented. It is argued that any medical act is subject to ethical norms and is at the same time a consequence of the physician's commitment through the *Hippocratic Oath*, which induces the altruistic principle of medical act.

On the other hand, it can be admitted that there may be an impediment to the free circulation of information, so a "restriction" of the dissemination of the results by patenting inventions and innovations, which impose the obligation of keeping the secret.

There is a contradiction because patenting entails a strong publicity, which means implicitly a wide recognition associated with the gaining of financial rights (in relation to the legal quality of the researcher), thus enabling the continuation of research, ultimately with a positive impact on the quality of life.

☐ Data protection and intellectual property, an important subject reflected in article

Data protection, medical scientific research and intellectual property are regulated at European level and increasingly analyzed at the level of each country, the subject being not only a major concern but also one that requires the formation of opinion leaders capable of ensuring the correct implementation of international directives [24–26].

The problems are very important and many researchers are preoccupied by this, as is show in the next figures.

The 797 publication between 1979 and 2018 have a Hirsch (*H*)-index of 52, an average citation/item of 12.89 and 9652 citations without self-citation. All of this data show the importance of the subject (Figure 4).

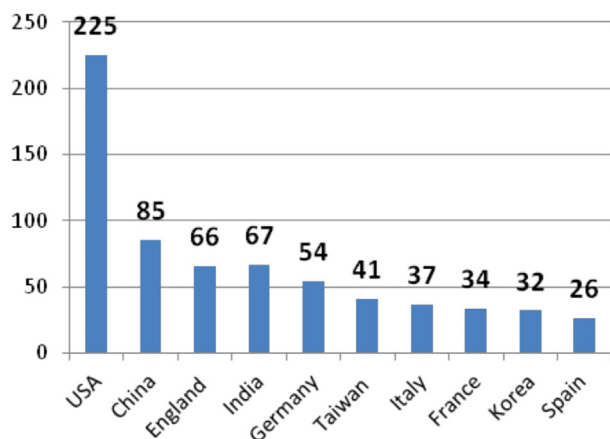


Figure 4 – The first 10 countries all over the world for which the topics data protection and intellectual properties were included in articles abstracted and indexed in Clarivate Analytics databases.

In the last years, the trends of citation were ascendant, with a maximum of 1352 in 2017, as is show in Figure 5.

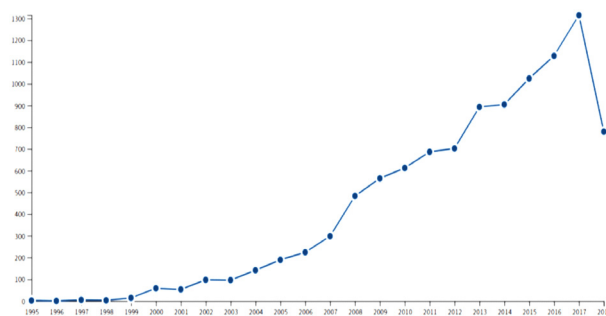


Figure 5 – The trends of citation for the topics data protection and intellectual properties of the articles abstracted and indexed in Clarivate Analytics databases.

In Springer, between 1979 and 2018 were published 11 403 articles, 10 997 after 1989 and 902 in 2018.

In Scopus, the 359 items are distributed over the years, as shown in Figure 6.

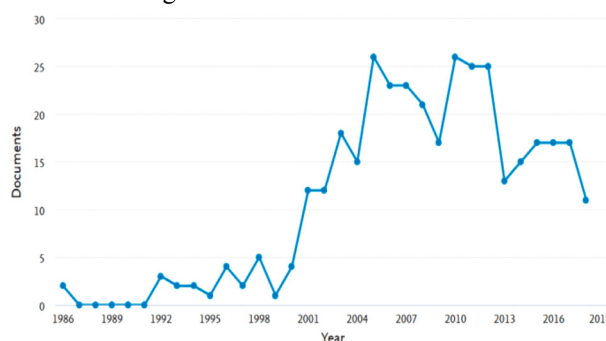


Figure 6 – The trends of published articles related to GDPR and intellectual property in Scopus. GDPR: General Data Protection Regulation.

For the same subject, *PubMed* show a number of 243 items, with a different trend in the same period, so we can conclude that in medicine the subject is still unevenly approached in different period of time (Figure 7).

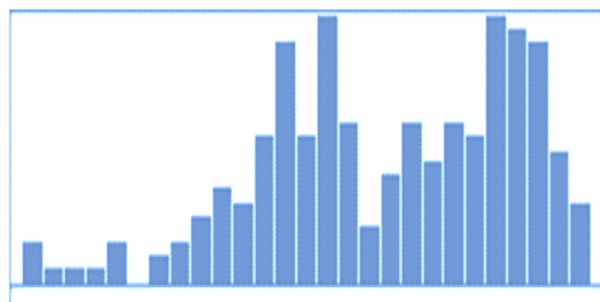


Figure 7 – The trends of publishing article related to GDPR and intellectual property in PubMed. GDPR: General Data Protection Regulation.

☐ Conclusions

Compliance between GDPR and intellectual property assure the implementation of new EU directive and have an impact of developing an coherent policy of protecting in the same time the public health (globalization) and individual one (individual intellectual property rights). In the last years, the societies tolerate less the risk in medical research and in that context, it was developed many rules like GDPR, TRIPS, and *Universal Declaration of Human Rights*. Respecting the international standards on personal data protection, associated with the develop-

ment of research and the dissemination of results in the medical field, is an image of a society that requires customized conduct with an effect on the individual, as well as on the evolution of the knowledge of the human universe.

Conflict of interests

The authors declare that there is no conflict of interests regarding the publication of this paper. All authors read and approved the final manuscript.

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Corresponding author

Iulian Gabriel Popescu, PhD Student, Department of Intellectual Property Law, Law School, University of Craiova, 107D Calea București Avenue, 200478 Craiova, Dolj County, Romania; Phone +40774–400 313, e-mail: iuliangabriel125@yahoo.com