Chicago-Kent Journal of Intellectual Property

Volume 14 | Issue 2 Article 8

5-1-2015

Enabling Access to Clinical Trial Data: When is Unfair Use Fair?

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ENABLING ACCESS TO CLINICAL TRIAL DATA: WHEN IS UNFAIR USE FAIR?

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ABSTRACT

This inquiry is prompted by the unprecedented policy of the European Medicines Agency that enables the disclosure of clinical trial reports submitted for drug marketing authorization, effective as of January 1, 2015. It addresses the question whether such practice is in compliance with the international standard of clinical data protection under Article 39.3 of the TRIPS Agreement. Most scholarly and policy debate regarding this provision analyzes whether it precludes the referential use of data to facilitate the approval of a generic drug. Rather than focusing on a particular use, this Article seeks to identify the principle underlying the protection obligation by which the legitimacy of "use X" can be evaluated. In doing so, it interprets the provision from literal, historical and teleological perspectives, and it analyzes a peculiar overlap between three legal regimes: unfair competition, trade secret, and *sui generis* data protection.

The proposed principle allows avoidance of situations where, due to the ambiguous notion of unfair commercial use, the protection of data under the TRIPS Agreement can be stretched indefinitely. With regard to data disclosure for experimental use, it is argued that the protection obligation under 39.3 TRIPS does not justify monopoly type protection of clinical trial data, neither does it require the reservation of experimental use exclusively for the data originator, even if such use can have commercial benefits for competitors.

INTRODUCTION

Clinical trials play a crucial role in evidence-based medicine. Trial results present unique knowledge on the effect of drugs on the human organism. Companies that conduct clinical research with great risk, effort and expenditure[1] assert property rights in the generated data and protection under confidentiality. From the regulatory perspective, clinical trial reports must attest to drug safety, quality and efficacy before a health authority will approve of the drug for marketing.

This article addresses the unprecedented practice of the European Medicines Agency ("EMA")[2] of clinical trial data disclosure, effective as of January 1, 2015.[3] While the earlier policy provided for "reactive," or request-based, access the 2015 initiative implements "proactive" access to clinical reports for drugs approved for marketing, on-screen as well as in downloadable and searchable formats.[4]

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1. THE INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS ASSOCIATIONS (IFPMA), ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: THE ROLE OF DATA EXCLUSIVITY 6–7 (2000) (claiming that "[a] new drug costs, on average, $500 million and requires as long as 15 years to develop, if preclinical and clinical trial phases are taken into account."). While the IFPMA does not provide a breakdown of these expenditures, the European Commission, for instance, reports that "approximately 1.5% of the turnover of pharmaceutical companies were [*sic*] spent on basic research, the remainder of R&D expenditures mainly concern clinical trials and tests. The biggest cost blocks for originator companies were marketing and manufacturing." EUROPEAN COMMISSION, PHARMACEUTICAL SECTOR INQUIRY FINAL REPORT (2009), http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf (last visited Apr. 28, 2015).

2. The EMA is a drug authority established under Regulation (EC) No 726/2004. Among others, the EMA is in charge of the EU-wide marketing authorization for pharmaceutical products of medicinal products through a centralized procedure. Commission Regulation 726/2004, 2004 O.J. (L 136) 1.

3. Eur. Meds. Agency, The European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use, EMA/240810/2013 (Oct. 2, 2014), *available at* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf; Press Release, Eur. Meds. Agency, Publication of Clinical Reports: EMA Adopts Landmark Policy to Take Effect on January 1, 2015 (Oct. 2, 2014), http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/10/WC500174767.pdf (last visited Apr. 28, 2015).

4. The new initiative is a step forward from the EMA's access policy of 2010, but a "reversal" on the original policy proposal announced in 2012 that envisaged publication of *full* reports. *See* Press Release, Association Internationale de la Mutualité et al., EMA's Final Policy On Access To Clinical Data: Proactive Access To Some Data, But Strings Attached (Oct. 16, 2014)), http://english.prescrire.org/Docu/DOCSEUROPE/20141016_JointStatement_EMA_NewTransparencyPolicy.pdf (last visited Apr. 28, 2015).

As aspired to by the EMA, the publication of clinical trial data "avoid[s] duplication of clinical trials, foster[s] innovation and encourage[s] development of new medicines."[5]

During public consultations, an exceptional number of contributions were submitted featuring highly polarized positions.[6] Not surprisingly, the disclosure initiative was highly acclaimed by the scientific community and strongly opposed by the biopharmaceutical industry.[7] Criticism included the allegation that the EMA's policy "could . . . conflict with the EMA's obligation under Article 39(3) of the WTO TRIPS Agreement to protect the data submitted for [marketing authorization] purposes against unfair commercial use."[8]

Shortly after the EMA access policy was announced, the U.S. Chamber of Commerce carried out a study to examine existing international practices on regulatory data disclosure and concluded that the EMA's initiative "is a stark contrast and break from preceding EMA practices,"[9] and "in a broader context . . . also contrasts starkly with existing international practices."[10]

In light of these observations, this article addresses the issue of the legitimacy of disclosure of clinical trial reports by a drug authority for experimental use under the international standard of clinical data protection. In particular, it examines the compliance of such practice with Article 39.3 of the World Trade Organization's 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights ("39.3 TRIPS"), which is the only binding obligation for protection of data

5. *Publication of Clinical Data*, EUR. MEDS. AGENCY, ttp://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000555.jsp (last visited Apr. 28, 2015).

6. Eur. Meds. Agency, Management Board Minutes of the 84th Meeting of the Management Board, EMA/MB/325638/2014 (Jul. 3, 2014,) 8, *available at*

http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2014/09/WC500171976.pdf (last visited Apr. 28, 2015).

7. For an overview of submissions, *see* Eur. Meds. Agency, Publication and Access to Clinical Data: An Inclusive Development Process,
http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000556.jsp&mid=WC0b01ac0580614159 (last visited Apr. 28, 2015).

8. Eur. Meds. Agency, *Overview of Comments Received on 'Publication and Access to Clinical-Trial Data'* (EMA/240810/2013), EMA/344107/2014, 86, *available at*
http://www.ema.europa.eu/docs/en_GB/document_library/Overview_of_comments/2014/09/WC500174225.pdf (last visited Apr. 28, 2015).

9. U.S. CHAMBER OF COMMERCE GLOBAL INTELLECTUAL PROPERTY CENTER, HEADING IN A DIFFERENT DIRECTION?: THE EUROPEAN MEDICINES AGENCY'S POLICY ON THE PUBLIC RELEASE OF CLINICAL TRIALS DATA, 27 (2014), http://www.theglobalipcenter.com/wp-content/uploads/2014/05/EMA-Study-COMPLETE.pdf (last visited Apr. 28, 2014).

10. *Id.* at 15.

submitted for regulatory approval of pharmaceutical products under international law.[11]

The provision mandates the WTO Member states to implement two types of protection: protection against unfair commercial use of regulatory data, and protection against their disclosure. The second obligation envisages two conditions for exception. Clinical trial data shall be protected 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."[12]

Both types of protection are conditioned on the notion of unfair commercial use. At the outset, one may think that the experimental use of data is non-commercial and that it would not interfere with the protection obligation of 39.3 TRIPS. However, the borderline between commercial and non-commercial use does not appear clear in the context of drug R&D—any use of data within the drug development can be viewed as directed at the subsequent product commercialization.[13] But rather than the commercial aspect, it is the notion of fairness that ultimately matters for the legitimacy of use.

From the perspective of the data originators,[14] any unsolicited and unsanctioned use of their data shall be seen as unfair, and any actual or potential benefit that a third party can derive by accessing clinical data can be alleged as "reaping without sowing" or "riding on the coattails" of the originator's investments. In the scientific and technology-intense industries such as pharmaceuticals, R&D goes to the essence of firms' competitive capacity. By accessing clinical trial reports, a competing firm can gain competitive advantage in terms of strengthening its R&D capacity and facilitating the developmental of potentially competing products.[15] For instance, the Roche policy on clinical data-sharing

11. Agreement on Trade-Related Aspects of Intellectual Property Rights. art. 39, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 [hereinafter TRIPS Agreement].

12. *Id.*

13. For instance, the issue whether the use for experimental purposes qualifies as fair use in the context of drug development was examined in a WTO case. The decision is, however, of limited relevance for the present discussion since it interpreted the fair use exception under Article 30 of the TRIPS Agreement applicable to patent rights. Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000).

14. The term "data originator" can embrace different entities involved in clinical research and data generation including trial investigators, researchers, sponsors, and drug companies. By data originators, this article refers to pharmaceutical companies that sponsor and arrange clinical data holders of clinical trial data that are submitted to a drug authority in support of drug marketing authorization.

15. *See, e.g.*, C-389/13, Eur. Meds. Agency v. AbbVie, Inc., http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:62013CO0389, ¶ 18 (citing AbbVie's assertion that "clinical study reports describe the manner in which the AbbVie companies planned and implemented the clinical trials necessary in order to obtain the [marketing authorization] for that medicinal product for

states, "We will protect our intellectual property rights, and we will prevent others from using our data to *develop* intellectual properties that *interfere* with our ability to develop and commercialize our products."[16]

Does the protection obligation under the TRIPS Agreement provide grounds in support of such assertions? As questioned by Antony Taubman, "Should the conception of unfairness be broadened to accommodate broader claims of 'sweat of the brow' or Lockean property entitlements, or should it be calibrated strictly to meet the utilitarian requirements of society?"[17]

The imprecise wording of the provision risks a situation of the "perpetual check," where virtually any use of data can potentially be subject to a violation claim. Policy and scholarly debate regarding 39.3 TRIPS focused mostly on the issue of whether the provision requires the WTO Member states to implement protection in the form of data exclusivity, i.e., as non-reliance for the purposes of establishing bioequivalence between the branded and generic products.[18] As for the

the indication of Crohn's disease and therefore provide a very specific road map for a company wishing to develop a medicinal product in the very competitive field of tumour necrosis factor (TNF) antagonists").

16. ROCHE, *Roche Global Policy on Sharing of Clinical Trials Data*, 1, http://roche-trials.com/pdf/RocheGlobalDataSharingPolicy.pdf (last visited Apr. 28, 2015) (emphasis added); *see* E-mail from Jane Leung, Compliance Oversight Lead, Pfizer Corporation Hong Kong Limited to the author (Nov. 24, 2014, 12:43 CST) (on file with author) ("for sole purpose of scientific research can be requested by qualified researcher, and . . . will decide whether or not to disclose data case by case. Considerations will be made according to research team composition of the researcher, conflict of interest, and if it is for commercial purpose, etc.").

17. *See* Antony Taubman, *Unfair Competition and the Financing of Public Knowledge Goods: The Problem of Test Data Protection*, 3 J. INTELL. PROP. & PRACTICE 591, 600 (2008).

18. The literature on this subject is extensive and includes JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 185–206 (2001); CARLOS MARÍA CORREA, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT (2002); G. Lee Skillington & Eric. M Solovy, *The Protection of Test and Other Data required by Article 39.3 of the TRIPs Agreement*, 24 NW. J. INT'L L & BUS. 1 (2003); Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPS Agreement*, 45 HARV. INT'L L.J. 443 (2004); UNCTAD- ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT: AN AUTHORITATIVE AND PRACTICAL GUIDE TO THE TRIPS AGREEMENT (2005), *available at* http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm; Lucas R. Arrivillaga, *An International Standard of Protection for Test Data Submitted to Authorities to Obtain Marketing Authorization for Drugs*, 6 J. WORLD INTELL. PROP. 139 (2003); Jean-Frédéric Morin, *Tripping Up TRIPS Debates IP and Health in Bilateral Agreements*, 1 INT. J. INTELL. PROP. MGMT. 37 (2006); SHAMNAD BASHEER, PROTECTION OF REGULATORY DATA UNDER ARTICLE 39.3 OF TRIPS: THE INDIAN CONTEXT (2006), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=934269; CHARLES CLIFT, DATA PROTECTION AND DATA EXCLUSIVITY IN PHARMACEUTICALS AND AGROCHEMICALS, in INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES ch. 4.9 (Anatole F. Krattiger et al. eds,., 2007); Jerome Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1 (2009); Carlos M. Correa, *Test Data Protection: Rights Conferred Under the TRIPS Agreement and Some Effects of TRIPS-plus Standards*, *in* THE LAW AND THEORY OF TRADE

WTO jurisprudence, 39.3 TRIPS as currently amended has not been interpreted.[19]

However, even if use for generic approval was either granted or denied as constituting "unfair commercial use," the question would still remain—how should fairness be evaluated with regard to other possible uses of data, e.g., their use or disclosure for experimental purposes?

Meanwhile, the World Intellectual Property Organization ("WIPO") does consider the disclosure of regulatory data for research purposes as constituting an act of unfair competition. While Article 6 (4) of the WIPO Model Provisions on Protection Against Unfair Competition essentially reflects the same obligation promulgated by 39.3 TRIPS, Note 6.26 of the Model Provision states, "The act of disclosure of [test data] is . . . considered an act of unfair competition. The unauthorized disclosure may consist in publishing the information or in passing it on to others, for example for research purposes."[20]

Although the WIPO Model Provisions are not binding law,[21] their authority for national lawmaking cannot be underestimated, especially if the Provisions are viewed as an attempt to bring 10*bis* of the Paris Convention "up to contemporary standards in the field of trade and competition."[22]

The benefits of clinical data disclosure are broadly associated with scientific advancement and healthcare improvements. Access to clinical trial reports can contribute to various research-related activities such as testing secondary hypotheses, developing new statistical methods and designing future trials; allow additional scrutiny of drug safety and quality; contribute to greater transparency and accountability of a drug authority; and reduce the risk of publication bias when reporting trial results.[23] Clinical data-sharing can support the emerging

SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH 568 (Rochelle Cooper Dreyfuss & Katherine Jo Strandburg eds, 2011); NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENTS AND TEST DATA (2014). Some positions on interpretation of data protection obligation are referenced in the subsequent sections.

19. *See infra* notes 60–66 and the accompanying text.

20. WORLD INTELLECTUAL PROPERTY ORGANIZATION, MODEL PROVISIONS ON PROTECTION AGAINST UNFAIR COMPETITION, 60 (1996).

21. Marcus Höpperger & Martin Senftleben, *Protection Against Unfair Competition at the International Level –The Paris Convention, the 1996 Model Provisions and the Current Work of the World Intellectual Property Organisation*, *in* LAW AGAINST UNFAIR COMPETITION.: TOWARDS A NEW PARADIGM IN EUROPE? 61, 72 (Reto M. Hilty et al. eds,., 2007).

22. FRAUKE HENNING-BODEWIG, INTERNATIONAL HANDBOOK ON UNFAIR COMPETITION 28 (2013).

23. On benefits of access to clinical data, *see*, *e.g*., Press Release, Association Internationale de la Mutualité et al., EMA's New Policy on Access to Clinical Data: About to Privatise Pharmaceutical Knowledge? The Proof Will be in the Pudding (June 24, 2014), http://www.en.bukopharma.de/uploads/file/Presse/pm_20140623_EMA_newpolicy.pdf (last visited Apr. 28, 2015); WORLD HEALTH ORGANIZATION, WHO Statement on Public Disclosure of

models in clinical research and medical innovation based on the open-source approach, as well as promote efficiency in resource allocation.

There are no binding requirements under international law for the disclosure of clinical trial information.[24] However, trial results can become publicly available because of the mandatory registration of clinical trials and the subsequent reporting of the results,[25] as well as by voluntary disclosure by investigators and researchers in scientific publications.[26]

In view of the increasing calls for broader public access to clinical trial data,[27] the importance of legal certainty for policies enabling such access cannot be underestimated. At stake are the benefits associated with data-sharing for public health and medical innovation; at risk is a

Clinical Trial Results, http://www.who.int/ictrp/results/Draft_WHO_Statement_results_reporting_clinical_trials.pdf?ua=1 (last visited Feb. 17, 2015) ("The benefit of sharing research data and the facilitation of research through greater access to primary datasets is a principle which WHO sees as important. This statement is not directed towards sharing of primary data. However WHO is actively engaged with multiple initiatives related to data sharing, and supports sharing of health research datasets whenever appropriate. WHO will continue to engage with partners in support of an enabling environment to allow data sharing to maximise the value of health research data."). On the problem of publication bias and selective reporting of clinical trial results, see generally Peter C. Gøtzsche, *Why We Need Easy Access to All Data from All Clinical Trials and How to Accomplish It*, 12 TRIALS 249 (2011); MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT (2005); BEN GOLDACRE, BAD PHARMA: HOW DRUG COMPANIES MISLEAD DOCTORS AND HARM PATIENTS (2012); Christopher W. Jones et al., *Non-Publication of Large Randomized Clinical Trials: Cross Sectional Analysis*, 347 THE BMJ (2011), http://www.bmj.com/content/347/bmj.f6104 (last visted Apr. 28, 2015) (reporting that "[o]f 585 registered trials, 171 (29%) remained unpublished. These 171 unpublished trials had an estimated total enrollment of 299[,]763 study participants. The median time between study completion and the final literature search was 60 months for unpublished trials.").

24. For the international ethical standards of conducting clinical research and reporting trial results, see WORLD MED. ASS'N, DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS DECLARATION OF HELSINKI ON ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS ¶ 36 (2013), http://www.wma.net/en/30publications/10policies/b3/ (last visted Apr. 28, 2015) (stipulating that "[r]esearchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports" and that "[n]egative and inconclusive as well as positive results must be published or otherwise made publicly available").

25. *See*, *e.g.*, EU CLINICAL TRIALS REGISTER, https://www.clinicaltrialsregister.eu (last visited Apr. 28, 2015) (containing data on clinical trials conducted in the EU or the European Economic Area after May 1, 2004); *International Clinical Trials Registry Platform*, WORLD HEALTH ORG., http://apps.who.int/trialsearch/ (last visited.Apr. 28, 2015).

26. *See, i.e.*,The International Committee of Medical Journal Editors, Clinical Trial Registration, http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html (last visited May 21, 2015) (requiring and recommending that all medical journal editors require the registration of clinical trials in public trials registries as a condition of the publication of research results.).

27. For an overview of international initiatives for clinical data sharing, *see*, *e.g.*, Gøtzsche, *supra* note ,23, at 4. Recently, the World Health Organization conducted public consultation on the WHO draft statement regarding public access to clinical trial results. *Call for Public Consultation: WHO Statement on Public Disclosure of Clinical Trial Results*, WORLD HEALTH ORG., http://www.who.int/ictrp/results/en/ (last visited Apr. 28, 2015).

claim of non-compliance with the obligation under the TRIPS Agreement.

Against this background, this article aims to identify the principle by which the legitimacy of use can be evaluated under the standard of protection provided in 39.3 TRIPS. The principle is formulated based on three readings of the provision, as follows. Section II discusses the legal status of clinical trial reports and defines the applicable standard of protection. Section III identifies the limitations of literal interpretation in giving a precise meaning of the minimum international standard of data protection. Section IV provides a historical perspective on the original intention behind the initial proposals on the protection of undisclosed information and the polarized debate during TRIPS negotiations. Section V gives a teleological interpretation and derives the principle of legitimacy of data use in light of the specific purposes of 39.3 TRIPS and the overall objectives of the TRIPS Agreement and in view of a peculiar overlap between three legal regimes—unfair competition, trade secret, and *sui generis* data protection. Section VI concludes.

I. THE LEGAL STATUS OF CLINICAL TRIAL DATA AND THE INTERNATIONAL STANDARD OF PROTECTION

Clinical trial reports submitted for drug approval comprise different species of data including trials results, the protocol detailing trial design, methodology of results interpretation and analysis, various types of analyses, and participant-level data[28]

The research-based industry regards test data as proprietary assets and claims protection under exclusivity—as "an independent intellectual property right . . . [that] provides the holder with specific rights, namely that the data generated by the holder may not be referred to or used by another person or company for a specific period of time."[29] In the views of others, "there is no protection by intellectual property law on data that are gathered for research purposes."[30]

28. For the detailed specification of the structure and content of clinical study reports, *see*, *e.g.*, INT'L CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARM. FOR HUMAN USE, ICH HARMONISED TRIPARTITE GUIDELINE: STRUCTURE AND CONTENT OF CLINICAL STUDY REPORTS (1995.), http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E3/E3_Guideline.pdf (last visited Apr. 28, 2015).

29. IFPMA, *supra* note 1, at 1.

30. Iain Hrynaszkiewicz et al., *Preparing Raw Clinical Data for Publication: Guidance for Journal Editors, Authors, and Peer Reviewers*, 11 TRIALS 9, 12–13 (2010), *available at* http://www.trialsjournal.com/content/pdf/1745-6215-11-9.pdf (last viewed Apr. 28, 2015).

National laws can vary in recognizing substantive rights in different types of test data and defining the scope of such rights. Some data, such as product development strategy and technological know-how,[31] can qualify for trade secret protection;[32] while others can be defined as database and works of authorship (e.g., scientific analyses) and thus be protected under specific rights.

Given the heterogeneity of clinical trial data, it appears difficult to identify the common legal basis for protection. Yet, in one particular situation, clinical data can be protected in their entirety—i.e., when trial reports are submitted to a health authority for the purpose of drug marketing approval.

At the international level, the obligation to protect regulatory data is laid out in Article 39 of the TRIPS Agreement. The obligation is located in the section on undisclosed information and consists of three paragraphs. The first paragraph mandates the WTO Member states to protect undisclosed information effectively from unfair competition, and it references the Paris Convention[33] when it states, "In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3."

The second paragraph defines the criteria of eligibility for protection:

> Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices [Note 10] so long as such information:

31. *See*, *e.g.*, Eur. Meds. Agency, *supra* note 8, at 27 (asserting that "[d]uring the development of a biotech product a substantial amount of data is generated and significant know-how is developed.," which "includes an intimate knowledge about the product, company-specific characterisation of data, technological and manufacturing processes or computer codes").

32. *See*, *e.g.*, EUROPEAN COMM'N, STUDY ON TRADE SECRETS AND CONFIDENTIAL BUSINESS INFORMATION IN THE INTERNAL MARKET, MARKT/2011/128/D, 122 (2013) (reporting that "[i]n pharmaceuticals, the most valuable secrets lie in marketing data and planning"); *see also* WESLEY M. COHEN ET AL., NAT'L BUREAU OF ECON. RESEARCH, PROTECTING THEIR INTELLECTUAL ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) (2000) (analyzing responses the U.S. manufacturing sector regarding the legal mechanisms of appropriating the returns to product and process innovation and finding that, in the case of product innovations, drug companies perceive trade secret protection to be nearly as effective as patents, whereas, in case of process innovation, secrecy prevails over patent protection).

33. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, as rev. at Stockholm, July 14, 1967, 21 U.S.T. 1583., 828 U.N.T.S. 305.

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

Note 10: For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

The third paragraph stipulates a sector specific obligation to protect data submitted for regulatory review:

> 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.

While this provision applies to clinical trial data as *lex specialis*, the obligation should be interpreted in conjunction with 10*bis* of Paris Convention ("10*bis* PC"), which states:

(1) The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition.

(2) Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition.

(3) The following in particular shall be prohibited:

(i) all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor;

(ii) false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;

(iii) indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.

II. THE LITERAL INTERPRETATION OF THE DATA PROTECTION OBLIGATION

39.3 TRIPS stipulates two types of protection of data—that against unfair commercial use and that against disclosure. These two modes are distinct, as indicated by the conjunction "[i]n addition," and are directed at the same subject matter, as emphasized by the demonstrative pronoun "such" referring to data).

The provision stipulates two substantive criteria of eligibility for protection that apply cumulatively: (i) the data should be submitted in support of pharmaceutical products that utilize new chemical entities, and (ii) the origination of data should involve a considerable effort.

Two conditions are envisaged for data disclosure, namely, "where necessary to protect the public", or when "steps are taken to ensure that the data are protected against unfair commercial use." Under the first factor, for instance, disclosure would be necessary[34] to allow an external investigator to conduct an independent analysis if there are grounds to question the accuracy of original clinical trial results attesting to drug safety and efficacy. Compulsory license under a health emergency would also require disclosure.[35]

The second exception for disclosure is conditioned on the meaning of the notion "unfair commercial use." This term is not defined and appears as a metonymic expression that indirectly refers to a specific kind of data use, supposedly known to the addressee, but preferred not to be called by its actual name.

Of importance, commercial use is not outlawed *per se*, but only when it is unfair. While the term "unfair" is polysemous, the reference to 10*bis* PC suggests that it should be interpreted in the context of the commercial and industrial relations between competitors.

10*bis* PC is directed at the repression of unfair competition, and it exemplifies the types of conduct associated with dishonest practices, contrary to business ethics and fair dealing. The provision is structured as a general clause with a catalogue of acts of unfair competition. While it is clear that the list of unfair competition acts is non-exhaustive, it is unclear whether the scope of protection is confined to the semantic

34. On the standard of "necessity" of disclosure, see Fellmeth, *supra* note 18, at 450–51 (noting that in the interpretation of the WTO dispute settlement panels the term "necessary" as meaning that "no alternative measure existed"). Such requests are not unusual; *see*, *e.g.*, EUR. MEDS. AGENCY, *supra* note 5 (reporting that "between November 2010 and April 2013, the [EMA] released over 1.9 million pages of clinical-trial data in response to safety-related requests").

35. For a discussion, see, Watal, *supra* note 18, at 185–206.

fields of dishonesty, fraud and breach,[36] and, if not, how fairness should be evaluated.

The notion of "unfair" is inherently subjective. From the patient's perspective, the use of data that can advance medical innovation is justified and fair. From the perspective of the data originators and sponsors, any unsolicited and unsanctioned use of the data can be seen as unfair. Any benefit that a third party can derive by accessing clinical data, can be alleged as free-riding on the originator's efforts and assets.

What is clear from the "plain" language of 39 TRIPS is that it does not mandate the protection of undisclosed information under property rights.[37] The second paragraph of the provision avoids any indication of the entitlement to legal protection ("persons shall have the *possibility* of preventing information lawfully *within their control*"). The third paragraph is silent on the legal status of an entity that submits the data for regulatory review.

Beyond this, the interpretation of the content and scope of protection under 39.3 TRIPS calls for more context.

III. THE LEGISLATIVE HISTORY OF 39.3 TRIPS

What is curious about the drafting history of 39 TRIPS is that, while the drafting records evidence a polarized debate regarding test

36. With regard to the problem of definition of unfair competition in general, see Milton Handler, *Unfair Competition*, 21 IOWA L. REV. 175, 175 (1936) ("There is probably no term in law or economics which is more difficult to define than "unfair competition". The phrase is obviously more of an epithet than a word of art. Its legal usage embodies a conclusion rather than the means of determining the legality of business behavior. Definition by illustration merely exhibits a multiplicity of usage rather than any identity of meaning. Temporal and personal factors are also significant."). In particular, with regard to the scope of protection under 10*bis* PC, see STEPHEN P. LADAS, PATENTS, TRADEMARKS AND RELATED RIGHTS: NATIONAL AND INTERNATIONAL PROTECTION 1685 (1975) (arguing that "more concrete and detailed stipulations concerning acts of unfair competition [beyond explicitly stated in 10*bis* PC would be] extremely difficult, if not impossible"); G. H. C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY AS REVISED AT STOCKHOLM IN 1967, 144 (stating that "[t]he various countries of the [Paris] Union have different concepts of what is to be understood by "*unfair competition"* and further stating that "[i]n giving effective protection against unfair competition, each country may itself determine which acts come under this category, provided however, that paragraphs (2) and (3) of the Article under consideration are complied with"); Annette Kur, *What to Protect, and How?: Unfair Competition, Intellectual Property, or Protection Sui Generis*, MAX PLANCK INST. FOR INTELL. PROP. AND COMPETITION LAW, 2–3, *available at* http://ssrn.com/abstract=2268585 (concluding that "the scope and practical impact of internationally mandatory protection outside the core area of representations which mislead the public as to the properties and commercial origin of goods, or which discredit competitors by false allegations, are likewise quite uncertain" and "unlike trademarks, patents and industrial designs, the contours of what is meant by protection against unfair competition have not become more visible in the TRIPS Agreement, which even does not refer to that term anywhere in the text").

37. Reichman, *supra* note 20,7,, at 19 (concluding that "the collocation of clinical test data within the provisions regulating unfair competition negated any inference that the TRIPS drafters had imposed an exclusive intellectual property right on this subject matter . . . .").

data protection, they do not clarify how the "common intention"[38] on the minimum standard of data protection was finally achieved. Rather than providing a detailed chronicle of negotiations of 39.3 TRIPS,[39] this section focuses on the conceptual aspects of draft proposals.

The negotiation records reveal striking differences in the positions of the negotiating parties regarding the protection of undisclosed information, in general, and of regulatory data, in particular. India, for instance, argued that "trade secrets could not be considered form of intellectual property . . . . [T]he fundamental basis of an intellectual property right was the *disclosure, publication and registration* of the subject matter of protection, whereas confidentiality and secrecy were fundamental to trade secrets".[40] In sharp contrast, the U.S. asserted that the "issue underlying the protection of trade secrets was the same as that underlying the protection of intellectual property rights generally, namely *that of not benefitting from the fruits and labours of others improperly*. . . . [I]n no event should the recipient of the information be allowed to use such information to *compete* with the person who had generated it."[41] In line with this argument, Switzerland stated that "[a]lthough *proprietary information* differed from other intellectual property rights in terms of the disclosure requirements, it embodied the central idea underlying IPR protection, namely that of the *preservation of the exclusive commercial use of information created by investment of time, human and financial resources.*"[42] Canada emphasized the importance of protection of trade secrets for "providing a secure environment for the *transfer of technology*" but insisted that the protection of trade secrets be confined to uses contrary to honest commercial practices.[43]

38. Appellate Body Report, *European Communities–Customs Classification of Certain Computer Equipment*, para. 84, WT/DS62/AB/R, (*adopted* June 22,), ("The purpose of treaty interpretation under Article 31 of the Vienna Convention is to ascertain the common intentions of the parties. These common intentions cannot be ascertained on the basis of the subjective and unilaterally determined 'expectations' of one of the parties to a treaty.").

39. For detailed legislative background, *see generally* DANIEL GERVAIS, THE TRIPS AGREEMENT, THE DRAFTING HISTORY AND ANALYSIS (2012); NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENTS AND TEST DATA (2014).) (emphasis added).).

40. Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, *Note by the Secretariat: Meeting of Negotiating Group of July 12–14, 1989*, para. 90, MTN.GNG/NG11/14 (Sept. 12, 1989).) (emphasis added).).

41. Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, *Note by the Secretariat: Meeting of Negotiating Group of October 30–November 2, 1989*, para. 61, MTN.GNG/NG11/16 (Dec. 4, 1989) (emphasis added).

42. Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, *Note by the Secretariat: Meeting of Negotiating Group of December 11, 12 and 14, 1989*, para. 44, MTN.GNG/NG11/17 (Jan. 23, 1990) (emphasis added).

43. Standards for Trade-Related Intellectual Property Rights, para. 18(H), MTN.GNG/NG11/W/47, (Oct. 25, 1989).) (emphases added.).).

The negotiations of the would-be 39 TRIPS took place mostly during the second stage of the Uruguay round in 1990-1991. Three drafts represent the main stages of negotiations: the Chairman's report of July 23, 1990 (providing "a compilation of the options for legal commitments as they have emerged from a process of informal consultations [and] . . . intended as a basis for further negotiation");[44] the Brussels draft of December 3, 1990 ("a first approximation to the Final Act embodying the results of the Uruguay Round of Multilateral Trade Negotiations");[45] and the Dunkel draft of December 20, 1991 ("offer[ing] a concrete and comprehensive representation of the final global package of the results of the Uruguay Round").[46] The Dunkel draft was eventually adopted as the final version of the TRIPS Agreement on April 15, 1994.

The protection of regulatory data was initiated by the U.S., which included it within a set of provisions on trade secrets:

> D. Trade secrets
>
> 6. Conditions on Government Use
>
> Trade secrets submitted to governments shall not be disclosed or used for the benefit of third parties except in compelling circumstances involving major national emergencies posing an imminent unreasonable risk to health or the environment, or to facilitate required health and safety registrations. Government use or disclosure on the basis of a national emergency may only be made where other reasonable means are not available to satisfy the need for which the government seeks to disclose or use the trade secret, and the government may use it only for the duration of that emergency. Government use or disclosure to facilitate required health and safety registrations may only be made if the trade secret has not been submitted within the previous ten years and full compensation is made for the use or disclosure. In any case, a government shall not use or disclose a trade secret to an extent greater than required to achieve one of the above needs without providing the submitter with a reasonable opportunity to oppose the proposed use or disclosure, including the opportunity to secure judicial review, or without

44. Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, *Report by Chairman: Status of Work in the Negotiating Group*, MTN.GNG/NG11/W/76 (Jul. 23 1990) [hereinafter Chairman's Report].

45. Trade Negotiations Committee, *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, MTN.TNC/W/35/Rev.1 (Dec. 3, 1990) [hereinafter The Brussels draft].

46. Trade Negotiations Committee, *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, MTN.TNC/W/FA (Dec. 20, 1991) [hereinafter The Dunkel draft].

> providing for the payment of full compensation as in the case of *personal property*.[47]

A conceptually different proposal was later tabled by the EC:

> G. Acts contrary to honest commercial practices including protection of undisclosed information
>
> Article 28
>
> In the course of ensuring effective protection against unfair competition as provided for in Article 10*bis* of the Paris Convention -
>
> [. . .]
>
> (b) Contracting parties, when requiring the publication or submission of test or other data, the origination of which involves a considerable effort, shall protect such efforts against unfair exploitation by competitors. The protection shall last for a reasonable time commensurate with such efforts, the nature of the data required, the expenditure involved in their preparation and shall take account of the availability of other forms of protection.[48]

The U.S. and EC approaches differed in several principal aspects. Whereas the U.S. stipulated the protection of trade secrets as personal property, the EC subjected the protection of undisclosed information[49] to unfair competition. The U.S. focused on *government* use as a special case within a comprehensive set of provisions on trade secrets, whereas the EC directed the protection against unfair exploitation *by competitors*. Whereas the U.S. stipulated the protection of *data*, the EC required the protection of *efforts* involved in data generation. The U.S. prescribed a specific *mode* of protection—a ten-year term of non-use of test data for generic approval.[50] In contrast, the EC proposed the *principle* of protection based on the idea of proportionality and case-by-case appraisal—the "reasonable" measure of protection intended to be correlated with the value of data, efforts and expenditures involved in their generation, as well as the availability of other forms of protection.

47. Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, *Suggestion by the United States for Achieving the Negotiating Objective*, § III(D)(6), MTN.GNG/NG11/W/14/Rev.1 (Oct. 17, 1988) (emphasis added).

48. Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, *Draft Agreement on Trade Related Aspects of Intellectual Property Rights*, MTN.GNG/NG11/W/68 (Mar. 29, 1990).

49. The term "undisclosed information" was proposed by the EC as being "less likely to generate confusion" than "proprietary information" earlier suggested by Switzerland. *See* Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, (*see Meeting of Negotiating Group of May 14, 1990*, para. 45, MTN.GNG/NG11/21, (Jun. 22, 1990).

50. Later on, the U.S. draft proposal was criticized for "tend[ing] to put too much emphasis on the interests of owners over users of intellectual property rights, on the role of governments over private parties in their enforcement, on detail over principles, and on effectiveness over safeguards for legitimate traders." *Id*., para. 13.

The version in the Brussels draft was essentially based on the EU proposal, but it also incorporated the non-use rule of the U.S. submission:

> 4A. PARTIES, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall [protect such data against unfair commercial use. Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, PARTIES shall] protect such data against disclosure, except where necessary to protect the public.][51]

As evidenced, the entire section on the protection of undisclosed information is still square-bracketed remaining among the "major outstanding issues on points of substance" that required further negotiation.[52] Inside the brackets, two options can be distinguished: the first contained a detailed explication of the non-reliance rule, the second contained a more generally phrased requirement to protect regulatory data against disclosure with only one exception – "where necessary to protect the public".

The second condition for data disclosure "slipped into" the text at the end of the very late stage of the negotiations. Although during the meetings held in September 1991 "some discussion on Paragraph 4A [the would-be TRIPS 39.3] had taken place"[53], as of November 1991 "the outstanding issues [were] still essentially as contained in the Chairman's [draft/version]".[54] The following representation shows the

51. Brussels draft, *supra* note 45, at 215.

52. The Brussels draft, *supra* note 45, at 195. The main divide concerned the issue whether trade secrets constitute intellectual property. *See also* Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, *Note by the Secretariat: Meeting of Negotiating Group of Oct. 30-Nov. 21*4*, 1989*, para. 63, MTN.GNG/NG11/16, (Sept. 12, 1989) (reporting that "[s]ome delegations reiterated their view that trade secrets did not constitute a form of intellectual property and therefore fell outside the scope of the work of the Group. Since there was no disclosure it could not be regarded as a form of intellectual property and there would be no means of knowing what any intellectual right actually protected. Some of these participants said that this did not mean that they did not recognise the need for know-how to be protected and also its importance for the transfer of technology. However, such protection should be accorded under other civil and criminal law, including contract law, not by IPR law."); Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, *Note by the Secretariat: Meeting of Negotiating Group of May 14–16, 1990*, para. 49, MTN.GNG/NGll/21, (Jun. 22, 1990) (citing participants who proposed that "trade secrets protection should be left to national law.").

53.), Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, *Note by the Secretariat:*), *Meeting of Negotiating Group of September 16 and 20, 1991*, para. 10, MTN.GNG/TRIPS/2, (Oct. 7, 1991).

54. Trade Negotiations Committee, *Progress of Work in Negotiating Group: Stock-Taking* 8, MTN.TNC/W/89/Add.1 (Nov. 7, 1991).

rapid change that occurred within a few weeks and it was adopted as the final version concluding the results of the negotiations.

> ~~4A~~ 3. PARTIES, when requiring, as a condition of approving the marketing of ~~new~~ pharmaceutical ~~products~~ or of ~~a new~~ agricultural chemical ~~product~~ 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. ~~Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation~~. In addition, PARTIES 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.[55]

Thus, the detailed exposition of the non-reliance rule was crossed out, and the second factor of disclosure—"or unless steps. . ."—added on the exception part.

There are several ways to interpret this change. One can assume that the non-use rule was a stand-alone obligation and, once it was gone from the final draft, there is no obligation to restrict the referential use of data to facilitate generic approval. In favor of this version speaks the fact that the notion of unfair commercial exploitation and the non-use rule originated from different draft proposals.

However, the way that the non-reliance rule was later positioned in the Brussels draft suggests that it was related to the notion of unfair commercial use. The relationship between the two first two sentences can be viewed as a general clause with explication—*i.e.*, the non-reliance rule was the only, exhaustive, content of unfair competition use. In this case, the ellipsis of the explication from the final draft can be interpreted that its meaning remained present in the obligation "in spirit."[56] This explanation, however, does not seem logical: if the parties reached the consent on the standard of protection, why would the non-reliance clause be crossed out?

Alternatively, the relationship between the first and the second sentences can be seen as a general clause with illustration—*i.e.*, the non-reliance rule was meant to be one of the possible modes of protec-

55. The Dunkel draft, s*upra* note 46, at 75. (emphasis added).

56. For instance, in the words of Jacques Gorlin, "United States negotiators agreed to drop the non-reliance language, because they viewed the phrase as no more than 'belts and suspenders', that is, the accepted definition at the time of 'protection against unfair commercial use' included non-reliance for a fixed period of time for new chemical entities and the second phrase was, therefore, not needed." JACQUES J. GORLIN, AN ANALYSIS OF THE PHARMACEUTICAL-RELATED PROVISIONS OF THE TRIPS (INTELLECTUAL PROPERTY) AGREEMENT 48 (1999).

tion. In this case, the deletion of the second sentence can be interpreted to mean that the countries agreed not to impose data exclusivity as the only possible form of protection, strictly conditioned on the consent, compensation and specific time period.[57] Such a compromised interpretation can justify policies based on the compensatory liability approach.[58] At the same time, the question of the minimum standard of protection as mandated under 39.3 TRIPS remains unsettled. [59]

57. Such intermediary position seems to prevail among scholars. *See*, *e.g.*, Aaron Xavier Fellmeth, *Secrecy, Monopoly and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPs Agreement*, 45 Harv. Int'l L.J. 443, 453 (2004) (arguing that "rel[anceianceance] on this [marketing approval] data to obtain marketing approval for similar or identical drugs, [does not] violate standards of honesty or mislead anyone."); CARLOS MARIA CORREA, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT 51 (2002) (stating that the "wording, context and purpose of the article does not support an interpretation that the required protection can be implemented only on the basis of an exclusivity protection."); Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data*, *in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ INTELL. PROP. L. REV.REVIEW 1, 65–66 (2009) (arguing that 39.3 TRIPS "does not prevent governments from authorizing the generic manufacture of bioequivalent products on the basis of foreign regulatory approvals and the relevant scientific literature. . . . If some form of compromise on the issue of clinical test data becomes unavoidable, developing country negotiators should stand firm on cost-sharing counter-proposals that would at least avoid barriers to entry for generic producers."); Carvalho, *supra* note 39, para. 39.137 (stating that "although draft language that would clarify the meaning of the term "unfair commercial use" has not been retained, the text of Article 39.3 contains elements that lead to the inevitable conclusion that the primary purpose of that provision is . . . to protect test data . . . from preventing governments from relying directly or indirectly on data provided by the first registrant and thus saving its competitors the efforts of developing and submitting their own test data - unless those competitors obtain authorization from the first registrant or if the law so permits, pay him compensation.").

58. On the cost-sharing approach to test data protection, s*ee generally* Judit Rius Sanjuan, James Love, Robert Weissman, *A Cost Sharing Model to Protect Investments in Pharmaceutical Test Data*, CPTech Policy Brief No. 1 (2006) *available at* http://www.cptech.org/publications/recent-publications.html,1 (2006); Fellmeth, *supra* note 57 (proposing a "readjustable royalties model" based on the cost-sharing approach for regulating the use of test data as a possible solution to reconcile imperatives of public health and innovation); Shamnad Basheer, *Protection of Regulatory Data Under Article 39.3 of TRIPS: The Indian Context*, 23–29 (2006) (discussing compensatory liability model as an alternative approach to data protection and an intermediate standard under 39.3 TRIPS.).

59. *See* U.S. Gov't Accountability Office, GAO-08-751, U.S. TRADE POLICY GUIDANCE ON WTO DECLARATION ON ACCESS TO MEDICINES MAY NEED CLARIFICATION, 30–31 (2007) (addressing the issue whether the requirements imposed in Free Trade Agreements (FTAs) went beyond the TRIPS Agreement, admitted that the provision was not *amenable* to such a clear interpretation: "[W]hether FTA provisions on data exclusivity go beyond TRIPS is less clear[. . .]. . . .[. . .] There are different interpretations of the obligations under TRIPS 39(3), and exactly what practices can be considered a fulfilment of this obligation. One interpretation of TRIPS 39(3) requires members to grant the originator of the data a period of exclusive use similar to that provided by data exclusivity laws in the United States. Under this interpretation, FTA provisions do not go beyond TRIPS. Others do not believe that Article 39(3) of TRIPS confers exclusive rights, but instead simply requires countries to prevent third parties from using the originators' data for unfair commercial purposes. This interpretation suggests that the FTA provision goes beyond the TRIPS requirement."). *Cf*Compare*Cf* the official position of the EC in this regard is that "the [TRIPS] Agreement does contain an obligation to protect test data against 'unfair commercial use', and that the most effective method of doing so is to deny the regulatory authorities the possibility of relying on such data for a reasonable period of time." Council Discussion on Access to Medicine,paper, *Paper Submitted by the EU to the TRIPS Council, for the Special Discussion on Intellectual Propertyspecial*

A. The WTO jurisprudence

Hitherto, 39.3 TRIPS has not been given interpretation in the WTO jurisprudence.[60] At one point, the U.S. Government requested consultations with the Government of the Republic of Argentina raising the issue of compliance of national law of Argentina with the TRIPS Agreement concerning, among others, test data protection.[61] Later on, the parties notified the Dispute Settlement Body that, upon consultations, they had "reached an agreement on all of the matters".[62] With regard to test data protection, the settlement agreement states:

> In addition, the Parties agree that should the Dispute Settlement Body adopt recommendations and rulings *clarifying the content of the rights related to undisclosed test data* submitted for marketing approval according to Article 39.3 of the TRIPS Agreement, and should Argentinean law be inconsistent with Article 39.3 as clarified by the above-mentioned recommendations and rulings, Argentina agrees to submit to the National Congress within one year an amendment to Argentinean law, as necessary, to put its legislation in conformity with its obligations under Article 39.3 as clarified in such recommendations and rulings.[63]

As of today, the disputed provision under Argentinian law remains intact.[64]

In some cases, the implementation of data protection in the form of non-reliance was required in the course of the WTO accession, as,

discussion on intellectual property and access to medicinesAccessaccess to Medicines, para. 15*medicines*, IP/C/W/280 (2001));) available at https://www.wto.org/english/tratop_e/trips_e/paper_eu_w280_e.htm;)); s*ee also* the EU Commission, *Compulsory Licensing and Data Protection* 21 (2001) *available at* trade.ec.europa.eu/doclib/html/122031.htm (stating that "[o]n its face, Article 39.3 of TRIPs contains an obligation to protect test data against """unfair commercial useuse'use, and it seems that the most effective way to fulfil that objective, as envisaged by the TRIPs negotiators, is to provide for data exclusivity over a reasonable period of time. Whether any system other than data exclusivity over a reasonable period of time would meet the requirements of Article 39.3 of the TRIPs Agreement is to be assessed on a case-by-case basis, but examples of actual application by WTO Members of alternative - and TRIPs compliant - systems to non-reliance over a reasonable period do not appear to exist.").

60. *See* World Trade Organization, *WTO Analytical Index: TRIPS. Agreement on Trade-Related Aspects of Intellectual Property Rights*, *available at* http://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_e.htm (last accessed Feb. 11, 2015).

61. World Trade Organization, *Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement*, WT/DS171/3, WT/DS196/4, IP/D/18/Add.1, IP/D/22/Add.1 (Jun. 20, 2002).

62. *Id.*

63. *Id*. at para. 9. (emphasis added).

64. Ley N° 24.766 de Confidencialidad sobre Informacion art. 4 (Sancionada: Diciembre 18 de 1996).

for instance, in case of China.[65] One would assume that stipulating such accession obligation is a *prima facie* proof in favor of data exclusivity as the standard of protection under the TRIPS Agreement. However, while the Report of the Working Party stipulates data protection under exclusivity, it avoids direct reference to 39.3 TRIPS as the mandatory standard protection.[66]

Thus, the issue remains open for speculation. Meanwhile, countries that, during the TRIPS negotiations, advocated for the protection of test data under exclusivity regime pursued a different strategy to promoting data exclusivity under bilateral and regional trade and investment agreements.[67]

IV. THE TELEOLOGICAL INTERPRETATION OF 39.3 TRIPS

This section seeks to identify the principle by which the legitimacy of data use under 39.3 TRIPS can be evaluated. It starts with defining the purpose and meaning of protection under 39.3 TRIPS (A) in conjunction with the referenced 10*bis* PC and (B) as distinct from 39.2 TRIPS. Furthermore, the principle is formulated (C) with regard to the

65. *See* World Trade Organization, *Report of the Working Party on the Accession of China*, paras 282, 284, WT/ACC/CHN/49, (Oct. 1, 2001).)During the accession negotiations, some Members of the Accession Working Party "expressed concerns"that China did not expressly provide in its laws and regulations for protection "against unfair commercial use of undisclosed test or other data submitted . . . in support of applications for marketing approval of pharmaceutical or of agricultural chemical products which utilize new chemical entities" *by providing* that no person other than the person that submitted such data may, without the permission of the person initially submitting the data, *rely on* such data in support of an application for product approval for a period of at least six years from the date on which marketing approval to the person that submitted the data had been granted." *Id.* at para. 282" (emphasis added).

66. *Id*., Annex 1A, § VI (a) (requiring as a part of "[i]nformation to be provided by China in the context of the transitional review mechanism", the submission of "amendments to Copyright, Trademark and Patent Law, as well as relevant implementing rules covering different areas of the TRIPS Agreement bringing all such measures into *full compliance* with and full application of the TRIPS Agreement *and* the protection of undisclosed information" (emphasis added).).

67. For the recent statistics on special pharmaceutical provisions in regional trade agreements, *see*, *e.g*., Raymundo Valdés and Maegan McCann, *Intellectual Property Provisions in Regional Trade Agreements: Revision and Update*, World Trade Organization,,, 8 (2014) (examining the sample of 245 regional trade agreements [RTAs] notified to the WTO and in force by February 2014. The statistical analysis accounts for the increase in RTAs with provisions related to pharmaceuticals including patent linkage and clinical data protection which "would be even more apparent if the agreements establishing the EEC, EFTA and the Andean Community were excluded from the count as initially they did not contain significant pharma-related provisions as such but rather established the legal frameworks within which such provisions were subsequently introduced"). *See also* the Bipartisan Trade Promotion Authority Act of 2002, 19 U.S.C.A. §3802 (2004) (mandating that "the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in United States law"); Ingo Meitinger, *Implementation of Test Data Protection According to Article 39.3 TRIPS: The Search for a Fair Interpretation of the Term 'Unfair Commercial Use'*, 8 J. WORLD INTELL. PROP. 123, 133–134 (2005), at 131 (noting that some Eastern European countries implemented data exclusivity in the course of the EU accession).

objectives of the TRIPS Agreement, in particular, protecting against trade distortions, and (D) in view of a peculiar intersection between three regimes – unfair competition, trade secret, and *sui generis* data protection.

A. The composite view of 39.3 TRIPS and 10bis PC

What was the purpose of collocating regulatory data protection with the repression of unfair competition? What does the clause "In the course of ensuring effective protection against unfair competition" suggest about the functional relation between the two provisions? There is some unease in picturing such a "course" of events: normally, a drug authority would not be expected to enforce unfair competition law. Data submitted to for regulatory review would be subject to regulation under administrative law, whereas "unfair competition is generally an issue between the competitors"[68] its "reference points" are "actual commercial practices",[69] and its enforcement is primarily carried out by the means and mechanisms of private law.[70]

Yet, the reference to 10*bis* PC cannot be seen meaningless for the interpretation of the obligation.[71] Neither should it be seen only as a matter of formality—*i.e.*, serving the purpose of bringing into the TRIPS Agreement the new subject matter of protection without exceeding the negotiations mandate.[72] While, as a matter of historical fact, concerns over exceeding the negotiation mandate cannot be denied,[73] as a matter of positive law, 10*bis* PC should be given effective

68. Rudolf Callmann, *He Who Reaps Where He Has Not Sown: Unjust Enrichment in Unfair Competition*, 55 HARV. L. REV. 595, 608 (1941).

69. FRAUKE HENNING-BODEWIG, UNFAIR COMPETITION LAW. EUROPEAN UNION AND MEMBER STATES 10 (2006).

70. Thomas M. J. Möllers & Andreas Heinemann, *Outlook: The Link Between Unfair Competition Law and Antitrust Law*, in THE ENFORCEMENT OF COMPETITION LAW IN EUROPE 659, 663 (Moellers & Heinemann, eds, 2008).

71. Meitinger, *supra* note 67, at 127 (stating "the reference of Article 39.1 TRIPS to Article 10*bis* of the Paris Convention does not seem to provide for any guidance regarding the interpretation of Article 39.3 TRIPS".).

72. *See* Wadlow, *supra* note 18, at 30 (stating that "the dependency of Article 39(3) on Articles 39(1) and 10*bis* [. . .]. . . .[. . .] deliberate, it was presumably intended to meet the objection that the negotiating mandate was at risk of being exceeded.").

73. *See* GATT Secretariat, *Meeting of Negotiating Group of 10-21 September 1990*, MTN.GNG/NG11/25 (Oct. 8, 1990) (citing a participant, who "on behalf of several developing countries . . . expressed serious reservations about what he considered to be an expansion of the mandate to include trade secrets".); GATT Secretariat, *Meeting of Negotiating Group of 8 and 18 October 1990*, MTN.GNG/NG11/26, para. 7 (Oct. 31, 1990) (citing a participant stating that the fourteen countries that had sponsored document NG11/W/71 "were ready to negotiate on all aspects, except trade secrets which they continued to have difficulty with treating is as an intellectual property right". Those fourteen countries included Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay.).

interpretation[74] in terms of adding substantive meaning to the data protection obligations. Thus, legal protection under 39.3 TRIPS should be applied in the context of competition; however, it should be differentiated from the protection provided under 39.2 TRIPS.

B. Protection under 39.3 vs. 39.2 TRIPS

Is 39.2 TRIPS applicable to regulatory data, and, if so, how does the protection differ? As long as clinical data meet the criteria of secrecy, commercial value and efforts to keep such data confidential, protection shall be accorded. One could argue that, if a drug authority is referred by "persons within the circles that normally deal with the kind of information in question", then the submission of clinical data in support of drug marketing approval would be "secrecy destroying" and such data can no longer satisfy the condition under 39.2(a) TRIPS. However, the clinical trial data become known to a drug authority only because of their disclosure by a drug applicant in the course of drug registration. Such disclosure does not change the status of the data of not being "generally known" either to a drug authority before application or to the public in general. As for the conditions of commercial value and efforts to keep data confidential under 39.2 (b) and (c), clinical data should normally satisfy them due to the substantial investment incurred in the data generation.

In terms of the type of protection, under 39.2 TRIPS the regulatory data shall be protected against unauthorized use, acquisition and disclosure associated with dishonest commercial practices. Consequently, the meaning of protection against unfair commercial use under 39.3 TRIPS should be sought beyond the competitors' practices that constitute the core area of unfair competition.

C. The purpose of protection under 39.3 TRIPS in view of the objectives of the TRIPS Agreement

In practical terms, the TRIPS Agreement aims to protect international trade against the distortions that can arise from, among others, the lack of effective and adequate protection of intellectual property rights and impede the commercial interests of rights holders in foreign

74. *See* Appellate Body Report, *United States–Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, p. 23, DSR 1996:I, 3, at 23 (stating that "[o]ne of the corollaries of the '"general rule of interpretation in the *Vienna Convention* is that interpretation must give meaning and effect to all the terms of a treaty. An interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility.").

markets.[75] In the pharmaceutical sector, a particular type of market distortion can be caused by drug regulations that can impact competition between the originator and the generic companies.

As a sector-specific provision, 39.3 TRIPS targets a particular situation when clinical trial data are submitted for a regulatory review and held by a government authority.[76] As evidenced from the negotiations history, the inclusion of protection of regulatory data was initiated and most actively negotiated by countries with strong research-based pharmaceutical industries[77] and opposed by those with robust generic sectors.[78] The pertinent concern addressed during negotiations related to the protection of trade and commercial interests of innovator companies against generic competition, especially, in the markets, where patent protection for drugs was not available (and would not be available for some time due to the transitional arrangements). In such markets, innovator companies can rely on the regulatory barrier that can eliminate the competition which can be significantly high due the substantial burden of compliance that requires the conduct of highly risky, investment-intensive and time-consuming clinical trials.[79]

75. *TRIPS Agreement: Preamble*, WTO.ORG, https://www.wto.org/english/docs_e/legal_e/27-trips_02_e.htm (last visited April 28, 2015).. *See also* GATT Secretariat, *Meeting of 25 March 1987*, MTN.GNG/NG11/1, para. 4 (10 April 1987) (citing participants who "spoke of the trade problems they saw as arising from the inadequate or ineffective protection of intellectual property." [. . .] It was said that *trade distortions and impediments* were resulting from, among other things: the displacement of exports of legitimate goods by unauthorized copies, or of domestic sales by imports of unauthorized copies; the *disincentive effect* that inadequate protection of intellectual property rights had on inventors and creators to engage in research and development and in trade and investment. . ."); GATT Secretariat, *Meeting of Negotiating Group of 2, 4 and 5 April 1990*, MTN.GNG/NG11/20, para. 4 (Apr. 24, 1990) (citing a representative of the EC explaining that the EC proposal attempted to address "the substance of the problem of the *potential for trade distortion* if undisclosed information of commercial importance was not adequately protected under domestic law"); Meeting of Negotiating Group, *supra* note 49, para. 11 (Jun. 22, 1990) (citing a representative of the United States commenting on the U.S. draft proposal that "it did not seek to harmonise legislations . . . it tried to create an agreed level of obligations with respect to those aspects of intellectual property regimes which had led to the greatest *trade distortions*" (emphases added).).

76. Initially, draft proposals were comprised under the heading "Government Use" (s*ee* Chairman's Report, *supra* note 44, at 42).

77. For an account of lobbying campaigns of the pharmaceutical industry in setting the TRIPS agenda, s*ee generally* Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, U. 17 PA. J. INT'L ECON. L. 1069 (1996).

78. With regard to the position of India, *see* Meeting of Negotiating Group, *supra* note 40, para. 90; with regard to the position of Canada, *see* Meeting of Negotiating Group, *supra* note 41,, at 15 (reporting that the Canadian delegation "considered that the TRIPS negotiations were perhaps not the appropriate forum to deal with concerns in respect of government use of trade secrets".).

79. THE WORLD TRADE ORGANIZATION, WORLD TRADE REPORT 2004:. EXPLORING THE LINKAGE BETWEEN THE DOMESTIC POLICY ENVIRONMENT AND INTERNATIONAL TRADE 153 (2004) (defining regulatory barriers as government policies that control entry into industry or a particular market; the

However, in many jurisdictions drug authorities approve the generic versions of originator drugs on the basis of bioequivalence,[80] whereby a generic applicant needs to submit evidence attesting that the drug is therapeutically equivalent to and interchangeable with the originator's product. For that, there is no need to conduct full-scale clinical trials—the health authority can issue marketing authorization based on the clinical trial results of the innovator company.

From the healthcare perspective, policy measures facilitating generic competition are justified on public health grounds—*i.e.*, to secure the greater availability and affordability of drugs. From the market perspective, such provisions under drug regulation can be seen as state intervention that can distort the market by "artificially" changing the competition conditions.[81]

Since a generic competitor can bring the product to the market at a fraction of the originator's expenditures, it can be sold by the competitor at a fraction of the originator's price. Once a generic product is launched, the originator can no longer compete on product differentiation,[82] while competition on price impairs its ability to earn a "fair rate of return" on investments.

Vested with the function of granting marketing authorization, a drug authority in this situation plays the role of "gatekeeper", *de facto* regulating competition and the market. However, it differentiates be-

definition also includes cases when "acquisition of a permit may be allowed, but the cost of doing so may be prohibitive").

80. *See* IFPMA, *supra* note 1, at 7 (defining that "[b]ioequivalency between a generic and a pioneer drug is demonstrated by the bioavailability of the two products. Bioavailability is the extent and rate at which the body absorbs the drug. Scientists measure the time it takes the generic drug to reach the bloodstream. The generic drug must deliver the same amount of the active ingredient in the same time period as the pioneer drug in order to be bioequivalent.").

81. Jochen Gloeckner, *The Law Against Unfair Competition and the EC Treaty*, in LAW AGAINST UNFAIR COMPETITION. TOWARDS A NEW PARADIGM IN EUROPE? 77, 79 (Josef Drexl *et al.*, eds, 2007) (stating that the "concept of "distortion" . . . comprises not only direct interventions in the freedom of activity of the market participants involved in or affected by anticompetitive practices, but also other "artificial" changes of competitive conditions".); CARL MICHAEL VON QUITZOW, STATE MEASURES DISTORTING FREE COMPETITION IN THE EC, at 44, 216 (2002) (defining passive distortion of competition as the "category of State measures which affect market conditions" and set market prerequisites that "affect the opportunities to carry out certain activities . . . to compete with economic operators already existing in the market" as distinguished from active distortions of competition, *i.e.*, direct state interference in the market.").

82. European Medicines Agency, *Questions and Answers on Generic Medicines*, EMA/393905/2006 Rev. 2, at 1 (Nov. 22, 2012) (defining generic medicine as "medicine that is developed to be the same as a medicine that has already been authorised (the 'reference medicine'). A generic medicine contains the same active substance(s) as the reference medicine, and it is used at the same dose(s) to treat the same disease(s) as the reference medicine."); *see also* THE WORLD HEALTH ORGANIZATION, MARKETING AUTHORIZATION OF PHARMACEUTICAL PRODUCTS WITH SPECIAL REFERENCE TO MULTISOURCE (GENERIC) PRODUCTS: A MANUAL FOR DRUG REGULATORY AUTHORITIES, Regulatory Support Series No. 005 (1998) (defining a "generic product" as a pharmaceutical product "intended to be interchangeable with the innovator product".).

tween competitors and it distributes the burden of compliance unevenly—while some traders need to bear the full costs of conducting clinical trials, others are granted a relief. Such relief can be seen as a specific form of state aid in a sense that a public authority favors certain undertakings and goods, and, as a result, "a business that benefits from such aid thus enjoys an advantage over its competitors".[83]

Thus, the particular "harm" for which the remedy was sought can be seen in the distorting effect of state intervention that can cause "differences in the prerequisites to compete".[84] From the originator's perspective, the practice a drug authority can be seen as particularly unfair because the originator's assets are used to aid the efforts of competitors and result in putting the former at a competitive disadvantage.

In this sense, protection under 39.3 differs from 39.2 TRIPS that applies to the competitors' practices. In the case of the abbreviated approval of a generic drug, the originator's loss of market share upon the generic entry is offset by the competitor's gain; however, the redress cannot be claimed from the latter because a generic company itself does not use the originator's data. While protection under 39.2 TRIPS is directed at fairness of the means of competition, protection under 39.3 is directed at fairness of competition as an institution, *i.e.*, the "order of struggle" that is "upheld by rules which ensure that each trader succeeds through his own unaided efforts, and not through the gaining of an advantage at the expense of an opponent".[85]

Admittedly, protection against competitive inequalities arising due to state regulation might not be the core function of unfair competition law; it is certainly not within those practices explicitly outlawed under 10*bis* PC as minimum protection. At the same time, unfair competition law has a potential to encompass within its ambit the regula-

83. The European Union, Summaries of EU legislation, Glossary *available at* http://europa.eu/legislation_summaries/glossary/state_aid_en.htm (last visited Feb. 10, 2015) (defining state aid as "action by a (national, regional or local) public authority, using public resources, to favour certain undertakings or the production of certain goods. A business that benefits from such aid thus enjoys an advantage over its competitors. Control of state aids thus reflects the need to maintain free and fair competition within the European Union."). In the case of the abbreviated generic approval, a peculiar trait is that a drug authority does not use "public resources" to facilitate generic competition but the originator's private assets.

84. Quitzow, *supra* note 81, at 5 (distinguishing between the notions of "distortion" and "restriction" of competition, *i.e.*: "Whilst a 'restriction' is an effect of a conduct, a distortion occurs due to differences in the prerequisites to compete or measures which create such differences.").

85. Sam Ricketson, *Reaping without Sowing: Unfair Competition and Intellectual Property Rights in Anglo-Australian Law*, 7 U.N.S.W.L.J. 1, 3 (1984).

tion of the relationships between the state and the private sector when the former can impact competition in the market.[86]

Perhaps it would be a stretch to assume that, at the time of the negotiations, the drafters had an elaborate concept of how the interface between regulatory data protection and unfair competition law was supposed to work for the purpose of data protection. The level of sophistication in intellectual property matters alone differed to an extent that some negotiators admitted that they "were not clear as to what were the trade-related aspects of intellectual property rights".[87] The hypothesis here is that the only competition-related instrument under international law that could be applied to remedy a potentially distorting effect of drug regulation on competition and trade was 10*bis* PC. Given nearly a hundred-year difference between the two provisions,[88] their collocation might not be the perfect match.

Notably, it was the EC that proposed to collocate the protection of undisclosed information with the repression of unfair competition.[89] By the time of TRIPS negotiations, the EC already had experience in protecting *fair* competition against market distortions in the context of intercommunity trade. The Preamble and Article 3 (1) (f) of the Treaty of Rome of 1957 (at present Article 3 (1) (g)) can be recalled in this regard that required the EC member states to "guarantee balanced trade and fair competition" and institute a system "ensuring that competition in the common market is not distorted". These provisions have

86. *See* Handler, *supra* note 36, at 178 (stating "the plane of competition is determined not only by the horizontal controversies among competitors but also by the vertical conflicts between seller and buyer and by the restraints imposed and enforced by the state."); GUSTAVO GHIDINI, WELFARE IN INTELLECTUAL PROPERTY LAW 240–241 (2010) (observing that "the initially supplemental role played by unfair competition law has positively evolved, going from being a doctrine at the service of exclusionary rights of intangible assets and goodwill to one that is at the service of an open market. [. . .]Therefore, the overall interpretative and legislative developments . . . seem to herald a new perspective that attributes to unfair competition law a scope that goes beyond the mere boundaries of the private individual business interests directly involved in competition disputes.").

87. GATT Secretariat, *Meeting of 25 March 1987*, MTN.GNG/NG11/1, para. 6 (Apr. 10, 1987); *see also* Wadlow, *supra* note 18, at 31 (stating that "the majority of the delegates at the TRIPs negotiations were extremely unsophisticated in their understanding of intellectual property rights and the existing international regimes, and that the briefing materials provided by WIPO on confidential information, regulatory data, and unfair competition were almost non-existent").

88. Article 10*bis* was introduced into Paris Convention upon the Revision Conference of Brussels in 1900. (Bodenhausen, *supra* note 36, at 142).

89. Notably, the US regarded its proposal for protection of trade secrets under property rights in line with 10*bis* PC. *See* Meeting of Negotiating Group, *supra* note 49, para. 12 (citing a representative of the United States stating "[r]egarding acts contrary to honest commercial practices including protection of trade secrets, the [US] proposal attempted to provide greater *precision* to Article 10*bis* of the Paris Convention" (emphasis added).).

been interpreted as incorporating the antitrust and unfair competition branches of competition law.[90]

Thus, the special purpose of 39.3 TRIPS can be seen in protecting the commercial interests of the originator companies against the distorting effect of drug regulation on competition. However, it is not the equality of competitive conditions that is the ultimate concern and objective of 39.3 TRIPS. The main object of protection of the provision is not the repression of unfair competition, but the data themselves. Such subordination arises from the prevailing type of legal protection.

D. 39.3 TRIPS as an overlap between trade secret, unfair competition, and sui generis data protection

From the legislative perspective, 39.3 TRIPS presents a peculiar case of intentional overlap between trade secret, unfair competition, and *sui generis* types of protection.

The heading of the provision points out the trade secret regime. However, among the two types of protection stipulated under 39.3 TRIPS, protection against disclosure is rather a supplementary obligation (as emphasized by the conjunction "In addition. . ."). Being the primary obligation, 39.3 TRIPS requires the protection of data against specific—"unfair commercial"—uses.[91]

The collocation of unfair competition and IP types of protection does not appear as something artificial or extraordinary. The two legal regimes are inherently related. In the words of Professor Ladas, unfair competition law "forms the background, and constitutes the general principle of which the laws protecting the various branches of industrial property" and aims at protecting the same interests as specialized branches of industrial property, *i.e.*, "interests acquired by lawful efforts, research, labor, investment or by conducting a lawful business".[92]

90. *See* Reto M. Hilty, *The Law Against Unfair Competition and Its Interfaces*, in LAW AGAINST UNFAIR COMPETITION. TOWARDS A NEW PARADIGM IN EUROPE? 1, 11–12 (Josef Drexl *et al.*, eds, 2007) (stating that the "prevailing interpretation is that [Art. 3 Para. 1 (g) EC] is primarily aimed at the legal activity of the Community in the field of antitrust law. However, if one includes the preamble, paragraph 5 of which also requires "fair competition" to be guaranteed, there is no reason why the completely open-ended wording of Art. 3 Para. 1 (g) EC should not also be understood as being aimed at the law against unfair competition."); Gloeckner, *supra* note 81, at 77–78 ("Admittedly competition is primarily protected by means of the rules on competition in Art. 81 *et seq*. EC. Nevertheless Art. 3 Para. 1 (g) requires not only measures against classical infringements of Antitrust law but also against unfair competition if the infringement is capable of interfering with the functions of competition.").

91. *See* Carvalho, *supra* note 39, para. 39.137 (referring to protection against data disclosure "as adjective protection" and protection against uncompensated reliance on data for generic approval as "substantive protection" under 39.3 TRIPS).

92. *See* LADAS, *supra* note 36, at 1675–1676.

Furthermore, some specific IP rights evolved from unfair competition domain—the legislative precedents of neighboring rights and *sui generis* protection of databases can be invoked in this regard.[93]

However, 39.3 TRIPS does not grant a new IP right in the meaning of protection against all, but rather provides for the *sui generis* type of data protection. Yet, in some way, it appears similar to IP right: although protection is not granted in the form of an exclusive right, it intends to achieve an exclusionary effect—to preclude particular, albeit vaguely defined, uses of test data. In this sense, the protection of test data is in line with the concept of negative rights under IP law.[94]

There is, at least, a formal distinction between unfair competition and IP law as providing conduct-oriented *vis-à-vis* object-related protection.[95] The wording of the provision suggests that the *sui generis* type of protection is prevalent: although protection is directed at particular practices that constitute unfair commercial use, the focus is on the data themselves ("[m]embers. . .shall protect. . .data against unfair commercial use"). This suggests that fairness and equality of competitive conditions are rather a secondary concern; the main purpose is to protect the achievement in data generation.[96]

The qualification criterion of considerable effort involved in data generation emphasizes the investment rationale for protection. The requirement of the utilization of new chemical entities suggests that protection is intended to reward achievements that significantly contribute to innovation. Thus, the purpose of data protection under 39.3 TRIPS is two-fold: to provide for investment amortization, and to en-

93. *See* Annette Kur, *What to Protect, and How? Unfair Competition, Intellectual Property, or Protection Sui Generis*, MAX PLANCK INSTITUTE FOR INTELLECTUAL PROPERTY AND COMPETITION LAW RESEARCH PAPER SERIES No. 13–12, at 8–10 (2013) (accounting for protection under unfair competition when it "served as an 'incubator' for new types of rights, or where it has led to an extension of existing IPRs to new areas or objects of protection.").

94. *See* Panel Reports, *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WT/DS174/R, para. 7.210 and WT/DS290/R, para. 7.246 (stating that the "principles [under Article 8.1 of the TRIPS Agreement] reflect the fact that the TRIPS Agreement does not generally provide for the grant of positive rights to exploit or use certain subject matter, but rather provides for the grant of negative rights to prevent certain acts. This fundamental feature of intellectual property protection inherently grants Members freedom to pursue legitimate public policy objectives.").

95. *See, e.g.*, ESTELLE DERCLAYEDERCLAVE, THE LEGAL PROTECTION OF DATABASES. A COMPARATIVE ANALYSIS 251 (2008) (distinguishing between unfair competition and IP on the basis that the former defines specific subject matter of protection while the latter protects against the competitor's unfair behavior); Kur, *supra* note 93, at 8 (arguing that the distinction between intellectual property and unfair competition law as object- and conduct-related protection appears "as a matter of pure semantics, or rather of perspective".).

96. Kur, *supra* note 93, at 6 (arguing that the "basic axiom is that unfair competition does not provide any basis for protecting valuable achievements, i.e., it is not object-oriented, but only concerns the evaluation of conduct".).

courage continuing innovative activity. In that, data protection reflects the logic underlying patent protection that is based on the idea that legal monopoly of patent rights allows for the *ex-post* recovery of investment and motivates *ex ante* to undertake further R&D activity.

E. The principle

In view of these considerations, the principle underlying protection under 39.3 TRIPS can be defined as follows: the use of data constitutes "unfair commercial use" and shall be prevented when excluding others from such use is the only means for the originator to amortize investment in data generation. In other words, the legitimacy of a third party's use of data shall be evaluated with regard to its effect on the originator's capacity to innovate—i.e., protection should be accorded when such use interferes with the originator's ability to recover costs incurred in the generation of the original dataset to an extent that it erodes the incentive to undertake further inventive activity.[97]

Under this principle, compliance with the obligation under 39 TRIPS is rather a question of finding the proper means to structure protection that would allow the originator to amortize investment in data generation. At this point, one may ask: what uses of data realize the investment amortization function of test data? Apart from generic approval, what other uses can possibly interfere with the originator's ability to earn returns on investment? Are the clinical trial data "exploited" as an asset in the course of commercial activities after obtaining marketing authorization, in the sense that, when a competitor is excluded from such use, the originator can charge higher prices?

A better understanding of the economic value of clinical data upon marketing approval, as well as the means of its realization is needed in order to conceive the appropriate legal rules. At the outset, it appears implausible to correlate legal protection with the measure of compensation R&D expenditures for each drug on an individual basis, especially in view of the global pharmaceutical trade. To a great extent, the actual return on investment can depend on the particular market conditions. One drug can earn different profits from sales in different markets, even if those jurisdictions provide identical provisions on data

97. As observed by Professor Reichman, if unjust enrichment is included "within the purview of its domestic unfair competition law . . . courts could consider the extent to which allowing regulatory approval on the basis of bioequivalence, without more, destroyed any incentive to generate the data needed to bring the product to market as well as the extent to which that incentive had been amply sustained in the country of origin (or other relevant countries)"(Reichman, *supra* note 57, at 20)..)

protection. On the other hand, in one and the same market, one drug can generate profits that would be a "fair return" on R&D investment, while another might not.[98]

The unfeasibility to adjust protection based on the *ex-ante* assessment of the amount of compensation does not mean that some form of *ex-post* investment recovery should not be guaranteed at all. At the same time, the boundary of legal protection should be set not to preclude the uses of data that do not negatively impact the originator's sales from the drug, for which the initial dataset was generated.

F. Implications for data disclosure for experimental purposes

According to the stated principle, the experimental use of regulatory data shall not constitute unfair commercial use within the meaning of Article 39.3 TRIPS, insofar as it does not impede the originator's ability to recoup investment into data generation. Such an impeding effect is unlikely since the development and commercialization of a new product resulting from the enabled experimental use would require time. The new product might not be in direct competition with the one for which the original dataset was produced.[99]

The question arises with regard to the scope of protection: should protection be confined to the profits derived from the sales of the referenced drug, or should the originator be entitled to potential benefits[100] including possible inventions that might "lay dormant" in clinical trial data and not yet be realized in the marketed drug? The motivation of data originators to restrict access to data for experimental use is understandable: it would be practically impossible to prove that a competitor's new product resulted from the experimental use of the originator's data. At the same time, as a non-rivalrous good, clinical trial data can be used for experimentation by different re-

98. Suzanne Scotchmer, *The Political Economy of Intellectual Property Treaties*, 20 J.L. ECON. & ORG. 415, 422 (2004) (noting that "for some subject matter, protection in any one of the large markets, the United States, Europe, or Japan, is enough to compensate an inventor, regardless of where the inventor is domiciled").

99. *See* John P. Dawson, *The Self-Serving Intermeddler*, 87 (7) HARVARD LAW REVIEW, 1409, 1416 (1974) (arguing that the "principalprinciple purpose in controlling free riders was to prevent one competitor profiting from the investment . . . of another competitor in situations where both of them competedcompete directly".).

100. As originally proposed by the United States, "[t]rade secrets submitted to governments as a requirement to do business shall not be disclosed except in extreme circumstances involving national emergencies or, in the case of public health and safety, provided that such disclosure does not impair *actual or potential markets* of the submitter or the value of the submitted trade secrets" (emphasis added).)Suggestion by the United States, *supra* note 47, at 8.

searchers at the same time and, at least theoretically, lead to independent inventions.

Policies enabling regulatory data disclosure for experimental purposes can be justified under the overall objectives of the TRIPS Agreement. Access to clinical trial data by the research community can prevent conducting duplicative trials[101] and avoid the needless exposure of human subjects to trial risks, whereas restrained access and monopoly type protection can lead to the underutilization of clinical trial data and the internalization of positive externalities. Benefits for healthcare improvement associated with the broader access to regulatory data can "contribute to the promotion of technological innovation and to the transfer and dissemination of technology",[102] whereas access to data by other researchers can promote the allocative efficiency of resources and be seen as a measure "necessary . . . to promote the public interest in sectors of vital importance to [the] socio-economic and technological development"[103] as aspired by the goals and principles of the TRIPS Agreement. In this sense, policy measures enabling access to clinical data are in line with the WTO concept of policy coherence.[104]

CONCLUSION

Admittedly, the definition of the minimum protection requirement under 39.3 TRIPS leaves room for speculation. The three readings offered in this article show that the protection obligation shall not be interpreted as precluding any seemingly unfair use of data, even when it is exercised by competitors with commercial intent and generates commercial benefits.

Beyond the core area of unfair competition—acts associated with dishonest practices—protection against unfair commercial use should not be interpreted as the prohibition of a specific act *as such* but rather

101. Bryan C. Mercurio, *TRIPS-Plus Provisions in FTAs: Recent Trends*, *REGIONAL TRADE AGREEMENTS AND THE WTO LEGAL SYSTEM* 215, 227 (Lorand Bartels & Frederico Ortino, eds, 2006) (stating that "duplication of testing is arguably unethical, as it simply is repetition in testing and clinical trials where the safety and efficacy of a product has already been determined"); *also* Carvalho, *supra* note 18, para. 39.143 (stating that "exclusive protection of test data leads to waste of scarce resources, because it requires competitors to repeat the same test on a product that is known [and] leads to the re-invention of the wheel").

102. TRIPS Agreement art. 7, Jan. 1, 1995.

103. TRIPS Agreement art. 8, Jan. 1, 1995.

104. The WTO, *supra* note 79, at 151 (emphasizing efficiency in resource allocation as "the prism through which [the WTO] view[s] coherence in trade, competition and environmental policies").

be based on the appraisal of particular circumstances.[105] Since the *sui generis*—IP-type—of data protection prevails in 39.3 TRIPS, the protection should be confined to situations when its absence impairs the innovator's capacity and motivation to engage in further innovative activity. As long as the experimental use of data does not offset the profits from the drug, for which the initial dataset was generated, policies that enable the disclosure of trial reports for experimental use shall not be considered to violate 39.3 TRIPS.

Specialized branches of IP law delineate legal protection and define conditions, when the protected subject matter enters the public domain and when its use by others is legitimate. In view of the growing importance of data protection in the biopharmaceutical sector,[106] the need for such delineation would be highly appreciable a it would contribute to legal certainty and support innovative activity in the sector.

Restrained access to clinical data as well as greater data-sharing can cause multiple effects on innovative activity by different actors. The further analysis of the scientific and economic value of regulatory data would yield a better understanding of the costs and benefits associated with restricted access to data as well as their disclosurer for experimental use. Such analysis would be necessary to inform policy-makers who seek a balanced solution in healthcare and innovation regulation.

105. *See* Ansgar Ohly, *Reverse Engineering: Unfair Competition or Catalyst for Innovation?*,? PATENTS AND TECHNOLOGICAL PROGRESS IN A GLOBALIZED WORLD 535, 552 (W. Prinz zu Waldeck und Pyrmont *et al*., eds, 2009) (concluding with regard to unfair competition, trade secret protection and reverse-engineering that "[t]here should be no general presumption that obtaining a secret outside relations of confidence is unfair as such. Rather, the broad notion of "fairness" or "honest practices" allows a balancing exercise which takes into account the interests of the owner of the information of the person interested in obtaining it and of the general public.").

106. Yaniv Heled, *PatentsParents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. TECH. L. REV. 419, 424 (2012) (questioning whether "the statutory exclusivity regime in biologics [could] mark the dawn of a new era in the protection and incentivizing of innovation and the beginning of a gradual replacement of the old patent system with modern schemes of statutory exclusivities; or is it just a peculiar case of a legal regime shaped by an unusually powerful industry").