

4 INTELLECTUAL PROPERTY PROTECTION OF CLINICAL TRIAL DATA

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ABSTRACT

Researchers who conduct clinical research with human subjects face a profound problem related to the protection of their work throughout the study and before reaching the final result. Clinical trial processes are one of the most important and perilous scientific processes, particularly from the legal perspective. There are various legal instruments embodying the legal and ethical principles, rights and obligations of research subjects and investigators, and procedures relating to the clinical trial process.

Current protection under intellectual property rights (IPRs) does not provide appropriate legal coverage of the clinical trial process. In order to ensure a suitable degree of protection, a new form of IPR is required that would be compatible with the nature of the data and information collected. The form of IPR proposed in this Paper will be known as the Clinical Trials Right (CTR). The CTR would protect all data and information stemming from the drug development process. It would also cover the work carried out by investigators before and during the trial.

Creating a new form of clinical trial data and information protection would encourage investments in the field of pharmaceutical inventions and provide an effective process for the circulation of information. In addition to enhancing pharmaceutical research and industries, it would also ensure a balance of benefits between the sponsor and investigators on the one hand, and the competitors on the other.

Keywords: *Clinical trials, works of investigators, new form of intellectual property rights, data protection*

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I. INTRODUCTION

The clinical trial process is one of the most important and perilous medical and scientific processes, particularly from the legal perspective. There are several reasons for this. First, it is a vital step in the drug development process since no drug or medicine can enter the markets without undergoing a clinical trial. Second, if they have not been provided with a proper degree of legal protection, this process could infringe the safety, security and welfare of the individuals who are subject to it. Hence, the process should be governed by precise laws and legislations to ensure a suitable degree of protection for research subjects.

There are several international legal instruments dealing with the clinical trial process. These legal instruments deal with legal and ethical principles, the rights and obligations of both research subjects and investigators, and the procedures to be followed during the clinical trial process. The most important instruments are the Nuremberg Code and the Declaration of Helsinki.

Both of these international legal instruments, as well as others, are silent, whether explicitly or tacitly, as to the method of data and information collection during the clinical trial process. In fact, the clinical trials process is costly in most cases in the long run¹, and thus necessitates a proper degree of legal protection.²

The author's suggestion that the work undertaken by investigators during the clinical trial process should be protected is based on reviewing the different forms of legal protection available for intellectual property rights (IPRs), analysing the possibility and scope of application, and selecting the best form of protection and how it might be useful. This article will cover the following topics: a brief overview of clinical trials, the various types of protection for the IPR and finally, it will determine the best form of protection for clinical trial data and information.

II. WHAT ARE CLINICAL TRIALS?

It seems difficult to imagine our life without clinical trials because medicines and drug inventions have been developed as a result.³ A clinical trial is a process carried out in scientific fields to test and study the effects of a new medicine by experimenting it on human subjects. The aim of the clinical trial is to test the safety and

¹ Joseph A DiMasi, Ronald W Hansen and Henry G Grabowski, 'The Price of Innovation: New Estimates of Drug Development Costs', (2003) 22 Journal of Health Economics 151.

² Tomi Suryo Utomo, 'Pharmaceutical Patent Protection and the Introduction of Generic Drugs in Indonesia in the Post-TRIPS Era -- Is Patent Law the Only Factor Affecting the Introduction of Generic Drugs?', (2011) 42 International Review of Intellectual Property and Competition Law, 767.

³ Sara Fovargue, "'Oh Pick Me, Pick Me'"--Selecting Participants for Xenotransplant Clinical Trials' (2007) 15 Medical Law Review 176.

medical efficacy of the new drug, and establish its advantages and drawbacks, as well as its side effects and use.⁴ The European Union Council defines clinical trials as:

any investigation in human subjects intended to discover or verify the clinical, pharmacology and/or pharmacodynamics effects of one or more investigational medicinal products, and/or to identify any adverse reactions to one or more investigational medicinal products and/or to study the absorption, distribution, metabolism and excretion of one or more investigational medicinal products with the object of ascertaining the safety and/or efficacy thereof.⁵

Likewise, the Medicine for Human Use Regulations 2004 (UK) defines clinical trials as:

any investigation in human subjects, other than a non-interventional trial, intended: (1) to discover or verify the clinical, pharmacological or other pharmacodynamics effects of one or more medicinal products; (2) to identify any adverse reactions to one or more such products; or (3) to study absorption, distribution, metabolism and excretion of one or more such products, with the object of ascertaining the safety or efficacy of those products.⁶

At the international community level, there are numerous legal documents that deal expressly with the clinical trial process. The most important one and the oldest is the Nuremberg Code, which dates back to the Nuremberg trials, when Nazi physicians and researchers had been found to conduct medical experiments on prisoners and hostages without their consent and without any means of compensation or recovery. This Code sets out the principles that were embodied in the judgement of the Court that decided this case in August 1947, and these principles were subsequently approved by the United Nations in 1948.⁷

In addition, the Declaration of Helsinki enacted by the World Medical Association in June 1964 sets out the ethical principles relating to medical research that

should be adopted in every clinical research involving human subjects.⁸

Moreover, the European Union Council has adopted several directives for member States to manage all aspects of clinical trials, including EU Directive 2001\20\EC and EU Directive 2005/28/EC.

On the national level, not all countries have adopted laws or regulations on organizing and managing the clinical trial process. Indeed, there are no legal instruments or regulations in some countries governing clinical trial-related matters, except largely broad provisions in their constitutions or in their national civil codes and other related legislations. By contrast, other countries, such as the United States of America⁹ and the United Kingdom¹⁰, have a well-organized legal system dealing with the clinical trial process.

Indeed, it is crucial to ensure the legal and medical protection of human subjects in medical and scientific research, because in a few cases this process may lead to death or severe injuries and reactions being sustained. Recent examples of clinical trials ending in catastrophic results are TGN1412¹¹ and *Abdullahi v. Pfizer*.¹²

⁸ Declaration of Helsinki 1964, available at: <<http://www.wma.net/en/30publications/10policies/b3/17c.pdf>>

⁹ Mainly, the clinical trials process is governed in the United States by the Code of Federal Regulation, Title 21 (Food and Drug) and Title 45 (Public Welfare).

¹⁰ The clinical trials' process is governed by the Medicines for Human Use regulations 2004 and its amendments.

¹¹ In 2006, a scientific research centre called 'Parexel' was tasked to operate and manage the clinical trials of a new drug called 'TGN1412' for a German company for the industrialization of medical instruments called 'TeGenero'. The new drug was developed for the treatment of rheumatoid arthritis and leukaemia. In March 2006, phase I of the clinical trial took place involving six of the healthy volunteers in order to examine the safety of this drug. After the first dosage, all the subjects experienced severe reactions, including multiple organ disfunction, and they were then hospitalized in critical care in Northwick Park Hospital in London. In June 2006, five of the volunteers recovered and left the hospital, while the sixth volunteer was in a coma for three weeks and after awakening, discovered that he might lose parts of his fingers and toes, which had turned black because of the reaction to the drug. For more details about this case, see Pamela R Ferguson, 'Clinical Trials and Healthy Volunteers' (2008) 16; Medical Law Review 23; Sara Fovargue, "'Oh Pick Me, Pick Me"--Selecting Participants for Xenotransplant Clinical Trials', (2007) 15 Medical Law Review, 176; MJH Kenter and AF Cohen, 'Establishing Risk of Human Experimentation with Drugs: Lessons from TGN1412' (2006) 368 The Lancet 1387:91.

¹² In this case, a new medicine called 'Trovan' invented in 2002 by Pfizer, one of the largest pharmaceutical companies in the United States, which applied to experiment this drug on children in Nigeria. The investigation team selected 200 children as subjects in this clinical trial, and divided them into

⁴Pamela R Ferguson, 'Clinical Trials and Healthy Volunteers' (2008) 16; Medical Law Review 24

⁵ European Union Directive 2001\20\EC, Part 2 – Definitions - (a).

⁶ Medicines for Human Use Regulation 2004, Article 2(1), clinical trials.

⁷ Code of Nuremberg 1947, available at: <<http://history.nih.gov/research/downloads/nuremberg.pdf>>

The clinical trials process involves the following steps:

- Preclinical Testing I: scientists in their laboratories predict that certain chemical components may be effective in the treatment of a certain disease. A series of scientific experiments is then conducted in a laboratory to understand how those components work and what the most suitable chemical form is. The resulting information may or may not be proved to be useful for the treatment of the illness in the subsequent steps.
- Preclinical Testing II: in this step, scientists and researchers test the new components, which may be deemed to be useful or not, on animals in the laboratories. The aim is to examine the safety and medical effects of these components on animals that may have certain medical features similar to those of human beings. If scientists find that the new chemical entity could be useful to treat a certain disease, they can move to the next step and apply for the 'New drug investigation' process through the competent administrative authority.¹³
- Clinical trial Phase I: this is considered the first step in the clinical trial process. In phase I of the clinical trial process, the investigators select a limited number of human research subjects. The purpose of this phase is to test the safety of the new components when used on individuals and whether or not they may cause severe problems. In this phase, the number of research subjects is limited to

two groups. The investigators used the new drug with the first group, while the second used a placebo. As a result, eleven children died, six from the first group and five from the second one. In addition, a large number of children from the two groups experienced severe reactions, including paralysis, amnesia, deafness and blindness. The guardians of those children brought a case before the US District Court, Southern District of New York, requesting legal protection, because Pfizer did not abide by the legal rules governing clinical trials regarding the necessity of informed consent of the research subjects.

For more details about *Abdullahi v. Pfizer*, see Dennis M Coyne, 'International Pharmaceutical Mistrials: Existing Law for The Protection of Foreign Human Subjects and a Proposal for Reform', (2011) 29 Boston University International Law Journal 427; Finnuala Kelleher, 'The Pharmaceutical Industry's Responsibility for Protecting Human Subjects of Clinical Trials in Developing Nations' [2004] Columbia Journal of Law and Social Problems 67.

¹³ 'Understanding the Clinical Research Process and Principles of Clinical Research' (HIV/AIDS Network Coordination), p.9, available at: <http://www.hptn.org/web%20documents/CIPDocs/CABTraini ngMaterials/Participant's%20Guide.pdf>

between five to ten, and they usually receive a small dosage of the new drug.

In most clinical trials, the subjects in this phase are healthy volunteers, who agree to participate in the study and provide informed consent to this end.¹⁴ Owing to the inherent danger of this step, the investigator and his or her team collect detailed data and an up-to-date description of the research subjects, in order to determine whether to continue with the study or not, based on the results obtained during this phase.¹⁵

- Clinical trial phase II: if the investigators of the clinical trial are satisfied with the results of the previous phase, they then move to Phase II of the study. In this step the purpose of the trial is to examine the medical effects of the drug, to determine the proper dosage for treatment and to ascertain its side-effects. In this phase, the number of research subjects is increased to between 50 and 100 subjects.¹⁶ Selected volunteers may be patients or a mix of healthy and patient volunteers. The testing method is the control group technique, in which the volunteers are divided into two groups: the first group are given the new drug, while the second group are given the placebo. The aim of this phase is to test the medical effects of the new drug when compared with the placebo or the old medicine. If this step is completed successfully, the investigators can proceed to the next one.¹⁷
- Clinical trial Phase III: in this phase, a large number of patient volunteers are used to establish the safety degree of the drug and its medical effect, as well as its side-effects.¹⁸ The number of research subjects that participate in this phase may be around 200 patients.¹⁹ During all these phases of the trial, the progress of all the subjects and the interaction of the new drug with their medical situation

¹⁴ Sara Fovargue, "'Oh Pick Me, Pick Me'--Selecting Participants for Xenotransplant Clinical Trials', (2007) 15 Medical Law Review, 177.

¹⁵ David B Resnik, 'Compensation for Research-Related Injuries: Ethical and Legal Issues' (2006) 27 Journal of Legal Medicine, 265.

¹⁶ Pamela R Ferguson, 'Clinical Trials and Healthy Volunteers' (2008) 16 Medical Law Review, 25.

¹⁷ Richard M Cooper, "'Response", a Response to an Article Published in the Harvard Law Review", (2008) 121 Harvard Law Review Forum, 36; Joseph A DiMasi, Ronald W Hansen and Henry G Grabowski, 'The Price of Innovation: New Estimates of Drug Development Costs', (2003) 22 Journal of Health Economics, 157.

¹⁸ Emma Cave, 'Seen but Not Heard? Children in Clinical Trial' (2010) 18 Medical Law Review, 3.

¹⁹ Pamela R Ferguson, 'Clinical Trials and Healthy Volunteers' (2008) 16 Medical Law Review, 25.

are recorded by the investigators and assistance team. All these data must then be submitted to the competent authorities, who review all the phases of the study and decide whether to approve, require revision or reject it.²⁰

During these phases, all the collected data and information is recorded and analysed by the investigators and the team of researchers, who have undertaken the clinical research, so as to decide whether to continue with the process or not. This critical data and information is of high commercial value and will be used in subsequent steps of the process and in the licencing of the new drug (New Drug Application process (NDA)). When deciding to grant a licence for the new drug, licencing authorities are required to review the clinical trial's protocol and the outcomes of the clinical trial phases.

There is a need to protect all such data for a reasonable period of time during and after the clinical trials, and during the application of a licence and after it has been granted. However, neither the Nuremberg Code nor the Declaration of Helsinki expressly provide for protection of such data. Similarly, the Food and Drug Administration or the Medicines for Human Use Regulation are silent on the protection of work undertaken by researchers during the clinical trial process.

The often conflicting interests of stakeholders and the possible forms of protection for data and information collected before, during and after the clinical trial process will be discussed below.

III. CONFLICT OF INTERESTS WITHIN THE CLINICAL TRIAL PROCESS

The clinical trial process embodies a wide range of rights, advantages and interests for stakeholders. All those involved stand to gain from this process with different degrees of interest, including the pharmaceutical companies that fund the trial, the researchers and investigators that conduct the research, the research subjects and the public itself. However, these benefits and interests potentially conflict with one other.

The desire to protect data collected during the clinical trial process is a clear example of how stakeholders' interests might often conflict. Indeed, all the individuals

involved in the clinical trial process have differing interests in the data and information collected.

First, the pharmaceutical companies that sponsor and fund the research from its early moments until the marketing stage want the protection of all the trial data and information to be used exclusively for an extensive period of time.²¹ This interest may be understood given the economic value of the clinical trial information, which gives the sponsor a chance to maximize profit from marketing the new drug.

The process of developing new drugs costs millions of dollars²² and lasts for a sustained period of time.²³ In order for this process to be profitable, all these expenditures need to be protected during the development process and for a reasonable period of time. Although this point of view somewhat contradictory to the strategies adopted in most countries, some scholars consider that in order to ensure profitability, all data and information from the development process should be obscured and kept undercover, so as to prevent others from knowing, utilizing or exploiting them.²⁴

Second, the researchers and investigators involved in the development of the new drug have a scientific interest in the clinical trial data and information. The work undertaken in laboratories and in research centres includes formulating a new chemical entity; investigating the new chemical entity in preclinical phases on animals; investigating the new chemical entity in the phases of the clinical trial on human subjects; and observing its medical effect and safety after marketing.²⁵ The interest of the researchers and investigators is reflected in their desire to declare any progress achieved in their research and studies, to make it public in academic conferences or by publication in scientific journals and reviews.²⁶ Researchers stand to

²⁰ Richard M Cooper, "'Response', a Response to an Article Published in the Harvard Law Review", (2008) 121 Harvard Law Review Forum, 36; Joseph A. DiMasi, Ronald W Hansen and Henry G Grabowski, 'The Price of Innovation: New Estimates of Drug Development Costs', (2003) 22 Journal of Health Economics, 157.

²¹ Pamela Andanda, 'Managing Intellectual Property Rights Over Clinical Trial Data to Promote Access and Benefit Sharing in Public Health', (2013) 44 International Review of Intellectual Property and Competition Law, 140.

²² A study in 2010 estimated the values of developing new drugs to exceed \$1.8 Billion. Steven M Paul and others, 'How to Improve R&D Productivity: The Pharmaceutical Industry's Grand Change', (2010) 9 Nature Reviews: Drug Discovery, supplementary information box2.

²³ The drug development process takes about ten to fifteen years to formulate a new chemical entity, to examine its safety and efficiency through clinical trials and to apply for the necessary licensing and marketing approvals.

²⁴ Pamela Andanda 'Managing Intellectual Property Rights Over Clinical Trial Data to Promote Access and Benefit Sharing in Public Health' (2013) 44 International Review of Intellectual Property and Competition Law, 140.

²⁵ Carl H Coleman, 'Duties to Subjects in Clinical Research' (2005) 58 Vanderbilt Law Review, 387.

²⁶ Pamela Andanda, 'Managing Intellectual Property Rights Over Clinical Trial Data to Promote Access and Benefit Sharing in

gain from the announcement of the clinical research results in terms of their academic and scientific careers.²⁷

Third, research subjects have a personal interest not to reveal research data and information as the publication and announcement of the research results constitute an infringement of their confidentiality and privacy, as well as exploitation of their personal data for the sake of economic profit and scientific reputation. Yet, some potential research subjects ask to be clearly aware of previous studies in deciding whether to participate in the research.²⁸ The double standards methodology makes it difficult for research subjects to decide whether to support or oppose the protection of clinical trial data.

Furthermore, it is in the interest of the public to have updated knowledge and access to all data and information related to health-care and medicines sectors. The principle of access and benefit sharing (ABS) with respect to public health means that all studies and research in the medical field should be available and accessible to the public.²⁹ The goal of applying this principle is to enhance the ability of workers in the medical sector to deal with diseases and to ensure a proper degree of welfare for the public. In this regard,

[...] the struggle to combat human disease and to promote health is inherently international in character and is recognized as an element of maintaining international peace and security.³⁰

As a result of the conflict of interests inherent in the clinical trial process and especially when dealing with clinical data and information, it could be argued that these opposing interests make it difficult to adopt one point of view over the other. At the same time, these opposing interests pose considerable challenges in creating a unified system to address the issue of clinical trial data on an equal footing of profit for all stakeholders.

Public Health' (2013) 44 International Review of Intellectual Property and Competition Law, 140.

²⁷ Rachel Kreppel, 'Clinical Trials: A New Form of Intellectual Property?' 4, available at:

<http://www.kentlaw.iit.edu/Documents/Academic%20Programs/Honors%20Scholars/2002/Rachel-Kreppel-paper.pdf>

²⁸ Pamela Andanda, 'Managing Intellectual Property Rights Over Clinical Trial Data to Promote Access and Benefit Sharing in Public Health' (2013) 44 International Review of Intellectual Property and Competition Law, 141.

²⁹ Pamela Andanda, 'Managing Intellectual Property Rights Over Clinical Trial Data to Promote Access and Benefit Sharing in Public Health', (2013) 44 International Review of Intellectual Property and Competition Law.

³⁰ Antony Taubman, 'The International Patent System and Biomedical Research: Reconciling Aspiration, Policy and Practice' (2008) 10 The American Association of Pharmaceutical Scientists Journal, 526.

IV. WHAT KIND OF DATA SHOULD BE PROTECTED?

Before and during the clinical trial process, a vast amount of data is collected during every phase and submitted for the licensing process. Broadly speaking, the clinical trial data, which are intended to be protected, include³¹:

- Chemical formulas;
- clinical trial protocols;
- files of information provided to potential volunteers to clarify their knowledge;
- data and statistics collected during the various phases of the clinical trial; and
- final research results.

It should be noted that these are the minimum amounts of data which require legal protection. The exact set of data differs from case to case according to the type of study and its scientific value.³²

A. POTENTIAL WAYS TO PROTECT CLINICAL TRIAL DATA

In order to ensure a suitable degree of protection for clinical trial data, it is important to determine, firstly, the nature of the data and information. Essentially, all the data and information collected should be considered a form of intellectual property resulting from the mental work and efforts undertaken by the researchers and investigators involved in the process. Accordingly, the best method to protect these data and information would be recourse to the legal protection provided for IPRs in international conventions and national legislations.

Generally speaking, the different types of IPRs are³³: copyright and related rights; trademarks; geographical indications; industrial designs; patents; layout-designs (topographies) of integrated circuits; and undisclosed information. The TRIPS Agreement and other international conventions dealing with IPRs fail to

³¹ Pamela Andanda, 'Managing Intellectual Property Rights Over Clinical Trial Data to Promote Access and Benefit Sharing in Public Health', (2013) 44 International Review of Intellectual Property and Competition Law, 145.

³² Rachel Kreppel, 'Clinical Trials: A New Form of Intellectual Property?' 4, available at:

<http://www.kentlaw.iit.edu/Documents/Academic%20Programs/Honors%20Scholars/2002/Rachel-Kreppel-paper.pdf>

³³ As stated in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), administrated by the World Trade Organization (WTO) 1994.

address the protection of clinical trial data.³⁴ Hence the focus will be on already established IPRs, especially those that lend themselves to ensuring suitable protection of clinical trial data and information. A detailed explanation will follow on the applicability of copyrights, patents and undisclosed information to clinical trial data.

Copyright: From the standpoint of the clinical trial process, copyright could be used to protect the broad range of work undertaken by both researchers and investigators, including written reports and statistics, published papers on the study's results, and any files and documents submitted to the administrative authorities as a condition for the application of a licence or for marketing approval.³⁵

As stated, protection under copyright could be applicable to the work undertaken by investigators in the clinical trial process. However, because copyrightable works need to be published or made available for the public to benefit from copyright protection, this type of protection is unsuitable in the clinical trial arena. In other words, this work cannot be covered by copyright since the goal is to protect the work undertaken by investigators during the clinical trial process and before arriving at the final results or publishing them in conferences or scientific reviews. It is well known that in order to protect the data and information gathered during the clinical trial process, the work must be announced to the public.³⁶

Patents: When patent rules are applied to clinical trial data, the patent protection may include the new chemical entity, the formulation of the new drug, and the final results of the study and the manufacturing method of this new drug. All these inventions are patentable as provided for in the TRIPS Agreement.

In the pharmaceutical industry, both the pharmaceutical product itself and the manufacturing process can be patented. The application for a patent should therefore clearly state the subject matter of the patent application, and whether it concerns a new drug or the manufacturing process or both, the patent protection being restricted to the subject matter of the patent application.³⁷

By contrast, the following are not patentable: the clinical trial's protocol; any data and statistics collected during the various phases of the clinical trial; and data and files submitted to the authorized licencing agencies.³⁸ This is normal, because the previous types of clinical trial data do not satisfy patent requirements, especially the condition of capability of industrial application.³⁹ From this perspective, sponsors and investigators do not have the right, either to have exclusive use of these data during the trial, or to prevent others from using, exploiting, selling or offering such data for sale.

In short, patent rights may be used to protect certain forms of clinical trial data, but are not applicable to other forms due to the absence of patent conditions and requirements.

Undisclosed Information: When the rules of Undisclosed Information (UI) are applied to clinical trial data, one can say that there is a wide range of data and information that may be protected by the UI, including the clinical trial's protocol; files and documents made available to potential research subjects; files and documents submitted to administrative authorities; data and statistics on the progress of research subjects; final results of the research; and any other information that may be useful during the research.

As this protection, according to UI rules, neither requires any administrative procedures nor must last for a certain period of time, this valuable information is protected as long as it is kept secret. Even when this information is submitted to administrative bodies for approval and the granting of a licence, it is still protected pursuant to paragraph 3 of TRIPS Article 39, which provides that:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.

³⁴ Jeremy de Beer, 'Applying Best Practice Principles to International Intellectual Property Law-making' (2013) 44 *International Review of Intellectual Property and Competition Law*, 885.

³⁵ Rachel Kreppel, 'Clinical Trials: A New Form of Intellectual Property?' 4, available at: <http://www.kentlaw.iit.edu/Documents/Academic%20Programs/Honors%20Scholars/2002/Rachel-Kreppel-paper.pdf>

³⁶ Article 9/2 of the TRIPS Agreement.

³⁷ *Daiichi Sankyo Co Ltd and Another v. DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon* [2013] Court of

Justice of the European Union [2013] All ER (D) 262 (Jul), All England Reporter, paragraph 84.3.

³⁸ Rachel Kreppel, 'Clinical Trials: A New Form of Intellectual Property?' 4, available at: <http://www.kentlaw.iit.edu/Documents/Academic%20Programs/Honors%20Scholars/2002/Rachel-Kreppel-paper.pdf>, 12.

³⁹ Rachel Kreppel, 'Clinical Trials: A New Form of Intellectual Property?' 4, available at: <http://www.kentlaw.iit.edu/Documents/Academic%20Programs/Honors%20Scholars/2002/Rachel-Kreppel-paper.pdf>, 12.

Pursuant to this article, Member States have a duty to maintain and guarantee the confidentiality of the information submitted to administrative agencies upon application for a licence.⁴⁰ This rule applies where the information submitted includes details about a new chemical entity, test data or any other secret information, if related to a pharmaceutical or agricultural licence.⁴¹ This article provides that, administrative bodies, which are authorized to receive such data, are obliged to protect the confidentiality of this data during the licensing process and after granting the licence for the stated period of time.⁴²

The interpretation of this article of the TRIPS Agreement raises many legal issues.⁴³ Developed Member States explain it in their national legislations as it grants the right of the exclusive use of the protected data and information for the stated period of time. On the other hand, developing Member States interpret it as it only protects the submitted data from being undisclosed, used or exploited by the competitors in a manner which is inconsistent with fair competition.⁴⁴

Another issue related to the application of this article concerns the impact on national legislations. This issue is related to the second application for the similar chemical entity. As a result of protecting the UI of the first registration of the new chemical entity, any other application for registering a similar entity must submit new data and information and cannot rely on the data of the previous application. This is the rule adopted by developed countries, which aim to control competition in the markets of the pharmaceutical industry. On the other hand, developed countries will permit the registration of the similar chemical entity, which relied on the data and information of the previously registered chemical entity. This is the rule even when the second

application is made during the period of the protection, as long as the first chemical entity was patented.⁴⁵

The variation in the application of Article 39.3 of the TRIPS Agreement among Member States raises many practical issues. For instance, Argentinian Courts adopt the second point of view to allow other companies to use the data and information of chemical entities already registered.⁴⁶

In short, the protection provided for UI under the TRIPS Agreement affords protection, first, for valuable secret information, as long as it is kept secret; and second, for information provided to administrative agencies under the licence procedures.

Consequently, it is apparent from this overview that among the potential forms of legal protection for clinical trial data and information, not all the types of protection are applicable to the various forms of clinical trial process data. Consequently, stakeholders need to resort to more than one track protection for their work, as follows:

- Chemical formula: patent;
- clinical protocol: undisclosed information;
- informed consent files: undisclosed information;
- clinical data and statistics: undisclosed information;
- final results: patent; and
- published papers and researches: copyright

Although UI seems to be the best technique, it only covers two types of data, namely, (1) secret data and statistics collected during the trial itself, and (2) data and statistics provided to administrative agencies for licence and approval.⁴⁷

⁴⁰ Jonathan de Ridder, 'Data Exclusivity: Further Protection for Pharmaceuticals', available at:

<<http://www.findlaw.com.au/articles/1576/data-exclusivity-further-protection-for-pharmaceut.aspx>>

⁴¹ Sam Ricketson, 'The Future of the Traditional Intellectual Property Conventions in the Brave New World of Trade-Related Intellectual Property Rights' (1995) 26 *International Review of Intellectual Property and Competition Law*, 890.

⁴² Public Citizen Health Research Group v. Food and Drug Administration [1997] United States District Court for the District of Columbia

⁴³ Karin Timmermans and Togi Hutadjulu, 'The TRIPS Agreement and Pharmaceuticals - Report of an ASEAN Workshop on the TRIPS Agreement and Its Impact on Pharmaceuticals' (World Health Organization 2000), 39.

⁴⁴ Tomi Suryo Utomo, 'Pharmaceutical Patent Protection and the Introduction of Generic Drugs in Indonesia in the Post-TRIPS Era -- Is Patent Law the Only Factor Affecting the Introduction of Generic Drugs?' (2011) 42 *International Review of Intellectual Property and Competition Law*, 768.

⁴⁵ Karin Timmermans and Togi Hutadjulu, 'The TRIPS Agreement and Pharmaceuticals - Report of an ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals' (World Health Organization 2000), 39.

⁴⁶ *Novartis Pharma AG v. Monte Verde SA and Varios Propiedad industrial e intelectual*, the Federal Civil and Commercial Court of Appeals in Argentina, Case No. 5.619/05. See text below to n 55.

⁴⁷ Undisclosed information is considered the best technique to protect researchers' work during the clinical trials' process as a result of the express protection provided by Article 39.3 of the TRIPS Agreement. See Jonathan de Ridder, 'Data Exclusivity: Further Protection for Pharmaceuticals', available at: <<http://www.findlaw.com.au/articles/1576/data-exclusivity-further-protection-for-pharmaceut.aspx>>(n 39).

Therefore, the UI remains for information already registered such as a chemical formula or published information such as final research results, which should be covered by other forms of IPRs. In addition, the UI is inapplicable in cases related to the approval of similar pharmaceutical products.

In *Novartis Pharma AG v. Monte Verde SA & Varios Propiedad industrial e intelectual*, under Argentine Confidentiality Act No. 24,766, the right of confidentiality is granted to the first pharmaceutical product applied for only and the information from any subsequent application containing similar ingredients is made available for public use. The Argentine Law provides that such data is not required to be protected where similar products have been approved in one of the other countries.⁴⁸ Hence, even in the case of applying Article 39.3 of the TRIPS Agreement regarding the protection of data submitted to licenced authorities, the UI remains a problematic issue.

The proposed solution in this case is the creation of a new form of protection under the umbrella of IPRs, in order to cover the mental work undertaken by researchers and investigators during the clinical trial process from A to Z. The proposed form of protection called Clinical Trials Rights (CTR) would provide the following set of rights for stakeholders in the clinical trial process:

B. PROPOSED FORM OF PROTECTION: THE CLINICAL TRIAL RIGHT

As stated, this Paper proposes the CTR as a form of IPR that would protect the work undertaken by investigators and researchers during clinical trials. The CTR would provide stakeholders with the following rights:

- The right to protect all data and information used, submitted or resulting from the clinical trials process against unfair competition: according to this right, the government would be responsible for providing a wide range of protection for work performed by investigators against any form of exploitation or misuse by other competitors in the field of drug development. Governments, in this regard, would be required to impose criminal sanctions i.e. fines and imprisonments, for violators of the protected CTR.
- The right to maintain the confidentiality of the registered data for a certain period of

⁴⁸ Jorge Otamendi, 'Confidential Data in the Approval of a "Similar" Pharmaceutical Product' No. 19, July 2011, available at: <[https://www.aippi.org/enews/2011/edition19/Pharmaceutica I Product.html](https://www.aippi.org/enews/2011/edition19/Pharmaceutica%20Product.html)>

time: the government administrative agencies responsible for receiving requests for licensing of the new drugs are obliged to maintain the confidentiality of the submitted data and information. This obligation lasts for a certain period of time to be expressly determined by national legislations. Accordingly, in case of negligent infringement to this right by the administrative agency, a remediable compensation would be paid to the owner of the CTR. Nevertheless, in case of intentional infringement by the responsible officials at the administrative agency or by other competitors, a criminal sanction would be imposed.⁴⁹ The aim of this right is to ensure a suitable degree of protection for data and information submitted to the licencing body, in order to guarantee effective protection against unfair competition in the drug development market.

- The right to exclusive use of the registered data for a certain period of time: as a result of granting the CTR to the sponsor of the new drug, both the latter and the investigators should have the right to exclusive use of the clinical trial data and information. This exclusive right includes using the data before, during and after the trial, as long as the period of the protection is still running. The duration of the protection should cover the various phases of the trial, as long as it did not exceed ten years. Such protection terminates after the declaration of the final results or after a lapse of ten (10) years, whichever is shorter. In case of intentional infringement of this right, a remediable compensation and a criminal sanction should be imposed.
- The right to prevent others from using or exploiting the registered data or for applying for a licence for a certain period of time: The foregoing right of exclusive use of the clinical trial data entails the right of the owner to prevent others from using or exploiting this data and to apply the required procedures in case of any infringement. This right also prevents others from applying to conduct clinical trials for the new drug as long as it is proved that the data utilized were obtained

⁴⁹ The intentional infringement of the CTR takes the form of disclosing, acquiring, using or exploiting such information by other competitors without the consent of the owner in a manner contrary to honest commercial practices. It may also take the form of facilitating the disclosure, use or exploitation of the information by the employee, who is responsible for its confidentiality.

by illegal means. The governmental body that grants the CTR should provide the CTR owner with all the necessary means to benefit from this right and to prevent others from minimizing or limiting such benefit.

The advantages of the CTR as a form of IPR are that it would provide a wide range of protection for clinical data before, during and after the trials. This protection would cover all forms of data and information used and resulting from the trials. This right would also be granted by a specialized governmental agency, which reviews the request for protection, grants the CTR and protects it against any unauthorized use by other competitors.

With regard to the governmental body which grants the CTR, a specialized agency should be established to deal with all matters related to this new right. This agency would have the authority to:

- Revise the request to obtain the CTR;
- register the protected data and information;
- grant the CTR to the sponsor of the drug development process;
- grant the licence for exclusive use of the registered data and information;
- create a registry of all protected drug development processes and protected data from each process;
- follow precautionary procedures to ensure the required protection of registered data and information; and
- apply the procedures for prosecution of violators of the CTR.

All details relating to the authorities and structure of the granting agency should be clearly mentioned in national legislations, according to the administrative system of each country.

Concerning the protection of data and information from failed clinical trials, the CTR aims to protect the work performed by investigators during clinical trials in order to allow them to benefit from their efforts after declaration of the final results. However, what is the aim of such protection if the clinical trial failed and the sponsor has declared its termination? In other words, what is the effect of declaration of the failure of the clinical trial on the conferred CTR?

Declaration of the failure of a clinical trial leads to the termination of the CTR granted and results in the possibility of registration of new trials to benefit from

the protection under the CTR. However, what is the legal situation of the ex-protected data and information? Are they still covered by the CTR or do they lose such protection and become available for public use?

Dealing with ex-protected data results in a conflict of interest between the owner of such data and other competitors who stand to gain from the protection under the CTR. On the one hand, the owner of the ex-protected data would clearly like to maintain protection as long as possible to preserve the efforts of the investigators during the period that preceded the clinical trial's declaration of failure. On the other hand, other competitors would like to have the ex-protected data made available for public use, in order to improve the work undertaken previously and benefit from any flaws.

Clearly, it would be unfair if the ex-protected data are disclosed and made available for public use, as the sponsor and the investigators would not benefit from all their efforts. It would also be unfair to provide protection for failed clinical trials and prevent other competitors from benefiting from such protection, signifying that the failed trial is still protected.

To resolve these conflicting interests, a special mode of protection should be adopted. In fact, the ex-protected data should be covered by the CTR, even after the declaration of the clinical trial's failure, however, this protection should last for three (3) years only from the date of the declaration. During this period, it should be prohibited to disclose, sell, use or exploit the ex-protected data without the consent of the owner. Other competitors would then have the right to register new clinical trials (of the same type) to be protected by the CTR as long as the submitted data and information stem from personal efforts of the investigators of the new trial.

After the expiry of the three-year period, the ex-protected data would be disclosed and made available for public use.

At the end of the clinical trials and after the final result is declared, the CTR would terminate and all the protected data and information should be disclosed to the public. Such a disclosure is part of the procedures for protecting new drugs through the patent system.

V. CONCLUSION

The clinical trial process differs from other types of mental works, since more than one form of IPR is required to ensure a suitable degree of protection. The CTR is a proposed as a form of protection covering any data and information provided or used during the drug development process or resulting from it. The CTR would cover any work performed by investigators

before and during the trial. After the termination of the clinical trial and declaration of the final results, the CTR would to an end and the new drug would be protected by patent rights, if applicable. The CTR would last for a specific period of time or for the completion of the trial, whichever is shorter.

Ultimately, this new form of protection for clinical trial data and information would encourage investments in the field of pharmaceutical inventions, while ensuring an effective process for the circulation of information. It would also ensure a balance of benefits between the sponsor and the investigators on the one hand, and other competitors on the other, as well as, enhancing pharmaceutical research and industries.

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