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A EUROPEAN TRANSPARENCY CHALLENGE: CAN COMMERCIAL CONFIDENTIALITY IN CLINICAL TRIALS DATA BE OVERCOME?

Candidata

Giulia Schneider

Relatrice

Chiar.ma Prof.ssa Dianora Poletti

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A European Transparency Challenge: can commercial confidentiality in clinical trials data be overcome?

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"All industries are different, but some are more different than others.
The pharmaceutical industry fits the latter category"

(SCHERER, *Industry structure, Strategy and Public policy,* New York, Prentice Hall, 1997, 336)

Abstract

Il presente lavoro di ricerca si propone di indagare la relazione tra istituti di proprietà intellettuale previsti nell'ordinamento internazionale ed europeo e la regola di trasparenza dei dati derivanti da sperimentazioni farmaceutiche contenuta all'art. 8,4 del Regolamento UE sulle sperimentazioni cliniche n. 536/2014.

Scopo ultimo della tesi è quello di giustificare soluzioni di trasparenza e accesso alle informazioni riguardanti le proprietà di efficacia e sicurezza dei prodotti farmaceutici immessi in commercio, sulla base dell'individuazione della *ratio* economica e giuridica dell'eccezione di riservatezza commerciale posta dall'art. 81,4 del citato Regolamento.

Il tema, ampiamente esplorato in letteratura, dell'accesso ai farmaci è analizzato in questa sede da un punto di vista non già quantitativo, bensì qualitativo: l'accesso alle informazioni derivanti da sperimentazioni cliniche viene difatti letto come una precondizione essenziale ad un più sicuro e consapevole accesso, e dunque consumo, di prodotti ad alto impatto sulla salute individuale e collettiva.

Punto di partenza dell'analisi è la considerazione del duplice valore dei dati desunti dai processi di ricerca e sviluppo farmaceutico. Tali dati sono difatti da un lato fonte di vantaggio competitivo per le società che li hanno prodotti, e dall'altro materiale informativo altamente prezioso per la comunità scientifica, la cui conoscenza appare direttamente funzionale al soddisfacimento di diritti fondamentali dell'Unione Europea, quali il diritto alla informazione e alla salute di pazienti e consumatori.

Il duplice valore, al contempo commerciale e informativo, dei dossier di sperimentazione clinica, è stato cristallizzato nell'art. 81,4 del Regolamento sulle sperimentazioni cliniche, ove ad una regola di trasparenza viene opposta una eccezione di riservatezza commerciale, sulla scia dello schema

normativo già fatto proprio dal Regolamento EC 1049/2001 sull'accesso ai documenti delle istituzioni europee, e più specificamente dalle Regole di attuazione dello stesso Regolamento riguardanti l'accesso ai documenti dell'Agenzia Europea del farmaco.

La prassi amministrativa e giurisprudenziale ha fino ad oggi risolto il contrasto interpretativo tra i due opposti interessi quasi sempre a favore delle ragioni di riservatezza commerciale, ratificando così sul piano propriamente giuridico le pratiche di distorsione informativa (*reporting biases)* perpetrate dalle società farmaceutiche, con conseguenti esiti di grave compressione del diritto alla salute di cui all'art. 35 della Carta dei diritti fondamentali dell'Unione Europea, e all'art. 12 dell*'International Covenant on social and political rights.*
Come dimostrato anche dalla controversia tra il gruppo di ricercatori danese *Cochrane Collaboration* e l'Agenzia europea per i medicinali (EMA), definitivamente risolta con la pronuncia del difensore civico europeo nel 2010, le richieste di accesso ai dossier clinici sono state in gran parte rigettate dall'agenzia di regolazione.
A completamento del quadro, in due noti casi del 2013- *Abbvie* e *Intermune*- la Corte di Giustizia dell'Unione Europea si è pronunciata ponendo in evidenza le notevoli difficoltà tecnico-interpretative sottostanti alla creazione di meccanismi di trasparenza di dati commercialmente sensibili.

I richiami a politiche di maggiore trasparenza riguardanti i dati di sperimentazioni cliniche provenienti da numerosi documenti internazionali, quali la Dichiarazione di Helsinki *on Ethical Principles for Research Involving Human Subjects* promossa nel 2008 dalla *World Medical Association,* e lo *Statement on Public Disclosure of Clinical Trials Results* emanato nel 2014 dall'Organizzazione Mondiale della sanità, sono stati alla base delle recenti istanze di cambiamento in seno alle stesse istituzioni europee.
La necessità di un pubblico scrutinio da parte della comunità scientifica circa gli esiti delle sperimentazioni farmaceutiche, insieme alla opportunità

del re-impiego dei dati da queste prodotti ai fini del progresso della conoscenza scientifica, hanno condotto nel 2014 l'Agenzia europea per i medicinali alla revisione delle proprie policy di accesso ai dossier farmaceutici.
Sulla scia di questo indirizzo, l'Unione Europea ha cercato di assumere posizioni più decise anche sul piano legislativo, con la emanazione della *Clinical Trials Regulation* EU n. 536/2014- Regolamento sulla sperimentazione clinica dei medicinali per uso medico-, ove all'art. 81, 4 si prevede proprio l'istituzione ad opera dell'Agenzia europea per i medicinali di un database pubblicamente accessibile al fine di "consentire ai cittadini europei l'accesso alle informazioni sui prodotti farmaceutici".

Tuttavia, sia le nuove politiche di accesso annunciate dall'Agenzia europea per i medicinali, sia la istituzione di un database pubblicamente accessibile e contenente tutte le informazioni sottomesse all'agenzia di regolazione necessitano di essere meglio valutate in punto di effettività.

Infatti, ad un più attento vaglio, le condizioni d'uso dei dati derivanti da sperimentazioni cliniche, messe a punto dalla stessa Agenzia europea per i medicinali, risultano essere animate da principi ben diversi rispetto a quelli posti alla base della trasparenza sull'informazione scientifica, mentre la tenuta della regola di trasparenza di cui all'art. 81, 4 del Regolamento sui dati clinici potrebbe essere ampiamente svigorita per effetto di un'interpretazione eccessivamente generosa della eccezione posta a tutela della riservatezza commerciale.

La prospettiva del bilanciamento tra opposti interessi, implicitamente deferito agli organi amministrativi e giudiziali dallo stesso Regolamento EU n. 536/2014, si è dimostrata particolarmente debole rispetto al fine del perseguimento di politiche di maggiore accesso ai protocolli di sperimentazione clinica.

Il presente studio si propone dunque lo scopo di pervenire a soluzioni di contemperamento maggiormente risolutive dal punto di vista sistematico: la problematicità interpretativa del rapporto tra regola generale di trasparenza e la eccezione di riservatezza commerciale contenute nell'art. 81,4 del Regolamento sulle sperimentazioni cliniche, diventa spunto per un più profondo esame sul rapporto strutturale tra normative europee di accesso ai dossier clinici sottoposti all'Agenzia Europea del Farmaco, e le normative poste a tutela della segretezza commerciale, quali la Proposta di direttiva sui segreti commerciali in attesa di definitiva approvazione e la regola di *data exclusivity* di cui all'art. 10 della direttiva 2001/83/CE recante un codice comunitario sui medicinali ad uso umano.

Contrariamente alle aspettative, proprio nell'ambito della disciplina della proprietà intellettuale farmaceutica sono da rinvenirsi le tracce di un paradigma giuridico in grado di soddisfare le esigenze di pubblica trasparenza senza intaccare il vantaggio competitivo che le società farmaceutiche hanno conseguito mediante gli investimenti in attività di ricerca e sviluppo.

Introduction

The issue of pharmaceutical's intellectual property protection tools raises traditionally two very broad concerns, regarding their effects on free competition mechanisms and on the level of access to medicines generally assured.

These two separate fields are deeply intertwined[1], given that the degree of the pharmaceutical products available on the market largely depends on the legitimate- or illegitimate- uses of the intellectual property protections schemes by pharmaceutical companies[2].

More directly speaking, the misuse of the intellectual property safeguards- mainly of the patent system-by pharmaceutical companies[3], hinders free competition mechanisms from ensuring an efficient functioning of the drug market in terms of quantity and affordability[4].

The complex economic and legal implications become even more evident by considering the two-folded nature of drugs: they are at the same time the result of a long[5] and expensive[6] R&D process worthy of economic reward

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[1] For a general assessment see GHIDINI, *Innovation, Competition and Consumer Welfare in Intellectual Property Law,* Cheltenham, Edward Elgar, 2010, 13 ss. and ID., *Intellectual property and Competition Law- The innovation nexus*, Cheltenham, Edward Elgar, 2006, 23 ss., and 99 ss..

[2] BERGER, *Advancing public health by other means: using competition policy,* in ROFFE-TANSEY-VIVAS EUGUI, *Negotiating Health- Intellectual Property and Access to medicines,* London, Earthscan, 2006, 181 ss.. On the point also GHIDINI, *Innovation, Competition and Consumer Welfare in Intellectual Property Law, supra,* 239 ss..

[3] One must think for example of secondary patenting, patent related agreements and disputes, settlements, litigations, interventions. ADAMINI-MAARSE-VERSLUIS-LIGHT, *Policy making on Data exclusivity in the European Union: from industrial interests to legal realities,* in *Journal of Health Politics, Policy and Law,* 34, 6, 2009, 979 ss., 1003. Cf. also AREZZO, *Strategic patentig e diritto della concorrenza: riflessioni a margine della vicenda* Ratiopharm-Pfizer, in *Giurisprudenza commerciale,* 2, 2012, 404 ss., and ULLRICH, *Strategic patenting by the pharmaceutical industry: towards a concept of abusive practices of protection,* in DREXL-LEE, *Pharmaceutical innovation, competition and patent law,* Cheltenham, Edward Elgar, 2013, 241.

[4] See ROSENBERG, *Market concentration of the Transnational Pharmaceutical Industry and the Generic Industries: trends on Mergers, Acquisitions and other Transactions,* in ROFFE-TANSEY-VIVAS EUGUI, *Negotiating Health- Intellectual Property and Access to medicine, supra, 65 ss..*

[5] The average R&D time is considered to be between ten and fifteen years. See LYBECKER, *The Economics of Access to Medicines: meeting the challenges of Pharmaceutical Patents, Innovation, and access for Global Health,* in *Harvard International Law Journal Online,* 53, 2011, 26 ss., 28.

[6] The effective costs of a R&D in the pharmaceutical industry are highly controversial, as …. states, attention must be paid to the distinction which reflects itself also in a cost distinction between chemical and biotechnological drugs. See DIMASI-GRABOWSKI, *The cost of biopharmaceutical R&D:*

by means of an appropriate legal defence[7], and a vital good for the wellbeing of people, and of society as a whole[8].

Hence, the need to strike a balance between the necessity to *promote* "technological innovation and the dissemination of technology"[9], and to preserve the "economic and social welfare"[10] "to the mutual advantage of producers *and users* of technological knowledge"[11].

However, what art. 7 of the TRIPs Agreement mandates as a "*balance* of rights and obligations"[12], turns out to be a serious conflict involving on the one side the demand of further incentives[13] for pharmaceutical research[14], which is governed by an increasing degree of risk and uncertainty[15], and on the other side, short term public health aspirations[16].

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is biotech different? 28 MANAGERIAL & DECISION ECON. 2007, 469, 476-477, estimating biotech R&D around 1.3 billion USD.

[7] "The research-based pharmaceutical industry tends to be firm in its defence of intellectual property rights because they are lifeblood of our industry- we literally could not exist without them". That is the remark of the former Chairman and CEO of Glaxo Wellcome, Sir Richard Sykes, as quoted by PUGATCH, *The international Political Economy of intellectual property rights,* Edward Elgar, 2004, 101. The European Federation of Pharmaceutical Industries and Associations (EFPIA) has also pointed out how the development of pharmaceutical industry crucially relies on intellectual property rights", and that "any small change, positive or negative in the IP rules could dramatically make our pharmaceutical companies more or less advantageous in developing new, risky and costly technologies". *Ibid.*. Cf. also EISENBERG, *Patents, product exclusivity and information dissemination: how law directs biopharmaceutical research and development,* in 2 Fordham L. Rev. 2003-2004, 477ss., 479.

[8] On this point see MATTHEWS, *Intellectual property, human rights and development-The role of NGOs and Social Movements,* Cheltenham, Edward Elgar, 2011, 15 ss.

[9] As literature points out, this is the ratio of the intellectual property protection as a whole. See GOREN, *Pharmaceutical innovation and intellectual property rights: a global public good?,* in PUGATCH, *The intellectual property debate- Prospectives from Law, Economics and Political Economy,* Cheltenham, Edward Elgar, 2006, 159 ss..

[10] Art. 7 of the TRIPS Agreement: "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

[11] *Ibid.,* emphasis added.

[12] Emphasis added.

[13] Incentives have to be shaped with particular attention in the pharma sector where the production of a new drug is very difficult and costly, whereas reproduction of an already invented drug is easy and relatively cheap. The free riding of competitors has to be faced as a serious risk, conceived by the economic literature as a real market failure that has to be correct by means of legal forms of protection of the original investments. Cf. so LYBECKER, *The Economics of Access to Medicines: meeting the challenges of Pharmaceutical Patents, Innovation, and access for Global Health, supra,* 28. Cf. GAMBARDELLA-ORSENIGO-PAMMOLLI, *Global Competitiveness in Pharmaceuticals- A European Perspective,* published on November 2000, online available at http://ec.europa.eu/health/files/docs/comprep_nov2000_en.pdf, 77-78, warning against the risks of strengthening the forms of intellectual property rights protections.

[14] See GOREN, *Pharmaceutical innovation and intellectual property rights: a global public good?, supra,* 162 and 164.

[15] "It is important to note that even when research and development efforts are successful and a safe and effective drug is developed, it may not necessarily profitable, with lifetime sales that exceed average R&D costs", so LYBECKER, *The Economics of Access to Medicines: meeting the challenges of Pharmaceutical Patents, Innovation, and access for Global Health, supra,* 32. See also FACKELMAN, *Clinical*

In fact, the market exclusivity granted by the different forms of intellectual property- as we will see, not only by patents- and the control over price that it grants to companies[17], create time- and cost- barriers delaying- if not preventing at all- generic companies to access the market.

This deters the awaking of "competition by imitation" mechanisms[18], capable of sinking prices and of fostering medicine's varieties[19].

Exploitations of patents[20] and of regulatory procedures aimed at excluding generic competition[21], lay therefore the grounds to barriers restricting patients' and consumers' access to needed medical treatments[22].

From this perspective, literature[23] has been focusing on the relationship between international trade agreement provisions referring to drug's

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data, data exclusivity and private investment protection in Europe, in DREXL-LEE, *Pharmaceutical innovation, competition and patent law- A trilateral perspective,* Cheltenham, Edward Elgar, 2013, 147 and EISENBERG, *Patents, product exclusivity and information dissemination: how law directs biopharmaceutical research and development, supra,* 478.

[16] ROFFE-SPENNEMANN-VON BRAUN, *From Paris to Doha: the WTO Doha Declaration on the TRIPS Agreement and Public Health,* in ROFFE-TANSEY-VIVAS EUGUI, *Negotiating Health- Intellectual Property and Access to medicine, supra,* 9 ss..

[17] Control over price means also the ability to segment different markets and charge different prices. See LYBECKER, *The Economics of Access to Medicines: meeting the challenges of Pharmaceutical Patents, Innovation, and access for Global Health, supra,* 26 ss.. Worth noting is also the so called Ramsey pricing strategy, consisting in charging different consumers different prices on the basis of their price sensitivity, as explained by DANZON, *Making sense of drug prices,* 23, REGULATION, 56, 61 (2000), online available at http://object.cato.org/sites/cato.org/files/serials/files/regulation/2000/4/danzon.pdf. See also ROSENBERG, *Market concentration of the Transnational Pharmaceutical Industry and the Generic Industries: trends on Mergers, Acquisitions and other Transactions, supra,* 65 ss..

[18] FACKELMAN, *Clinical data, data exclusivity and private investment protection in Europe, supra,* 156.

[19] BERGER, *Advancing public health by other means: using competition policy, supra,* 13.

[20] Cf. European Generic Medicine Association, *Patent-related barriers to Market Entry for Generic Medicines in the European Union- a review of weakness in the current European patent system and their impact on market access of generic medicines,* published on May 2008, online available at http://www.egagenerics.com/images/Website/IP_Barriers_web_Patent-related_Barriers.pdf.

[21] Cf. DG Competition of the European Commission, *Pharmaceutical Sector Inquiry- a preliminary report,* published on 28th november 2008, online available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf, 13, states that " in many instances originator companies use two or more instruments from the "tool box" in parallel and/or successively in order to prolong the lyfe-cycle of their medicines". A perfect example of the strategic abuse of regulatory procedures for anticompetitive purposes, is given by the Astrazeneca v. Commission case, decided on the 6 december 2012 by the European Court of Justice C-457/10 P, with particular reference to the second abuse, concerning the filing for a marketing authorisation for a drug in tablet formulation, combined with the request of de-registering the market authorisation already had for the same drug's version in capsules. Cf. NEGRINOTTI, *Abuse of regulatory procedures in the intellectual property context,* in GOVAERE-ULLRICH, *Intellectual property, Market Power and the Public interest,* Brussels, Peter Lang, 2008, 143 ss..

[22] As the DG Competition of the Eu Commission has pointed out, "these tactics significantly increase legal uncertainty to the detriment of generic entry and can cost public health budgets and ultimately consumers significant amount of money". DG Competition of the European Commission, *Pharmaceutical Sector Inquiry- a preliminary report*, *supra*, 5.

[23] Cf. European Generic Medicines Association, *How to increase Patient Access to Generic Medicines in European Healthcare systems- A report by the EGA Health Economics Committee,* published on June 2009,

intellectual property protection, and state's obligations to accomplish the fundamental right to health.

Policy concerns related to price heights[24] have thus led on the one hand to compulsory licensing systems and allowance of production or export of generic versions of specific pharmaceutical products in developing countries[25], and on the other hand to the enhancement of antitrust tools acting as remedies for "ip imbalances"[26].

Accordingly, national courts have been defining the access to life-saving drugs at a reasonable cost as a structural component of the right to health[27].

However, a more accurate consideration of the very nature of the right to health, suggests that the effects of intellectual property protection on the degree of access to medicines do not only involve price heights.

Indeed, given the fact that 90% of patents granted for the drugs mentioned in the list of Essential Drugs have expired[28], legal literature has underlined how patents and international patent protection obligations are not the main obstacle to adequate supply of necessary pharmaceuticals[29].

In addition- and in some cases, alternatively- to patents[30], there are other layers of pharmaceuticals' protection that affect, as usual, both drug's availability and affordability.

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online available at http://www.medicamentsgeneriques.info/wp-content/uploads/2010/10/ega_increase-patient-access_update_072009.pdf.

[24] For a general overview of the issue cf. DANZON, *Making sense of drug prices, supra,* 56 ss..

[25] Cf. CORREA, *Intellectual property rights, the WTO and developing countries: the TRIPS agreement and policy options,* London, Zed Books, 2000, 88 ss..

[26] FLANAGAN-GHEZZI-MONTAGNANI, *The search for EU boundarie: IPR exercise and enforcement as* misuse, in FLANAGAN-MONTAGNANI, *Intellectual property law, Economic and social justice perspectives,* Edward Elgar, 2010, 140. See also ADAMINI-MAARSE-VERSLUIS-LIGHT, *Policy making on Data exclusivity in the European Union: from industrial interests to legal realities, supra,* 1003.

[27] LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency,* in *American Journal of Law & Medicine,* 38 (2012), 63 ss., 65-66.

[28] FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement,* in *Harvard International Law Journal*, 45, 2, 2004, 443 ss., 445. For a broader analysis cf. LYBECKER, *The Economics of Access to Medicines: meeting the challenges of Pharmaceutical Patents, Innovation, and access for Global Health, supra,* 34 ss.., stating that "since access is clearly a problem even in the absence of patents, the results suggest that something beyond patents prevent access": poverty, taxation of pharmaceutical therapies, inefficient government regulatory procedures, and counterfeiting have also to be taken into consideration.

[29]FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 444.

[30] Cf. CORREA, *Protecting Test data for Pharmaceutical and Agrochemical Products under Free Trade Agreements,* in ROFFE-TANSEY-VIVAS EUGUI, *Negotiating Health- Intellectual Property and Access to*

However there's more: in fact, such other forms of protections also lead to the relatively unexplored[31] matter of the lack of reliable information about pharmaceutical products[32], to be considered highly relevant from a public health perspective.

In this light, a deeper analysis of the scope of the right to health[33] as defined by international human rights treatises- such as the International Covenant on Economic, Social and cultural rights[34]- suggests the need to consider the issue of access to medicines not only from a *quantitative*, but also from a *qualitative* standpoint.

In other words, not only access to medicine in the strict sense, but also *access to information* regarding medicines, has to be addressed, if full compliance to the right to health wants to be achieved[35].

As some literature has pointed out[36], adequate access to reliable information can be seen as a key point in the debate concerning the improvement of access to medicines[37], given the risks, both for industrialised and developing countries, of improper prescription and overconsumption of drugs[38].

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medicines, supra, 81 ss., stating that exclusive rights over test data "operate, in some cases, like a substitute for patent protection thereby removing from public domain products that should be freely available", 95.

[31] SALINAS, *Open access to research protocols and results: intellectual property and the right to health,* in *Global Forum Update on research for Health- Equitable access: research challenges for health in developing countries, supra,* 47 ss..

[32] "the global system of protection of intellectual property rights has ended up being a barrier not only for access to drugs, but also a barrier for accessing information on the efficacy and safety of drugs". *Ibid.*.

[33] See *infra* Conclusions 1.1.

[34] Cf. art. 12 of International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), U.N. GAOR, Supp. No. 16, U.N. Doc. A/6316,1966.

[35] Cf. SALINAS, *Open access to research protocols and results: intellectual property and the right to health, supra,* 47 ss..

[36] LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 66.

[37] Cfr. FAEH, *Giving Information on Medicinal Products to the General Public- In Search of a Definition to Safeguard the Patient,* in *European Journal of Health Law,* 21, 2014, 176 ss., 191 ss., stating how "patient information is a means for allowing patients to obtain more information about a prescribed product. Information enables patients to make informed decisions about using a product".

[38] LEMMENS, *Pharmaceutical knowledge governance: a human rights perspective,* in *Journal of Law, Medicine and Ethics,* 41*,* 1*,* 2013, 163 ss., 164. This risk has been widely underlined by the CJEU in the ruling Case C-316/09, *MSD Sharp & Dohme v. Merckle,* 2011. For a comment of this important judgment see SEITZ, *No prohibition of Dissemination of information on Prescription-only Medicinal Products on a Manufacturer's Website,* in *European Journal of Risk Regulation,* 2011, 447-449.

Shaping the topic

It is on these premises that the political and legal debate around the granting of access to clinical trials data arises.

As this study argues, the information embedded in clinical trial protocols turns out to be a precious source for the evaluation of drug's safety and efficacy, the awareness of which is thus to be considered essential for protecting patients' and consumers' health.

From a pharmaceutical knowledge governance [39] perspective, adequate protection of public health and scientific research interests[40] can only be achieved through the fulfilment of individuals' and public's right to be informed about pharmaceutical product's benefits and risks.

Hence the establishment of appropriate information systems providing access to test data is required.

However, in addition to their *informational* value, clinical trials data also have a second important *regulatory* value, which is directly related to competition concerns[41].

In fact it is on the basis of the outcomes of the clinical trials conducted by the sponsor, that the regulatory agency evaluates the release of a marketing authorisation.

From this further point of view, test data result to be of crucial significance for competitors aiming to enter the market with a generic product, similar to the one already approved[42].

The high commercial value of clinical trials data has caused pharmaceutical companies to seek secrecy protection regarding this information, as a means

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[39] *Ibid.,* 163 ss..

[40] MCGARITY-WAGNER, *Bending Science: How special interests corrupt Public Research,* Harvard University Press, 2012, 59 ss..

[41] Cf. LIETZAN, *A new framework for assessing clinical data transparency initiatives,* 18 Marq. Intell. Prop. L. Rev. 33, 2014, 5-6.

[42] For this perspective, PUGATCH, *Intellectual Property, data exclusivity, innovation and market access, ICTSD-UNCTAD Dialogue on Ensuring Policy Options for affordable Access to Essential Medicines Bellagio, 12-16 October 2004,* online available at http://www.iprsonline.org/unctadictsd/bellagio/docs/Pugatch_Bellagio3.pdf.

of shielding the competitive advantage deriving from long and costly investments[43].

As far as the legal framework is concerned, general provisions underlining the relevance of the public interests and rights at stake have to be confronted with specific measures to be found on the international level by intellectual property law in the forms of clinical trials data protection, and implemented in various countries through the so called data exclusivity regimes[44], providing guarantees of exclusivity to clinical testing data used to obtain marketing approval[45].
Recent transparency initiatives brought up both at international and (supra)national levels, are characterised by substantial legal weakness when confronted with the strong exceptions to the general rules of accessibility and with the related data protection regimes.

Two are the main legal viewpoints from which the issue of test data's secrecy must be looked at: the first is related to the question of whether under international trade agreements, states, and through them pharmaceutical companies, face a duty or a prohibition to disclose trial's information; the second, directly stemming from the first one, regards the *forms* and *degree* of protection that states in virtue of Free Trade Agreements and supranational provisions effectively grant to test data.
This last perspective opens up the door to the discussion about the possible legal qualification of such protection, and whether the so called data exclusivity regimes can be seen as a peculiar form of intellectual property (so called *sui generis* protection), as the provision under the TRIPS agreement would suggest[46]; as a mere form of commercial investment protection,

[43] *Ibid.,* 9-10.
[44] Cf. *infra* chapter 2.
[45] FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 445. See also FACKELMAN, *Clinical data, data exclusivity and private investment protection in Europe, supra,* 141 ss..
[46] BRAUN-PUGATCH, *The changing face of pharmaceutical industry and intellectual property rights,* in *The Journal of World Intellectual Property,* 8, 5, 2006*,* 599 ss..

more close to trade secrets[47]; or finally as a portion of drug authorisation law[48].

As this paper will assess, also privacy restraints are raised to support the path of secrecy.

The debate over the forms of control of this particular kind of data turns out to be of great practical importance from both a drug policy and competition standpoint, and from a fundamental rights protection perspective.

If data exclusivity protection is justified on the basis of the need to secure research-based company's investments and more in general the industry's innovation and productivity rate[49], the secrecy regime as it is currently shaped and interpreted, turns out to have unbearable social externalities, due to the technical and clinical value of the information hidden[50].

As regards to the first aspect, the granting of an exclusivity period over which the competent authorities cannot rely on the data submitted for application in order to grant other marketing authorisations, can have the undesirable effect of excessively delaying competitor's market entrance[51]: this non-reliance obligation is associated, in fact, with a non-disclosure duty, causing generic companies either to duplicate clinical trials, raising serious financial and ethical problems[52], or to wait until the exclusivity period

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[47] PUGATCH, *Intellectual Property, data exclusivity, innovation and market access, supra,* 6: "theoretically, the underlying logic of data exclusivity suggests that it is an expression of trade secrets (…)".

[48] FACKELMAN, *Clinical data, data exclusivity and private investment protection in Europe, supra,* 172 ss..

[49] PUGATCH, *Intellectual Property, data exclusivity, innovation and market access, supra,* 3.

[50] LIETZAN, *A new framework for assessing clinical data transparency initiatives, supra, passim.*

[51] ATTARAN-CARTAGENA, *A study of Pharmaceutical Data Exclusivity Laws in Latin America: is Access to affordable Medicines threatened?,* 2009, 17 Health Law Journal, 269 ss., online available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1620606.

[52] Cf. ANDANDA, *Managing intellectual property rights over clinical trial data to promote access and benefit sharing in public health, supra*, 153-154, mentioning concerns related to the compliance to paragraph 32 of the Declaration of Helsinki, according to which "the benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances: the use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patient who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option". World Medical Association Declaration of Helsinki- Ethical principles for Medical Research involving Human beings, current version 2013, online available at http://jama.jamanetwork.com/article.aspx?articleid=1760318.

expires in order to have access to the information needed to "imitate" the original product, with additional time delays[53].

If, as some intellectual property scholars have pointed out[54], intellectual property rights are not an end in themselves, for their being instruments for "preserving and enhancing the system of free enterprise and competition"[55], several doubts come up as to the pro-competitiveness of the data exclusivity provisions as such[56].

Getting to the second point, secrecy causes the amount and trustworthiness of the scientific information publicly available to be utterly compromised, in a manner that ends up threatening the accomplishment of consumers' right to information as well as patients' right to health [57].

If the non-reliance obligation on clinical trials data is economically justified because originators are shielded from the free-riding of competitors, the non-disclosure requirement [58] has to be better understood and legally justified in front of the overriding public interests of stimulating regular competition, and assuring individuals' health and safety.

Thus, the peculiarities of these data exclusivity regimes raise concerns that are slightly different from the ones related to the patent protection traditionally enjoyed by pharmaceutical products[59]: as some literature has underlined, the dispute over clinical trials data protection "seems to mark a shift from the conventional debates over patent protection and drug

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[53] *Ibid.,* 273.

[54] GHIDINI, *Intellectual Property and Competition Law. The innovation nexus, supra*, 2 ss..

[55] *Ibid.,* 12.

[56] ATTARAN-CARTAGENA, *A study of Pharmaceutical Data Exclusivity Laws in Latin America: is Access to affordable Medicines threatened?, supra,* 274. Sharing this perspective, FACKELMANN, *Clinical data, data exclusivity and private investment protection in Europe, supra,* 179 and ANDANDA, *Managing intellectual property rights over clinical trial data to promote access and benefit sharing in public health,* in *Journal for intellectual property and competition law,* 44, 2, 2013, 141 ss..

[57] This point is particularly stressed by LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra, passim.* See also LEMMENS, *Pharmaceutical knowledge governance: a human rights perspective, supra, passim* and LEMMENS- BOUCHARD, *Mandatory clinical trial registration: rebuilding public trust in medical research,* in *Global Forum Update on research for Health-Equitable access: research challenges for health in developing countries,* volume 4, London, Pro-Book Publishing, 2007*,* 43.

[58] See Global Intellectual Property Center- U.S. Chamber of Commerce, *Heading in a Different Direction?- The European Medicines Agency's Policy on the Public Release of Clinical Trials Data,* published on the 29th May 2014, online available at http://www.theglobalipcenter.com/wp-content/uploads/2014/05/EMA-Study-COMPLETE.pdf, 10-11.

[59] On this point CORREA, *Protecting Test data for Pharmaceutical and Agrochemical Products under Free Trade Agreements, supra,* 81-82.

prices", involving "political and economic interests", in addition to "safety issues that guarantee to make it one of the more interesting as well as heated subjects in the IPR field"[60].
Public and private interests collide here in the face of information disclosure or concealment.

This study aims to define a legal framework of the clinical trials data, by investigating the endurance of international and the European provisions of data secrecy in front of growing demands for disclosure.
Legal disclosure prohibitions will be read in light of competition and public health concerns.

In section one the technical dimension of clinical trials data will be assessed from a pre-market as well as from a post-market point of view, with regards to the two-sided regulatory and clinical nature of test data.
Firstly, their crucial importance in the R&D process and in the gaining of market approval will be justified.
Secondly their relevance as regards the drug's safety and efficacy will be examined, especially in respect of the problem of the inaccuracy of the data published after agency's approval: biased reporting practices and the enormous amount of information hidden by pharmaceutical companies emphasise the need of transparency.
In this light, current registration practices will be explored, with particular attention given to the relatively recent EMA controversy.

Shifting to a purely legal perspective, section two will provide an overview of the provisions constituting the legal basis for secrecy on the international and European level, with respect to trade secret protection; to pharmaceutical data protection under art. 39.3 of the TRIPS agreement and

[60] PUGATCH, *The intellectual property debate- Perspectives from Law, Economics and Political Economy, supra,* 126.

finally to the data exclusivity regime posed by art. 10 of the Directive 2001/83/EC.
Following these lines of reasoning, also privacy concerns emerge as a legal barrier to disclosure, given the vast amount of personal data embedded in the results of test data.

Abandoning the fields of intellectual property and privacy law, we will finally look at other areas of law, such as consumer and human rights law, in order to find, if not direct legal grounds for positive disclosure, at least some valid interpretational tools.
These tools are needed firstly for a better understanding of international obligations under the TRIPS agreement; secondly for envisaging the contrast of the data exclusivity regime as it is presently shaped, in respect of ordinary free market and competition goals; finally, for bridging the demand to access to clinical trials data and market-transparency necessities.

Chapter 1

Clinical trials data and current reporting practices

1. Nature of clinical trials data

1.1 Regulatory value of clinical trials data

Clinical trials data, also known as drug marketing approval data, document the safety and efficacy features of the drugs aiming to enter the market.
They are thus the crucial tool for gaining the marketing authorisation needed to distribute the new pharmaceutical product as a consumer good.
Within the EU, and specifically for high technology medicinal products[61], this authorisation is provided by the European Medicines Agency established as a Community institution by regulation (EC) 726/2004 of 31 March 2004, defining Community procedures for the authorisation and supervision of medicinal products for human and veterinary use[62].

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61 Cf. FACKELMAN, *Clinical data, data exclusivity and private investment protection in Europe, supra,* 149 ss.. As regards to drugs that do not fall in the category of high technology medicinal products, the alternative between a EU wide marketing authorisation in virtue of the decentralised procedure, also known as mutual recognition procedure, laid down by Directive 2001/83, and a national marketing authorisation procedure, is given. However it must be noted how it is no longer possible to file parallel applications in different Member States regarding the same pharmaceutical product. The purpose of this is the achievement of uniform marketing authorisation requirements throughout the European Union. See also LORENZ, *Das gemeinschaftliche Arzneimittelzulassungsrecht,* Baden-Baden, Nomos, 2006, 187 ss..

62 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency, 2004 OFFICIAL J. EUR. UNION L 136/1, L 136/22-23 (2004), online available at http://ec.europa.eu/health/files/eudralex/vol-1/reg_2004 726 cons/reg 2004 726_consen.pdf.

In accordance to this regulation the centralised procedure is compulsory, stimulating the building of a common market for pharmaceuticals[63], in compliance to art. 114 TFEU, and at the same time assuring a uniform degree of scientific evaluation of medicines in the European area[64].

This should result in patients and healthcare providers having a homogeneous level of confidence in the safety and efficacy of drugs marketed in all EU member states[65].

Authorisation is granted by the regulatory authority in accordance with the requirements defined by the Medicinal Product Directive 2001/83/EC, establishing in chapter 3 the "procedures relevant to the marketing authorisation"[66].

The same Directives also specifies the degree and the type of scientific and administrative information that the license application must include[67].

Moreover, observance must be given to the manufacturing and facility safety standards[68], expressed by the *good manufacture practices*, providing "quality assurance which ensures that product are consistently produced and controlled to the quality standards appropriate to their intended use"[69].

With specific regards to clinical trials, the standards needed to be accomplished have been recently reformed by the new Clinical Trials Regulation n. 536 entered into force on June 2014[70].

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[63] This issue is examined by LORENZ, *Das gemeinschaftliche Arzneimittelzulassungsrecht,* Baden-Baden, Nomos, 2006, 33 ss.. Cf. also FACKELMAN, *Clinical data, data exclusivity and private investment production in Europe, supra,* 152.

[64] SPALCKE, *Arzeneinmittelungsverfahren in der Europäischen Union und den Vereinigten Staaten von Amerika: Entwicklung und Harmonisierung,* Frankfurt am Main, Peter Lang, 2004, 112.

[65] FACKELMANN, *Clinical data, data exclusivity and private investment production in Europe, supra,* 152.

[66] Parliament and Council Directive 2001/83/EC of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use, online available at http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf.

[67] *Ibid.,* annex 1.

[68] FELLMETH, *Secrecy, Monopoly and Access to Pharmaceuticals, supra,* 445.

[69] Cf. European Medicines Agency, *Good manufacturing practice and good distribution practice compliance,* online available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000154.jsp.

[70] In virtue of the importance of clinical accuracy of trial-procedures and of the information deriving from it, in 2012 the Commission has published a proposal for a specific regulation on clinical trials on medicinal products, Cf. European Commission, *Medicinal Products for Human Use- Cinical Trials*, online available at http://ec.europa.eu/health/files/clinicaltrials/2012_07/proposal/2012_07_proposal_en.pdf, and European Commission, Proposal for a regulation of the European Parliament and of the council on

The need of a regulation has been perceived for a long time, due to the poor effectiveness[71] of the "improvements in the safety and ethical soundness of clinical trials"[72] declared by the former Clinical Trials directive 2001/20/EC[73].

The regulation provides identical rules for conducting clinical trials throughout the European Union. This uniformity assures, in return, an even ground for the regulatory agency in assessing applications[74].

Before the regulation becomes effective- no earlier than 26th May 2016[75]- all clinical trials conducted in the European Union have to be carried out in accordance to the mentioned Clinical Trials Directive, to the Good Clinical Practice Directive 2005/28/EC, and the Directive 2003/94/EC providing guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use[76].

However, as regards the good manufacture practices, the Commission calls upon the adoption of "a new delegated regulation (…) to set the GMP rules for Investigational Medicinal Products", that "will apply to all clinical trials authorised on the basis of the Clinical Trials Regulation"[77].

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clinical trials on medicinal products for human use and repealing Directive 2001/20/EC, online available at http://ec.europa.eu/health/files/clinicaltrials/2012_07/proposal/2012_07_proposal_en.pdf. The compromise text of the Clinical Trials Regulation ha resulted in Regulation EU 536/2014 of the European Parliament and of the council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC, online available at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536.

[71] "The clinical trials directive is arguably the most heavily criticised piece of legislation in the area of pharmaceuticals". European Commission, *Medicinal Products for Human Use- Cinical Trials, supra,* 2.

[72] *Ibid.*.

[73] Directive 2001/20/EC of the European Parliament and Commission, of 4 april 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, online available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF.

[74] Cf. European Commission, *Clinical Trials, General Information,* online available at http://ec.europa.eu/health/human-use/clinical-trials/information/index_en.htm#ct2.

[75] *Ibid.*.

[76] *Ibid.*.

[77] *Ibid.*.

1.2 Informational value of test data

In order to meet these requirements, and thus before qualifying for regular application, pharmaceutical companies have to undergo laborious and time-consuming test procedures[78], at the end of which a document[79] is laid down collecting all, or better said, *nearly* all, pre-clinical and clinical studies, together with relevant experts reviews[80].

Additional clinical data shall be given in case of extension of a marketing approval to other medical indications, or to other dosage forms of the same active substance[81]: in these cases test procedures must be repeated.

The final report serves as proof of the safety and efficacy of the new pharmaceutical product.

However, compliance with the formal standards, needed to get authorisation, is not itself provide a full proof of pharmaceuticals' effective safety.

Indeed, after the granting of market authorisation, publicly available information about the safety of the so approved medicines[82] is only a small top of the iceberg[83], due to widespread selective-reporting practices[84], or

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[78] Cf. FACKELMANN, *Clinical data, data exclusivity and private investment production in Europe, supra,* 144 ss., who explains how these test procedures usually are divided into three compulsory phases, that can be followed by a fourth one following the marketing authorisation. As far as the first three steps are concerned, the first one implies the testing of a new discovered active substance on humans for the first time; in the second one aims to test the effects in respect of the specific indications for which the tested drug would be prescribed, in order to provide "proof of efficacy, compatibility testing and risk assessment in case of longer treatment durations"; finally, the third phase aims to define the drug's (side-)effects using a great number of volunteers. Cf. also PUGATCH, *Intellectual property and pharmaceutical data exclusivity in the context of innovation and market access, supra,* 1.

[79] Cf. art 5 of Clinical Trials Regulation n.536/2014, *supra*: "in order to obtain authorisation, the sponsor shall submit an application dossier (…)". Cf. artt 25 ss. of the same Regulation.

[80] Cf. BANZI-BERTELE'-GARATTINI, *Drug data access: The new EMA policy,* in *Giornale italiano di Farmacoeconomia e Farmacoutilizzazione,* 2014, 6, 5 ss., 8.

[81] *Ibid.*.

[82] On the wider issue of the very little safety knowledge about drugs approved mainly for the marketing in developed countries cf. Report of the WHO Commission on Intellectual Property, Innovation and Public Health, *Public health, innovation and intellectual property rights,* Geneva, WHO Press, 2006, 154 ss..

[83] Cf. CHAN-HRÓBJARTSSON-HAAHR-GØTZSCHE-ALTMAN, *Empirical evidence for selective reporting of outcomes in randomised trials: comparison of protocols to published articles,* JAMA, 2004, 291, 2457 ss..

[84] Cf. DHIR, *Corporate selective reporting of clinical drug trial results as a violation of the right to health,* in RIOUX et al., *Critical Perspectives on Human Rights and Disability Law*, Leiden, Martinus Nijhoff Publishers, 2011, 341 ss..

the phenomenon of publication biases[85], through which the benefits of a certain product are amplified, and conversely the side effects minimised[86].

Thus, the information provided by scientific research through published articles turns out to be qualitative and quantitatively different from the data entrenched in the dossier handed to the regulatory authority[87].

Due to this kind of informational distortions, also the line between what can be considered scientific information, and latent advertisement appears to be blurred[88].

However, the problem of selective reporting may be also found at a pre-market stage, affecting the final report as well[89], given that the clinical testing is carried out by trial sponsors (mainly pharmaceutical companies) who have an interest in the marketing success of the product at stake.

This risk has not only been signalled by NGO's such as the Consumer Project on Technology[90], and by some scholars[91], but has also been

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85 GØTZSCHE-JORGENSEN, *Getting access to unpublished clinical trials at the European Medicines Agency,* BMJ, 2011, 342.

86 The issue is also discussed by REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: The case for a public goods approach,* 13 MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW 1 (2009).

87 LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 96. HILL, *Access to Information and Medicines Regulation in New Zeland,* 45 Victoria U. Wellington L. Rev. 549 2014, 554 ss..

88 On this point cf. JEFFERSON et al., *EMA's data sharing policy-Toward peeping tom based medicine?,* published on 22nd May 2014, online available at http://blogs.bmj.com/bmj/2014/05/22/tom-jefferson-et-al-emas-data-sharing-policy-towards-peeping-tom-based-medicine/. Cf. also LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in an environmental health, and safety law,* 2007, 78 University of Colorado Law Review, 465 ss., 520, stating that "the only type of information that firms generally want to distribute is advertisement or its equivalent, positive descriptions of their activities".

89 The "incentive to cheat" is very high also, and maybe above all, at a pre-market stage. Cf. GØTZSCHE, *Why we need easy access to all data from all clinical trials and how to accomplish it,* published online the 23rd November 2011, available at http://www.trialsjournal.com/content/pdf/1745-6215-12-249.pdf. FAEH, *Giving Information on Medicinal Products to the General Public- In Search of a Definition to Safeguard the Patient, supra*, 180, underlines the difficulty of establishing whether a message is of promotional nature or, as expressed in the Directive 2001/83/EC, "designed to promote": the Author cites the CJEU ruling *MSD Sharp & Dohme v. Merckle*, *supra,* where the Court has accepted a broad definition of advertisement, including "any form" of promotion "in light of the serious consequences for health which maya rise from improper use or overconsumption" of medicinal products. Par. 30-31- 32.

90 Cf. SANJUAN, *Us and Eu Protection of pharmaceutical Test data, Consumer Project on Technology,* (CPTech) discussion paper no. 1., Washington, D.C., published on 12th April 2006, online available at CPTech. www.cptech.org/publications/CPTechDPNo1TestData.pdf.

91 Cf. DHIR, *Corporate selective reporting of clinical drug trial results as a violation of the right to health, supra,* 349, underlining the "fact that corporations fail to disclose the totality of sudies conducted with respect to particular drugs- and the resulting risk implications, before a drug goes to market".

practically shown by two notorious cases[92], in which the concrete and devastating consequences of biased and unreliable reporting also in the application *dossier*, were at once clear.

The first case involved the pharmaceutical company GlaxoSmithKline (GSK) and the use of its antidepressant Paxil for the treatment of paediatric depressions.

Among the reasons of the prosecution carried out in 2004 by the Attorney General of New York, publications to promote off label prescriptions, selective reporting of positive trial data and hiding of negative data at a pre-market stage were to be found[93].

Another controversy regarded the pain relief medication Vioxx[94], which had caused a vast amount of myocardial infractions and cardiac deaths[95].

Also in this situation the lack of the reporting of complete test data, as well as the use of ghost-writing in scientific publications[96], turned out to be of calamitous relevance.

The withdrawal of the Vioxx medicine from the market[97] proves that if at the time of the filing for market authorisation, the FDA had had a more accurate report about clinical trials results, the drug would have been very unlikely to reach the market, avoiding significant money and life losses[98].

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[92] Cf. LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 69.

[93] See New York v. GlaxoSmithKline, N 04-CV-5304 MGC, 2004 WL 1932763 (S.D.N.Y. Aug. 26, 2004), commented by JUREIDINI-MCHENRY-MANSFIELD, *Clinical Trials and Drug promotion: Selective reporting of study,* 329, 20, *INT'L L RISK & SAFETY MED.* 73, 2008.

[94] Cf. LAW, *Big pharma- exposing the global healthcare agenda,* New York, Carroll & Graf Pub, 2006, 126; LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 69.

[95] It is has been proofed that the drug has caused more than 100.000 deaths due to infarctus or stroke. *Ibid.,* 95.

[96] The problem of ghost-writing in medical research, involving articles to be written by unkaknowledged authors, and through industry's financial support. Cf. ROSS et al., *Guest Authorship and Ghostwriting in publications related to Rofecoxib, A case study from industry documents from Rofecoxib Litigation,* JAMA, 2008, 299, 1800 ss..

[97] Cf. *FDA Public Health advisory*: *Safety of Vioxx,* published on the 30th september 2004, online available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106274.htm, announcing the "withdrawal of Vioxx from the US market due to safety concerns".

[98] This is expressed very well in the words of Dr. David Graham of the FDA in relation to hte Vioxx catastrophe: "(we) are faced with what may be the single greatest drug safety catastrophe in the history of this country or the history of the world. We are talking about a catastrophe that . . . should have been largely or completely avoided", as reported by CAHOY, *Medical Product Information Incentives and the Transparency Paradox,* 2007, 82, Indiana Law Journal, 50, 623. Cf. also HORTON, *Vioxx, the*

The two above mentioned cases have gained a particular notoriety for their serious public health implications, caused by the hiding of vital information about otherwise unknown side effects, leading in the first case to serious risks for children, in the second to hundreds of thousands of premature deaths[99].

Also within the European Union, voluntary failures to report safety data[100] have caused an impressive number of pharmaceuticals to be withdrawn from the market, with the retreatment of the marketing authorisation explained by safety reasons[101].

Scientific research has shown how the decision over a market withdrawal is mainly based on post-market information, such as case control studies carried out in order to identify new safety evidences and unexpected drug interactions[102].

This is related to the fact that some adverse drugs reactions emerge only after consumption by a larger population and with interactions with other drugs.

However, these adverse reporting studies constitute only the embryo of a pharmacovigilance system, that necessarily needs to be improved, if not newly implemented at all, as far as the methodologies and the object of the drug monitoring practices themselves are concerned.

In fact, with regards to the first issue, at present, pharmacovigilance studies are nearly entirely based on spontaneous research initiatives[103], raising the

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implosion of Merck and Aftershocks at the FDA, published online on 5th November 2004, available at http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(04)17523-5.pdf.

[99] LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 69. Many other cases have however been reported by literature. On the point see also GØTZSCHE-JORGENSEN, *Getting access to unpublished clinical trials at the European Medicines Agency, supra,* 18, recalling the cases concerning the anti-arthritis drug, rofecoxib, in respect of which the drug company Merck had missed to report cases of myocardial infractions and deaths, leading to the death of thousand patients, and the Pfizer's drug celecoxib, the publications on which resulted dramatically misleading compared to the trial protocols.

[100] For a list of controversial pharmaceutical product, see GØTZSCHE-JORGENSEN, *Getting access to unpublished clinical trials at the European Medicines Agency, supra, passim.*

[101] On the issue MCNAUGHTON-HUET-SHAKIR, *An investigation into drugs products withdrawn from the EU market between 2001 and 2011 for safety reasons and the evidence used to support the decision making,* in *BMJ Open,* 2014, online available at http://bmjopen.bmj.com/content/4/1/e004221.full.pdf+html. Between 2001 and 2011 ninteen drugs were withdrawn for pharmacovigilance reasons.

[102] *Ibid.,* 2.

[103] *Ibid.,* 4. Cf. also LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 67.

question of the completeness and efficiency of such an "independent" scrutiny.

Secondly, and most importantly, the speed and the consistency of those monitoring studies are substantially dimmed if no access to the genetic features of a drug- that is to say the scientific information embedded in trials data- is to be found[104].

In fact, as scientists have demonstrated, the chemical and biological peculiarities found in early clinical testing phases could be used to reliably predict adverse drug's reaction[105], being, as some studies show, a leading cause of death in hospitalised patients[106].

The above given scenario, raises two main legal issues.

On the one side there is the problem of assuring accuracy and completeness of test data handed to the regulatory agency[107], essential condition of every pre-market assessment.

Direct responses to this matter are provided by the new Clinical Trials Data regulation, enhancing safety standards by imposing uniform European criteria on the conducting of clinical trials and by requiring a certain level of detail of the test data resulting from the trials.

Also the approval of the invoked Good marketing Practice regulation, aimed at substituting the less stringent already existing directive, will be offering further relevant insights on this perspective.

This topic is therefore worthy of a future analysis, at a time when also this other new regulation will have come into force.

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[104] On this point GØTZSCHE-JORGENSEN, *Getting access to unpublished clinical trials at the European Medicines Agency, supra,* 5.

[105] LIU et al., *Large scale predicition of adverse drug reactions using chemicha, biological and phenotypic properties of drugs,* in *Journal of The American Medical Informatics Association,* 2012, 28. Cf. also DUKES, *Drug regulation and the tradition of secrecy,* in *International Journal of Risk & Safety in Medicine,* 9, 1996, 147. See also GØTZSCHE-JORGENSEN, *Getting access to unpublished clinical trials at the European Medicines Agency, supra,* 5, stating that "monitoring adverse effects reported by doctors to drug regulatory agencies would not have revealed that Vioxx causes heart attacks", and underlining how "less than 10% of such (adverse) events are ever reported (…)".

[106] LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 94.

[107] Cf. LIETZAN, *A new framework for assessing clinical data transparency initiatives, supra*, 19, underlining the need for a "requirement to report to the national regulatory authority the result of every trial relevant to safety and effectiveness of the drug (…)".

Strictly related to the former issue, but still sufficiently independent from it for an autonomous account, is the issue of the access to clinical trials as a fundamental tool for an effective pharmacovigilance system[108], able to prevent public health tragedies as the above listed ones.

However, the route toward this end goal is not that easy.

In fact, as some literature has noticed[109], the implementation of compulsory and publicly accessible reporting systems suggested by public health interests, could themselves embed the risk of decreasing information handed out to the regulatory agency for approval, due to the certainty that it will later enter the public domain. This phenomenon has been called the "information paradox"[110].

This risk could however be adequately shielded by the new Clinical trials Regulation through the definition of specific quality and quantity requirements that have to be observed by marketing approval data in order to become legally suitable for authority's evaluation.

Moreover, once the practical importance of access to clinical trials data is stated, the transparency demands raise complex legal issues, regarding the difficulty in defining the legal foundation for the duty to provide access to information about therapeutic products[111].

More structured information exchanges[112] about drugs' safety would increase the protection of the fundamental right to health[113] as defined by international human right treatises and in the European Convention on Human Rights, and provide compliance to the right to information seen as an essential condition for a more conscious consumer decision-making[114].

However, pharmaceutical companies have been shifting the discussion towards other fields of the law- namely the fields of intellectual property

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[108] Cf. European Commission-Public Health, *The Eu Pharmacovigilance system*, online available at http://ec.europa.eu/health/human-use/pharmacovigilance/index_en.htm.

[109] CAHOY, *Medical Product Information Incentives and the Transparency Paradox, supra*, 643.

[110] *Ibid.*.

[111] LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 67.

[112] Cf. ABBOTT, *Big data and pharmacovigilance, using health exchanges to revolutionise drug safety*, 2013, 99 Iowa L. Rev., 225.

[113] LEMMENS, *Pharmaceutical Knowledge Governance: A Human Rights perspective, supra, passim.*

[114] See *infra* Conclusions 1.1.

and of personal data protection- providing strong legal justifications to the policy of denying disclosure of trial registration.

In fact, the creation of publicly accessible clinical trials registry has been professed as contrary to normal business practices, given the great commercial value of the data set up through test procedures.

Before entering the highly controversial field of the forms of protection directly granted by international and European legislation to test data, it is first necessary to define the strategic significance of this kind of data from an economic point of view, and the degree of development of current reporting practices.

1.3 Economic value of clinical trials data

The selective reporting practices above mentioned are to be explained in light of economical rationales.

Test data is in fact a precious good for pharmaceutical companies, which spend vast sums of money on these trials.

Therefore, subjection to a sort of moral hazard, lying in the incentive to "paint the end results in the rosiest possible light"[115], is very likely to be found.

Test procedures are costly first of all from a time perspective, as they carry on for more than ten years[116], reaching in some cases the maximum length of twenty years[117].

Among the explanations for the increase in clinical studies' duration, there are also the more extensive normative requirements for the proof of drug safety and efficacy[118].

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[115] REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: The case for a public goods approach, supra,* 4.

[116] PUGATCH, *Intellectual property and pharmaceutical data exclusivity in the context of innovation and market access, supra,* 9, citing the study carried out by Di Masi, Hansen and Grabowski in 2003.

[117] FACKELMANN, *Clinical data, data exclusivity and private investment production in Europe, supra,* 148.

[118] Cf. *supra* par. 1

However, other factors[119] seem to play an important role, and in particular the more complex structure of medicinal products, the higher number of volunteers needed and the increasing number of so called orphan drugs for rare chronic diseases[120], which require longer study durations.

Length difficulties and scientific uncertainties account for these high costs[121], referring to the fact that only a very small part of the active substances that undergo clinical trials manages to reach the market stage[122].

This means that the costs of such failures must be recouped with those very few medicinal products that make it: in order to get the effective cost of the clinical trials of a certain drug, the costs of the vain tests must be also counted, easily reaching the one billion dollars[123].

From an economic standpoint, trials failures mean fruitless R&D expenditures, and the risk of losing market share to competitors[124].

Despite the lack of certain estimation of the effective costs of pharmaceutical R&D, it is evident that developing a new drug requires vast financial resources, causing test data to be a highly valuable commercial asset for research-based companies.

It is thus undeniable that the possession of trials data becomes a strategic tool in the competition game, being key to the exclusion or delay to generic companies' access to the market.

Indeed, as argued above, originators have to face long and costly test procedures carried out in order to produce the right amount of information required by normative approval-standards.

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119 FACKELMANN, *Clinical data, data exclusivity and private investment production in Europe, supra,* 149.

120 Cf. BAGLEY, *Patent term restoration and non-patent exclusivity in the US,* in DREXL-LEE, *Pharmaceutical Innovation Competition and Patent Law- A trilateral Perspective, supra,* 128 ss..

121 "It is important to note that the innnovator assumes the entire risk for the generation of the data". Cf. International Federation of Pharmaceutical Manufacturers and Associations, *Encouragement of new clinical drug development: the role of data exclusivity,* online available at http://www.ifpma.org/fileadmin/content/Publication/IFPMA_2011_Data_Exclusivity__En_Web.pdf, 5.

122 FACKELMANN, *Clinical data, data exclusivity and private investment production in Europe, supra,* 147, reporting that between 5000 and 10000 substances that are tested, only one obtains marketing authorisation.

123 REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: The case for a public goods approach, supra,* 4.

124 FACKELMAN, *Clinical data, data exclusivity and private investment production in Europe, supra,* 148.

The costs associated with trials constitute a substantial obstacle for generic companies that are financially too weak to reproduce this kind of tests[125].

In addition to the financial problems of test duplication, literature[126] has been stressing ethical concerns associated with repeating already existing trials[127].

Given the commercial value of the information collected through testing, research-based companies have been successfully lobbying for secrecy protection of this data[128], presented as the only way to prevent competitors' free riding.

Indeed, generic companies, once entered into possession of trials data, could easily file for marketing approval on the basis of the mere bioequivalence test[129], given the absence of any legal requirement to reproduce such data for obtaining market approval[130].

Economic inefficiencies, related to the decrease of incentives for innovators to conduct the necessary trials[131], and directly stemming from what some scholars have defined as "parasitism"[132], must not be underestimated.

The strategic importance of the data at stake, and the consequential rising pressure for specific legal protection for it, is also referable to

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125 SAN JUAN, *U.S and E.U Protection of Pharmaceutical Test Data*, CPTech Discussion Paper N. 1, published on 12th April 2006, online available at http://www.cptech.org/publications/CPTechDPNo1TestData.pdf.

126 Cf. CARVALHO, *The TRIPS regime of Patent Rights,* Wolters Kluwer, 2010, 605.

127Stressing this point also also European Generic Medicines Association, *Industrial Policy: making Europe a hub for manufacturing of generic and biosimilar medicines,* published on 11th January 2013, online available at http://www.apmgr.org/docs/EGA_INDUSTRIAL_POLICY_PAPER_11_Jan_2013_FINAL_01.pdf,8.

128 REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: The case for a public goods approach, supra,* 4.

129 FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 457.

130 COTTIER-MEITINGER-MEITINGER, *The protection of Test Data submitted to Governmental Authorities: The impact of the TRIPs Agreement on EC law,* in WERNER-STEIN, *Marketing Authorisation for Pharmaceutical Products and the Protection of Submitted Data,* Baden Baden, Nomos Verlagsgesellschaft, 2000, 53.

131 International Federation of Pharmaceutical Manufacturers and Associations, *Encouragement of new clinical drug development: the role of data exclusivity, supra,* 5.

132 CARVALHO, *The TRIPS regime of Patent Rights, supra,* 603. stating that "protection of test data is a social mechanism that shields originators against parasitism, which is not only socially reproachable but also leads to economic inefficiency".

the growing weakness of the patent system as a means to strengthening market control.

Other layers of protection are therefore sought, regarding something different from the newly invented product, but concerning information *about* the product itself, or better said, *about the properties* of the medicinal product[133].

This trend is to be justified by two lines of argument, one being the innovative productivity challenges the pharmaceutical industry has to face at present; the other directly related to the patent system's distortions, and more specifically to the numerous patent disputes between originators and generic based companies[134].

Indeed, granting patent protection for new products in the pharmaceutical environment is getting harder, due to the difficulty of coming up with products that can be considered really innovative[135] and thus patentable[136].

Hence the proliferation of the so-called me-too drugs[137], obtained through small changes of the molecular composition of already existing drugs, which companies seek to patent.

In second instance, in recent years many generic companies have undergone an economic enforcement[138] thanks to the development of successful strategic patent retaliation [139], and the connected phenomenon of authorised generics[140].

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133 *Ibid.,* 605.

134 PUGATCH, *Intellectual property and pharmaceutical data exclusivity in the context of innovation and market access, supra,* 9 ss..

135 *Ibid.,* 10, noticing that "during the late 1990s and early 2000s we experienced a decline in the number of new drugs approved for market use- from 53 new molecular entities during 1996 to a level of about 20 new molecular entities in 2000".

136 Also the statistics of the European Patent Office show a substantial decrease even in the number of pharmaceutical patent applications. Cf. European Patent Office, European Pharmaceutical Patent applications, online available at http://www.epo.org/about-us/annual-reports-statistics/annual-report/2014/statistics/patent-applications.html?tab=3.

137 Cf. BRAUN-PUGATCH, *The changing face of pharmaceutical industry and intellectual property rights, supra,* 606.

138 For an economic perspective, cf. LYBECKER, *The Economics of Access to Medicines: meeting the challenges of Pharmaceutical Patents, Innovation, and access for Global Health, supra,* 29 ss..

139 The advantages of adopting a patent sipute strategy is better understandable in light of the American provisions granting a 180 days market exclusivity period for generic companies challenging the validity of the original patent of a drug, in the course of submitting an abbreviated new drug application. Cf. Section 505 of the Federal Drug and Cosmetic Act grants. See PUGATCH,

Finally, the issue of the so-called patent-cliff[141] has to be acknowledged, related to the expiry of most of the best selling drugs[142].

It is undeniable how this peculiar economic environment[143] leads to an acknowledged growing ineffectiveness of the patents in securing a predictable and stable revenue stream for research based companies[144].

Indeed, pharmaceutical companies have argued how, compared to the long periods of trial and market approval, the twenty-years duration of patent protection result to be insufficient[145].

This leads in return to a shift of the focus of legal protection from final inventions towards other strategic assets relevant to the R&D race.

As shown above, test procedures are the greatest investment-consuming part in the course of a drug development[146]. The trials information collected is the direct result of this investment.

Given the informational nature of clinical trials, the tool that pharmaceutical companies have sought- especially in international trade agreements negotiations- in order to protect this investment *as such,* has been data's

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Intellectual property and pharmaceutical data exclusivity in the context of innovation and market access, supra, 11. It is interesting to notice that Europe doesn't have such a provision.

[140] The authorised generic strategy consists in the granting of a license given by the originator to the generic company in order to produce a generic substitute to the original drug. Cf. PUGATCH, *Intellectual property and pharmaceutical data exclusivity in the context of innovation and market access, supra,* 11.

[141] As Joseph Jimenez, CEO of Novartis has pointed out, "patent cliffs are one of the biggest issues facing our industry. To put this in perspective, IMS Health, a health care information provider, predicts that by 2016 patent expirations will have caused a loss of $106 billion in sales from branded drugs over the previous five years, with the heaviest burden in 2012 and 2013". JIMENEZ, *The CEO of Novartis on growing after a patent cliff,* published on December 2012 on Harward Business Review, online available at https://hbr.org/2012/12/the-ceo-of-novartis-on-growing-after-a-patent-cliff.

[142] LYBECKER, *The Economics of Access to Medicines: meeting the challenges of Pharmaceutical Patents, Innovation, and access for Global Health, supra,* 31.

[143] However, literature has been underlining also the opposite trend of the escalation of fruitful patent strategies, the ever growing exploitation of supplementary protection certificates, and the increase in innovative output being achieved by the biotechnology industry. See BRAUN-PUGATCH, *The changing face of pharmaceutical industry and intellectual property rights,* in *The Journal of World Intellectual Property, supra,* 606.

[144] *Ibid., passim.*

[145] COTTIER, *The protection of Test Data submitted to Governmental Authorities: The impact of the TRIPs Agreement on EC law, supra*, 55.

[146] According to the International Federation of Pharmaceutical Manufactorers and Associations (IFPMA), the costs involved in producing test data amounts to seventy per cent of the total cost of deveolping of a new drug. See International Federation of Pharmaceutical Manufacturers and Associations, *Encouragement of new clinical drug development: the role of data exclusivity, supra,* 6.

secrecy, perceived as imperative because of the commercial sensitiveness of the data itself[147].

Secrecy has therefore been presented as the best way for capturing competitive advantages stemming from the intangible asset at stake[148].

2. Current registration and reporting practices

Despite the unquestionable commercial value of test data, functioning as an economic basis for the demand of protection against parasitism and free-riding, it is the same economic standpoint that fuels the opposite need of clinical trials information transparency systems.

Indeed, as some scholars have pointed out, the tragic public health outcomes of selective reporting practices related to the hiding of already known side effects, result in detrimental financial consequences for pharmaceutical corporations themselves, due to the enormous loss of value that companies causing such scandals undergo[149].

Moreover, informational failures can lead to enormous waste of health care funds[150].

Approaching the legal wrinkles of the issue, the "overriding public (health) interest"[151] has been called upon, ever increasingly over the last years, both on the international and supranational level, in order to push states in the

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147 "Mandatory public disclosure of intellectual property, confidential commercial information, and proprietaty scientific methods found in clinical trials could stifle discovery, and open the possibility of competitors or unscrupulous actors using the information for their own products in other markets or countries. Without appropriate protection for intellectual property to incentivize the enormous investment risk involved, biopharmaceutical companies will be discouraged from investing in the next generation of new medicines, leading to patients and physicians being deprived of innovative therapies to tackle the serious and life threatening diseases of the 21st century." That is the position of president and chief executive officer, Pharmaceutical Research and Manufacturers of America (PhRMA), CASTELLANI, *Are clinical trials data sufficiently shared today? Yes,* published on 9 July 2013, online available at http://www.bmj.com/content/347/bmj.f1881.

148 Cf. CARVALHO, *The TRIPS regime of Patent Rights, supra,* 603.

149 As far as the Vioxx case is concerned, after Merck had to admit the hiding of relevant information, the company had to face a decrease of its value amounting about 30 billion dollars. DHIR, *Corporate selective reporting of clinical drug trial results as a violation of the right to health, supra,* 352.

150 Cf. Health Action International, *Protecting citizen's health: Transparency of clinical trial data on medicines in the Eu- Policy Paper,* published on October 2012, online available at http://haieurope.org/wp-content/uploads/2013/10/HAI_Protecting-citizenshealth-transparency-of-clinical-trial-data-on-medicines-in-the-EU.pdf.

151 Art. 39.3 TRIPS agreement, cf. *infra* chapter 2.

opposite direction of disclosure, through controlled sharing of the scientific test data[152].

If on one hand hiding the trials results is seen as a unique way to shield high research and development costs from competitors, on the other hand, the public and consumers demand information [153], in an increasingly commercialised research environment where obscuring practices seems to be corroding the integrity of the foundations of evidence based health care[154].

Especially after the two above-mentioned catastrophes, various relevant initiatives have been brought forward, in order to enhance access to information about the safety and effectiveness of drugs[155], and thus to advance the accountability of general scientific knowledge of approved pharmaceutical products[156].

From a strictly legal perspective, however, these actions appear to be vulnerable in the face of specific provisions of international trade agreements[157], continuously invoked by the International Federation of Pharmaceutical Manufacturers and Associations as a direct impediment to the promotion of access to clinical trials[158].

2.1 International and supranational evolutions

The first step towards an official consideration of the problem of accountability in medical research is to be found in the recitals of the

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[152] ANDANDA, *Managing intellectual property rights over clinical trial data to promote access and benefit sharing in public health,* in *Journal for intellectual property and competition law, supra,* 152 ss..

[153] Cf. COTTIER, *The protection of Test Data submitted to Governmental Authorities: The impact of the TRIPs Agreement on EC law, supra*, 53-54.

[154] On the issue cf. GOODYEAR-KRLEZA-LEMMENS*, The Declaration of Helsinki and the Ottawa Statement on Trial Registration,* publishe on 27th September 2007, online available at http://www.bmj.com/rapid-response/2011/11/01/declaration-helsinki-and-ottawa-statement-trial-registration.

[155] For example the costs of stockpiling a drug are to be considered, as LEMMENS, *Pharmaceutical knowledge governance: a human rights perspective, supra,* 165, recalls, commenting the Tamiflu case.

[156] Cf. LIETZAN, *A new framework for assessing clinical data transparency initiatives, supra*, 33.

[157] Cf. *infra,* chapter 2.

[158] International Federation of Pharmaceutical Manufacturers and Associations, *Encouragement of new clinical drug development: the role of data exclusivity, supra,* 6.

Statement on Health Research, written down on the occasion of the Global Forum and Ministerial Summit on Health research in Mexico, calling up the World Health Organization to establish "a platform linking a network of international clinical trials registers to ensure a single point of access and the unambiguous identification of trials"[159].

In direct response, in 2005, the World Health Organization implemented the International Clinical Trial Registration Platform (ICTP), as a result of the direct acknowledgment of the connection between the sharing of scientific test results and the fulfilment of the right to health.

The importance of the established system has to be recognized with regards to the formal layout, for having defined a standardisation for the registration of the trials themselves through the creation of a unique numbering mechanism, and as regards to the substantial profile, for fixing a minimal data set[160] required for registration.

The WHO platform however, is not a registry itself, but it defines a uniform system, providing a unique identifier for clinical trials submitted to primary registries to be implemented on a national level [161], such as the ClinicalTrials.gov[162] in the US and the European Clinical Trials Database[163] in the European area.

In 2008, during the Bamako Global Ministerial Forum for Health, governments were therefore encouraged to "develop, set, and enforce standards, regulations, and best practices for fair, accountable, and transparent research processes, including those related to . . . the registration

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[159] The Ministerial Summit on Health Research, Mexico City, Mexico, Nov. 16 -20, 2004, The Mexico Statement on Health Research, Knowledge for Better Health: Strengthening Health Systems 3, available at http://www.who.int/rpc/summit/agenda/en/mexico_statement_on_health_research.pdf; see also WORLD HEALTH ASSEMBLY, *Ministerial Summit on Health Research*, WORLD HEALTH ORG., available at http://apps.who.int/gb/ebwha/pdf_files/WHA58/WHA58_34-en.pdf. Cf. LEMMENS-TELFER, *Access to information and the right to health: The Human Rights Case for Clinical Trials Transparency, supra,* 70, and REVEIZ et al., *Do trialists endorse clinical trial registration? Survey on a Pubmed sample,* published on 23th October 2007, online available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2147029/#B2.

[160] This minimal data standard has been critised as inconsistent by some researchers, stressing the fact that the registration of various other important trials data was not included as a requirement for registration, LEMMENS-TELFER, *Access to information and the right to health: The Human Rights Case for Clinical Trials Transparency, supra,* 70.

[161] *Ibid.,* 72.

[162] Online available at https://clinicaltrials.gov/.

[163] Online available at https://eudract.ema.europa.eu/.

and results reporting of clinical trials and open and equitable access to research data"[164], thus putting another important brick in the wall of public transparency goals.

In line with the recent international trends, the Pan American Health Organization (PAHO) adopted in the same year of 2008 a new *PAHO policy on research for health*, stressing the need for clinical trials registration. As far as the American region is concerned, the PAHO policy had an important role in enhancing the information exchanges between more populated countries having already established national registry platforms belonging to the WHO Registry Network, and other smaller countries[165].

Responses to the WHO initiatives were brought forward also by the Ottawa Group[166], an international group of individuals and organizations from the international medical research community, publishing two documents, the Ottawa Statement on the Principles of Clinical Trial Registration[167] and the Ottawa Statement on the principles of its implementation[168], particularly underlining the ethical[169] and scientific rationales for international trial registration[170], and demanding a higher degree of detail of the trial protocols to be registered[171]- *i.e.* the inclusion of information of the full

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164 World Health Organization, *WHO's Role and Responsibilities in Health Research: Bamako Global Ministerial Forum on Research for Health*, published on 6th January 2009, online available at http://new.paho.org/hq/dmdocuments/2009/Bamako-Annex.pdf.

165 For example, the Brasilian trial registry has been used as a PAHO supported platform for the whole South America. Cf. LEMMENS-TELFER, *Access to information and the right to health: The Human Rights Case for Clinical Trials Transparency, supra,* 70-71.

166 REVEIZ et al., *Do trialists endorse clinical trial registration? Survey on a Pubmed sample, supra.*

167 *The Ottawa Statement Part One, Principles for international regstration of protocol information and results from human trials of health related interventions*, online available at http://ottawagroup.ohri.ca/statement.html.

168 *The Ottawa Statement Part two, Principles of operationalisation for international trial registration*, online available at http://ottawagroup.ohri.ca/statement2.html.

169 Cf. *The Ottawa Statement Part one*, *supra,* "above all, international trial registration is necessary to fulfill ethical obligations to research participants. When members of the public agree to participate in trials, it is on the understanding that they are contributing to the global body of health-related knowledge. It is thus unethical to conduct human research without ensuring that valid descriptions of the study and its findings are publicly available".

170 "Public access to trial protocol information and results will help to minimise known risks and potential harm arising from unnecessary exposure to previously tested interventions; accellerate research by making knowledge available about prior experiences with interventions; identify and deter unnecessary duplication of research and publication; identify and deter selective reporting of research (reporting biases); provide a means of comparing the original protocol upon which ethics approval was based with the study as it eas carried out; enhance collaboration among researchers by informing them of ongoing trials". *Ibid.*.

171 For a critical view of the issue see KREZLA-JERIC et al., *Principles for international registration of protocol information and results from human trials of health related interventions: the Ottawa Statement (part. 1),*

protocol, consent forms, details of ethics committee approval and other trial design information[172]-, as well as the institution of mandatory and legally enforceable mechanisms of trial reporting[173].

Furthermore, registers such as ClinicalTrials.gov and Controlled Clinical trials-ISRCTN established at the beginning of year 2000, saw a particular increase in the registered trials, after the International Committee of Medical Journal Editors introduced in 2005 the requirement for registration as a condition for publishing in the most leading medical journals[174].

However, the most important recognition of the principles of prospective public disclosure of research information and results through trial registration is to be found in the 2008 World Medical Association's Declaration of Helsinki on Ethical Principles for Research Involving Human Subjects[175], stating for the first time that "*every clinical trial* must be registered in a publicly accessible database"[176]- thus overcoming the debate over the scope of trial registration[177]- and that "researchers 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".

Furthermore, the Declaration advocates that "negative as well as positive results must be published or otherwise made publicly available", that "sources of funding, institutional affiliation and conflict of interest must be declared in the publication"[178], concluding with the general final statement

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published on 23rd April 2005, online available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC556346/.

[172] See LEMMENS-BOUCHARD, *Mandatory clinical trial registration: rebuilding public trust in medical research, supra,* 43.

[173] KREZLA-JERIC et al., *Principles for international registration of protocol information and results from human trials of health related interventions: the Ottawa Statement (part. 1), supra.* Cf. also LEMMENS-BOUCHARD, *Mandatory clinical trial registration: rebuilding public trust in medical research, supra,* 40.

[174] DE ANGELIS et al., *Clinical trial registration: a statement from the International Committee of Medical Journal Editors*, N Engl J Med.2004, 351 ss.. Cf. REVEIZ et al., *Do trialists endorse clinical trial registration? Survey on a Pubmed sample, supra,* and LEMMENS-BOUCHARD, *Mandatory clinical trial registration: rebuilding public trust in medical research, supra,* 40.

[175] World Medical Association Declaration of Helsinki- *Ethical Principles for Medical Research Involving Human Subjects*, *supra.* Cf. LEMMENS-TELFER, *Access to information and the right to health: The Human Rights Case for Clinical Trials Transparency, supra,* 71.

[176] World Medical Association Declaration of Helsinki- Ethical Principles for Medical Research Involving Human Subjects, *supra.*

[177] Cf. KREZLA-JERIC et al., *Principles for international registration of protocol information and results from human trials of health related interventions: the Ottawa Statement (part. 1), supra.*

[178] World Medical Association Declaration of Helsinki- Ethical Principles for Medical Research Involving Human Subjects, *supra.*

that "in all cases, new information should be recorded and, were appropriate, made publicly available"[179].

From a technical standpoint, the progressive nature of the declaration of Helsinki lies in the requirement of the completeness of the trials registration and in the fact that the registration of the trial results is mentioned.

This is to be considered the direct transposition of the call of many influential organizations, such as the US Institute of Medicine, and again the International Committee of Medical Journal Editors, asking for the direct access for the final outcomes[180].

The WHO itself has recognized the problem, and established a Study Group on the Reporting of Findings of Clinical Trials, which is looking at the development of criteria and standards of results disclosure. The Study Group has released at the end of 2014 a Draft of a WHO Statement on Public Disclosure of Clinical Trials Results[181], stating that "clinical trials results are to be reported within 30 days of the study completion date", by submitting them for "publication in a peer reviewed journal" through "open access mechanisms", and "in addition" by making these results publicly available on the result section of the primary clinical trial registry"[182].

However, as literature has been stressing[183], the requirement of the completeness of registration, recently settled as regards to the existing European Database[184], won't achieve any effectiveness until reporting practices become mandatory *as such* in pursuance of specific provisions[185].

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[179] *Ibid.*.

[180] Cf. DE ANGELIS et al., *Clinical trial registration: a statement from the International Committee of Medical Journal Editors*, 351.

[181] World Health Organisation, *Statement on Public Disclosure of Clinical Trials Results- Draft*, online available at http://www.who.int/ictrp/results/Draft_WHO_Statement_results_reporting_clinical_trials.pdf?ua=1.

[182] *Ibid.*.

[183] LEMMENS-BOUCHARD, *Mandatory clinical trial registration: rebuilding public trust in medical research, supra,* 43, and also LEMMENS-TELFER, *Access to information and the right to health: The Human Rights Case for Clinical Trials Transparency, supra,* 73.

[184] European Medicines Agency, *Posting of clinical trial summary results in European Clinical Trials Database (EudraCT) to become mandatory for sponsors as of 21 July 2014,* online available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/06/news_detail_002127.jsp&mid=WC0b01ac058004d5c1. As far as the US is concerned, in 2007 the FDA Amendments Act introduced for the first time the requirement to register also the summary results of the already registered trials. Cf. *Current and Ongoing Transparency Activities in the Pharmaceutical Industry, Brief of the Multi-Regional Clinical Trials Center at Harvard University to the Standing Senate Committee on Social*

On the other hand, as will be further examined, current national regimes have until recent times lacked of trial data transparency provisions, thereby affecting the health standard collectively and individually enjoyed[186].

Indeed, research and trial registration practices have mainly remained outside the scope of legal rules, mostly being object of the soft regulation of non-binding research ethics guidelines and clinical practice standards[187].

Registration practices have been mostly the product of scientific and ethical responsibility, instead of resulting from mandatory provisions and enforcement mechanisms[188].

The few legislative undertakings aimed at shifting towards this latter form of regulation, have generally resulted in nothing more than window-dressing, due to the ineffective nature of the norms deriving from them.

In 1997, for instance, the Food and Drug Administration Modernisation Act required all trials for serious and life-threatening diseases to be registered in the ClinicalTrial.gov platform[189].

However, the lack of definition of the scope of the notion of "serious disease", and the reliance on the FDA to negotiate registration requirements with the pharmaceutical stakeholders, nullified the apparent good intentions of the American legislator[190].

As the FDA's Status Report on implementation acknowledged, the absence of enforcement tools and the consequent dependence on pharmaceutical

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Affairs, Science and Technology, published on 1st October 2014, online available at http://mrct.globalhealth.harvard.edu/files/mrct/files/2014_10_1_harvard_mrct_brief_of_mrct_on_bill_c-17.pdf.

It has to be noticed however, how the mandatory result submission requirement is to be refferred only to the trials that are voluntarily registered by the sponsor. One thing is the mandatory requirements of trials registration practices that are still based on the free will of the sponsor, other being the mandatory nature of reporting practices as such. Cf. *infra* in the same parapgraph.

185 LEMMENS-BOUCHARD, *Comments on the Legal, Regulatory and Ethical Aspects of the WHO Clinical Trial Registry Platform- submitted as part of the Formal Consultation on Disclosure Timing Policy,* online available at http://www.who.int/ictrp/011_Lemmens_Bouchard_5April06.pdf., 1-2.

186 *Ibid.*.

187 LEMMENS-TELFER, *Access to information and the right to health: The Human Rights Case for Clinical Trials Transparency, supra,* 73.

188 Cf. World Trade Organization, World Intellectual Property Organization and World Health Organization, *Promoting access to medical technologies and innovation, Intersections between public health, intellectual property and trade,* London, Book now Ltd., 2012, 113-114.

189 On the issue cf. *Current and Ongoing Transparency Activities in the Pharmaceutical Industry*, *supra*, 2.

190 LEMMENS-TELFER, *Access to information and the right to health: The Human Rights Case for Clinical Trials Transparency, supra,* 73.

industry's participation, caused only thirty-five per cent of industry sponsored trials to be effectively registered[191].

Despite this first unsuccessful legislative attempt regarding the issue of clinical trials transparency, in 2007 the US came to a second, more effective, solution to the problem, by imposing the duty to register in the ClinicalTrials.gov, all trials, and most importantly the final results, of medical devices and pharmaceutical products filed for drug regulatory approval[192].

However, the turning point is not to be found in the statement of such a duty, but rather in the definition of clear severe financial penalties for non-compliance, together with the posting of official notices of non-compliance in the same database[193].

2.2 The European case- from the prior reporting systems to regulation EC n. 536/2014

The European Union's heading towards a paradigm of compulsory and complete trial registration system has been slower and more complicated.

As far as the European normative framework is concerned, the legal basis for transparency is to be found in art. 15 of the Treaty on the Functioning of the European Union (TFUE), stating that "any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, shall have a right of access to documents of the Union's institutions, bodies, offices and *agencies*[194](…)".

This right to information is further developed by Regulation EC n. 1049/2001 on public access to European Parliament, Council and

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[191] Food and Drug Administration, *Guidance for Industry- Report on the status of Postmarketing Study Committments- Implementation of Section 130 of The Food and Drug Administration Modernization Act of 1997*, published in February 2006, online available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080569.pdf; cf. also *Current and Ongoing Transparency Activities in the Pharmaceutical Industry, supra*, 3.

[192] Cf. Food and Drug Amendment Act 2007 §303-Reporting Requirements.

[193] LEMMENS-TELFER, *Access to information and the right to health: The Human Rights Case for Clinical Trials Transparency, supra,* 74-75.

[194] Emphasis added.

Commission documents, whose purpose, in accordance to recital 4, is to "give the fullest possible effect to the right of public access to documents"[195], and more specifically also by art. 80 of Regulation EC n. 726/2004[196] ensuring "the availability to the public of regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products *which is not of a confidential nature*[197]".

The two already existing reporting platforms do not provide at present a satisfactory fulfilment of the cited provisions.

In fact, as some scholars have also been underlining[198], the Eu Clinical Trials Database (Eudra-Ct) established in accordance of art. 11 of the Clinical Trials Directive 2001/20/EC[199], is intended to be a confidential database, accessible only by competent national authorities[200], and controlled by the European Medicines Agency.

According to art. 57 of Regulation EC n. 726/2004[201] and art. 41 of Paediatric Regulation EC n. 1901/2006[202], the European Medicines Agency

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[195] According to recital 8 of Regulation 1049/2001, "all agencies established by the institutions should apply the principles laid down in this regulation".

[196] Regulation EC of the European Parliament and of the European Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, online available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:en:PDF.

[197] *Ibid.,* art. 80. Emphasis added.

[198] LEMMENS-TELFER, *Access to information and the right to health: The Human Rights Case for Clinical Trials Transparency, supra,* 74-75.

[199] Directive 2001/20/EC of the European Parliament and Commission, of 4 april 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, *supra.*

[200] Cf. European Medicines Agency, *Eu Clinical Trials Register- Questions and answers relating to practical and technical aspects of the EU Clinical Trials Register,* published on the 7th March 2014, online available at https://www.clinicaltrialsregister.eu/doc/EU_CTR_FAQ.pdf.

[201] Art. 57 of Regulation EC n. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community Procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, "The Agency shall provide the Member States and the institutions of the Community with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use which is referred to it in accordance with the provisions of Community legislation relating to medicinal products. To this end, the Agency, acting particularly through its committees, shall undertake the following tasks (…) (l) creating a database on medicinal products, to be accessible to the general public, and ensuring that it is updated, and managed independently of pharmaceutical companies; the database shall facilitate the search for information already authorised for package leaflets; it shall include a section on medicinal products authorised for the treatment of children; the information provided to the public shall be worded in an appropriate and comprehensible manner. (…)The database provided for in paragraph 1(l) shall include the summaries of product characteristics, the patient or user package leaflet and the information shown on the labelling. The database shall be developed in stages, priority being given to medicinal products authorised under this Regulation and those authorised under Chapter 4 of Title

has to provide the public with *appropriate*[203] information stored in the EudraCt database.

With considerable delay, in 2011 the European Commission established the European Clinical Trials register[204] providing information[205] about any clinical trial of medicinal products with at least one site within the European Union, in compliance to the recommendation of the European Commission[206], and about any paediatric clinical trial with investigator sites within or outside the European Union[207].

This registry is thus innately incomplete, and therefore of little scientific value[208], given that full test data reporting is assured only as regards the paediatric trials[209]: outside the paediatric field, only trials conducted in the area of the European Union are to be recorded, notwithstanding the fact

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III of Directive 2001/83/EC and of Directive 2001/82/EC respectively. The database shall subsequently be extended to include any medicinal product placed on the market within the Community".

[202] Art. 41 of Regulation EC n. 1901/2006 of the European Parliament and the Council of 12 December 2006 on medicinal products for paediatric use, "(…)by way of derogation from the provisions of Article 11 of Directive 2001/20/EC, the Agency shall make public part of the information on paediatric clinical trials entered in the European database. 27.12.2006 EN Official Journal of the European Union L 378/13 2. Details of the results of all the trials referred to in paragraph 1 and of any other trials submitted to competent authorities in compliance with Articles 45 and 46 shall be made public by the Agency, whether or not the trial was terminated prematurely (…)".

[203] According to art. 57 Regulation EC n. 726/2004, *supra*, it is EMA's task to ensure "the dissemination of information on adverse reactions to medicinal products authorised in the Community, by means of a database permanently accessible to all Member States; health-care professionals, marketing authorisation holders *and the public shall have appropriate levels of access to these databases, with personal data protection being guaranteed*".

[204] Cf. *Pharmaceuticals: Today the EU register of Clinical Trials is launched,* published on the 22nd March 2011, online available at http://ec.europa.eu/health/files/clinicaltrials/ip-11-339_en.pdf.

[205] See European Commission, *Lists of fields contained in the EudraCt Clinical Trials database to made public, in accordance with art. 57(2) of Regulation EC n. 726/2004, and its implementing guideline 2008/C168/02,* published on the 4th February 2009, online available at http://ec.europa.eu/health/files/eudralex/vol-10/2009_02_04_guideline_en.pdf. Cf. also European Medicines Agency, *Eu Clinical Trials Register- Questions and answers relating to practical and technical aspects of the EU Clinical Trials Register, supra,* 2.

[206] European Commission, *Communication from the Commission regarding the guideline on the data fields contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC to be included in the database on medicinal products provided for in Article 57 of Regulation (EC) No 726/2004,* in *Official Journal of the European Union,* 2008, C 168/3, online available at http://ec.europa.eu/health/files/eudralex/vol-10/2008_07/c_16820080703en00030004_en.pdf.

[207] More specifically, the register includes clinical trials contained in the so called Paediatric Investigation Plan, that is the research and development program that aims to generate the data required to authorise a medicinal product for use in children. See *Pharmaceuticals: Today the EU register of Clinical Trials is launched, supra,* 1.

[208] Stressing this point GØTZSCHE-JORGENSEN, *Getting access to unpublished clinical trials at the European Medicines Agency, supra, passim* and LEMMENS-TELFER, *Access to information and the right to health: The Human Rights Case for Clinical Trials Transparency, supra,* 74-75.

[209] Cf. GØTZSCHE-JORGENSEN, *Getting access to unpublished clinical trials at the European Medicines Agency, supra,* 8.

that most of the trials relevant for the granting of marketing authorization are conducted outside the European Union[210].

In the realm of European clinical data reporting platforms, it is worth to mention also the Eudravigilance system, which is however not a real clinical trials database, but rather a collection of the European Medicines Agency's reports on drug's safety and effectiveness, used by the Committee for Medicinal Products for human use, and the Pharmacovigilance Risks Assessment Committee as evidence to invoke regulatory actions[211].

Only in 2014, with the approval of the new regulation n. 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use[212], establishing a publicly accessible European database of "all trials conducted in the Union"[213], a step forward has been made in ensuring a "sufficient level of transparency in clinical trials"[214].

In fact, in accordance to the general confinement of the regulation to trials situated within the Union[215], the regulation defines a specific duty of the trial sponsor to "submit to the EU database a summary of the results of the clinical trials" "within one year from the end of a clinical trial in all Member States concerned"[216], irrespectively of the outcome of the trial itself.

A broader perspective is nonetheless adopted as regards the case "a clinical trial *was intended to be used for a marketing authorisation for the investigational medicinal product*"[217], in respect of which a specific provision binds the applicant to "submit to the EU database the clinical study report within 30

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[210] See European Medicines Agency, *Clinical Trials submitted in marketing-authorisation applications to the European Medicines Agency- Overview of patient recruitment and the geographical location of investigator sites-containing data from 2005 to 2011,* published on 11th December 2013, online available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500016819.pdf, underlining the trend of increasing number of patients being recruited outside of Europe for pivotal clinical studies.

[211] See European Medicines Agency, *EudraVigilance*, online available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000239.jsp.

[212] Regulation EU 536/2014 of the European Parliament and of the council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC, *cit.*.

[213] Art. 2 Regulation n. 536/2014, *supra.*

[214] *Ibid.*.Cf. recital 67.

[215] This is to be derived from the joint provisions of art. 1 of the Regulation, restricting the Scope of it to "all clinical trials conducted in the Union", and art. 81 (1), stating that "the EU database shall contain the data and information submitted in accordance with this regulation". *Ibid.*.

[216] *Ibid.*. Art. 37.

[217] *Ibid.*. Emphasis added.

days after the day the marketing authorisation has been granted, the procedure for granting the marketing authorisation has been completed, or the applicant for marketing authorisation has withdrawn the application"[218].

This clinical study report shall contain a summary of all the trials conducted in order to get marketing approval for a specific pharmaceutical product, thus also the ones carried out outside the European Union, in respect to whom the European Commission has stated the need to assure compliance "with regulatory requirements at least equivalent to those in the EU, including rules on transparency"[219].

The clinical study report is thus to be considered of crucial importance given its fundamental regulatory value- in fact it entails the information assessed by the competent agency in order to release the marketing authorisation-, and high scientific and informational value, due to the fact that it furnishes a complete overview of the trials relevant for a specific pharmaceutical product.

It can be thus argued that the revolutionary impact of the new European transparency provisions lies exactly in the mandatory requirement of clinical study report's publicity.

However, the effective degree of the informational transparency enhancement provided by the new mandatory reporting system stated in the regulation has to be defined in light of the exemptions under art. 81(4), stating that "the Eu database shall be publicly accessible, *unless*, for all or part of the data and information contained therein, confidentiality is justified on any of the following grounds: a) *protecting personal data in accordance with Regulation EC n.45/2001; b) protecting commercially confidential information, in particular through taking into account the status of the marketing authorisation for the medicinal product, unless there is an overriding public interest in disclosure* (…)"[220].

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[218] *Ibid.*.

[219] European Commission, *New rules for clinical trials conducted in the EU,* published on the 2nd April 2014, online available at http://europa.eu/rapid/press-release_MEMO-14-254_en.htm.

[220] Emphasis added.

The regulation seems thus having perfectly embedded the conflict between the two opposite interests involved- the public and the private one.

However it is specifically in respect of clinical study reports, that the regulation provides a fundamental interpretational benchmark for the assessment of the balance to be addressed.

Indeed, recital 68 of the regulation states that "for the purposes of this regulation in general the data included in a clinical study report *should not be considered commercially confidential* once a marketing authorisation has been granted, the procedure for granting the marketing authorisation has been completed, the application for marketing authorisation has been withdrawn"[221], with that excluding the appliance of the above mentioned exemption at all.

More generally, as far as the clinical trials are concerned, the same recital provides that "the main characteristics of a clinical trial", that is to say most of the information entailed in it, "(…) should not be considered confidential", thus leaving in that case a bigger room for what turns out to be a very delicate matter of interpretation.

In fact pharmaceutical companies have been calling upon privacy restrictions and the protection of commercially confidential information under the current international and European data exclusivity regime[222], as legally founded obstacles for disclosure.

Three as thus the legal issues at stake.

First, as far as the protection of commercial information is concerned, one must define *what* part of clinical trials information has to be considered commercially confidential, and thus protected under specific international and supranational norms.

Second, once the layers of protection are identified, it must be stated whether they entail a specific ban to disclose these kind of information.

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[221] Emphasis added.

[222] See *infra* chapter 2.

Third, as regards to the privacy implications, it is necessary to define the scope of the data protection regime in respect of the release of clinical trials data containing personal information of trials volunteers, by verifying if any of the exemptions provided by the current privacy framework could apply.
The last two issues will be addressed in the next chapter.

As regards to the first matter, the new European Medicines Agency policy on publication of clinical data[223], released on the 2nd of October 2014, provides another important tool for the interpretation of the exception contained in art. 81 (4) of the Clinical Trials Regulation[224].
In fact, although the Agency acknowledges the competing interest of protecting patient's personal data and commercially confidential information (CCI), it expressly states that "in general, however, clinical data cannot be considered CCI", being there only "limited circumstances where (this kind of) information could constitute CCI"[225].
Hence the Agency's approach to the question seems to follow the path of a narrow interpretation of the notion of commercially confidential information in respect of the information entailed in clinical trials data, already affirmed in recital 68 of the new regulation.
This becomes even more important if one considers that art. 81 of the same regulation appoints the European Medicines Agency as the direct controller of the database to be established[226].
However, as it will be shown, this public friendly route may be destined to confinement on the field of theoretical declarations.
In fact, although these statements contribute to further circumscribe the question at stake, they do not however give direct answers to the problem

[223] European Medicines Agency, *European Medicines Agency policy on publication of clinical data for medicinal products for human use,* released on the 2nd October 2014, online available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf.
[224] Regulation EU 536/2014 of the European Parliament and of the council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC, *cit.*.
[225] *Ibid.,* 4.
[226] Cf. art. 81: "(…) The Agency shall be considered to be the controller of the EU database, and shall be responsible for avoiding unnecessary duplication between the EU database and the EudraCT and Eudravigilance databases".

of what exactly constitutes commercial confidential information in a clinical study report.

The issue has been generally discussed by the Agency in a few draft papers[227], and in the latest Policy Document, where a definition of commercially confidential information is given, as regards "any information contained in the clinical study reports submitted to the Agency by the applicant that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant"[228].

Annex 3 of the same policy document more specifically identifies some categories of information that may be considered of commercially confidential interest, including details about the product itself and about the "product development rationale"[229].

However, under these categories, also "benefits and risks conclusions" and "efficacy and safety variables", regarded as commercially sensitive in light of a possible "unfair commercial use"[230] by competitors, and also "novel statistical or other analytical methods and exploratory endpoint results about potential new uses of a medicine that are not the subject of the marketing authorisation application[231]" can qualify as commercial confidential information[232].

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[227] Cf. for exaple, European Medicines Agency- Heads of Medicines Agencies (HMA), *HMA/EMA Guidance document on the identification of commercially confidential information and personal data within the structure of the marketing authorisation application-Release of information after the granting of marketing authorisation,* released in 2010, online available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/06/WC500106995.pdf and Heads of Medicines Agencies and European Medicines Agency, *The identification of commercially confidential information and personal data within the structure of the marketing authorisation (MA) application-Release of information after the granting of a marketing authorisation,* Guidance Document 2012, online available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500124536.pdf.

[228] European Medicines Agency, *European Medicines Agency policy on publication of clinical data for medicinal products for human use, supra,* 3.

[229] *Ibid.,* 17.

[230] Cf. art. 39.3 of the TRIPS Agreement, which will be discussed in the next chapter.

[231] Cf. European Medicines Agency, *Redaction Principles- Draft,* published on the 5th May 2014, online available at http://www.ombudsman.europa.eu/resources/otherdocument.faces/it/54535/html.bookmark.

[232] See LEMMENS, *EMA's proposed Data release Policy: promoting transparency or expanding Pharma control over data?,* published on 30th May 2014, online available at http://blogs.plos.org/speakingofmedicine/2014/05/30/emas-new-data-release-policy-promoting-transparency-expanding-pharma-control-data/.

Particular attention must be given to this last reference to "results about potential new uses of a medicine", implying also clinical trials data related to off-label use of a drug.

Off-label uses[233] are the second major cause -together with the above discussed biased reporting practices- of threats to patients' health, directly arising from the deficiency of knowledge about pharmaceutical products[234].

That means in return, that important information about safety and effectiveness of pharmaceuticals product may still be withheld, as a consequence of the interpretational enlargement of the exemption to the general transparency rule stated in art. 81.4 of the Clinical Trials Regulation[235].

Hence, the general transparency rule risks to be overridden by its own exemptions.

Ultimately, the scope of the information available is the result of the European Medicines Agency's discretion in evaluating the balance between the protection of the commercial confidentiality of sponsor's data and the "need to inform the public in the interests of public health and transparency"[236], the outcome of this balance depending solely on the definition of what portion of clinical data has to be qualified under the mentioned categories of exemptions[237].

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233 On the issue of drug's off label use see ARNAUDO, *The strange case of Dr. Lucentis and Mr. Avastin. The Italian Competition Authority fines Roche and Novartis for collusion,* in *European Competition Law Review,* 35, 7, 2014, 347 ss..

234 It is relevant noticing that also the European Legislator has correctly evaluated the role of clinical trials regarding uses of drug's that are not in accordance with the marketing authorisation, by qualifying these trials as "low-intervention clinical trials" that should, according to recital n. 11, "be subject to the same application procedure as any other clinical trial", thus implying also the transparency duties that sponsor have to fulfil. Art. 81 about the European database does however not expressly mention the reporting requirement regarding these low-intervention clinical trials, thus leaving room for interpretation.

235 Regulation EU 536/2014 of the European Parliament and of the council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC, *cit.*.

236 European Commission, *Communication from the Commission regarding the guideline on the data fields contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC to be included in the database on medicinal products provided for in Article 57 of Regulation (EC) No 726/2004, supra,* under §3 *Scope*.

237 This has been underlined by the same Agency, declaring how "the EMA is responsible for ruling on any redactions of documents to be published", and for these purposes a careful assessment is to be made as regards "the specific request", and "in accordance with existing laws and internal implementing rules". European Medicines Agency, *EMA responds to European Ombudsman,* published

2.2.1. The European Medicines Agency's new policy on access to clinical data- only theoretical declarations?

The European Medicines Agency's policy of access to clinical study reports is a separate initiative in respect of the establishment of the European database announced by the examined regulation[238].

By defining the objectives of its policy, the European Medicines Agency underlines the need for "public scrutiny" and "application of new knowledge in future research" in order to establish a "level playing field that allows all medicine developers to learn from past successes and failures", and to "enable the wider scientific community to make use of detailed clinical data to develop new knowledge in the interest of public health"[239].

However, the practical implications of these statements rather seem to head in the opposite direction of obscurantism if one examines the severe terms of use governing the access to and use of clinical trials reports submitted to the Agency by marketing applicants and rendered publicly accessible in accordance to the new policy.

The same terms of use in fact appear to insist on the concept of commercially confidential information as a ground for substantially restricting access to test data, by the possible "redaction", *i.e.* manipulation, prior to publication of the clinical study report [240], "when needed to protect those specific elements which qualify as CCI that should not be released"[241].

The scope of this redaction again depends on the definition of what is to be considered of commercial confidentiality interest, thus leaving room for

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on the 11th November 2014, online available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/11/news_detail_002210.jsp&mid=WC0b01ac058004d5c1.

[238] Cf. *Current and Ongoing Transparency Activities in the Pharmaceutical Industry*, *supra*, 4.

[239] European Medicines Agency, *European Medicines Agency policy on publication of clinical data for medicinal products for human use, supra*, 4

[240] *Ibid.,* 6, stating further that "Where redaction of CCI is proposed by the applicant/MAH, a consultation with the applicant/MAH will be undertaken, following scrutiny by the Agency of the proposed redaction, including the justification provided by the applicant/MAH, as to whether the definition of CCI applies".

[241] *Ibid.*.

discretion of the Agency itself in deciding what kind of information has to be hidden[242].

In addition to this possible enlargement of the scope of the exemptions, various technical restrictions on data access itself play an important role in blurring the effectiveness of transparency.

Indeed, by signing the Terms of Use, users have to "acknowledge (…) that the information is protected by copyright and proprietary rights, and can be considered commercially valuable"[243].

From a legal technical point of view, these statements are too vague to be taken seriously, being totally unclear to which copyright (the User interface?), or which other "property right" (database protection?) they refer to.

The clinical report will be also available only "on screen", due to the legal prohibition, accepted with the signing of the terms of use, and the technical impossibility "to download, save, edit, photograph, print, distribute, the Clinical trial reports"[244].

Moreover, the user also agrees to not "access the Clinical Reports using a method other than the interface provided by the EMA, or remove, bypass, circumvent, neutralise or modify any technological protection measures which apply to the Clinical Reports*'*[245].

If copyright protection has to be called upon, it is arguable whether these "fair use crippling contractual terms"[246] comply with the exceptions to the reproduction right and to the right to communication to the public, provided by the EU Copyright Directive[247], and more specifically by art. 5(3), as regards the "use for the purpose of (…) scientific research", "*use for the purposes of public security or to ensure the proper performance or reporting of*

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[242] LEMMENS, *EMA's proposed Data release Policy: promoting transparency or expanding Pharma control over data?, supra,* 2.

[243] European Medicines Agency, *European Medicines Agency policy on publication of clinical data for medicinal products for human use, supra*, 10.

[244] *Ibid.*.

[245] *Ibid.*.

[246] Quoting REICHMAN, *A Reverse Notice and Takedown Regime to Enable Public Interest Uses of Technically Protected Copyrighted Works,* in *Berkeley Technology Law Journal,* 22, 2007, 981.

[247] Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society.

administrative, parliamentary or judicial proceedings" [248] , and "use by communication or making available, for the purpose of research or private study"[249].

More generally speaking, these terms of use provisions dramatically clash with the declared liberalist intents of enhancing the degree of researcher's scientific awareness, and the level of information enjoyed by European patients, thus revealing the innate contradictory nature of European Medicines Agency's transparency policy.

Little wonder, if one considers that the same document is the "end product" of a long-lasting policy controversy directly involving the European Medicines Agency, and in second instance, also the European Court of Justice.

2.2.2. The EMA controversy - The Ombudsman' decision

The controversy involving the European Medicines Agency and the Danish research group Cochrane Collaboration, provides indeed a fundamental background for a better understanding of the new policy on access to clinical trials data, to become effective on the 1st January 2015.

The latest policy document is in fact the result of a drastic change of position of the European Medicines Agency, which initially denied access to test protocols.

In 2007 the research group Cochrane Collaboration sought access to clinical trials protocols of an anti-obesity pill, whose effect on weight loss was suspected by the researchers to be very small, compared to the risks of cardiac and pulmonary complications, and also psychiatric disturbances that were likely to be caused by the medicine itself[250].

The analysis of the trials' outcomes would have been necessary to evaluate the scope of these risks.

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[248] Emphasis added.
[249] *Ibid.,* art. 5(3) lett a), e), n).
[250] GØTZSCHE-JORGENSEN, *Getting access to unpublished clinical trials at the European Medicines Agency, supra,* 342 ss..

The research group was thus asking the European Medicines Agency for an independent assessment of these test data, for specific research purposes, resulting necessary due to the incompleteness of the publicly accessible information, and in order to "provide healthcare providers and patients with reliable information about the benefits and harms of anti-obesity drugs"[251].

According to the researchers the documents which they were asking access to, did not contain any commercially confidential information, provided that these same documents "were based on general and well known principles which could be applied to any drug trial"[252], and that the Guidelines on the conducting of the trials[253] did not "suggest that any information contained in the clinical study report could be considered as a trade secret"[254].

Because of the likeliness of the "widespread use in the future of this drug"[255], the researchers affirmed that "societal interests"[256] were at stake, for the fulfilment of which European provisions assure "the widest possible access to documents the Agency receives or has in its possession", as it is stated in art. 1 of the Rules for the implementation of Regulation EC N. 1049/2001 on access to EMEA documents[257], reproducing the right generally acknowledged in art. 15 of the Treaty of the Functioning of the European Union.

The study group was thus seeking the openness that according to recital 2 of the Regulation EC n. 1409/2001, is essential in order to enable "citizens

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[251] *Ibid.,* 350.

[252] *Ibid.*, 353.

[253] Cf. European Medicines Agency, *Structure and Content of Clinical Study Reports- Note for Guidance on Structure and Content of Clinical Study Reports,* online available at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002832.pdf.

[254] European Ombudsman, *Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medecines Agency,* Strasbourg, 24th November 2010, online available at http://www.ombudsman.europa.eu/cases/decision.faces/en/5459/html.bookmark, paragraph 55; Cf. also GØTZSCHE-JORGENSEN, *Getting access to unpublished clinical trials at the European Medicines Agency, supra,* 359.

[255] *Ibid.,* 343.

[256] *Ibid.,* 343.

[257] Cf. Rules for the implementation of Regulation EC N. 1049/2001, on access to EMEA documents, EMEA/MB/203359/2006 Rev.1 Adopted. Management board meeting 19 December 2006, online available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/02/WC500070829.pdf.

to participate more closely in the decision-making process"[258], and to assure "that the administration enjoys greater legitimacy and is more effective and more accountable to the citizens in a democratic system"[259].

However, the researchers argued that even if commercial interests would have been thought to be at stake, the Rules for the implementation of the Regulation would have still assured the release of the remaining parts of the clinical study reports not covered by exceptions[260].

Furthermore, the existence of an "overriding public interest" in the accessibility of the reports, acknowledged by art. 3 of the Rules for implementation as an exception to the exceptions given to the general transparency rule[261], had to be taken into consideration.

Also non-binding provisions were mentioned to enforce the researchers' position, such as the ones contained in the Declaration of Helsinki, defining in art. 30 the duty for authors "to make (…) the results of their research" publicly available[262].

Thus, according to the research group's reasoning, a general and strict refusal to access would not have been justifiable in any way under the cited normative provisions[263], and also in the face of the recent statements of the European Commission, intending to "signal the importance of (…) access to and dissemination of scientific information"[264].

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[258] Recital 2 of Regulation EC n. 1049/2001 of the European Parliament and of the Council, of 30 May 2001, regarding public access to European Parliament, Council and Commission Documents, online available at http://www.europarl.europa.eu/RegData/PDF/r1049_en.pdf.

[259] *Ibid.*. See also CARVALHO, *The Trips regime of Patent Rights, supra*, 605, stating that "excessive concealment prevents the public at large from checking the quality of product registrations granted by governmental agencies". Cf. LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in an environmental health, and safety law, supra,* 510: "to the extent that data is withheld from social processes of risk assessment, it undermines personal autonomy, participation, and efficiency across the society".

[260] Cf. art. 3 (6) of the Rules of implementation of Regulation EC N.1049/2001, *supra*, stating that: "if some parts of the requested document are covered by any exceptions, the remaining parts of the document shall be released".

[261] *Ibid.,* art. 3(2): "The Agency shall refuse access to a document where disclosure would undermine the protection of a) commercial interests of a natural or legal person, including intellectual property (…) *unless there is an overriding public interest in disclosure*". Emphasis added.

[262] See World Medical Association Declaration of Helsinki- Ethical principles for Medical Research involving Human beings, *supra.*

[263] GØTZSCHE-JORGENSEN, *Getting access to unpublished clinical trials at the European Medicines Agency, supra,* 354. Cf. on the point, GARATTINI, *Confidentiality,* published on the Lancet, on the 27th September 2003, online available at http://www.ncbi.nlm.nih.gov/pubmed/14522545.

[264] European Commission, *Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, on scientific information in the digital age: access, dissemination and*

The European Medicines Agency, on defence, took the exact opposite stand, and went on defining the legal framework for concealment.

The complexity of the issue at stake is interestingly shown by the fact that the regulatory agency based its reasoning on the same provisions that provided the complainants the grounds for requesting disclosure.

In fact, the European Medicines Agency appealed to the same Rules on implementation in order to leverage on the exemption provided by art. 4(2) of the Rules of implementation, shielding "information that could be of benefit for a competitor, the disclosure of which could cause a disproportionate prejudice to and seriously harm the commercial interest of the party"[265].

This was according to the Agency the case of the data contained in clinical study reports, that are "extremely detailed and extensive"[266], and contain "full detail of the clinical development programme for a medicinal product" [267], representing the "most substantial part of applicants investment"[268].

The disclosure would have thus permitted competitors to use the information contained in the documents made available as a basis for starting developing similar medicinal products and "to obtain valuable information about the marketing authorisation holders long term clinical development strategies"[269].

The interest of protecting a third party that would be adversely affected "in case of improper disclosure of the content of the concerned

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preservation, published on 14th February 2007, online available at http://ec.europa.eu/research/science-society/document_library/pdf_06/communication-022007_en.pdf.

[265] European Ombudsman, *Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency,* paragraph 43.

[266] *Ibid.,* paragraph 17.

[267] *Ibid.*.

[268] GØTZSCHE-JORGENSEN, *Getting access to unpublished clinical trials at the European Medicines Agency, supra,* 351.

[269] European Ombudsman, *Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency,* paragraph 55.

documents"[270], had thus to be adequately valued also in front of the public interest of publishing these data.

According to the regulatory Agency, although the presence of an overriding interest in a better assessment of the effects of the anti-obesity drug could be acknowledged, this did not lead to an automatic disclosure obligation[271].

In fact, this same interest was already being addressed by the Agency through the publication of summary of products features and the control of the written information for patients entailed in the package leaflet in all European languages, in compliance with art. 57 (1)[272] and art. 80[273] of Regulation EC n. 726/2004, from whom the Agency's task to inform healthcare and patients on information relating to medicinal products approved or rejected by the Community[274], is derived.

These summaries already provided an evaluation of the benefits and risks of a pharmaceutical product, and were constantly updated in virtue of the Agency's monitoring activity of the (side-)effects of a specific pharmaceutical product[275].

That is why "with this regard (…) the Agency" could not "identify any overriding public interest that could justify the disclosure of the concerned documents"[276].

Furthermore, the Agency argued that grounds for non-disclosure were also to be found at the international level in art. 39.3 of the TRIPS

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[270] GØTZSCHE-JORGENSEN, *Getting access to unpublished clinical trials at the European Medicines Agency, supra,* 348.

[271] *Ibid.,* 348-349.

[272] Art. 57 (1) EC n. 726/2004, *supra*: "The Agency shall provide the Member States and the institutions of the Community with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use which is referred to it in accordance with the provisions of Community legislation relating to medicinal products".

[273] Art. 80 Regulation EC n. 726/2004, *supra*:"To ensure an appropriate level of transparency, the Management Board, on the basis of a proposal by the Executive Director and in agreement with the Commission, shall adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products which is not of a confidential nature. The internal rules and procedures of the Agency, its committees and its working groups shall be made available to the public at the Agency and on the Internet".

[274] GØTZSCHE-JORGENSEN, *Getting access to unpublished clinical trials at the European Medicines Agency, supra,* 348.

[275] *Ibid.*.

[276] *Ibid.,* 349.

Agreement[277], imposing on the World Trade Organization members a specific obligation of protection of undisclosed information which must be protected against "unfair commercial use"[278], except "where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use" [279].

This provision refers to the specific case of the submission to the test data "as a condition of approving the marketing of pharmaceutical"[280].

This is why it is to be interpreted as *lex specialis*- thus prevailing- in respect of the general rules for accessibility of the documents entailed in Regulation EC n. 1049/2001 and the Rules of implementation related to it, invoked by the research group for disclosure[281].

Further normative referrals for the refusal to give access to raw data were, according to the Agency, to be found also in the data protection provisions laid down by Regulation EC n. 45/2001 [282] expressly evoked by the Agency[283].

Indeed, clinical trials data result to be structurally made up not only by commercial confidential information, but also by the personal data of the volunteers who have been submitted to them.

The only way for disclosure to be allowed would have been the redaction of the raw test information in order to erase the sensible parts entailed in it[284].

This would have however caused the Agency a "disproportionate effort in terms of time and resources"[285], distracting the Agency itself from its core

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[277] European Ombudsman, *Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency,* paragraph 18.
[278] Art. 39.3 TRIPS Agreement.
[279] *Ibid.*. Cf. *infra* chapter 2.
[280] Art. 39.9 TRIPS Agreement.
[281] European Ombudsman, *Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency,* paragraph 18.
[282] Regulation EC n. 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, online available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:008:0001:0022:en:PDF.
[283] European Ombudsman, *Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency,* paragraph 86.
[284] *Ibid.,* 87.
[285] *Ibid.,* 17.

business activities, as foreseen by art. 57 of the Regulation EC n. 726/2004[286].

The difficulty and the length of the process of examining the documents, would thus have resulted in an excessive burden for the administration, justifying, as the European Court of Justice has stated, "a derogation from that obligation to examine the documents"[287].

Moreover, according to the Agency, the redaction of the protocols would have itself deprived the documents of "all the relevant information"[288].

In assessing the two opposite positions, the European Ombudsman decided in favour of the research group, identifying a right for the complainants to access the documents of the clinical trials data.

The decision released on the 10th May 2010, was taken on the grounds of the same normative framework, which both the complainants and the defendants referred to in order to support their claims.

First of all the Ombudsman contested the interpretation of art. 39.3 TRIPS Agreement as a *lex specialis* in respect of the general rules entailed in Regulation EC n. 1049/2001 and in the Rules of implementation of the same regulation.

This interpretation is to be considered wrong, because the two set of rules pursue completely different aims: the international provision contains a general rule for non-disclosure, whereas the European norms state a general obligation to grant access[289].

Moreover, strictly interpreting the article, it was acknowledged how the obligation for non-disclosure given by TRIPS provision is only limited to the event of "commercial use" of the data submitted in the realm of a

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286 Art. 57 Regulation EC n. 726/2004, *supra*: "The Agency shall provide the Member States and the institutions of the Community with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use which is referred to it in accordance with the provisions of Community legislation relating to medicinal products".

287 Case T-2/03, *Verein für Konsumenteninformation vs. Commission,* 2005, ECR II-1121, cited by the European Ombudsman, *Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency,* paragraph 36.

288 *Ibid.,* 54.

289 *Ibid.,* 22-23.

pharmaceutical market authorisation, this being not the case of the research purposes declared by the complainants, which have been motivating access only by purely scientific concerns.

Art. 39.3 TRIPS did not therefore prevent private access for research purposes[290].

Furthermore, the Ombudsman stated how the provisions of Regulation EC n. 1049/2001 assure a general obligation for disclosure, and hence a general right of the public to access official documents, *independently* from the future use of the accessed information[291].

As far as the exceptions to this general rules are concerned, the Ombudsman underlined how they must be applied in the narrowest possible way, following the interpretation given by the case law of the Community Courts: the application of the exemption would therefore not been justified by "the mere fact that a document concerns an interest protected by an exemption"[292].

The exemption offered by the regulation is only to be relied on as regards to the specific condition that the threat of the commercial interests' frustration is *actual* and *specific*[293].

Thus, this risk must be "reasonably foreseeable and not purely hypothetical"[294].

Given this normative scenario, according to the Ombudsman, the European Medicines Agency had failed to adequately proof various points, relevant for a legitimate refusal for disclosure.

First of all, the regulatory agency had not provided any accurate evidence of the fact that the clinical study reports in respect of which request of access was presented, effectively contained commercially confidential information.

As regards to this, the Ombudsman recognised the heaviness of such a burden of proof, given that the current European legislation provides no

[290] *Ibid.,* 24-25.
[291] *Ibid.,* 24.
[292] *Ibid.,* 28.
[293] *Ibid.*.
[294] *Ibid.,* 32.

specific definition of what is to be considered of commercial confidential value[295].

At the same time, distance had to be taken from excessively broad interpretations of the notion given by the jurisprudence, as the one according to which "all information relating to a company and its business relations"[296] is to be considered of commercially confidential value: this broad interpretation would in fact "not give effect to the general principle of providing the public with the widest possible access to documents held by institutions"[297].

In the Ombudsman's opinion, the documents for which access was requested did not entail commercially confidential information[298].

As far as the presence of personal data in the trials protocols was concerned, the Ombudsman noticed that the requested documents did not identify the patients by their name, but "by their identification and test centre numbers"[299], not qualifying as personal data due to the difficulty to associate them to a specific individual[300].

However, even if the presence of commercially confidential information or personal data, had been shown, or presumed, no proof had been anyway given of the fact that the disclosure of the reports would have *actually* and *specifically* compromised the protection of commercial interests, in order to apply the exception[301].

In second instance, even if this last proof had been given, the law still would have required disclosure, "if steps" were "taken to ensure that the data are protected against unfair commercial use"[302], that meaning, if an adequate

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295 *Ibid.,* 71.
296 *Ibid.,* 76.
297 *Ibid.*, 72
298 *Ibid., passim.*
299 *Ibid.,* 86.
300 "Patients could therefore be identifiable, provided that, in case of disclosure or otherwise, information on the attribution of particular numbers to particular patients is also available. However, neither the requested documents nor other information in the public domain appeared to allow a link to be made between a given identification number and a particular patient, thus making it possible for himlher to be identified". *Ibid.*.
301 *Ibid.*, 82
302 Art. 39.3 TRIPS Agreement.

erasure of the sensitive information was made in order to render the data accessible.

By comparing the regulatory agency's acting with the collaborative approach taken by the European Investment bank in a similar case involving access to confidential information[303], the Ombudsman noted that the European Agency did not offer sufficient reasons for its refusal: no adequate proof of the "excessive administrative burden" that the redaction of the protocols would have caused, had indeed been given[304].

The Ombudsman also underlined how the exception of the administrative burden affirmed by the European Court of Justice in the controversy *Verein für Konsumenteninformation vs. Commission* was to be confined to the "exceptional" cases of an individual examination that appears "to be particularly heavy, therefore exceeding the reasons of what may be reasonably required (…)"[305].

This failure of proof was to be considered in the Ombudsman's opinion as a sign of maladministration in respect of the obligation entailed in art. 18 of the European code for good administrative behaviour[306], stating that every decision taken by an institution "shall clearly state the legal basis of the decision"[307].

Finally the Ombudsman stated that also if the action of erasure had turned out to be excessively burdensome, still disclosure would have been possible, according to both the international and European provisions, if the presence of an "overriding interest" had been acknowledged[308].

Unfortunately however, the Ombudsman did not provide any reasoning about the existence of a possible overriding public interest, given that his understanding of this specific case was in the sense of the absence of any

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303 European Ombudsman, *Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency,* paragraph 39.

304 *Ibid.*, 37

305 Case T-2/03, *Verein für Konsumenteninformation vs. Commission, supra.*

306 European Ombudsman, *Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency,* paragraph 20.

307 European Ombudsman, European Code of Good Administrative Behaviour, online available at http://www.ombudsman.europa.eu/en/resources/code.faces#/page/1.

308 European Ombudsman, *Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European* Medicines *Agency,* paragraph 20 and 50.

data to be considered of commercial confidentiality, without any need thus to get deeper in the second and the third arguments[309].

This understanding of the case by the Ombudsman resulted to be wholly in line with the European Medicines Agency's main purpose, that is the assessment of the risks and benefits of a drug[310].

This essential task had to be adequately evaluated in order to effectively protect the "health of European citizens": in this perspective it was therefore "of utmost importance for EMA to give the widest possible access to documents and also to pursue a proactive information policy for the benefit of citizens"[311].

The Ombudsman's decision provides a very precious assessment of the normative grounds and juridical arguments that can be used in favour or against disclosure.

The fact that the same provisions can be read in both directions, offers clear evidence of the weakness of the legislative structure on this delicate issue.

As some scholars have pointed out, such weakness is easily exploited by the more influential part[312].

The decision gives an interesting insight on the issue, by proposing a sort of "three-step test" to solve the disclosure/secrecy dichotomy, that the defendant has to overcome in order to oppose a legitimate refusal for disclosure: the defendant must in this light face the burden of proof regarding first the presence of a commercially confidential interest resulting *actually* and *specifically* at risk, second the subsequent excessive administrative burden caused by the erasure of the sensitive data entailed in the document for which the access is requested, and finally the absence of an overriding public interest.

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309 Cf. GØTZSCHE-JORGENSEN, *Getting access to unpublished clinical trials at the European Medicines Agency, supra,* 362.

310 *Ibid.,* 363.

311 *Ibid.,* 364.

312 See ANDANDA, *Managing intellectual property rights over clinical trial data to promote access and benefit sharing in public health, supra*, 162.

The impact of the Ombudsman's decision is to be evaluated as regards the subsequent Policy Documents on access to clinical trials data[313] of the regulatory Agency, having allegedly shifted its position towards a more public-friendly approach[314].

The new trend of releasing clinical trials protocols that followed the decision has been firmly obstructed by pharmaceutical companies: two of them, *AbbVie* and *Intermune* sought injunctive relief in front of the European Court of Justice in order to prevent the regulatory Agency from disclosing trials reports[315].

In November 2013 however, the Court of Justice[316] annulled the interim injunctions against the European Medicines Agency, given the absence of sufficient proof provided by the complainants of the "risk of serious and irreparable harm" to the companies' "fundamental right to the protection of their business secrets, enshrined in article 339 TFEU, art. 8 of ECHR, and in article 7 of the Charter and of their right to an effective remedy, enshrined in article 6 of the ECHR and art. 47 of the Charter"[317].

Despite the substantial step-forwards made by law and the jurisprudence in recent years, much is yet to be done in the definition of the criteria that are relevant in the guidance of the balance between the two opposite interests involved in the debate over access to clinical trials data, on the one hand the economic and competitive interests of originators, on the other, public

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[313] Cf. *supra.*

[314] See European Medicines Agency, *Mid-year report, January-June 2014,* published on the 19th September 2014, online available at http://www.ema.europa.eu/docs/en_GB/document_library/Report/2014/10/WC500175116.pdf, 27, where the numbers of documents released after the Ombudsman's decision in the years 2011, 2012 and 2013 are shown. However it has to be underlined how the number of documents released in 2014 has impressively decreased, this to be explained in light of the "Court cases" that ruled in favour of the rejection of the access.

[315] The injunctive measure was at first instance given, *AbbVie, Inc. and AbbVie Ltd vs. EMA* T-44/13 R (Order of the President of 25th April 2013), Reports of Cases. Not yet published (General Report - Section "Information on unpublished decisions"); *Intermune Uk e. a. vs. EMA* T-73/13, Reports of Cases. Not yet published (General Report - Section "Information on unpublished decisions").

[316] C-390/13, *European Medicines Agency vs. Intermune,* Order of the Vice-President of 28th November 2013, online available at http://curia.europa.eu/juris/document/document.jsf?text=&docid=145281&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=860401; C-389/13 P(R), *European Medicines Agency vs. AbbVie,* Order of the Vice-President of 28th November 2013, not published.

[317] Paragraph 45.

interests related to the collective goods of health, information and scientific research.

Both the interpretational gaps left open by the new Clinical Trials regulation, and the contradictory nature of the latest EMA policy advocate a deeper understanding of the legal grounds and layouts for the protection of industries' commercially confidential information, and a stronger inquiry over the public interests capable of overriding the reasons for secrecy.

3. The European stance on clinical trials transparency in the context of the latest international trade developments

The latest positions of the European Medicines Agency as regards clinical trials data transparency, as well as the disclosure mandate provided by art. 81(4) of Regulation EC 536/2014[318], have shuttered American regulators' quietness in the context of the TTIP negotiations.

Indeed, despite the negotiating intents of the European Union aiming at reducing "regulatory differences" in the pharmaceuticals sector [319], "including consideration of approaches relating to regulatory harmonization, equivalence, or mutual recognition, where appropriate"[320], the direction ultimately taken up by the European Union with regards to its transparency policy and legislation seems to irretrievably lead to the opposite arrival point.

It is exactly in the realm of the discussions related to the creation of common pharmaceutical regulatory standards, that the strategic importance of clinical trials regulation emerged again.

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[318] Regulation EU 536/2014 of the European Parliament and of the council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC, *cit.*.

[319] European Commission, *The Transatlantic Trade and Investment Partnership (TTIP). Regulatory Issues. EU position on pharmaceutical products*, 14.5.2014, Brussels 2014, http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152471.pdf .

[320] So EU Council, *Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America*, 11103/13 DCL1, 9.10.2014, Brussels, 13. Indeed, as it is stated, an agreement on high transatlants standards, would have the benefit of saving on costs, and also lead to a faster market authorization of medicinals. On this issue, and specifically focusing on the consumer/patient outcomes, see DIELS-THORUN, *Chancen und Risiken der Transatlantischen Handels- und Investitionspartnerschaft (TTIP) für die Verbraucherwohlfahrt,* Friedrich-Ebert-Stiftung, WISO Diskurs, Bonn 2014, 26-32.

Indeed, one of the discussed standards precisely regards the exchanging of *"confidential/trade secret information"*[321], including data from applications for authorization, between the EU and the US authorities in charge of pharmaceutical products, *i.e.* EMA and FDA.

The reference to the *confidential nature* of the information at stake, results of particular interests, clearly revealing the negotiating parties' approach to the issue: *confidentiality* is in fact *assumed*[322], in that way threatening a correct interpretation of both EMA's transparency policy, and the latest Clinical Trials Regulation[323].

Given that the mentioned Regulation expressly states that "clinical trials results (…) in general, should not be considered confidential"[324], the implications of this sort of 'European schizophrenia' need to be more carefully assessed.

Indeed, on the one hand, it is clear that a systematic exchange of regulatory data[325] between the two regulatory agencies, as the European Commission document states[326], would have considerable benefits in terms of "avoiding unnecessary clinical trials/testing replication"[327], and would facilitate

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321 Emphasis added, European Commission: *The Transatlantic Trade and Investment Partnership (TTIP). Regulatory Issues. EU position on pharmaceutical products*, 2.

322 In this sense, see MAIER-RIGAUD, *Between Transparency and Secrecy- How does the TTIP impact the publication policy of clinical studies in the pharmaceuticals field?,* Bonn : Friedrich-Ebert-Stiftung, Dep. for Economic and Social Policy, 2015, online available at http://library.fes.de/pdf-files/wiso/11151.pdf, stating that "(…) it is problematic that the Commission's TTIP position focuses on the handling of confidential information, *and thus apparently a need for confidentiality is assumed in spite of the controversy raging over transparency of clinical study reports*". Emphasis added.

323 WEISS, *Trading Health? UK Faculty of Public Health Policy Report on the Transatlantic Trade and Investment Partnership,* online available at http://www.fph.org.uk/uploads/FPH%20Policy%20report%20on%20the%20Transatlantic%20Trade%20and%20Investment%20Report%20-%20FINAL.pdf.

324 *Ibid.*. Cf. recital 68 Reg. EC 536/2014.

325 The idea is that of "a permanent cooperation mechanism (e.g. Regulatory Cooperation Council), provisions on sharing information on planned regulation and the possibility for the other party to comment on it at an early stage, cooperation in collecting data and evidence underlying regulatory action and exchange of such information (…)". See GERSTETTER, *Regulatory cooperation under TTIP- a risk for democracy and national regulation?,* September 2014, online available at https://www.boell.de/sites/default/files/ttip_study_regulatory_cooperation_under_ttip_1.pdf, 5.

326 European Commission, *The Transatlantic Trade and Investment Partnership (TTIP). Regulatory Issues. EU position on pharmaceutical products*, *supra,* 3.

327 *Ibid.*.

agencies' administrative assessments[328], saving a large amount of testing costs, with the associated human and ethical gains[329].

However, on the other hand, if a robust information sharing system between the FDA and the EMA could have many positive effects not only as regards the overall trade and economic interactions[330], but also as regards the "issues unrelated to trade and marketing authorization"[331], more attention is to be given to the connotation of confidentiality given to the information at stake. Indeed, such an approach could sensitively restrict the use of clinical trials data[332], in light of the abovementioned exemptions of commercial confidentiality posed by the cited Regulation to the general disclosure rule under art. 81.4[333].

Harmonization[334] would therefore be easily achieved through the interpretative extension of the vague confidentiality exemption[335] posed by the Clinical Trials Regulation, blurring in that way the important differences

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328 Indeed, it has been argued that "with a robust regulatory environment and sharing of information, faster achievements could be made to improve the therapeutic benefits of medicines coming to the market". So European Public Health Alliance, Pharmaphorum- TTIP, *Bringing benefits to patients or Big Pharma*?, published on 22nd September 2014, online available at http://www.pharmaphorum.com/articles/ttip-bringing-benefits-to-patients-or-big-pharma.

329 *AmCham EU's position on the Translatic Trade and Investment Partnership (TTIP), Building the framework for strenghtening the transatlantic partnership,* published on 14th March 2014, online available at http://www.amcham.it/detail.asp?c=1&p=0&id=9111, 8, affirming that a common regulatory regime for test data, "would avoid unnecessay animal testing and save costs for companies and public authorities, while accelerating efforts to protect consumers and the environment".

330 As the EU Directorate General for Internal Policies has stated, "harmonisation could make life easier for business and innovators, since, by doing away with existing divergences in definitions, regulatory mechanisms and criminal penalties, innovation could be incentivised, cross-border sharing of innovation facilitated, competitiveness increased, and hostile take-overs made less attractive". So the EU Directorate General for Internal Policies, *Trade Secrets*, published in April 2014, online available at http://www.europarl.europa.eu/RegData/etudes/note/join/2014/493055/IPOL-JURI_NT(2014)493055_EN.pdf, 12-13. For a broader assessment of the benefits of a International Regulatory Cooperation (IRC), see WIENER-ALEMANNO, *The Future of International Regulatory Cooperation: TTIP as a learning process toward a Global Policy Laboratory,* (December 16, 2015), Law & Contemporary Problems, Forthcoming; Duke Law School Public Law & Legal Theory Series No. 2016-6, online available at http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=4742&context=lcp.

331 Regulatory agencies could in fact be facilitated to collaborate on rare diseases, paediatrics, medicines barcoding for hospitals, and medicines shortages". European Public Health Alliance, Pharmaphorum- TTIP, *Bringing benefits to patients or Big Pharma*?, *supra*, 5.

332 *Ibid.*.

333 Art. 81.4 of Regulation n.536/2014/EC of the European Parliament and of the Council on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC, *supra.*

334 For a general overview on the issue of Transatlantic Regulatory Cooperation, see ALEMANNO, *The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences,* Journal of International Economic Law, 2015, 18, 625–640.

335 For a broader assessment of the issue, see *infra* chapter 2.

between national EU and US Regulation[336], as regards drugs' safety and efficacy data transparency. Indeed, the US still lacks a mandatory disclosure requirement for pharmaceutical test data[337], Europe thus being- with regards to industrial transparency policies- at the forefront[338].

Although it is true, as suggested by some scholars[339], that regulatory schemes animated by different policy intents are difficult to reconcile, and that "TTIP and any structure for regulatory cooperation created under it will have to build on these rules, and is highly unlikely to modify them"[340], different conclusions are to be reached as regards those regulatory spots that are governed by more (political and thus interpretational) uncertainties, as is the case of the disclosure rule of pharmaceutical test data. Indeed, it should not be underestimated how the youngest and more controversial regulatory developments, and most of their future implementation, will be influenced by international trade agreements[341]. These are in fact very likely to permeate the delicate EU internal equilibrium between opposite stakeholders, breaking through weak normative provisions, and taking with that control of the discretion left to regulatory agencies [342] by

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[336] GERSTETTER, *Regulatory cooperation under TTIP- a risk for democracy and national regulation?, supra,* 5, underlining how regulatory differences are nothing else than the product of divergent policy orientations regarding pharmaceutical industry and more in general health risks.

[337] Cf. *supra.* On the point, see GALBRAITH, *Dying to know: A demand for Genuine Public Access to clinical trials result data,* Mississippi Law Journal, 78, 4, 2009, 705 ss., 720, referring the words of Abbey S. Meyers, President of the National Organization for Rare Disorders, that has significantly declared how the "FDA is probably one of the most secretive government agencies that any consumer will ever have to deal with. Virtually everything about a drug is considered proprietary. Agency officials will not talk to anyone about the drug unless the manufacturer gives them permission to do so". Cf. BECKHAUS, *A new prescription to balance secrecy and disclosure in drug-approval processes,* 46 U. Mich. J. L. Reform 135 (2012), 144.

[338] CHOI, *Increasing Transparency of Clinical Trials Data in the United States and in Europe,* 14 Wash. U. Global Stud. L. Rev. 521 (2015), online available at http://openscholarship.wustl.edu/law_globalstudies/vol14/iss3/9, 527 ss..

[339] GERSTETTER, *Regulatory cooperation under TTIP- a risk for democracy and national regulation?, supra,* 6.

[340] *Ibid.*.

[341] *Ibid.,* underlining how in the "cases where executive bodies are afforded much leeway for independent decision-making when implementing legislation, there appears to be the risk that they could use that power strategically to implement decisions on harmonization". More specifically, "where an agency (…) wields significant independent decision making power, it could use that power strategically to implement decisions taken in the framework of a Regulatory Cooperation Council (RCC)". *Ibid.*, 32.

[342] Already stressing the discretion enjoyed by regulatory agencies as a consequence of the short circuit between general rules and exemptions, MCGARITY, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEo. L. J. 729, 741-43 (1979); SHAPIRO-MCGARITY, *The trade Secret Status of Health and safety testing information: Reforming Agency Disclosure Policies*, in Harvard Law Review, 93, 5, 1980, 837 ss..

interpretational ambiguities[343] to the benefit of economic interests and to the detriment of the fulfilment of other EU "constitutional" obligations[344], such as the ones of patients and consumers' protection, as well as of competition encouragement[345].

In this perspective, the latest European transparency tendencies have already been strongly condemned by the American Chamber of Commerce to the European Union, affirming that the new policy of test data access could significantly "undermine the trust in the regulatory approval system, introducing risks of misinterpretation and misuse of clinical data into the process; and weaken incentives for companies to invest in biomedical research by disclosing companies' commercially confidential information"[346]. In order to maintain a high degree of investments in clinical trials, the solution pursued by the American party is the one of protection of "patient privacy and commercial confidential information and trade secrets in their respective clinical trials and marketing authorization disclosure policies"[347]. According to the American Chamber of Commerce to the European Union, a different attitude towards the protection of the strategic commercial asset of pharmaceutical testing data, would clearly lead towards solutions that are inconsistent with both Europe's and America's

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343 Cf. LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in an environmental health, and safety law*, 2007, 78 University of Colorado Law Review, 465 ss., 466-467, underlining how the "lack of clarity in the law has led to a default mode of decision making, case-by-case balancing of interests. This approach tends to favour the party with the more immediate, concrete, and well financed interest, which is most often the commercial party", and further noting how "loose exemptions for commercial information allow firms to opt out of societal learning and drain resources from the market, from research, and from regulation". Cf. also LYNDON, *Secrecy and Innovation in Tort Law and Regulation,* 23 N.M.L Rev. 1 (1993), online available at http://lawschool.unm.edu/nmlr/volumes/23/1/01_lyndon_secrecy.pdf, 2 ss..

344 PETERSMAN, *Transformative Transatlantic Free Trade Agreements Without Rights and Remedies of Citizens?,* in *Journal of International Economic Law*, 2015, 18, 579–607, who especially insists on art. 21 of the Lisbon Treaty on the functioning of the EU, listing the guiding principles of the Union's action on the international scene, amongst which also "(…) human rights and international principles of law", therefore shaping a European Union citizenship that "goes beyond membership in the political communities of EU Member States and of the EU itself". *Ibid.,* 580.

345 For a broader assessment on the issue see MATTHEWS, *Intellectual Property Rights, Human Rights and the Right to Health,* Queen Mary School of Law Legal Studies Research Paper 24/2009, online available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1414900, stressing on the importance of art. 25 of the Universal Declaration of Human Rights, and art. 12 of the International Covenant on Economic, Social, and Cultural Rights regarding Access to Medicines in the broadest sense possible.

346 *AmCham EU's position on the Translatic Trade and Investment Partnership (TTIP), Building the framework for strenghtening the transatlantic partnership, supra*, 11.

347 *Ibid.,* 15.

international obligations as established in the TRIPs Agreement under art. 39[348]. According to this view, this is exactly what the latest European developments end up doing: infringing already established international standards of protection[349].

These same WTO standards would be substantially improved if the Transatlantic Trade and Investment Partnership were to become "living law"[350]. Indeed the bilateral agreement at stake would evidently raise the threshold posed by the WTO Agreement on trade related aspects of intellectual property rights (TRIPs), as a consequence of a greater- and stricter- attention given to trade secret protection[351], without any mentioning of the public interest or of a commercial use that must be unfair in order to meet the protection requirements[352]. In fact, during the negotiations carried out so far, the importance of enhancing the protection of trade secrets as a form of intellectual property has been firmly stressed[353]. However, at a closer look, the enforcement of trade secret protection has been pursued not only by the USA[354] but also by the European Union[355], calling for broader commercial confidentiality[356] in the

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[348] *Ibid.,* 35.

[349] "The Us should raise trade related concerns with these EMA policies in the context of the TTIP discussions". *Ibid.*.

[350] Cf. ALEMANNO, *The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences, supra*, 625 ss..

[351] HUFBAUER-CIMINO-ISAACS, *How will TPP and TTIP change the WTO system?,* in *Journal of International Economic Law* (2015), 18 (3), 679-696

[352] Cf. art. 39.3 TRIPs Agreement. See *infra* chapter 2.

[353] "As knowledge and information become increasingly valuable and increasingly targeted for theft by domestic competitors and, in some cases, foreign entities and even governments, mechanisms to protect trade secrets become essential. TTIP should include strong protections for trade secrets, which should be done through expressly recognising trade secrets as intellectual property, in line with TRIPS articles 1.2 and 39. Governments could also consider ways they could work together to promote adequate and effective trade secret protections in third countries. This could be achieved through the inclusion of robust trade secret protections in bilateral and multilateral instruments pursued by each government, for example". *AmCham EU's position on the Translatic Trade and Investment Partnership (TTIP), Building the framework for strenghtening the transatlantic partnership, supra*, 36-37. Cfr. EU Directorate General for Internal Policies- Trade Secrets, *supra*, 10.

[354] Cf. YEH, *Protection of Trade Secrets: overview of Current Law and Legislation,* released on the 5th September 2014, online available at https://www.fas.org/sgp/crs/secrecy/R43714.pdf.

[355] WEISS-MIDDLETON-SCHRECKER, *Warning: TTIP could be hazardous to your health,* J. Of Public Health, Sept. 2015, 37, 367-369.

[356] European Commission, *Study on Trade Secrets and Confidential Business Information in the Internal Market,* published on April 2013, online available at http://ec.europa.eu/internal_market/iprenforcement/docs/trade-secrets/130711_final-study_en.pdf, 15.

latest Proposal for a European Trade Secret Directive[357]. Here, an extremely vague definition of the same notion of trade secret is given[358], in that way strewing uncertainties[359] on three different- though intertwined- legislative levels, namely EU intellectual property regulation, EU data transparency regulation, and finally international trade investment law.

4. Normative flexibilities and the "reflexive governance" over clinical trials data

A critical assessment of the latest regulatory and policy developments achieved by European institutions in the field of pharmaceutical regulatory data shows the weakness- or better said the ineffectiveness- of legal solutions regarding the management of such a strategic commercial asset.
Apart from the dubious valence of the European Medicines Agency's policy document, that is to be referred to the bizarre terms of use of the published clinical study reports, greater attention is to be given to the disclosure obligation under art. 81 (4), and more generally to the other European transparency norms, such as the ones on access to EU documents[360]. Indeed the normative technique used by the European legislator in the

[357] Proposal for a Directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets), against their unlawful acquisition, use and disclosure, 28 November 2013, online available at http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52013PC0813. See SOUSA-SILVA, *What exactly is a trade secret under the proposed Directive?,* in *Journal of Intellectual Property Law & Practice*, 2014, 9, 11 ss.; cf. also GRASSIE, *Trade Secrets: The new EU enforcement regime,* Journal of Intellectual Property Law & Practice (2014) 9 (8), 677-683. For a rather positive comment on the normative text, see KNAAK-KUR-HILTY, *Comments of the Max Planck Institute for Innovation and Competition of 3 June 2014 on the Proposal of the European Commission for a Directive on the Protection of undisclosed Know-How and Business Information (Trade Secrets) against their unlawful acquisition, use and disclosure of 28 November 2013*, online available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2464971. For a deeper assessment see *infra* Chapter 2.

[358] SOUSA-SILVA, *What exactly is a trade secret under the proposed Directive?, supra,* 12. Criticising such an approach, LEVINE, *The People's Trade Secrets?,* 18 Mich. Telecomm. & Tech. L. Rev. 61 (2011), 10, underlining how a broad definition of trade secrets becomes particularly dangerous when applied in the context of Freedom of Information Laws' exemptions: "particularly because the focus in such cases is public values such as disclosure of information through transparency, *narrowingly tailoring the definition of a trade secret is a good idea"*. Emphasis added.

[359] Stressing the need for greater legal clarity, APLIN, *A critical evaluation of the proposed Trade Secret Directive,* July 2014, online available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2467946&download=yes, 32 ss..

[360] E.g. Regulation EC 1049/2001 of the European Parliament and of the Council of 30 May 2001, regarding public access to European Parliament, Council and Commission documents, *supra.* Cf. *supra.*

ordering of opposite interests of different stakeholders is the one of a hierarchical disposition of them[361], in the form of a normative structure combining them along the lines of a general rule (sustaining the higher public interest) and of an exemption (defending-although in a subordinate position- the particular commercial interest). Also existing literature on the subject matter has been adopting a hierarchical approach to justify the reconciliation of contrasting demands, by focusing on the definition of the higher public interest in access to research knowledge [362] from a fundamental rights perspective [363], as well as a public good rationale standpoint[364].

However, not far from theoretical declarations, in the leap from books to action, things change drastically, and the clarity of legislative and policy orientations starts to fade away in the moment of the concrete settlement of clashing interests during practical- *i.e.* judicial and administrative- assessment of the interaction between general disclosure rules and particular confidentiality exemptions.

4.1 Judicial balancing tests and contingent interpretative solutions

The European Ombudsman's decision reflects the difficulty of the balancing between opposed interests [365], even if guided by the abovementioned judicial "three-step test"[366]. As literature has noticed[367],

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[361] Cf. SVETIEV, *European Regulatory Private Law: From Conflicts to Platforms,* in PURNHAGEN-ROTT, *Varieties of European Economic Law and Regulation, Liber Amicorum for Hans Micklitz,* Springer, 2014, 154 ss..

[362] See *infra* Conclusions 1.2.

[363] LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 65.

[364] REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: The case for a public goods approach, supra,* 4.

[365] Cf. BECKHAUS, *A new prescription to balance secrecy and disclosure in drug-approval processes, supra*, 143, with particular reference to the US Supreme Court ruling *Chrysler Corp. v. Brown*, 441 U.S. 281, 290-91 (1979), where the need for a "balancing" between private and public interests" is regarded by the Court as an essential means for the concrete evaluation of the commercial valence of corporates' information. Cf. also UNLU, *It Is Time: Why the FDA Should Start Disclosing Drug Trial Data*, 16 MICH. TELECOMM. & TECH. L. Rav. 511, 525-35 (2010), 525 ss..

[366] Cf. *supra.*

[367] LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in environmental, health, and safety law, supra,* 523.

the balancing between different interests is very likely to become an effective presumption in favour of secrecy.

Likewise, these kinds of judicial tests[368] can surely be a precious guide for a contingent decision-making based on an *aut-aut* perspective[369]-, but they appear to be far from addressing the necessity of establishing a clear legal framework, functioning as an effective basis for the shaping of public friendly legal solutions[370].

To the contrary, literature[371] has been underlining how vague normative confidentiality exemptions have constituted an open door for the successful accomplishment of information segregation practices regarding regulatory data[372], as well as other allegedly commercial sensitive information, such as the one related to the environmental impact of corporate activities[373]. Loose exemptions for commercial information have therefore allowed firms to "opt out of societal learning and drain resources from the market, from research, and from regulation"[374].

In this light, especially American case law shows how, although "the plain text of the legal framework suggests otherwise"[375], litigation interactions end up overturning legislative schemes.

Indeed, if there are very few European rulings to be found as regards access

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368 On the issue, see UNLU, *It Is Time: Why the FDA Should Start Disclosing Drug Trial Data*, *supra*, 525.

369 LEVINE, *The people's trade secrets, supra,* 85. Cf. also LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in environmental, health, and safety law, supra,* 467, observing how "balancing may also be short sighted, as decision makers may fail to perceive the systemic implications of each particular dispute".

370 Cf. GIVELBER-ROBBINS, *Public Health vs. Court sponsored secrecy,* 69 LAW & CONTEMP. PROBS., 131 (2006); see also V.V. A.A., *Symposium Secrecy in Litigation,* 81 CHI. KENT L. REV. (2006) 301, 301–808.

371 BECKHAUS, *A new prescription to balance secrecy and disclosure in drug-approval processes, supra,* 142 ss..

372 Not only in the field of pharmaceuticals, but also chemicals cf. LYNDON, *Secrecy and Innovation in Tort Law and Regulation,* 23 N.M. L. Rev. 1 (1993), 2 ss..

373 Regarding environmental information, see LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in environmental, health, and safety law, supra, passim*; SAND, *The Right to Know: Environmental Information disclosure by Government and Industry,* 2002, online available at https://www.researchgate.net/publication/228464480_The_Right_to_Know_Environmental_Information_Disclosure_by_Government_and_Industry; American Bar Association, Section of Environment, Energy, and Resources, *Trade Secret and Confidential Business Information Briefing Paper,* published in March 2014, online available at http://www.americanbar.org/content/dam/aba/administrative/environment_energy_resources/whitepapers/tsca/TSCA_paper_CBI_briefing.authcheckdam.pdf. For a deep general assessment see BÜNGER, *Deficits in EU and US Mandatory Environmental Information Disclosure,* Springer, 2011.

374 LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in environmental, health, and safety law, supra,* 468.

375 BECKHAUS, *A new prescription to balance secrecy and disclosure in drug-approval processes, supra*, 143.

to pharmaceutical safety data requests[376], the US jurisprudence[377] is considerably richer and has established various rules for the definition of the scope of the fourth exemption[378] to the American Freedom of Information Act. One worth to mention, for example, is the famous ruling *Pub. Citizen Health Research Grp. v. FDA*[379], where the Court of Appeals for the District of Columbia has identified the "decisive" criterion for the solution of the secrecy/transparency dilemma in the "substantial harm" that disclosure would cause to the "competitive position of the (legal) person from whom the information was obtained"[380].

The case in question is important because it offers a relatively unique attention towards public interest concerns[381], running with that contrary to the typical broad interpretation of the fourth FOIA exemption traditionally given by courts[382].

Indeed, in the American judicial panorama, the case in question appears to be isolated from the majority of the rulings, which have generally failed to

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[376] Cf. *supra.*

[377] For a general assessment see UNLU, *It Is Time: Why the FDA Should Start Disclosing Drug Trial Data, supra,* 528 ss.; see also BECKHAUS, *A new prescription to balance secrecy and disclosure in drug-approval processes, supra*, 141 ss..

[378] Cf. Department of Justice- Guide to the Freedom of Information Act, *Exemption 4,* online available at https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/exemption4_0.pdf, 263 ss..

[379] *Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d 1280, 1290-91 (D.C. Cir. 1983). For a broad comment see Department of Justice- Guide to the Freedom of Information Act, *Exemption 4, supra*, 273 ss..

[380] *Ibid.*.

[381] UNLU, *It Is Time: Why the FDA Should Start Disclosing Drug Trial Data, supra,* 527, recalling a footnote of the cited ruling, in which the court concluded that "lumping health and safety testing data with all other types of information is inherently suspect".

[382] Significantly, the Court underlined the inadequacy of the common notion of trade secrets, originated in the context of breaches of contract by employees and of "other fiduciary obligations", but resulting "ill-suited for the public law context in which the FOIA determinations must be made". Hence, the need of a proper determination of trade secret protection on the basis of the context of its implementation: more specifically, in the Court's belief, the freedom of information context should lead the legal reasoning to the necessary consideration of the theoretical underpinnings of trade secret protection itself, to be carefully evaluated and weighted in order to respect the core value of transparency in the public infrastructure More specifically, *Public Citizen* adopts a utilitarian acceptation of trade secrets defined as "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort". *Pub. Citizen Health Research Grp. v. FDA, supra,* 1289. LEVINE, *The people's trade secrets, supra,* 81. For a comment, see also BOYCE, *Disclosure of Clinical Trials Data: Why Exemption 4 of the Freedom of Information Act Should be Restored,* 2005 DUKE L. & TECH. REV. 3, 16 ss.. Cf. also BECKHAUS, *A new prescription to balance secrecy and disclosure in drug-approval processes, supra*, 143, "(…) hence, documentation in the drug-approval process that manufacturers identify as a trade secret or as otherwise commercially relevant is not commonly disclosed to the public".

strike the right balance of interests[383], and which have not quite considered the public interest in disclosure when deciding over attempts to access research data held by the regulatory agency[384]. Especially lower courts have easily found the mentioned "competitive harm" requirement satisfied[385], given the evidence of the existence of actual competition in the drug business, and more precisely between the "small fraction" of drug firms who reach the market stage, and the manufacturers seeking approval to market the drug in generic form[386]. As a strand of the literature has noticed[387], approaching the problem in these terms makes it very easy for manufacturers to oppose disclosure, by stating that some competitor *could* gain competitive benefits from the publicity of test data[388]. Indeed, if the competition harm test developed by US Courts implies, as stated, a qualitative threshold to be found in a *substantial* harm, it does not require actuality of the competitive damage[389], in that way considerably extending the legal space for judicial secrecy demands. Ultimately, "the confidentiality test thus appears to be incapable of balancing interests because it focuses extensively on the nature and magnitude of competitive harm to private interests and fails to consider the extent or magnitude of the public

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383 UNLU, *It Is Time: Why the FDA Should Start Disclosing Drug Trial Data*, *supra,* 526; LURIE-ZIEVE, *Sometimes Silence can be like the Thunder: Access to Pharmaceutical data at the FDA,* 69 *Law and Contemporary Problems* 85-98 (2006), online available at http://scholarship.law.duke.edu/lcp/vol69/iss3/5.

384 BOYCE, *Disclosure of Clinical Trials Data: Why Exemption 4 of the Freedom of Information Act Should be Restored, supra,* 16-18.

385 On the issue LEVINE, *The people's trade secrets, supra,* 111-112, recalling a ruling by the Ombudsman from New Zealand, who established a precise set of rules, to be applied in the decision between disclosure and commercial confidentiality: in balancing the public interest in information and the commercial interest in confidentiality, the Ombudsman weighs 1) the specific market activity to which the information is related, 2) number of competitors, degree of competition and other characteristics of the market, (…) 3) the degree to which disclosure would put a competitor to an advantage. "While still focused on commercial gain, this test has two primary strenghts: 1) it forces governments (*alias* regulatory agencies) to establish a clear connection between the information and its commercial efforts and 2) it implicitly recognizes that there may be information for which even commercial concerns are not significant enough to warrant denial of disclosure".

386 Cf. UNLU, *It Is Time: Why the FDA Should Start Disclosing Drug Trial Data*, *supra,* 528, quoting the case *Citizens Comm'n on Human Rights v. FDA*, 1993 WL 1610471, where the court stated how a competitor in possession of raw research data and results "could also use the information to submit its own NDA to FDA for the same or similar drug product".

387 LEVINE, *The people's trade secrets, supra,* 85.

388 UNLU, *It Is Time: Why the FDA Should Start Disclosing Drug Trial Data*, *supra,* 529, citing the case *Pub. Citizen Health Research Group v. Nat'l Inst. of Health*, 209 F.Supp. 2d 37, 51. (D.D.C. 2002)

389 As required, to the contrary, by the judicial test developed by the European Ombudsman, see *supra.*

interest"[390]. Moreover, due to the recalled interpretational uncertainties, and the courts' difficulty to line drawing, these judicial tests only end up increasing litigation rates[391], with the result of a long series of oscillating judicial *ad hoc* decisions, that add nothing to the deeper theoretical problem of the relationship between trade secrets rules and those on freedom of information[392].

4.2 The role of administrative agencies as soft regulators in the context of healthcare policy

At this point, a step back should be made: indeed, it has been just demonstrated how courts have come to reverse normative prescriptions, by regarding health and safety information about marketed medicinal products' as a companies' commercial asset worth of protection under trade secret schemes.

However, the judicial stage is only the second one of a litigation *route* that has its starting point in the direct request of the clinical trials protocol to the regulatory agency that has assessed the same test data for marketing purposes. As regards the regulatory agency's access policy, the European case has already been analysed above and, with that, its criticalities revealed.

As far as the American regulatory policies are concerned, a trend very similar to the judicial one should be highlighted. Indeed, as literature has widely underlined[393], despite the enactment in 1967 of the Freedom of Information Act provisions and of further provisions encouraging disclosure, the Food and Drug Administration has tended, to "act cautiously, even fearfully, when dealing with proprietary claims to information" [394], and has hence withheld health and safety data as confidential.

Normative flexibilities and consequent legal uncertainties surrounding

[390] UNLU, *It Is Time: Why the FDA Should Start Disclosing Drug Trial Data*, *supra,* 529.
[391] LEVINE, *The people's trade secrets, supra,* 113.
[392] *Ibid.*.
[393] LYNDON, *Secrecy and Innovation in Tort Law and Regulation, supra*, 23.
[394] *Ibid.*.

transparency provisions have therefore left even administrative agencies as rulers of their own policies, resulting particularly sensitive to the demands of marketing firms for broad confidentiality[395]. To put it in other words, thus, under current normative frameworks and at a pre-litigation stage, disclosure of R&D data has been predominantly a matter of administrative discretion[396], further widening "nondisclosure privileges"[397]. According to this perspective, regulatory agencies' have become managers of pharmaceutical firms' research agenda, and therefore regulators of innovation and entry in the pharmaceutical market[398]. However, as has been noticed[399], agencies have little evidence of the effective commercial value of the test data, being, as public institutions, necessarily external to the regulated industry, with no proper instruments to estimate the effects of releasing the information. Moreover, the only source they can enquire as regards the competitive value of the information at stake are the protocol submitters themselves[400], whose evaluation can evidently not be objective.

Furthermore, the combined analysis of the Clinical Trials Regulation's transparency mandate and the European Medicines Agency policy document have shown how the ultimate definition of what part of clinical trials data have to be considered of commercial value is competence of the regulatory agency[401]. In this light, the high administrative costs needed to evaluate the submitted protocols in order to identify what is commercially valuable, should be considered another factor feeding the scope of

395 SHAPIRO-MCGARITY, *The trade Secret Status of Health and safety testing information: Reforming Agency Disclosure Policies, supra,* 841.

396 Insisting on the point, even if in the context of the safety and efficacy data of chemical products, LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in environmental, health, and safety law, supra,* 501. Cf. *Secrecy and Innovation in Tort Law and Regulation, supra*, 35, stating how regulatory agencies "whose mandate is to foster health protection, end up in the anomalous position of 'sanitising' and protecting industry documents, editing chemical identities and health information out of disclosure systems, and thinking up ways of describing health effects so that no one will figure out what they are".

397 LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in environmental, health, and safety law, supra,* 469.

398 EISENBERG, *The Problem of new Uses,* 5 YALE J. HEALTH POL'Y, L. & ETHICS 717, 730 (2005).

399 LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in environmental, health, and safety law, supra,* 502; LYNDON, *Secrecy and Innovation in Tort Law and Regulation, supra*, 2.

400 *Ibid.*, indeed the "Agencies usually cannot contact the claimant's rivals—the most useful source for fact checking— without risking disclosure".

401 Cf. *supra.*

commercial exemptions to transparency laws, also at the administrative stage[402]. Indeed, the costs of simply claiming information as competitive or proprietary, are in major cases substantially lower[403].
Hence, legal uncertainties pave the way for a highly discretionary administrative decision-making, not always observant to the spirit of transparency laws.

These last acknowledgements lead to deeper, more general considerations, regarding the role of administrative agencies in the European healthcare regulation process and making[404]. Indeed, under such vague legislative schemes, administrative agencies themselves become the developers of "elaborate and flexible mechanisms for interaction of relevant stakeholders"[405] to specific regulatory problems[406].
More specifically, as regards the European framework, the case of clinical trials data transparency regulation offers a perfect example of how the promotion of different policy goals is often deferred by the legislator- also, as it is in this case, implicitly- to administrative institutions[407], working in that way as "reflexive platforms" for the governance[408], and thus

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[402] EISENBERG, *Patent, Product exclusivity and Information Dissemination: How law directs Biopharmaceutical Research and Development,* 72 FORDHAM L. REV. 477 (2003), 481. Cf. LYNDON, *Secrecy and Innovation in Tort Law and Regulation, supra*, 35, noticing how "the administrative process is cumbersome and has greater procedural burdens than parallel common law litigation".
[403] LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in environmental, health, and safety law, supra,* 519.
[404] For a general assessment regarding PERMANAND, *EU pharmaceutical regulation: The politics of policy-making,* Manchester University Press, 2006; MOSSIALOS-PERMANAND-BAETEN-HERVEY, *Health Systems Governance in Europe: The Role of EU Law and Policy,* Cambridge University Press, 2010.
[405] SVETIEV, *European Regulatory Private Law: From Conflicts to Platforms, cit,* 162.
[406] Cf. PERMANAND-VOS, *Between Health and the Market: the Roles of the European Medicines Agency and European Food Safety Authority,* Maastricht Faculty of Law Working Paper 2008/4, online available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1337111.
[407] SVETIEV, *European Regulatory Private Law: From Conflicts to Platforms, cit,* 170. PERMANAND-VOS, *Between Health and the Market: the Roles of the European Medicines Agency and European Food Safety Authority, supra,* 8 ss..
[408] BROUSSEAU-GLACHANT, *Regulators as Reflexive Governance Platforms,* in *Competition and Regulation in Network Industries,* 2011, 12, 3 194 ss.. Cf. EVERSONE-MAJONE-METCALFE-SCHOUT, *The Role of Specialised Agencies in Decentralising EU Governance,* 2000, report presented at the European Commission, online available at http://ec.europa.eu/governance/areas/group6/contribution_en.pdf. On the point also PERMANAND-VOS, *Between Health and the Market: the Roles of the European Medicines Agency and European Food Safety Authority, supra,* 6, referring to a "so-called new 'modes of governance' (NMG) approach to the making and enforcing of rules at EU level. The NMG debate focuses on the shift away from the traditional 'Community Method' *of regulation to embrace softer, more responsive and reflexive modes* (…)". Emphasis added. Talking about an emerging architecture

coordination, of different interests, rights, regulations, and, ultimately, policy goals[409]. In other terms, under a normative framework such as the one at stake, agencies appear to function as a legitimate and competent link between the collective interest and the other stakeholders involved, such as healthcare professionals, industry, patient and consumer organizations, and other non-governmental organizations[410].

Thus, it could be said that when the conciliation between contradictory interests appears to be particularly complex, effective regulation[411] happens in the shadows of the law, along the lines of what literature has defined as a "two stage implementation process"[412]: indeed, on the one side regulators implement the "basic ruling" as shaped by the legislator, improving "feasibility and efficiency of the law", supplying to "the lack of specialized knowledge" of the legislator" itself[413]. On the other side, however, this mechanism leaves free decisional space to agencies, capable of acting as "ex post minimisers" of legislators' strong stances in favour of one policy goal or the other[414], and sometimes ending up reversing normative dictates

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"experimentalist governance in the EU", SABEL-ZEITLIN, *Experimentalist Governance,* in LEVI-FAUR(ed.), *The Oxford Handbook of Governance,* Oxford University Press, 2012, 322 ss..

[409] "The role of regulators is therefore to attempt to ensure both, a sufficient coordination among actors to guarantee the long term dynamic of innovation and redistribution of welfare gains to the various stakeholders". So BROUSSEAU-GLACHANT, *Regulators as Reflexive Governance Platforms, supra,* 195. For a critical view, SVETIEV, *Private Actors and their Advisers in Administrative Agency Networks,* in BAILLEUX-VAUCHEZ, *Exploring the transnational circulation of policy paradigms: Law Firms, Legal Networks and the Production of Expertise in the Field of Competition Policies,* 2014, online available at http://globalgovernanceprogramme.eui.eu/wp-content/uploads/2013/05/21st-June_GGP_EUIEXPLORING-THE-TRANSNATIONAL-CIRCULATION-OF-POLICY-PARADIGMS_21st-June_GGP_EUI.pdf, 22, recalling how "various scholars from different disciplinary perspectives have suggested that these processes of 'agentification' and networking can be constitutionally suspect and can lead to a reduction of national autonomy in administrative as well in private law".

[410] PERMANAND-VOS, *Between Health and the Market: the Roles of the European Medicines Agency and European Food Safety Authority, supra,* 38. Cf. also PERMANAND, *EU pharmaceutical regulation: The politics of policy-making, supra*, 134 ss..

[411] Cf. GERADIN, *The Development of European Regulatory Agencies: Lessons from the American Experience,* in GERARDIN-MUNOZ-PETIT, *Regulation through Agencies in the EU, A new Paradigm of European Governance,* Cheltenham, Edward Elgar, 2005, 215 ss..

[412] BROUSSEAU-GLACHANT, *Regulators as Reflexive Governance Platforms, supra,* 201.

[413] *Ibid.*. Underlining this point also PERMANAND-VOS, *Between Health and the Market: the Roles of the European Medicines Agency and European Food Safety Authority, supra,* 5.

[414] BROUSSEAU-GLACHANT, *Regulators as Reflexive Governance Platforms*, *supra*, 194, even if the perspective adopted by the Authors is radically the opposite: indeed, the Authors argue that regulatory agencies act in order to remedy the "errors introduced by an excessive politicization of the law", and more in general "the sensitivity" of legislators "to pure political strategic lobbying". However, I believe that in the case of vague normative provisions, as the ones examined, also the opposite process that has been illustrated, can be made by regulators.

through evaluation of exemptions favouring private actors[415]. Hence, where hard law cannot properly fulfil its tasks[416], the result is that of a "re-regulation" of the European health(care) issues with internal market policy relevance: literature analysing this phenomenon[417], has therefore regarded the Medicines Agency's action as a fundamental part of what has been defined as the "new EU healthcare governance patchwork"[418], stressing the "resort to more soft mechanisms for deliberation and networking with the various actors"[419].

Against this backdrop, it cannot be overlooked how the pharmaceutical regulatory agencies' ruling over clinical trials protocols' access has until now, even in light of the new policy statements, run contrary to the nature of public institutions of the same agencies, who should have actually been more sensitive to the promotion of the general interest.

In this perspective, a final consideration seems to be necessary. Indeed, many authors have welcomed the above-illustrated subsidiary decision-making architecture, in light of agencies' technical and specialized expertise, that should lead to independent policy choices[420]. However, there's growing literature questioning this alleged independence[421]: also in this regards, the

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[415] In this sense SVETIEV, *Private Actors and their Advisers in Administrative Agency Networks*, *supra*, 21 ss..

[416] Stressing this point, MCKEE-MOSSIALOS, *Health policies and European Law: Closing the Gaps,* 2006, Public Health, online available at http://www.publichealthjrnl.com/article/S0033-3506(06)00189-2/pdf.

[417] PERMANAND-VOS, *Between Health and the Market: the Roles of the European Medicines Agency and European Food Safety Authority, cit, passim.*

[418] This expression has been successfully used by HERVEY-VANHERCKE, *Healthcare and the EU: The Law and Policy Patchwork,* in MOSSIALOS-PERMANAND-BAETEN-HERVEY, *Health Systems Governance in Europe: The Role of EU Law and Policy, supra*, 84 ss..

[419] PERMANAND-VOS, *Between Health and the Market: the Roles of the European Medicines Agency and European Food Safety Authority, supra,* 41.

[420] Cf. European Commission*, European Governance*: *a White Paper*, Brussels, 25 July 2001, online available at http://europa.eu/rapid/press-release_DOC-01-10_en.htm. For the relevant literature see MAJONE, *Two Logics of Delegation: Agency and Fiduciary Relations in EU Governance,* in European Union Politics, 2, 2001, 103 ss.; GROENLEER, *The actual Practice of Agency Autonomy: Tracing the developmental trajectories of the European Medicines Agency and the European Food Safety Authority,* published on 3rd August 2011, Open Forum CES, 5, online available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1904462, underlining how autonomy has been the major reason for the creation of administrative agencies such as the European Medicines Agency. For a general assessment cf. also VOS, *Indipendence, Accountability and Transparency of European Regulatory Agencies,* in GERARDIN-MUNOZ-PETIT, *Regulation through Agencies in the EU, A new Paradigm of European Governance, supra,* 120 ss..

[421] GROENLEER, *The actual Practice of Agency Autonomy: Tracing the developmental trajectories of the European Medicines Agency and the European Food Safety Authority, supra,* 1, noticing how "we do not know much about how EU agencies' *de facto* autonomy comes about". The Author interestingly

European Medicines Agency's attitude as regards test data's transparency requests, reveals a much greater complexity related to the actual "dependence" of the agency's action on the interests of the same actors the agency itself networks [422].

Indeed, the role of "private actors", and more specifically, of pharmaceutical industry, in the decision process should not be underestimated[423]. As it has been outlined[424], it is exactly in front of individual case-decision making, such as the decision over R&D protocols access requests, that the vulnerability of administrative institutions to the capture by the industry becomes less quiescent and more perceptible[425].

5. First Conclusions

In light of these concerns, it becomes clear how, although the same European Commission has declared that agencies "can adopt individual decisions in specific areas *but cannot adopt general regulatory measures*"[426] and that they cannot be granted decision-making powers "in areas in which they would have to arbitrate between conflicting public interests, exercise

distinguishes between "autonomy by design" or "*de jure* autonomy" and an "actual autonomy", noticing how "the close relationship between agencies and other actors make it difficult to point to autonomy in practice".

[422] Stressing this point, SVETIEV, *Private Actors and their Advisers in Administrative Agency Networks*, *supra*, 22-23.

[423] *Ibid.*, 21 ss., focusing on interactions between "authorities and private actors who are the objects" of authorities' policy making, examining in closer detail the 'infrastructure' of EU agency networks and the way in which this infrastructure affects agency's decision-making in individual cases and the interaction with private parties and their representatives and advisers".

[424] *Ibid.,* 23.

[425] Cf. PERMANAND, *EU pharmaceutical regulation: The politics of policy-making, supra,* 129-130, focusing on the European Medicines Agency members' relation to the industry. More specifically the Author cites the notorious 'Poggiolini affair' of 1990, where the head of an agency's committee, who was at the same time also the head of the Italian drug Agency, was accused of taking bribes and gifts by the pharmaceutical industry. Moreover, literature has also underlined how strict political interests and the ones of the industry are often deeply intertwined, and, therefore, how political and 'industrial' control of administrative agencies' policies run much more parallel that one could expect. Indeed it has been noticed hoe "the behaviour of board members is highly dependent on the interests that member states have in the agency's activities. *Countries with large pharmaceutical companies in particular want to keep a watchful eyes on the agency's activities, which has sometimes politicisized discussions in the board."* So GROENLEER, *The actual Practice of Agency Autonomy: Tracing the developmental trajectories of the European Medicines Agency and the European Food Safety Authority, supra,* 10.

[426] European Commission, *European Governance*: *a White Paper, supra,* 5. Emphasis added.

political discretion or carry out complex economic assessments"[427], in practice things are quite different. Indeed, exactly in those regulatory areas where legislation faces the difficulties of coordination between clashing interests, weak normative solutions- such as the one of the general rule-exemption scheme entailed in art. 81(4) of the European Clinical Trials Regulation- leave actually room for the European Medicines Agency's individual decision-making to become the source of *de facto* "general regulatory measures".

In this perspective, the establishment of a mandatory disclosure rule as regards clinical trials data, even if it reflects by the European legislator a greater consideration of the need of additional legal tools for the fulfilment of social distributive goals, hindered by excessive private control over health information[428], will not probably have the expected outcomes in terms of stronger substantial transparency over the safety and efficacy properties of marketed pharmaceutical products. Indeed, as it has been demonstrated above, an analysis of both the Regulation EC 536/2014 and the last EMA's policy document shows how disclosure is very likely to remain a question of administrative discretion, or, at second instance, of short-sighted judicial enforcement.

In this chapter we have shown how decisions over clinical trials data disclosure have been governed by interpretational uncertainties in the definition on the one side of the public interest underlying the examined transparency provisions, and on the other side, of the effective economic value of trials data. It has been also underlined how the approach of a case-to-case balancing and hierarchization of the involved interests leads to provisional legal answers, in most cases supporting industry's requests of strategic information concealment.

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[427] *Ibid.*. For a comment see GERADIN, *The Development of European Regulatory Agencies: Lessons from the American Experience, supra,* 225-226.

[428] HELLER, *The Gridlock Economy: How too much ownership wrecks markets, stops innovation, and costs lives*, New York, Basic Books, 2010.

However, the interpretational short-circuit between general rules and confidentiality exemptions, and the consequent ineffectiveness of legislative declarations characterising transparency regulations, could be overcome by abandoning a strict formalistic approach, and the *aut aut* perspective of the balancing between the two interests involved.

As it will be argued in the next chapter, composition of opposite demands is indeed possible, and necessarily starts from the consideration of the compound value of information generated in the R&D process, *i.e.* the commercial value in respect of the risk of free riding practices, and the social and public value.

This perspective is the starting point for a different outline of the examined topic. The assumption is that the difficult interplay between general disclosure rules and commercial confidentiality exemptions directly stems from the conflict between pharmaceutical firms' rights to protect their commercial confidential information, and the right of European citizens, patients and consumers to be informed about the safety risks of licensed pharmaceutical products. Following these lines of reasoning, the problem of clinical trials data transparency results to be contextualized in a broader field of enquiry: indeed, the conflict of two distinct rights must be in return read as a conflict of two distinct European regulatory sectors, i.e. the laws of intellectual property and the freedom of information[429], both ultimately pursuing different policy goals, respectively regarding the one of steering investments and innovation[430], and the one of protecting individuals' fundamental rights to information, health, and transparent scientific research. Only through an analysis of the structural interaction of the two bodies of law, interpretational ambiguities regarding the implementation of

[429] As far as the European framework is concerned, the set of rules recalled in this chapter are art. 15 TFUE; Regulation EC 1049/2001 on public access to European Parliament, Council and Commission documents (e.g. recital 4), *supra*, and Rules for implementation of the same Regulation, *supra*; art. 80 Regulation EC n. 726/2004 providing Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, *supra*; finally art. 81(4) Regulation EU 536/2014 on clinical trials data, *supra*.

[430] Cf. LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in environmental, health, and safety law, supra,* 467, underlining the increasing importance of information in the contemporary economy, and the consequent development of legal tools for the protection of strategic informational assets.

general disclosure rules against confidentiality exemptions can be definitively addressed.

This same analysis will ultimately lead to a reconsideration of European intellectual property and transparency rules within a legal model that is primarily based on business sustainment rationales, but which ultimately intends to bend R&D incentive goals to public health ones, by mandating information disclosure, once data's economic value has been secured within quasi-proprietary rights managed by the regulatory agency itself. In other terms, public friendly patterns will be shaped not *despite*, but rather *on the basis of* a correct acknowledgment and subsequent legal control of economic forces pressing against the disclosure option, for the sake of safeguarding companies' long and costly R&D processes.

Chapter 2

Secrecy's legal framework

1. Commercially confidential interests over clinical trials data

The definition of which part of clinical trials study reports is to be considered commercially confidential information, therefore falling under the exemption to general transparency rules, ultimately relies on the decision of the European Medicines Agency in assessing the weigh of private and public interests.

The weakness of this mechanism is illustrated by the decrease in the number of documents to which access has been given in 2014, due to "court cases"[431], where pharmaceutical companies succeeded in claiming proprietary rights over the whole amount of data submitted to regulatory authorities in the context of a filing application.

The economic "incentives to claim confidential business information", together with the legislative "ease of doing so", thus appear to be "feeding the expansion of exemptions"[432].

This expansion is to be referred to two main factors: on the one side is the interpretation of the notion of commercially confidential information, on the basis of which the regulatory Agency has to define which part of the clinical study reports is to be revealed or not; on the other side is the existence of other bodies of law, containing provisions specifically aimed at protecting pharmaceutical industry's data[433]. As a result of their combination, the implementation of mandatory results reporting systems of testing results has to be justified in light of the regulators' legal obligation to commercial data protection[434].

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[431] European Medicines Agency, *Mid-year report, January-June 2014, supra,* 7.

[432] LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in an environmental health, and safety law, supra,* 507.

[433] See *Infra.*

[434] Stressing this point LEMMENS- TELFER, *Access to Information and the Right to Health: the Human Rights Case for Clinical Trials Transparency, supra,* 81 ss..

The European Medicines Agency is indeed bound to protect commercial test data both under general trade secret provisions to be possibly enacted in the European Union with the definitive approval of a European Trade Secret Directive, and, more specifically, as a result of the obligation to data exclusivity posed on the same Agency by Directive 2001/83/EC[435], as the result of the transposition of the international obligation of scientific data protection binding WTO Members under art. 39.3 of the TRIPS Agreement.

In this chapter we will hence examine the effectiveness of a general transparency rule such as the one provided by art. 81(4) of the Clinical Trials Regulation[436] as opposed respectively to the forthcoming European discipline of trade secrets, to the TRIPS mandate to scientific test data protection under art. 39.3, and finally to the European data exclusivity provision posed by art. 10 of the Directive 2001/83/EC on medicinal products for human use.

2. Information exclusivities in the context of the intellectual property system - Some general policy considerations

Before examining more in detail the meaning and the economic implications of the regulatory ties allegedly blurring the scope of clinical trials information accessibility, some general considerations occur. Indeed, as the economy shifts from industrial to informational competition patterns[437], also the regulatory framework has undergone a move from invention-based protection towards new *sui generis* forms of information exclusivity[438].

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435 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, *supra.*

436 Regulation EU n. 536/2014, of the European Parliament ad of the Council, of 16 April 2014, on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, *supra.*

437 See REICHMAN, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation,* 53, 6 Vanderbilt Law Review, 2000, 1743 ss.; REICHMAN-UHLIR, *A contractually reconstructed research commons for scientific data in a highly protectionist intellectual property environment,* 66 Law and Contemporary Problems 2003, 315 ss..

438 BRAUN-PUGATCH, *The changing face of pharmaceutical industry and intellectual property rights, supra*, 599 ss..

The structure of the pharmaceutical sector's "safe harbour" from generic rivalry appears to be a complex and hybrid system, in behalf of additional layers of protection and in some cases alternative as regards to patents, strengthening the legal grounds for the concealment of test data underlying new medicinal products[439]. Indeed, apart from patents, companies seem to rely always more on other tools for the protection of their intangible assets that are to be systematically located at the edge of the intellectual property framework[440].

As it will be further demonstrated, the gradual expansion of (quasi)proprietary schemes regarding the protection of information goods in the era of what has been defined as "intellectual capitalism"[441], has led to the introduction in the international- and hence supranational- intellectual property system of new forms of legal protection of business investments that have been critically evaluated by some scholars[442], questioning their actual nature of intellectual proprietary rights- such as it has happened in respect of trade secrecy protection-; or underlining the *sui generis* nature of such a monopoly right in new knowledge in respect of traditional intellectual property tools- such as it has been done with regards to the *sui generis* database protection[443], or with regards to the *sui generis* pharmaceutical data exclusivity[444]. As it has been stated in literature[445], this trend has lead to the proliferation of "hybrid IP regimes" filling "other perceived gaps in the system", with the effect that there are "virtually no products sold on the general products market that do not come freighted up with a bewildering

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439 *Ibid.,* 610.

440 Cf. REICHMAN-SAMUELSON, *Intellectual Property Rights in Data?,* 50 Vanderbilt Law Review (1997), 52 ss..

441 DAVID, Koyaanisqatsi *in Cyberspace,* Stanford Institute for Economic Research, Discussion Paper n. 02-29, online available at http://econwpa.repec.org/eps/dev/papers/0502/0502007.pdf, 5.

442 For a general assessment see ULLRICH, *Expansionist Intellectual Property Protection and Reductionist Competition Rules: a TRIPS Perspective,* in *Journal of International Economic Law,* 7, 2004, 402 ss..

443 Specifically enquiring the issue of database protection REICHMAN-SAMUELSON, *Intellectual Property Rights in Data?, supra,* 64 ss..

444 See *infra.*

445 Cf. ULLRICH, *Expansionist Intellectual Property Protection and Reductionist Competition Rules: a TRIPS Perspective, supra,* 412 ss..

and overlapping array of exclusive property rights that discourage follow-on applications of routine technical know-how"[446].

More specifically, through these peculiar intellectual property tools, and through their *direct* or *indirect* secrecy outcomes, companies' valuable R&D information has been gradually shielded from the free-riding threats of the public domain[447].

It is exactly through consideration of the peculiar "public good" properties of intangible assets regarding scientific knowledge- being scientific information naturally non-rival and with high production and low re-production costs[448]-, that information protectionism tendencies have to be better assessed from the double standpoint of short term provision of other public goods such as health and scientific research, and of long term achievements in terms of innovation and competition[449].

Under these premises, the case of pharmaceutical test data protection appears to be of great paradigmatic significance[450].

Indeed trade secrets and data exclusivity, though very differently structured, turn out to have the same outcomes in terms of blocking the availability of upstream industrial information inputs, with that narrowing the access to the scientific research commons and limiting, as some scholars have widely stressed, the transfer of information technologies in that what has become a

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446 MASKUS-REICHMAN, *The Globalisation of Private Knowledge Goods and the Provatization of Global Public Goods,* in *Journal of International Economic Law,* 7, 2004, 279 ss., 297.

447 BOYLE, *The Second Enclosure Movement and the construction of the Public Domain*, 66 Law and Contemporary Problems 2003, 33 ss., and more generally see STIGLITZ, *Knowledge as a Public Good,* in KAUL-GRUNBERG-STERN, *Global Public Goods: International Cooperation in the 21st Century,* Oxford Scholarship Online, 2003, 75 ss..

448 DAVID, Koyaanisqatsi *in Cyberspace, supra,* 6; DAVID, *The Digital Technology Boomerang: New Intellectual Property Rights Threaten Global "Open Science",* Stanford Institute for Economic Research, Discussion Paper October 2000, online available at http://www-siepr.stanford.edu/workp/swp00016.pdf, 7, "knowledge is not an ordinary commodity; it has several properties that economists identify as those characterising the general class of "public goods"".

449 "As private interests take precedence over public concerns, moreover, we argue that the proliferation of exclusive rights could raise fundamental roadblocks for the national and global provision of numerous other public goods such including scientific research, education, health care, biodiversity environmental protection", and competition, MASKUS-REICHMAN, *The Globalisation of Private Knowledge Goods and the Provatization of Global Public Goods, supra,* 283 ss. and 308. See also DAVID, *The Digital Technology Boomerang: New Intellectual Property Rights Threaten Global "Open Science", supra,* 12 ss..

450 This has noticed also by HILGARTNER, *Potential Effects of a diminishing Public Domain in Biomedical research data,* in ESANU-UHLIR, *The Role of scientific and technical data and information in the public domain,* Washington, The National Academy Press, 2003, 133 ss..

transnational system of innovation and production[451]. This goes in return, from an internal market standpoint, to the detriment of generic producers' market entrance possibilities, and from a broader international economic viewpoint, at the additional expenses of the follower countries' ability to catch up with the pace of technological change[452].

On the other side, nonetheless, in the Pharmaceutical industry, just as in other markets, information secrecy is a source of sustained competitive advantage[453].

In fact, disclosure of trials information could have the effect of granting the competitor commercial benefits provided by products' insight useful for "starting developing the same or a similar medicinal product on their own, using the information and data for their own economic advantage"[454].

As the European Federation of Pharmaceutical Industries and Associations has underlined, the circulation of commercially valuable information could be used in order to develop a similar patented product[455].

Moreover, disclosure could allow competitors, relying on trials data of products marketed in the EU, to obtain a license for a same product in a foreign jurisdiction[456].

The "concealment" of clinical trials data thus serves as a means of avoiding economically inefficient free-riding practices impeding originators to recoup

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451 MASKUS-REICHMAN, *The Globalisation of Private Knowledge Goods and the Provatization of Global Public Goods, supra*, 309 ss..

452 *Ibid.*, 282, stating that "the proliferation of legal monopolies (over knowledge goods) and related entry barriers" would lead to "restraints on competition", consigning "the poorest countries to a quasi-permanent status at the bottom of the technology and growth ladder".

453 Such as the environmental one, for example, LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in an environmental health, and safety law, supra, passim.*

454 EMA, decision of the Ombudsman, no evidence of how insight of the drug development could be possible through the release of CSR.

455 Literature has however pointed out how this risk is in reality quite small, given that patent applications are filed "as soon as industry sees promise in a new compound", thus much earlier than the phase of the conducting of clinical trials. See LEMMENS-TELFER, *Access to Information and the Right to Health: the Human Rights Case for Clinical Trials Transparency, supra,* 24.

456 This is however a more difficult issue of marketing authorisation procedures in developing countries and the impact on them by foreign trade agreements. More specifically literature has underlined how the problemi is to define to which extent the free trade agreements rule over the competitor's rule of test data accessed in a third country. On the issues see SHAPIRO-MCGARITY, *The trade Secret Status of Health and safety testing information: Reforming Agency Disclosure Policies, supra,* 848.

the cost of investment in pharmaceutical development and safety evaluation[457].

Hence, the innovators' incentive *rationale* poses strong grounds as to the justification for the establishment of peculiar forms of protection regarding those companies' intangible assets that have a strategic role in the final product development.

However, as in the case of the patent system, a line has to be drawn between the area of protection that has positive incentive effects[458], and the area in which the same intellectual property tools are used in a distortive manner, delaying genuine competition through market predominance, and therefore affecting consumers' rights to information [459] and hence individual's fundamental rights to access to medicines[460].

These traditional tensions in the realm of legal and economic discussions concerning intellectual property policy[461], become particularly delicate for the protection of clinical trials data, *i.e.* protection of mere information.

In fact, pursuant to international standards of protection, such as the ones established in art. 39 of the TRIPS Agreement, regulatory agencies are required to maintain the confidentiality of test data under certain conditions[462].

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457 CORREA, *Protection of Data Submitted for the registration of Pharmaceuticals: Implementing the standards of the TRIPs Agreement,* Geneva, South Centre Pub., 2002, 12.

458 GOREN, *Pharmaceutical innovation and intellectual property rights: a global public good?,* in PUGATCH, *The IP property debate, Perspectives from Law, Economics and Political Economy,* Cheltenham, Edward Elgar Publishing, 2006, 159 ss..

459 For the examination of the theory considernig EC competition law's final objective, not competition as an institution, but rather the promotion of efficiency and consumer's welfare, see DREXL, *The relationship between the Legal exclusivity and Economic Market Power- Links and Limits,* in GOVAERE-ULLRICH, *Intellectual Property, Market Power and the Public Interest,* Brussels, Peter Lang, 2008, 171-172.

460 *Ibid.,* 162, stating that "on the one hand society wants to provide adequate reward/incentive to the innovator to continue to innovate and bring the results to patients; while on the other hand, we ensure society's maximal access to such innovations". Specifically as regards the issue of the access to medicines, see FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement,* 444 ss.. For a more general overview of the issue see MUZAKA, *Politics of Intellectual Property and Access to Medicines,* Basinstoke, Palgrave Macmillan, 2011, 18 ss..

461 On this issue see, RAMELLO, *Intellectual property, social justice and economic efficiency: insights from Law and Economics,* in FLANAGAN-MONTAGNANI, *Intellectual Property Law: Economic and Social Justice Perspectives,* Cheltenham, 2010, 1 ss..

462 FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra*, 446.

This norm is the international source of both the (supra)national trade secret protection, and the pharmaceutical data exclusivity.

As far as trade secrecy protection is concerned, it will be further shown how trade secrets, consisting in mere information secrecy as required by art. 39.2 TRIPS, appear to address only business sustainment tasks, in that way substantially clashing with economic and social needs of scientific information availability.

Things are quite different when it comes to data exclusivity regimes. Indeed, it is useful to anticipate that the international confidentiality requirement established under art. 39.3 TRIPS has been transposed at a European level in two main obligations to test data protection, weighing on drugs regulatory agencies and defined by literature as the non-disclosure and the non-reliance obligations[463].

The protection provided by data exclusivity has thus a more layered, structured natured as compared to trade secret protection: indeed, according to the first obligation, the regulatory agency must not permit generic companies to access to the application dossier, whereas under the second, the authorities themselves must not rely on the originator's dossier in order to release other marketing authorisations for similar products[464].

These two distinct obligations regarding clinical trials data perfectly reflect the two-folded nature of the information entailed in research protocols, namely the informational and the regulatory one.

If combined, the non reliance and the non-disclosure obligations would provide an extremely extensive protection of the strategic data produced in the R&D race by research-based companies[465].

Indeed, the non-reliance obligation faced by regulatory authorities appears to serve the necessary incentive rationale, for the sake of which a temporary market exclusivity is tolerated even at the cost of an initial low level of access to medicines caused by the increase of price heights.

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[463] PUGATCH, *Intellectual Property, data exclusivity, innovation and market access, supra,* 7.

[464] *Ibid.*.

[465] For the economic significance of test data see *supra* chapter 1.

However, the additional non-disclosure obligation that innovators want to directly derive from the non-reliance requirement, turns out to have detrimental consequences, both from a public health perspective, creating a climate of "secrecy and mistrust" that affects the "consumer's perception as to the accurateness and safeness of the pharmaceutical product"[466]; and also from a competition standpoint, being disclosure an immediate obstacle to the spread of the knowledge potentially stirring innovation's evolution[467]: this leads in return to a delay of the competition game also besides the strict term of protection[468], with substantial losses in terms of the advancement of technological progress.

From this latter point of view, invoking intellectual property protection, in order to justify scientific information secrecy turns out to be highly contradictory, given that the main driving force of competition and technological progress itself is exactly the sharing of this same information[469]: as it has been stated "excessive private control of health information (…) creates pockets of static information within a system that needs to be dynamic (…). Secrecy imposes costs that become imbedded in the infrastructure, and opportunities to develop better technologies and economic patterns are lost"[470].

Moreover, economic analysis has shown how a "hyper-appropriation" of scientific valuable information, and the exclusionary effects related to it, produce serious adverse outcomes also in terms of overall market efficiency, being knowledge itself a fundamental economic resource[471].

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[466] Cf. CORREA, *Protecting Test Data for Pharmaceutical and Agrochemical Products Under Free Trade Agreements, supra,* 86, further stating that "the public is entitled to know whether the product contains certain substances. (…) This information may also bear on test data"; ID., *Protection of Data Submitted for the registration of Pharmaceuticals: Implementing the standards of the TRIPs Agreement, supra,* 24. EISENBERG, *Patents, Product Exclusivty, and Information Dissemination: How law directs biopharmaceutical research and development,* 72 Fordham Law Review 2003, 477 ss., 482; LEMMENS-TELFER, *Access to Information and the Right to Health: the Human Rights Case for Clinical Trials Transparency, supra,* 85.

[467] RAMELLO, *Intellectual property, social justice and economic efficiency: insights from Law and Economics, supra,* 3 ss..

[468] Global intellectual property center- US chamber of commerce, *Heading in a different direction? The European Medicines Agency's Policy on the Public Release of Clinical Trials Data, supra,* 7.

[469] LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in an environmental health, and safety law, supra,* 467.

[470] *Ibid.,* 4-5.

[471] RAMELLO, *Intellectual property, social justice and economic efficiency: insights from Law and Economics, supra, passim.*

Indeed, secrecy- meaning the blocking of access to users-, by eroding economic freedom of third parties[472], inevitably freezes the cumulative process of production technology, with important reflexes on the field of social justice[473]. As it has been noticed, "the creation of new property rights for a social entity such as knowledge addresses the concept of social justice, since it impacts not only on the distribution of knowledge and rights over knowledge, but also the social relationships, communication processes and self-expression that access implies"[474].

In the first chapter it has been demonstrated that the core of the issue concerning clinical trials data's disclosure is to be found in the balancing between public interests, directly related to fundamental rights and freedoms, and private ones, regarding the protection of commercially sensitive information.

However, a deeper understanding of the forms of protection of these pharmaceuticals' commercially sensitive data provided by the international and European normative framework offers precious tools in order to shift the core of the issue regarding clinical trials data disclosure from an *interpretational* to a *structural* standpoint. Indeed, as it will be shown, the issues at stake will be correctly addressed only by examining the connection between the two regulatory frameworks- concerning both disclosure and protection of commercially valuable information- even before addressing any possible interpretation capable of narrowing the impact of the exemptions to the general disclosure rule.

Contrary to expectations, the latter normative framework provides no direct obstacles for test data disclosure. As counterintuitive as it might appear, at a deeper understanding, it is exactly from the layout of the *sui generis* intellectual property protection of data exclusivity, and more precisely from

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[472] See GHIDINI, *Innovation, Competition and Consumer Welfare in Intellectual Property Law, supra,* 19.

[473] Cf. RAMELLO, *Incentives, Efficiency, and Social Justice: the Strange Case of Intellectual Property and Knowledge*, POLIS Working Paper, October 2008, online available at http://www.serci.org/2007/Ramello.pdf., 4 ss..

[474] RAMELLO, *Intellectual property, social justice and economic efficiency: insights from Law and Economics, supra* 19.

the non-reliance obligation it entails, that direct positive grounds for information sharing can be found.

It is indeed thanks to this quasi-proprietary right[475] managed by the regulatory agency, that reporting systems of pharmaceuticals' safety data can function without the externality of nullifying companies' investments in R&D knowledge and subsequently the market advantages awarded by it.

3. Clinical Trials Data as trade secrets under the Proposed European Trade Secret Directive

Need we say that the assessment made by the regulatory agency of what has to be considered commercially confidential information, risks to be further oriented towards the non-disclosure option, in light of the broad definition of commercially confidential information contained in the "Proposal for a directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure"[476], according to which trade secret is to be considered "any information that is secret, has commercial value because it is secret and has been subject to reasonable steps to keep it secret"[477]. Such a definition seems to be the exact transposition on supranational level of the provision of art. 39.2 TRIPs imposing on WTO Members States the obligation to protect undisclosed information from a use that is "contrary to honest commercial practices (…)"[478].

In literature it has been underlined how this broad definition could provide a strong legal basis for pharmaceutical companies to refuse compliance to transparency policies[479], with the ultimate intent of preserving their

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[475] This concept will be better explained *infra*.

[476] Proposal for a Directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets), against their unlawful acquisition, use and disclosure, *supra*.

[477] *Ibid.,* Art. 2.

[478] See BRONCKERS-MCNELIS, *Is the Eu obliged to improve the protection of trade secrets? An inquiry into TRIPS, The European Convention on Human Rights and the EU Charter of Fundamental Rights,* in *European Intellectual Property Review,* 2012, 34, 10, 673 ss.. For a comment on the TRIPs provision of art. 39 see *infra*.

[479] Cf. Corporate Europe Observatory, *EU draft Trade Secrets Directive threats to free speach, health, environment and worker mobility- Joint Statement,* published on the 23rd March 2015, online available at

competitive position against rivals[480]. Indeed, it has been stated how the scope of the trade secret protection is capable of comprehending "any type of information" [481], in respect of which commercial value is alleged[482]. Indeed, the text seems not to ask a specific proof of commercial value, given that the commercial value itself is derived from the information being secret. Hence, the proof of secrecy is the only one required for the qualification of a certain information asset as a trade secret[483].

Limiting the analysis to the mere definition of trade secrets, thus, would lead to the acknowledgment of a structural incompatibility of trade secret protection with mandatory disclosure provisions, contrary to what happens as regards patent protection, where disclosure obligations directly counterbalance strong exclusive rights[484]. Indeed, disclosure of a trade secret to a third party usually takes the form of a non-disclosure agreement, imposing on the same party who has exceptionally been given the sensitive information, an enforceable duty of confidence[485].

In this regards, the latest economic literature[486] has interestingly observed that together with the growing importance of information assets in

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http://corporateeurope.org/power-lobbies/2015/03/eu-draft-trade-secrets-directive-threat-free-speech-health-environment-and.

480 Cf. GILOTTA, *The Conflict between Disclosure in Securities Markets and the Firm's need for confidentiality: Theoretical Framework and Regulatory Analysis,* published on 12th March 2012, online available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1709334, 13.

481 MYERS, *Principles of Intellectual Property Law,* West Academic Publishing, 2012, 363. Cf. SOUSA-SILVA, *What exactly is a trade Secret under the proposed Directive?, supra*, 932, commenting the vague definition given by the Proposed Directive, and concluding that "the broad meaning of 'trade secret' in the proposed directive may lead to the conclusion that, in a certain sense, 'anything worth misappropriating, is worth protecting', although specific circumstances may dictate otherwise".

482 This is particularly stressed by APLIN, *A Critical Evaluation of the Proposed EU Trade Secret Directive,* King's College Research Papers Series n.2014-25, published on the 18th July, online available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2467946, 13-14, stating that "the proposed Directive should seek to clarify that trade secret is limited to technical or commercial information, either through amending the recitals or including this language in article 2(1). Cf. SOUSA-SILVA, *What exactly is a trade Secret under the proposed Directive?, supra*, 927-928. See also HULL, *Trade Secret Licensing: The Art of Possible,* in *Journal of Intellectual Property Law and Practice,* 2009, 4, 3, 203 ss..

483 Hence, it seems that the commercial value can be merely potential, as some literature affirms. Cf. CARVALHO, *The TRIPS Regime of Antitrust and Undisclosed Information,* The Hague, Kluwer Law International the Hague, 2008, 233; *contra* , affirming the need of proof of actual economic value, CORREA, *TRIPS-A Commentary,* Oxford, Oxford University Press, 2007, 373.

484 GILOTTA, *The Conflict between Disclosure in Securities Markets and the Firm's need for confidentiality: Theoretical Framework and Regulatory Analysis, supra,* 20.

485 See HULL, *Trade Secret Licensing: The Art of Possible, supra,* 209-210. It is interesting to notice how some scholars have tried to underline the disclosure effects of such non disclosure agreements, although restricted between the contracting parties. For a survey on the issue European Commission, *Study on Trade Secrets and Confidential Business Information in the Internal Market, supra,* 86-87.

486 GOY-WANG, *Does knowledge tradeability make secrecy more attractive than patents? An analysis of IPR strategies and licensing, Oxford Economic Papers,* 68, 2016, 64 ss..

competition interactions, R&D based companies increasingly rely on trade secrets schemes for the protection of their know-how, and less on patents for the protection of their final products[487]. From a purely economic viewpoint, thus, it has been demonstrated that for firms, secrecy, and the competitive advantage that it shields, is more valuable than the market exclusivity gained through patents[488]. This is to be also explained on the basis of the enormous market potential of trade secrets, that originators can profitably sell on the market to other competing firms, through the mentioned non-disclosure agreements, that assume in their 'external' dimension[489] the form of very valuable trade secret license agreements: market mechanisms based on knowledge exclusivity[490], and on the same knowledge tradability, are expanding in a way that ends up even overwhelming the need for traditional legal intellectual property rights over other tangible assets[491].

It is hence not without grounds that some scholars have noticed how, in the expanding market area of trade secrets[492], the tension between disclosure and confidentiality reaches its highest levels[493].

However, a deeper look into the shape of trade secret protection shows how the proposed European trade secret discipline leaves open significant gaps, capable of better addressing- although not definitely and convincingly

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487 Cf. BRAUN-PUGATCH, *The changing face of pharmaceutical industry and intellectual property rights*, *supra,* 605. It must be however stressed that the growing reliance on trade secret protection, at the expense of patent protection, is due not only to the strategic importance of R&D information, but is to be referred also to other factors, such as the higher costs of a patent application, and the lack of time limits, that trade secret protection, contrary to patents, do not have. See European Commission, *Study on Trade Secrets and Confidential Business Information in the Internal Market, supra,* 91.

488 GOY-WANG, *Does knowledge tradeability make secrecy more attractive than patents? An analysis of IPR strategies and licensing, supra,* 66.

489 As opposed to the 'internal dimension' of NDA when the other contracting party is an employee of the same firm, Cf. SOUSA- SILVA, *What exactly is a trade Secret under the proposed Directive?, supra*, 927.

490 THOMAS, *Proprietary Rights in Pharmaceutical Innovation: issues at the Intersection of Patents and Marketing exclusivities, supra,* 5.

491 FORAY, *Economics of Knowledge*, Cambridge, Mit Press, 2004, 141ss., stressing how the shift from an invention based economy towards a knowledge based one, is to be associated with a turnaround within the dynamics of intellectual property policies, traditionally aimed at exploiting knowledge, and now used to shrink the scope of the public domain.

492 Cf. European Commission, *Study on Trade Secrets and Confidential Business Information in the Internal Market, supra,* 87-88.

493 GILOTTA, *The Conflict between Disclosure in Securities Markets and the Firm's need for confidentiality: Theoretical Framework and Regulatory Analysis, supra,* 20.

solving- the problem of the relationship between information disclosure and retention, respectively under transparency and confidentiality rules.

3.1 The scope of trade secret protection: "unlawful acquisition, use and disclosure" of undisclosed data

The specificities of trade secret protection in the context of intellectual property regulations has been widely commented in literature[494], and still the statements contained in the Draft Proposal For a European Trade Secret Directive do not offer decisive grounds for a solution to the problem of whether trade secrets should be considered or not a form of companies' proprietary rights *stricto sensu* and the debate is still on-going[495]. The option in favour of one interpretative solution or the other has important practical outcomes as regards the scope and enforcement of the trade secret protection itself, especially against third infringing parties[496].

However, despite the systematic preference for a stronger or relatively weaker trade secret protection, its basic scheme is that against the "unlawful acquisition, use and disclosure of trade secrets", or more precisely, of undisclosed information.

Hence, it is evident how trade secret protection, and subsequently trade secret enforcement, is confined only to cases of conducts that are to be

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494 EU Directorate General for Internal Policies- *Trade Secrets* , *supra*, 4, recalling the European Court of Justice ruling in *Microsoft Corp. Vs. Commission*, case T-167-08, where the Court mentioned trade secret as a different category from intellectual property rights. The referral of trade secret protection to the sector of intellectual property law has been put into question with the alternative of referring it to the area of unfair competition law. In this sense SOUSA-SILVA, *What exactly is a trade Secret under the proposed Directive?, supra*, 923. See also DIAS NUNES, *The European Trade Secrets Directive (ETSD): Nothing new under the Sun?,* published on the 25th July 2015, Lex Research Topics in Innovation 2015-1, online available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2635897. Italy is one of the few Member States that has adopted a clear position as regards the consideration of the "informazioni segrete" as intellectual property rights. See SCARPA, *Valore industriale dell'informazione societaria nel mercato,* in *Rivista di diritto industriale,* 2, 2015, 71 ss..

495 This is the thesis of APLIN, *Right to Property and Trade Secrets,* in GEIGER, *Research Handbook on Human Rights and Intellectual Property,* Cheltenham, Edward Elgar, 2015, 232 ss.. For an opposite view see BRONCKERS-MCNELIS, *Is the Eu obliged to improve the protection of trade secrets? An inquiry into TRIPS, The European Convention on Human Rights and the EU Charter of Fundamental Rights*, *supra,* 673 ss.. For a general assessment see HULL, *Trade Secret Licensing: The Art of Possible*, *supra*, 204.

496 Literature has indeed argued how the most effective reason for a qualification in the sense of property right of trade secrets, is to be referred to the enhancement of remedies available to the owner of information whose rights have been infringed especially by third parties. This is the theory proposed in early years in the well known article by KOHLER-PALMER, *Information and Property,* in PALMER-MCKENDRICK, *Interests in Goods,* London, Lloyd's of London Press, 1993, 187-206.

considered "unlawful". To put it in other terms, and as it is clearly to be derived from art. 3 of the proposed Directive[497], the unlawfulness of conducts is to be read as a *sine qua non* requirement of trade secret protection, in the same way that patent law requires the features of novelty, non-obviousness and inventive step for the enactment of protection[498]. Unfortunately, if this reasoning could have led to a restriction of the scope of protection, the consideration of the definition of the unlawfulness given by the proposed Directive shows to the contrary how the extent of secrecy protection is incredibly broad: following art. 3 the proposed legislative text, not only is the use or disclosure of a commercially sensitive information to be considered unlawful in case of "breach of a confidentiality agreement or any other duty not to disclose the trade secret"[499] or of "breach of a contractual or any other duty to limit the use of the trade secret"[500] or of conducts that are "contrary to honest commercial practices"[501], but also in case of any "*unauthorised access to, appropriation of, or copy of any documents, objects, materials, substances or electronic files (…) containing the trade secret (…)"* carried out "*without the consent of the trade secret holder"*[502]. This means that the unlawfulness

[497] Art. 3 of the Proposal for a Directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets), against their unlawful acquisition, use and disclosure, *supra*, "Member States shall ensure that trade secrets holders are entitled to apply for the measures, procedures and remedies provided for in this Directive in order to prevent or obtain redress for, the unlawful acquisition, use, or disclosure of a trade secret".

[498] Commenting the large definition of unlawful acquisition provided by art 3.3 of the proposed Directive, see DIAS NUNES, *The European Trade Secrest Directive (ETSD): Nothing new under the Sun?*, PAG 14.

[499] Cf. art 3, 3 lett. b of the Proposal for a Directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets), against their unlawful acquisition, *supra* .

[500] *Ibid.,* Art. 3,3 lett. c. It is interesting to notice how case law has recognised as unlawful also the disclosure of trade secrets occurred at a pre-contractual stage, in light of the recent concept of "parasitism", in light of which protection is given to sensitive information exchanged during the pre-contractual period, even if the parties are not in competition with each other. Cf. G'SELL-DURAND BARTHES, *Report on the protection against unlawful appropriation of trade secrets and confidential commercial information,* A Report for the European Commission, submitted by Fondation pur le Droit Continental, online available at http://www.fondation-droitcontinental.org/en/wp-content/uploads/2015/06/EN-Synth%C3%A8se-de-rapport-secrets-format-A5-version-definitive.pdf, 3.

[501] Art. 3,2 lett.b of the Proposal for a Directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets), against their unlawful acquisition, *supra.* For a comment on the possible meanings of the notion of unfair commercial practices see BRONCKERS-MCNELIS, *Is the Eu obliged to improve the protection of trade secrets? An inquiry into TRIPS, The European Convention on Human Rights and the EU Charter of Fundamental Rights*, *supra,* 678 ss..

[502] Art. 3,2 lett. a of the Proposal for a Directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets), against their unlawful acquisition, *supra.* Emphasis added.

of a trade secret's use occurs, according to the proposed Directive, every time the trade secret holder doesn't give its consent.

This statement is of particular importance for our purposes, firs of all because it reflects how trade secret protection moves towards absolute protection of an immaterial asset *as such*, that is very similar to a property right[503], despite the declarations in the recital 10 of the same proposed Directive affirming that its "provisions (…) should not create any exclusive right on the know-how or information protected as trade secrets"[504]; secondly, in light of the above mentioned provisions, the disclosure, carried out by the European Medicine Agency of a certain test data set, to which the originator has not given its consent to, would be regarded as unlawful, thus protectable under the trade secret protection.

The fact that the transparency obligation entails an express commercial confidentiality exemption, also prevents to affirm that in front of a mandatory reporting obligation, companies cannot refuse to grant their consent, being to the contrary obliged to it.

There is however more. Indeed, under the proposed set of rules, if the European Medicines Agency would publish clinical trials data without research-based companies' consent, and hence *unlawfully*, trade secret infringement liability would also fall upon third parties, e.g. researchers or consumers that subsequently would handle the pharmaceutical test data as a consequence of their right to access an open database, knowing that the regulatory agency didn't have the companies' permission to publish the sensitive data[505]; and also upon generic companies that would "produce, offer or place on the market infringing goods", *i.e.* goods that have been

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503 Cf. APLIN, *Right to Property and Trade Secrets, supra,* 232 ss..

504 *Id.*, Recital 10, with regards to independent discovery and reverse engineering practices that still remain possible.

505 Cf. Art. 3.4 of the Proposal for a Directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets), against their unlawful acquisition, use and disclosure, *supra*, considering unlawful "the acquisition, use or disclosure of a trade secret shall also be considered unlawful whenever a person, at the time of acquisition, use or disclosure, knew or should, under the circumstances, have known that the trade secret was obtained directly or indirectly from another person who was using or disclosing the trade secret unlawfully within the meaning of paragraph 3".

produced and marketed on the basis of the trade secret knowledge, while knowing that the accessed information wasn't allowed to be published[506].

In light of these remarks, it is clear that reading the commercial confidentiality exemption provided by the Clinical Trials Regulation 536/2014, as a door open for the enactment of trade secret protection, is destined to nullify the transparency rule expressed by the same Regulation[507].

3.2 Art. 4.2 of the proposed Trade Secret Directive and the *fair use* of undisclosed data

The possible application of the broad notion of trade secrets in the judicial evaluation of confidentiality exemptions' could be nonetheless prevented through the recognition of specific areas of trade secrets' *fair use*.

In this light it is interesting to notice how American literature has been trying to define a *fair use* doctrine also as regards trade secrets[508], this being a very difficult interpretative operation given the fact that the Uniform Trade

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[506] *Ibid.*, Art. 3.5, considering unlawful "The production, offering or placing on the market of infringing goods, or import, export or storage of infringing goods for those purposes, shall also be considered an unlawful use of a trade secret when the person carrying out such activities knew, or should, under the circumstances, have known that the trade secret was used unlawfully within the meaning of paragraph 3". See also recital 17, affirming how "a trade secret may be unlawfully used to design, manufacture or market goods, or components thereof, which may spread across the internal market, thus affecting the commercial interests of the trade secret holder and the functioning of the internal market. In those cases and when the trade secret in question has a significant impact on the quality, value or price of the resulting good or on reducing the cost, facilitating or speeding up its manufacturing or marketing processes, it is important to empower judicial authorities to order effective and appropriate measures with a view to ensure that those goods are not put on the market or are removed from it". For a comment see DIAS NUNES, *The European Trade Secrets Directive (ETSD): Nothing new under the Sun?, supra,* 13-14 and APLIN, *A Critical Evaluation of the Proposed EU Trade Secret Directive, supra,* 23-24, specifying how the notion of "infringing goods has to be referred to the fact that the goods, or better said, the development of such goods, "have significantly benefited from trade secrets unlawfully acquired, used, or disclosed". The Author underlines the breadth of such a notion of infringing goods, could lead to a considerable expansion of trade secret infringement liability.

[507] Cf. European Corporate Observatory, *Trade Secret Protection, A new Right to Secrecy for Companies, and a dangerous EU legislative Proposal which must be rejected,* published on 30th March 2016, online available at http://corporateeurope.org/power-lobbies/2016/03/trade-secrets-protection, mentioning the recent case of a man died in France after a clinical trial, and the subsequent refuse of the pharmaceutical company to disclose the trial protocol, by invoking trade secret protection over the information. The article concludes that "with the high financial penalties foreseen in the text for trade secret disclosure without their owners' consent, companies will be given an additional argument to threaten public authorities if these would want to publish these studies".

[508] VARADARAJAN, *Trade Secret Fair Use,* 83 Fordham L. Rev. (2014), 1401 ss..

Secret Act does not mention any case of "lawful" acquisition, use or disclosure of a trade secret and only defines what consists a case of "misappropriation by improper means"[509].

To the contrary, an analysis of the Proposed Trade Secret Directive shows how the European legislator has taken into account also information transparency concerns within the same Directive. In this perspective, a link between commercial confidentiality and mandatory disclosure rules seems to be possible, and disclosure options at the expense of information obscuration practices could be argued, as it has be done with privacy concerns, through evaluation of the reference to freedom of information and to the public interest expressly mentioned in the text[510].

More specifically, art. 4 of the Proposed Directive takes into account specific cases exempted from the prohibition faced in art. 3.

Amongst the so established fair uses of trade secrets, there are a few hypotheses that seem to perfectly respond to information transparency demands regarding pharmaceutical test data.

Indeed, the Proposed Directive establishes typical situations in which the "acquisition" and hence use and disclosure of a trade secret is to be considered lawful, and therefore falling outside the scope of trade secret protection and of the Proposed Directive's regulation. If art. 4.1 regards exemptions of *substantive* nature, such as the "independent discovery or creation" or reverse engineering acts that have to be considered lawful *as such*, the following paragraph of art. 4 provides exemptions that are rather to be considered of *procedural* nature, this meaning that these exemptions regard cases that would have been considered unlawful in absence of a normative specification.

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[509] See DIAS NUNES, *The European Trade Secrets Directive (ETSD): Nothing new under the Sun?, supra,* 16.

[510] Cf. the Proposal for a Directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets), against their unlawful acquisition, *supra*, at recital 11, stressing that "in line with the principle of proportionality the measures, procedures and remedies intended to protect trade secrets should be tailored to meet the objective of a smooth-functioning internal market for research and innovation, in particular by deterring the unlawful acquisition, use and disclosure of a trade secret, *without jeopardising or undermining fundamental rights and freedoms or the public interest, such as public safety, consumer protection, public health (…) protection (…)*". Emphasis added.

It is exactly with these exemptions that the European legislator has solved the balance between commercial and public transparency interests in favour of the latter. Indeed, the provision of art. 4.2 affirms how trade secret protection, and thus "the measures, procedures and remedies provided for" in the proposed Directive, does not apply when the sensitive information is used or disclosed "*(a) for making legitimate use of the right to freedom of expression and information"* such as the right to be informed about a pharmaceutical marketed products' features[511]; "*(c) for the purpose of fulfilling a non-contractual obligation*" as the one entailed in art. 81.4 of the Clinical Trials Regulation[512]; and finally *"(e) for the purpose of protecting a legitimate interest*".

Literature commenting these normative provisions has critically stressed the breadth and vagueness of these exemptions, whose scope appears to be very poorly defined, given for example the absence of any indication of what has to be considered a "legitimate interest". In this regards, some scholars[513] have criticised also the wording of "legitimate interest", claiming that the general clause of the "public interest" would have been more appropriate although posing, again, the same interpretative problems of scope definition.

However, although these critics perfectly suit the uncertainties governing legislative solutions in those regulatory areas where opposite animated branches of law collide[514], these exemptions appear to substantially address the case of the establishment of mandatory pharmaceutical test data reporting systems.

Indeed, the relationship between the two different regulatory sector, *i.e.* on the one hand the transparency rule and on the other the one of trade secret protection, is to be defined by the combination between general rules and the exemptions posed to them, as it has been done in respect of the

511 Cf. also recital (10b) stressing that "While this Directive provides for measures and remedies which may consist in preventing the disclosure of information in order to protect the confidentiality of trade secrets, it is essential that the exercise of the right to freedom of expression and information (…) be not restricted (…)". *Ibid.*.

512 Regulation EU n. 536/2014, *supra.*

513 DIAS NUNES, *The European Trade Secrets Directive (ETSD): Nothing new under the Sun?, supra,* 20.

514 Cf. LYNDON, *Trade Secrets and Access in Environmental Law*, in DREYFUSS-STRANDBURG, *The Law and Theory of Trade Secrets- A contemporary Research Handbook,* Cheltenham, Edward Elgar, 2011, 442 ss..

personal data protection concerns equally posed by the Clinical Trials Regulation.

Also in this case, the apparent contradiction of normative dictates can be interpretatively solved through the proper combination of general rules and exemptions posed by the two bodies of law examined.

As it has been demonstrated indeed, the commercial confidentiality exemption posed by art. 81.4 of the Clinical Trials Regulation should be read and substantiated in respect of the general rule of trade secret protection established by the proposed Trade Secret Directive. The acknowledgement of a very broad secret protection is therefore automatically destined to broaden the effectiveness of the confidentiality exemption. However, the exemptions protecting freedom of information and the fulfilment of a non-contractual obligation posed by the proposed Trade Secret Directive itself, lead back to the starting point of the general rule of clinical trials data transparency, ending up strengthening its effectiveness.

Hence, the circle of this complex legal structure appears to close itself in favour of the disclosure obligation posed by the general rule of art. 81.4 of the Clinical Trials Regulation.

Differently said, trade secret protection's confinement to the case of "unlawful acquisition, use, or disclosure", substantially unfolds the problem of the tenancy of legal mandatory disclosure obligations regarding commercially sensitive information against trade secret protection, in the sense that trade secret protection itself results, in light of the proposed exemptions, *ab origine* inconsistent with companies' mandatory reporting duties. Indeed, in light of specific information reporting obligation posed by the law- such as regards pharmaceutical trials data-, *trade secret protection should not technically apply*.

In this light recitals 9(a) and 9(b) result of decisive importance for our purposes, by declaring that the proposed Directive "*should not affect the application of Union or national rules that require the disclosure of information, including trade secrets, to the public or to public authorities, the rules that allow public authorities*

to collect information for the performance of their duties or rules that allow or require any further disclosure by those public authorities of relevant information to the public (…)[515] and that "the acquisition, use or disclosure of trade secrets, whenever imposed or permitted by law, *should be treated as lawful for the purpose of this Directive* (…)"[516].

Yet, uncertainties seem to re-emerge in front of the statement contained in the same recital 9(b), where the European legislator immediately appears to retract the above recalled assertions, by affirming that the eventual disclosure of sensitive information "*should nonetheless be without prejudice to any obligation of confidentiality as regards the trade secret or any limitation as to its use that Union or national law may impose on the recipient or acquirer of the information"*[517] , going on stating that "*in particular, this Directive should not release the public authorities from the confidentiality obligations to which they are subject in respect of information passed on by holders of trade secrets*"[518].

An accurate analysis of the proposed Trade Secret Directive has shown how the normative text recognizes some areas of *lawful* use of trade secrets in respect of a "non-contractual obligation" to disclose posed by the Clinical Trials Regulation.

However, the last cited recital seems to call back the regulatory agency's confidentiality obligation that the exceptions provided by art. 4.2 of the proposed Directive, had posed outside the scope of trade secret protection. Vacuum out the trade secret protection at night, and there is it again in the morning. Interpretative uncertainties will have to be managed by both regulatory agencies and judicial courts.

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[515] Recital 9(a) of the Proposal for a Directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets), against their unlawful acquisition, *supra*, goes on stating that "This concerns in particular rules on the disclosure by the Union's institutions and bodies or national public authorities of business-related information they hold pursuant to Regulation (EC) No 1049/2001 of the European Parliament and of the Council, Regulation (EC) No 1367/2006 of the European Parliament and the Council and Directive 2003/4/EC of the European Parliament and the Council or to other rules on public access to documents or on the transparency obligations of national public authorities".

[516] Recital 9(b) of the Proposed Trade Secret Directive, *supra*.

[517] *Ibid.*. Emphasis added.

[518] *Ibid.*. Emphasis added.

For now, the outcomes of an eventual definitive approval and subsequent enactment of the proposed Trade Secret Directive, as regards the trade off between sensitive information protection and disclosure, are still widely unclear.

This is exactly what the European legislator seems to have perceived, by demanding to the Commission the redaction of a specific report, to be completed four years after the end of the transposition period of the proposed Directive, through which the "possible effects of the application of this Directive on research and innovation (…) and on the exercise of the right of the freedom of expression and information"[519] will have to be taken into account.

Out of the box of trade secret protection technicalities, the scope of the trade secret exemption may still be narrowed in the face of practical phenomena: indeed, the large definition of trade secrets provided by the Proposal for a Directive must be read in light of the necessarily temporary dimension of commercial interests over data.

In fact, if only secret- that is to say undisclosed- information can enjoy trade secret protection, as soon as the information is disclosed, the trade secret protection itself breaks down[520].

As far as test data are concerned, some scholars have underlined how the competitive sensitiveness of the information embedded in trial protocols is naturally destined to decline, as a consequence of the product or process being known in the industry, and because over time information inevitably becomes visible to other market players[521].

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[519] Art. 17.2 of Proposal for a Directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets), against their unlawful acquisition, *supra.*

[520] Stressing the issue CORREA, *Unfair competition under the TRIPs Agreement: Protection of Data submitted for the registration of Pharmaceuticals,* in *Chicago Journal of International Law,* 3, 1, 2002, 73-74.

[521] LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in an environmental health, and safety law, supra,* 518. Stressing this point also WEISSMAN, *Data Protection: Options for implementation,* in ROOFE-TANSEY-VIVAS-EUGUI, *Negotiating Health- Intellectual Property and access to Medicines, supra*, 151 ss., affirming that free-riding practices are always very common, and form part of the normal competition information-interaction.

Hence the qualification of trials data as commercially sensitive information, and thus falling under trade secret protection, although broad in scope, could revel itself of short time duration, with important reflexions on the tenancy of the trade secret protection exemption to the general disclosure rule.

4. Pharmaceutical Data Protection under Art. 39.3 TRIPs Agreement

Art. 39.3 TRIPs[522] requires WTO Member States to protect test data submitted for the marketing approval of pharmaceutical and chemical products for agriculture.

The provision is found under art. 39 of the TRIPs Agreement, granting protection to "undisclosed information".

Literature regards what is referred to in art. 39 TRIPs as a form of "data protection", based on widely recognised legal principles concerning trade secrets[523] and unfair competition[524].

Art. 39 of TRIPs imposes to States an obligation to prevent that information submitted to regulators for marketing authorisation procedures for pharmaceutical products, are "disclosed, acquired, or used by others without their consent in a manner contrary to honest commercial practices"[525]. Art. 39.3 TRIPs provision imposes two distinct obligations on WTO Member States, relating both to the protection against "unfair commercial use", and secondly to the protection against disclosure *unless*

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[522] For a reconstruction of the TRIPs negotiating history, see SKILLINGTON-SOLOVY, *The Protection of Test and Other Data required by Article 39.3 of the TRIPs Agreement,* 24 Nw. J. Int'l L. & Bus. L. (2003-2004), 1 ss..; BLAKENEY, *A critical analysis of the TRPs Agreement,* in PUGATCH, *The intellectual Property Debate: Perspectives from Law, Economics, and Political Economy,* Cheltenham, Edward Elgar, 2006, 17 ss., stating that during TRIPs negotiations, "the pharmaceutical industry was one of the main lobbyists for the global extension of intellectual property rights"; CORREA, *Unfair competition under the TRIPs Agreement: Protection of Data submitted for the registration of Pharmaceuticals, supra,* 69 ss.; GERVAIS, *The TRIPs Agreement: Drafting History and analysis,* London, Sweet & Maxwell, 2008, 22 ss..

[523] CLIFT, *Data protection and Data exclusivity in Pharmaceuticals and Agrochemicals,* in V.V. A.A., *Intellectual Property Management in Health and Agriculture Innovation,* Oxford, MIHR, 2007, 431 ss., 432.

[524] *Ibid.*.

[525] REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 19.

such disclosure is necessary to protect the public or unless steps are taken to ensure that the disclosure does not result in "an unfair commercial use"[526]. Accordingly art. 39.3 addresses two issues: the *use* and the *disclosure* of the test data.

4.1 Pharmaceutical data protection against *unfair commercial* use

Literature has underlined how the obligations under TRIPs does not contain a property right entitling clinical trials' sponsors to exclusive use of the data[527]: it rather aims at preventing unfair commercial use by competitors under certain conditions[528].

Indeed, according to the same art. 39.3 TRIPs Agreement, WTO members' regulatory authorities have to bear a general duty of confidentiality, regarding data that are submitted for marketing approval, referring to new chemical entities the origination of which has required the research-based companies considerable efforts[529].

The condition of protection is that data must have been maintained undisclosed until the filing of the marketing application. This means that originators must have made reasonable steps in order to maintain the confidentiality of the clinical trials data[530].

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526 Art. 39.3 TRIPs Agreement: "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".

527 This is discussed by CORREA, *Protection of Data Submitted for the registration of Pharmaceuticals: Implementing the standards of the TRIPs Agreement, supra,* 5 ss.; CORREA, *Unfair competition under the TRIPs Agreement: Protection of Data submitted for the registration of Pharmaceuticals, supra,* 82, affirming that "The TRIPS Agreement clearly does not treat undisclosed information as property". Cf. also ANDANDA, *Managing intellectual property rights over clinical trial data to promote access and benefit sharing in public health, supra,* 148 ss..

528 This is particularly stressed by CORREA, *Protection of Data Submitted for the registration of Pharmaceuticals: Implementing the standards of the TRIPs Agreement, supra,* 8.

529 SKILLINGTON-SOLOVY, *The Protection of Test and Other Data required by Article 39.3 of the TRIPs Agreement, supra,* 20; CORREA, *Protection of Data Submitted for the registration of Pharmaceuticals: Implementing the standards of the TRIPs Agreement, supra,* 14 ss..

530 See REICHMAN, *The International Legal Status of Undisclosed Clinical Trials Data: From Private to Public Goods?,* in ROFFE-TANSEY-VIVAS-EUGUI, *Negotiating Health- Intellectual Property and Access to Medicines, supra*, 134 ss..

In return, it means that voluntary disclosure, for example through the publication of the data in an academic journal, or lack of protective measures, removes the obligation for the agencies to protect research protocols' information against disclosure, since the original confidential nature has been removed before the filing of marketing authorisation[531].

As far as the commercial value of the trials data is concerned, it is important to stress that the protection provided by the international provision is restricted only to *unfair* commercial uses practices, meaning competitors' dishonest commercial behaviours.

The protection is thus to be considered narrow in scope[532], and solely depending on the interpretation given to the notion of unfair commercial use[533].

However, these indications are particularly weak in light of the lack of clear definition of what has to be considered honest, fair or equitable[534] in a commercial perspective: if "commercial use" is to be defined "as an exchange of consideration between two or more parties on terms set by the market"[535], the notion of fairness is to be intended in an economic sense, meaning that commercial use of a trade secret is only unfair where an adequate compensation of the market value of the secret is not provided[536].

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531 REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 20.

532 REICHMAN, *Undisclosed Clinical Trial Data under TRIPs Agreement and its Progeny: a broader perspective, supra,* 2 ss.; CORREA, *Protection of data submitted for the registration of Pharmaceutical products: TRIPs requirements and TRIPs PLUS provisions,* in World Health Organization-Regional Office for South East Asia, *Intellectual Property and Access to Medicines: papers and perspectives,* India, 2010, 131 ss..

533 CORREA, *Unfair competition under the TRIPs Agreement: Protection of Data submitted for the registration of Pharmaceuticals, supra,* 81 ss..

534 REICHMAN, *Undisclosed Clinical Trial Data under TRIPs Agreement and its Progeny: a broader perspective, supra,* 12.

535 FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 464

536 In this direction, LEMMENS-TELFER, *Access to Information and the Right to Health,* 86. These considerations have indeed led some legal scholars to hypothesise a compensation obligation for generic drug companies that want to rely on the data of the innovator. See in particular CORREA, *Protection of Data Submitted for the registration of Pharmaceuticals: Implementing the standards of the TRIPs Agreement, supra,* 8-9; ID., *Unfair competition under the TRIPs Agreement: Protection of Data submitted for the registration of Pharmaceuticals, supra,* 70-71; REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 30; SANJUAN, *Us and Eu Protection of pharmaceutical Test data, Consumer Project on Technology, supra,* 5 ss..

In the absence of economic correspondence the use of protected data is to be considered unfair[537]. Unfair use is thus to be restricted to specific circumstances of misappropriation, such as industrial espionage or breach of contract[538].

Following this line of reasoning, some literature has mentioned "competitor's misrepresentation, fraud threats, defamation, disparagement, enticement of employees, betrayal of confidential information, commercial bribery (…)"[539].

But for these general considerations, the ultimate precise scope of the notion of unfair and dishonest practices depends on social perceptions in a particular country at a given time[540], and more specifically upon the kind of practices that domestic and foreign trade secrets laws have traditionally regarded as unfair[541].

However, legal scholars have underlined how as regards the international normative framework, art. 10 *bis* of the Paris Convention for the Protection of industrial property of 1883 provides an important interpretational tool for the definition of the notion of "unfair commercial use", by referring to the avoidance of "any act of competition contrary to honest practices in industrial or commercial matters"[542].

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537 FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 461.

538 FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 463. See also REICHMAN, *Undisclosed Clinical Trial Data under TRIPs Agreement and its Progeny: a broader perspective, supra,* 12, recalling the cases of disclosure caused by an employer to a competitor in order to provide him a commercially advantageous know-how, or the exploiting of the commercial advantage given by the knowledge of the test data by employers of the regulatory agency itself, in order to become a commercial rival of the submitting firm.

539 CORREA, *Protection of Data Submitted for the registration of Pharmaceuticals: Implementing the standards of the TRIPs Agreement, supra,* 41. On the point see also ANDANDA, *Managing intellectual property rights over clinical trial data to promote access and benefit sharing in public health, supra,* 162, stating that "these examples can help authors in making decisions on the publication of clinical trials results and guide regulatory authorities on sharing information that may have public health relevance".

540 CORREA, *Protecting Test Data for Pharmaceutical and Agrochemical Products Under Free Trade Agreements,* in ROFFE-TANSEY-VIVAS-EUGUI, *Negotiating Health- Intellectual Property and Access to Medicines, supra*, 83.

541 Underlining this point REICHMAN, *Undisclosed Clinical Trial Data under TRIPs Agreement and its Progeny: a broader perspective, supra,* 20.

542 CORREA, *Unfair competition under the TRIPs Agreement: Protection of Data submitted for the registration of Pharmaceuticals, supra,* 77 ss.. *Contra* FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 452, stating that "unfortunately the Paris Convention provides little help in interpreting the specific obligations of

In this light, it becomes evident how the purpose of the confidentiality requirement of art. 39.3 TRIPs Agreement, is that of preventing generic competitors from obtaining benefits or other advantages as a consequence of commercial practices regarded as unfair: as it has been stated, for this purposes it is thus "the qualification of the practice that counts, and not the mere existence of the advantage or benefit"[543].

Literature has drawn from these normative criteria some important conclusions.

First, it has been stated that obtaining a commercial advantage is not to be considered unfair *as such*.

Not even the granting marketing approval to a second generic entrant on the basis of the similarity with a previously approved product can be considered as a use relevant under 39.3 trips[544]. Indeed, it has been noticed that reliance on a previous market authorisation, in order to allow competitive production of bioequivalent products, would not constitute a direct use of the data, but rather a use of the safety and health outcomes expressed by the data themselves[545].

Such use is on the contrary to be considered fair and necessary in light of the need to promote competition in the market[546], and in order to provide compliance to "data-consideration and data-disclosure provisions"[547].

Indeed it can hardly be argued that the innovator's "reasonable investment-backed expectations are disturbed" when the regulatory agency "acts to use

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TRIPs Article 39.3", moreover noticing that "the relevance of Article 10 *bis* of the Paris Convention to Article 39.3 of the TRIPs Agreement is obscure", 453.

543 CORREA, *Trade related aspects of intellectual property rights, supra,* 382.

544 REICHMAN, *Undisclosed Clinical Trial Data under TRIPs Agreement and its Progeny: a broader perspective, supra*, 12.

545 *Ibid.*.

546 REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 21.

547 This has been the position of the American Supreme Court in the famous ruling *Ruckelshaus vs. Monsanto Co.* 467 U.S. 986, 1019-20 (1984) paragraph 6. Although referring to the protection of data submitted for agricultural products, literature regards this case as the pioneer case as regards disclosure of clinical trials data. See CORREA, *Protection of Data Submitted for the registration of Pharmaceuticals: Implementing the standards of the TRIPs Agreement, supra,* 33 ss.; REICHMAN, *Undisclosed Clinical Trial Data under TRIPs Agreement and its Progeny: a broader perspective, supra,* 12.

or disclose the data in a manner that was authorised by law at the time of the submission"[548].

This interpretation has been further supported in the important ruling of the Canadian Supreme Court of Appeal in the case *Bayer Inc. vs. Canada*[549], affirming compliance with international provisions of Canadian Law allowing demonstration of a generic medicinal safety and efficacy features, on the basis of the originator's application.

Accordingly, the claim made by the USA, concerning the lack of conformity to international obligations embedded in art. 39.3 TRIPs was rejected.

The Canadian court justified its decision by stating that no direct reliance on the innovator's confidential information as such can be found, in the cases that generic competitors are able to proof "the safety and effectiveness of its product on the basis of bioequivalence or bio-availability studies, without the Minister having to examine and rely on confidential data filed by the innovator"[550].

Therefore, according to this interpretation, allowing drug companies to rely on the originators' marketing application is not to be considered as a kind of unfair commercial use against which protection under art. 39.3 TRIPs is required[551]. This interpretation leads to the conclusion that the international framework of data protection does not therefore require the establishment of exclusivity rights over clinical trials data[552].

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548 *Ruckelshaus vs. Monsanto Co., supra,* paragraph 2.

549 REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 21-22.

550 *Bayer Inc. v. Canada* (Attorney General) (T.D.), (1999) 1 F.C. 553, paragraph 15.

551 This has also been the interpretation given by the World Trade Organization, *TRIPs and Public Health, submission by the African group, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela,* on the 20th June 2001, online available at https://www.wto.org/english/tratop_e/trips_e/mindecdraft_w312_e.htm paragraph 40, "the protection is to be granted against unfair commercial use of confidential data. This means that a third party could be prevented from using the results of tests undertaken by another company as background for an independent submission for marketing approval, *if the data had been acquired through dishonest commercial practices.* However, Art. 39.3 does permit a national competent authority to rely on data in its possession to assess a second and further applications, relating to the same drug, *since this would not imply unfair commercial use".* Emphasis added. Cf. REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 20.

552 LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 83 ss.; CLIFT, *Data protection and Data exclusivity in Pharmaceuticals and Agrochemicals, supra,* 433. *Contra* FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law:*

This has been underlined also by the WHO Commission on IP rights, Innovation and Public Health, expressly stating that art. 39.3 does not in fact "prevent authorities from using knowledge of such data"(…) "in order to assess subsequent applications by third parties for the registration of similar products"[553].

Also the dispute resolution body of the WTO has expressed a similar position, in occasion of a case brought up by the USA against Argentina, on the grounds of the alleged inconsistency of Argentinian law with Article 39.3 TRIPs, given that the state did not require a period of exclusivity of trial data[554]. The American claim was finally rejected, and Argentinian law did not have to change its pharmaceutical data provision.

4.2 Pharmaceutical data protection against *unfair commercial* disclosure

The narrow interpretation of the notion of unfair commercial *use* of test data has important repercussions also on the scope of the second obligation posed by the international provision, regarding clinical trials *disclosure*.

Indeed, being the protection of test data according to art. 39.3 TRIPs Agreement restricted to the protection against unfair commercial use by third parties, the conditions laid down by the provision do not contain a strict obligation to keep information undisclosed: in this light, it is to be stated that institutions do not face any obligation to keep the information submitted to them secret[555].

On the contrary, disclosure is expressly allowed in those cases in which sufficient "steps" are taken to ensure that the data are not used

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protection of marketing approval data under the TRIPS agreement, supra, 463, stating that "the prohibition of on unfair commercial use is best interpreted as a requirement for data exclusivity (…)".

[553] See World Health Organization, *Public Health innovation and intellectual property rights- Report of the Commission on intellectual property rights, innovation and public health, supra,* 126. See also ANDANDA, *Managing intellectual property rights over clinical trial data to promote access and benefit sharing in public health, supra,* 149.

[554] ATTARAN-CARTAGENA, *A study of Pharmaceutical Data Exclusivity Laws in Latin America: is Access to affordable Medicines threatened?, supra,* 277.

[555] Stressing this point, COTTIER-MEITINGER-MEITINGER, *The protection of Test Data submitted to Governmental Authorities: The impact of the TRIPs Agreement on EC law, supra,* 58.

commercially without the originator's "getting that to which it is entitled"[556].

Moreover, it has been noticed that the unfairness of a commercial practice is *a priori* to be excluded in those cases in which the law itself expressly requires or allows practices[557], as it is the case of mandatory disclosure of the test data in the European database established by art. 81 of the Clinical Trials Regulation[558].

The legal obligation of reporting drug's safety features, is thus to be considered perfectly compatible with the constraints posed by art. 39.3 TRIPs[559].

In fact, in the realm of this normative framework, states remain free not only to make non commercial uses of the data, but also uses that are to be considered fair, even if such uses produce a commercial impact[560].

In this light, literature has stressed that governmental use of test data to avoid health and safety risks[561] would be "fair by definition"[562], and that the need to promote research and science in the public interest "would allow some uses of the data that are both non-commercial and fair,

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556 FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 463: "the question then is what the initial registrant deserves- not as a matter of ethics, but as a matter of international law". The fairness of compensation is again a very difficult economic matter, for a possible economic model defining it see, *ibid.,* 470 ss..

557 REICHMAN, *Undisclosed Clinical Trial Data under TRIPs Agreement and its Progeny: a broader perspective, supra*, 6.

558 Regulation EU 536/2014 of the European Parliament and of the council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC, *cit.*.

559 CORREA, *Protecting Test Data for Pharmaceuticals and Agrochemical Products Under Free Trade Agreements, supra* , 84. See also, KITCH, *The law and Economics of rights in valuable information,* 1980, 9, The Journal of Legal Studies, 683, 649, stating that under Art. 39.3 TRIPs Agreement, "agencies have inherent power to control their records and, in the absence of statutory provisions prohibiting disclosure… an agency is free to choose to disclose".

560 COTTIER-MEITINGER-MEITINGER, *The protection of Test Data submitted to Governmental Authorities: The impact of the TRIPs Agreement on EC law, supra,* 64: "under Art. 39.3, publication is allowed, provided that unfair commercial use is avoided and competitors cannot directly or indirectly benefit from such publication".

561 FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 464, stating that "To the extent that the state can reasonably perform its function of protecting public health without compromising the initial registrant's trade secrets rights, disclosure of the marketing approval data is justified", and that "disclosure would be certainly justified to allow a third party, such as public interest organization, a university, a hospital, or another non-competitor of the drug developer, to review and verify the accuracy, reliability and completeness of the data".

562 REICHMAN, *Undisclosed Clinical Trial Data under TRIPs Agreement and its Progeny: a broader perspective, supra,* 141.

consistent with any research exemption embodied in the domestic patent laws"[563].

It is indeed the same provision that allows disclosure "where necessary to protect the public"[564].

Thus, uses for public health purposes, as the establishment of clinical trials databases clearly serve[565], would in any case be allowed under the TRIPs standard, in virtue of the exception provided by the same article as regards the public interest.

Unfortunately as literature has been pointing out, "public health concerns were only marginally present in the negotiation of the Trips Agreement"[566], thus, also in this case[567], no precise definition of the scope of the exemption can be found.

Discretion in what has to be considered relevant in terms of public interest, is thus, again, left to WTO Member States.

The only normative instruction to be found is the one on the *necessity* of the protection of public interest[568].

Literature has offered a variety of interpretations regarding the "necessity test" required by art. 39.3 TRIPs Agreement. According to the first position, and in order to comply with TRIPs' provision, states aiming to establish a disclosure system, must provide a precise definition of the data the disclosure of which is relevant to the protection of the public interest[569].

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563 *Ibid.*.

564 Art. 39.3 TRIPs Agreement.

565 LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 89 stating that such a (reporting) system can be seen as an essential tool to promote public health and protect the public from potential harm". See also CORREA, *Protection of Data Submitted for the registration of Pharmaceuticals: Implementing the standards of the TRIPs Agreement, supra,* 25, stressing that nondisclosure "facilitates the circulation and use of substandard drugs". More cautious is the position of FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 476, stating that whether clinical trials data disclosure "is necessary to protect the public, may be arguably in any given instance, but disclosure is certainly more helpful to that end than nondisclosure".

566 CORREA, *Protection of Data Submitted for the registration of Pharmaceuticals: Implementing the standards of the TRIPs Agreement, supra,* 22.

567 Cf. chapter 1, par. 2.2.

568 REICHMAN, *Undisclosed Clinical Trial Data under TRIPs Agreement and its Progeny: a broader perspective, supra,* 143.

569LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 87 ss..

Others have suggested that in order to determine whether a measure is to be considered necessary to protect the public interest under art. 39.3 TRIPs Agreement, indications have to be taken from the General Agreements on Tariffs and Trade panel reports, concerning art. 27.2 TRIPs, allowing states to exclude inventions from patentability when necessary to protect public order or morality[570].

As it has been argued, the fact that the public interest exemption is restricted to the necessity standard evidently narrows the scope of the exemption itself, reflecting the negotiators' belief that marketing approval data has to be considered a particularly sensitive trade secret[571], and therefore not intended to be regularly disclosed[572].

This argument is however easy to overcome in light of other dispositions of the TRIPs Agreement itself, such as art. 8, stating that WTO members "may adopt measures necessary to protect the public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development"[573].

Furthermore, as regards public interests, one cannot neglect the statements contained in the DOHA Declaration on the TRIPs in 2001[574], and especially in paragraph 4 of the same Declaration. It clearly provides "the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote

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[570] GERVAIS, *The TRIPs Agreement: Drafting History and analysis, supra,* 336 ss.., examining various appellate decisions involving a balancing between the public interest and the impact of the restrictions.

[571] FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 451, underlining the narrow perspective of the necessity standard.

[572] *Ibid.*, 463: "the public health language of Article 39.3, as an exception to the general rule of confidentiality, should not be read to authorize the disclosure of marketing approval data under all circumstances". The author further states that disclosure would only be possible for the sake of "protecting public health in an emergency".

[573] Commenting this provision, see MATTHEWS, *Intellectual Property, Human Rights and Development,* Cheltenham, Edward Elgar, 2011, 18-19.

[574] Doha Declaration on the TRIPs Agreement and Public Health, adopted on the 14th November 2001, online available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose"[575].

As literature has noticed, although not providing clear indications regarding the "relationship between states' obligation to protect intellectual property and obligation to ensure the right to access to medicines and the right to health", the cited statement surely stresses the need to exploit the interpretational flexibilities left open by the Agreement[576] in order to enhance the standards of access to medicines[577].

Also in light of these further declarations, it can be concluded that the international framework fully recognizes public health concerns, suggesting disclosure of marketing approval data at the condition that WTO members protect against unfair commercial use of the data.

This could be achieved in various ways, such as under a rule of data exclusivity disallowing competing registrations during the exclusivity period[578].

However, scholars have traced other possible solutions for preventing unfair commercial use, such as compensatory liability regimes, built upon "take and pay" liability rules for value adding uses of innovation[579] and therefore protecting test data against unfair commercial use without granting the innovator a monopoly on the marketing approval data.

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[575] Cf. YUNG-CHING YEH, *Pharmaceutical Data Protection Law and Policy, and their effects on the right to Medicines: a Comparative Analysis*, *supra*, 6.

[576] CORREA, *Implications of the Doha Declaration on the TRIPs Agreement and Public Health,* Geneva, World Health Organization, 2002, online available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf, 13 ss..

[577] On the issue MATTHEWS, *Intellectual Property, Human Rights and Development, supra,* 17 ss..

[578] FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 476.

[579] Under a cost-sharing option model, data can be automatically used from the time of its submission, following the payment of a reasonable compensation by the generic company wishing to enter the market. This is the proposal of REICHMAN, *Undisclosed Clinical Trial Data under TRIPs Agreement and its Progeny: a broader perspective, supra*, 15 ss..; ID., *Rethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 32 ss.. FELLMETHM, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 473 ss.. See also WEISSMAN, *Data Protection: Options for Implementation,* in ROFFE-TANSEY-VIVAS-EUGUI, *Negotiating Health- Intellectual Property and Access to Medicines, supra*, 151, distinguishing between a misappropriation approach, a cost-sharing approach and public health variants of the data exclusivity approach.

The purpose of the duties of confidentiality could be in fact maintained if disclosure has been released or reliance on the originator's test data is given to a competitor, provided that adequate compensation for the use of the test data is given as to render the reliance and the use "fair".

The lack of specific indications provided for the definition of the notion of fairness, renders the effective scope of art. 39.3 TRIPs unclear[580].

By establishing the basic obligation to consider test data as a trade secret proprietary to the submitter, the provision leaves to the discretion of member states the definition of the conditions under which disclosure and reliance on the submitted trials data for generic's entrance purposes is considered to be fair.

TRIPs Agreement establishes therefore a minimum international standard, that constitutes the basis for implementing TRIPs at a national level[581], leaving "wide room for manoeuvre for member countries"[582] to determine the appropriate ways for protection[583].

5. Data exclusivity under the European normative framework

An accurate interpretation of art. 39.3 TRIPs Agreement shows how international obligations do not impose any obstacles to disclosure in publicly accessible databases[584].

However, a completely different approach has been taken by WTO member states and in particular by the USA[585] and the European Union, by transposing the international provision at a supra-national level[586].

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[580] See COTTIER-MEITINGER-MEITINGER, *The protection of Test Data submitted to Governmental Authorities: The impact of the TRIPs Agreement on EC law, supra,* 60.

[581] CORREA, *Intellectual property rights, the WTO and developing countries: the TRIPS agreement and policy options, supra,* 46.

[582] CORREA, *Protection of Data Submitted for the registration of Pharmaceuticals: Implementing the standards of the TRIPs Agreement, supra,* 39.

[583] PUGATCH, *Intellectual Property and pharmaceutical data exclusivity in the context of information and market access, supra,* 1, talks about "ambiguity" of the TRIPs Agreement with regards the "operational translation of data exclusivity at the multilateral level creates a vacuum, and subsequently leads to the contemporary debate as to the scope and term of data exclusivity in each and every country". See also BAGLEY, *Patent term restoration and non-patent exclusivity in the US, supra,* 113.

[584] For the definition of "essentially similar medicinal products, see LISMAN-SCHOONDERBEEK, *An Introduction to EU Pharma Law,* London, Brookwood Booklets, 2005, 47 ss..

Indeed while art. 39.3. TRIPs is based on the concept of confidentiality, the supranational provisions have shifted the focus of protection on preventing regulatory authorities to release marketing licenses based on test data of a prior applicant to third parties, for a certain period of time[587].

Developed countries have in fact interpreted the international obligations in the opposite direction of assuring pharmaceutical companies' data a period of data exclusivity, interpreted by literature as a form of *sui generis* intellectual property right[588].

The data exclusivity protection is therefore a higher rearrangement of international boundaries provided by the TRIPs Agreement, requiring non-reliance obligations, and in second instance, following a particular interpretation, also stricter non-disclosure obligations.

According to these regimes, in fact, clinical trials data submitted for registration of pharmaceutical products are protected by a peculiar system of defence, based on a temporary right to exclusive use of such data by the originator.

Data exclusivity protection has to be counted among the normative tools for maximizing the market exclusivity period for pharmaceutical products, together with paediatric testing and orphan drug exclusivity[589].

It implies that generic manufacturers cannot rely on the registered data to file marketing authorisation for a similar product[590], given a period of

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585 Section 335 of the USA Federal, Drug, and Cosmetic Act of the US (1994) defines two categories of data exclusivity: a five years for products with new chemical entities, and three years for a new indication of a known product.

586 Cf. CLIFT, *Data protection and Data exclusivity in Pharmaceuticals and Agrochemicals, supra,* 432.

587 COTTIER-MEITINGER-MEITINGER, *The protection of Test Data submitted to Governmental Authorities: The impact of the TRIPs Agreement on EC law, supra,* 68.

588 BRAUN-PUGATCH, *The changing face of pharmaceutical industry and intellectual property rights, supra,* 602.

589 BAGLEY, *Patent term restoration and non-patent exclusivity in the US, supra,* 111. See also THOMAS, *Proprietary Rights in Pharmaceutical Innovation: issues at the Intersection of Patents and Marketing exclusivities,* online available at http://www.ipmall.info/hosted_resources/crs/RL33288_060320.pdf.

590 The similarity of the generic drug is to be proven in cases where, "1) the generic drug has the same active ingredient in the same qualitative and quantitative composition as the reference product; 2) the generic drug has the same pharmaceutical form as the reference product; 3) the generic drug is bioequivalent to the reference product; 4) there is no scientific evidence that the generic drug differs from the reference product with respect to safety and efficacy". See JUNOD, *Drug Marketing Exclusivity in the United States & European Union Law, supra,* 505. The similarity criterias have been pointed out in an important ruling by the ECJ in 1998, in the decision known as Generics, the court interpreted the notion of similarity in terms of "same qualitative and quantitative composition in terms of active principles and the same pharmaceutical form". Case C-368/96, Judgment of the

exclusive use of the same test data, granted to originators after marketing approval.

Over this period, the second entrant cannot therefore obtain a marketing authorisation for a similar drug through a facilitated procedure referring to trial data conducted by the pioneer company in order to support the new medicinal's safety and efficacy[591].

Under European legislation this period has been harmonized by art. 10 of Directive EC 2004/27[592], amending Directive 2001/83 EC with the *formula* of eight years of protection[593], in addition to whom other two years of market exclusivity in which generic companies are only allowed to submit bio-equivalence tests[594], and another year of protection for new indications of existing products[595], are granted[596].

According to this framework, the second applicant can therefore file its request for a generic marketing authorization after eight years, but has to wait until the two years of marketing exclusivity have expired for the license to become effective[597].

Court of 3 December 1998, The Queen vs. Licensing Authority (established by the Medicines Act 1968), *ex parte* Generics (UK) Ltd., The Wellcome Foundation Ltd., Glaxo Operations UK Ltd., and others 1998- E.C.R. I-7967, online available at http://curia.europa.eu/juris/showPdf.jsf;jsessionid=9ea7d2dc30dbe7249ce801c648dbaf4cfd341a24b280.e34KaxiLc3qMb40Rch0SaxuKb3n0?text=&docid=101225&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=27114. For a more accurate comment see COTTIER, MEITINGER-MEITINGER, *The protection of Test Data submitted to Governmental Authorities: The impact of the TRIPs Agreement on EC law, supra,* 75. Cf. also CORREA, *Protecting Test data for Pharmaceutical and Agrochemical Products,* in ROFFE-TANSEY-VIVAS-EUGUI, *Negotiating Health- Intellectual Property and Access to Medicines, supra*, 83.

[591] Cf. JUNOD, *Drug Marketing Exclusivity in the United States & European Union Law,* in *Food and Drug Law Journal,* 2004, 59, 479 ss., 479-480.

[592] The expressed purpose of the Directive of 2004 was that of "increasing incentives to offset the competitive decline of the EU pharmaceutical sector, with respect to the US sector". See REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 37. Cf. also PUGATCH, *Intellectual Property and pharmaceutical data exclusivity in the context of information and market access, supra,* 4.

[593] The protection is granted for products approved both through the centralized and the mutual recognition procedure. JUNOD, *Drug Marketing Exclusivity in the United States & European Union Law, supra,* 512. See *supra* chapter 1, par. 2.

[594] See *infra.*

[595] The additional one year protection, to be granted only once, can be demanded at any time, under the condition that the safety and efficacy of the new indications are adequatly shown through the support of clinical testing. JUNOD, *Drug Marketing Exclusivity in the United States & European Union Law, supra,* 513.

[596] Global intellectual property center- US chamber of commerce, *Heading in a different direction? The European Medicines Agency's Policy on the Public Release of Clinical Trials Data, supra,* 5.

[597] JUNOD, *Drug Marketing Exclusivity in the United States & European Union Law, supra,* 513.

Literature has noticed how granting research-based companies an exclusive right as regards the use of these test data, increases the level of protection as opposed to the sole prohibition of *use* of the data in a manner contrary to what is to be considered commercially fair, as stated in the international TRIPs provision[598].

It has been argued[599], that his exclusive right is to be justified on the basis of the intellectual process through which the information was originated, thus entitling the originator to "freely use, sell, modify, or destroy the information"[600].

In this perspective, also the European Court of Justice in the case *The Queen vs. The Licensing Authority Established by the Medicines Act 1968*[601] has labelled the pharmaceutical data's protection as "a right to property relating to pharmacological, toxicological and clinical data"[602]. This proprietary right would confer to the originator monopoly rights on the use of pharmaceutical data[603] forming the basis of the originator's marketing authorisation[604].

Hence, the data exclusivity regime creates a monopoly over the information, and not over the pharmaceutical product itself[605].

However, this kind of informational monopoly rebounds in an indirect monopoly over the product.

In fact, generic manufacturers are not prohibited to produce their own trials data regarding an already marketed active substance, in order to obtain a license for a similar product[606].

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598 Cf. CORREA, *Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements, supra,* 84.

599 Cf. FACKELMAN, *Clinical data, data exclusivity and private investment production in Europe, supra,* 172.

600 COTTIER-MEITINGER-MEITINGER, *The protection of Test Data submitted to Governmental Authorities: The impact of the TRIPs Agreement on EC law, supra*, 60.

601 European Court of Justice, C-368/96, *The Queen vs. The Licensing Authority Established by the Medicines Act 1968,* paragraphs 82 e 83. See DODDS-SMITH, *Data protection under the European Pharmaceutical Legislation and under Federal Legislation in the USA, supra,* 36 ss..

602 See comment of FACKELMAN, *Clinical data, data exclusivity and private investment production in Europe, supra,* 172.

603 *Ibid.,* 173.

604 Stressing this point LORENZ, *Das gemeinschaftliche Arzeneinmittelungszulassungsrecht, supra,* 206.

605 FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 446.

Yet, the important financial and ethical concerns [607] regarding the reproduction of trials by second comers, causes the informational exclusivity to have the effect of a *de facto* product exclusivity: this is why scholars have called upon data exclusivity as a "qualified market barrier", substantially delaying generic market entry[608].

This leads in return to price increases of medicines, not only because of the enforcement of the innovator's dominant position[609], but also due to the higher product development costs suffered by generic companies that must reproduce clinical trials and consequently rise the price of the generic end products finally marketed[610].

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[606] LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 83: "exclusivity regime is less restrictive than patent monopoly because it allows generic companies to produce their own materials of data".

[607] *Ibid.,* "generic drug manufacturers have to either wait until the exclusivity period expires, or to produce the required data independently", being the effective alternative "to wait until the exclusivity period ends and to demonstrate the bioequivalence instead of full clinical trials". This can in return cause animals and test subjects to be submitted to unnecessary duplicate testing.

[608] See PUGATCH, *Intellectual Property and pharmaceutical data exclusivity in the context of information and market access, supra,* 12. Cf. also LEMMENS-TELFER, *Access to Information and the Right to Health: the Human Rights Case for Clinical Trials Transparency, supra,* 74.

[609] ATTARAN-CARTAGENA, *A study of Pharmaceutical Data Exclusivity Laws in Latin America: is Access to affordable Medicines threatened?, supra,* 269; LEMMENS TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 84 data exclusivity can be one of several strategies applied by research-based companies, to delay generic price competition. See also ADAMINI-MAARSE-VERSLUIS-LIGHT, *Policy making on Data exclusivity in the European Union: from industrial interests to legal realities, supra,* 1003, underlining how "data exclusivity appears to be one of several strategies by the research- based industry to delay generic price competition. A recent study by DG Competition of the European Commission has found that "in many instances originator companies use two or more instruments from the 'tool box' in parallel and/or successively in order to prolong the life cycle of their medicines". These instruments notably include secondary patenting, patent-related contacts and disputes, litigation, settlements, and interventions. DG Competition of the European Commission concluded that these tactics "significantly increase legal uncertainty to the detriment of generic entry and can cost public health budgets and ultimately consumers significant amounts of money"".

[610] LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 85 and CHAKRABARTI, *Need of Data exclusivity: Impact on Access to Medicine,* in *Journal of Intellectual Property Rights,* 2014, 19, 325 ss., 333.

5.1. Data exclusivity and patent protection: intersections

Data exclusivity protection can function as an alternative layer of legal defence for pharmaceutical products, in the cases where the patent system itself fails to provide adequate market predominance[611].

Data exclusivity is indeed to be considered as an autonomous form of protection in respect of patents[612], given the absence of any reference to the patent law notions of novelty and inventive step in pharmaceutical development[613]: data exclusivity is in fact solely based on the "fixed event" of granting a marketing authorisation[614]. Indeed, the granting a marketing authorisation follows a very strict process, leaving "little room for any "creative" approaches"[615]: in order to grant data exclusivity protection there are no requirements of evidence that the original drug symbolizes a technical or therapeutic advancements as regards the "prior pharmacological art"[616].

The only precondition needed is that of pharmaceutical safety and efficacy.

Thus, the subjection of the data exclusivity on mechanical criteria, renders this kind of protection qualitatively stronger than a patent protection[617], not being exposed to generic disputes[618].

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611 PUGATCH, *Intellectual Property and pharmaceutical data exclusivity in the context of information and market access, supra,* 13. See also JUNOD, *Drug Marketing Exclusivity in the United States & European Union Law, supra,* 480, quoting Greg Perry of the European Generic Medicines Association (EGA), stressing the relevance of non patent exclusivity: "for originator pharmaceutical companies, the expansion of data exclusivity provisions has become one of the main ways of extending market protection and blocking generic competition. Data exclusivity is seen now as the principal means of extending market protection for new indications, pharmaceutical forms and other variations, especially where these are not innovative enough to gain patent protection".

612 Cf. EISENBERG, *Patents, Product Exclusivity, and Information Dissemination: How law directs biopharmaceutical research and development,* 72 Fordham Law Review 2003, 477 ss., 482. Literature has also been stressing the considerable less administrative and procedural burden of data exclusivity as confronted with the patent system, beimg "cheaper to obtain and to maintain". JUNOD, *Drug Marketing Exclusivity in the United States & European Union Law, supra,* 484.

613 FACKELMAN, *Clinical data, data exclusivity and private investment protection, supra,* 167.

614 *Ibid.*.

615 *Ibid.,* 176.

616 LISMAN-SCHOONDERBEEK, *An Introduction to EU Pharmaceutical Law, supra,* 42.

617 CLIFT, *Data protection and Data exclusivity in Pharmaceuticals and Agrochemicals, supra,* 433. COOK, *Regulatory Data Protection in Pharmaceuticals and Other Sectors* in V.V. A.A., *Intellectual Property Management in Health and Agriculture Innovation, supra,* 438.

618 Cf. PUGATCH, *Intellectual Property and pharmaceutical data exclusivity in the context of information and market access, supra,* 13-14.

Moreover, it has been noticed that unlike in the patent system, under data exclusivity regimes there are no compulsory license mechanisms to be found[619].

Indeed, most of the WTO Members have introduced provisions to override patent protection in cases of public health emergencies or for remedying anticompetitive behaviours[620].

However, since data exclusivity regimes do not assure any form of exemption to protection, in the cas a compulsory license is granted, generic pharmaceutical companies intending to enter the market, would be still required to obtain marketing authorisation, with the effect of potentially blurring the effectiveness of the license itself[621].

Literature has also been underlining a few other possible scenarios in which data exclusivity regimes interact with patent protection[622].

According to the first scenario, in some circumstances data exclusivity works as a "gap filling alternative" [623] for patent protection over pharmaceutical products[624].

This can happen for example in those circumstances in which a patent for a pharmaceutical product is not recognized[625]- for example in the case of biopharmaceuticals[626]- or for which the patent term has long expired before the granting of a marketing license[627].

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[619] CLIFT, *Data protection and Data exclusivity in Pharmaceuticals and Agrochemicals, supra,* 433.

[620] Cf. ANDERMAN, *The strategic uaw of Patent Enforcement and Acquisition Metgods and Competition Law,* in GOVAERE-ULLRICH, *Intellectual Property, Market Power and the Public Interests, supra,* 171 ss..

[621] Stressing this point WEISSMAN, *Data Protection: Options for implementation,* in ROOFE-TANSEY-VIVAS-EUGUI, *Negotiating Health- Intellectual Property and access to Medicines, supra*, 166.

[622] COOK, *Regulatory Data Protection in Pharmaceuticals and other Sectors, supra*, 438-439.

[623] REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 38. See also FACKELMAN, *Clinical data, data exclusivity and private investment protection, supra,* 166.

[624] CORREA, *Protecting Test data for Pharmaceutical and Agrochemical Products, supra,* 83. The American Congress has motivated the introduction of data exclusivity as a means of "enhancing the development and testing of unpatentable pharmaceuticals", as is recalled by REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 37.

[625] Countries such as Spain and Portugal did not have a patent system until the definitive enforcement of the TRIPs Agreement on the 1st January 2005, requiring all countries that were bound to it to grant protection for inventions in "all areas of technology". REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 37. In these cases data exclusivity has been a substitute for patent protection over the interested products. CORREA, *Protecting Test data for Pharmaceutical and Agrochemical Products, supra,* 83.

[626] Indeed, patent protection for biopharmaceuticals was given only in 2006. According to the European Generic Association, "data exclusivity was created at a time where there were no patents for biotech products. This data exclusivity period therefore provided a form of market protection for

In some cases, patent protection for a product approved by regulatory authorities may be very difficult, or impossible to obtain, for instance as for new physical forms, new synthetic processes, or new uses of old substances, that would not satisfy the innovative patentability requirements[628].

Data exclusivity can also have an important role in absence of patent protection, as a means of protection of studies for an additional medical use of a previously authorised original drug. Art. 10 (1)(4) and 10(5) of the Directive provides in fact an additional and separate year of data protection, covering each and every of the drug's indications, and also those already authorised for marketing[629]. This provision grants therefore protection to new therapeutic indications, but mostly becomes a means for innovators to maintain the market predominance in respect of previously authorised therapeutic indication[630].

When data exclusivity operates independently from the patent shield, literature has noticed how exclusive rights over test data have the effect of removing "from the public domain products that should be freely available" [631].

In other circumstances, data exclusivity has the function of "supplementary incentive" as regards the development of those pharmaceutical products that end up being protected by a shortened patent protection, due to the length of the regulatory approval procedure[632], or because of the length of clinical trials processes, such as the ones needed for the testing of orphan

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these products in the absence of patents, which was particularly important to those Member States with developing biotech industries. Patents now exist for biotech products". EGA, *Data exclusivity, a major obstacle for Innovation and Competition in the EU Pharmaceutical sector,* Brussels, 2000, 4.

627 One of the most notorious cases is the one of Taxol-Bristol-Myers Squibb's anti-cancer drug, discovered by the National Cancer Institute in 1962, and whose active substance was licensed for marketing only in 1991. Cf. PUGATCH, *Intellectual Property and pharmaceutical data exclusivity in the context of information and market access, supra,* 14.

628 Cf. COOK, *Regulatory Data Protection in Pharmaceuticals and Other Sectors, supra,* 438, talking about "second generation patents". See also JUNOD, *Drug Marketing Exclusivity in the United States & European Union Law, supra*, 483, talking about product line extensions, such as "slow release versions of pre-existing drugs".

629 FACKELMAN, *Clinical data, data exclusivity and private investment protection, supra,* 173 ss..

630 LISMAN-SCHOONDERBEEK, *An Introduction to EU Pharma Law, supra,* 56.

631 CORREA, *Protecting Test data for Pharmaceutical and Agrochemical Products*, *supra,* 95.

632 EISENBERG, *The role of the FDA in Innovation Policy, supra,* 374.

drugs, or biogenetic pharmaceuticals[633]. In these cases the effective term of patent protection is shorter than the term of protection provided by data exclusivity[634].

Finally, if a generic manufacturer manages to produce a *different* but *bioequivalent* form of an already patented product, this generic drug could be patented, but due to the data exclusivity regime, it would not be granted a marketing license before the expiry of the exclusivity period. Indeed, according to art. 10.2 of the Directive, "the different salt, ester, ethers, isomers, mixture of isomers, complexes or derivatives of an active substance *shall be considered to be the same active substance*"[635], and if the active substance thus falls in these categories, generic reference is not permitted, thus making the scope of the data exclusivity larger than that of patent protection[636].

These scenarios directly reflect that data exclusivity is centred in the grey area of non-patentable, but still economically valuable, pharmaceutical developments, extending the area of protection from competition enjoyed by pharmaceutical products.

5.2. Functions and dis-functions of Data exclusivity

Once having defined the scope of protection of data exclusivity, also its functions become clearer as well.

Some scholars have been welcoming this stronger form of protection, noticing that providing stronger incentives for the development of new drugs, will at the same time also improve the quality of clinical trials[637].

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633 REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 38.

634 PUGATCH, *Intellectual Property and pharmaceutical data exclusivity in the context of information and market access, supra,* 13.

635 Emphasis added.

636 FACKELMAN, *Clinical data, data exclusivity and private investment protection, supra,* 168.

637 EISENBERG, *The role of the FDA in Innovation Policy,* 2007, in *Michigan Telecommunications and Technology Law Review*, 345, 370; ID., *Patents, Product Exclusivity, and Information Dissemination: How law directs biopharmaceutical research and development, supra,* 489, stressing that that the non-disclosure and non-reliance obligations binding the regulatory agency, "although puzzling from a consumer protection perspective", are to be read in light of the perspective of promotion of innovation, to "promote investments in scientifically sound clinical trials, to generate valuable information about drugs".

However it must be noticed how other parts of pharmaceutical regulation already assure the qualitative enhancement of the conduction of clinical trials data[638]. Indeed, as it has been noticed, the completeness of clinical trials information is a requisite for the submission of any new drug marketing application[639].

Moreover, given that data exclusivity is particularly important in those cases where it exceeds patent protection, it has been stated that this form of protection has the effect of promoting sub-patentable research [640], functioning as an indirect incentive for innovation[641] particularly in those early stages of the R&D process in which there is still uncertainty whether the result of the same research will be patentable or not[642].

Indeed, in the absence of marketing exclusivity's "safe net", the uncertainty of the outcomes would have the effect of deterring research in both innovative and other less pioneering areas of scientific development[643].

In this light, exclusivity regime for clinical trials, has been seen as an incentive source for an "ever-widening" class of pharmaceuticals that would be denied patents[644]. The production of sub-patentable pharmaceuticals is to be considered functional to avoiding market failures in those cases where a certain medicine, even if non patentable, would have "saved or improved lives" or would have led to significant savings in other healthcare sectors (e.g. reduced hospitals stays)"[645].

However the incentive function as regards sub-patentable products assured by the data exclusivity protection, has been also criticised by other legal

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638 The issue has already been discussed above, chapter 1, par. 1.1.

639 JUNOD, *Drug Marketing Exclusivity in the United States & European Union Law, supra,* 485.

640 FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 473.

641 PUGATCH, *Intellectual Property, data exclusivity, innovation and market access, supra,* 6.

642 FACKELMAN, *Clinical data, data exclusivity and private investment protection, supra,* 179, stating that "in view of data exclusivity as a fall back option (…), an on-going R&D process might have better chances of being carried through".

643 JUNOD, *Drug Marketing Exclusivity in the United States & European Union Law, supra,* 483: " by denying market exclusivity to all non innovative/unpatentable research outcomes, one runs the risk of discouraging drug R&D that could have led to innovative/patentable products".

644 REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 38.

645 Cf. JUNOD, *Drug Marketing Exclusivity in the United States & European Union Law, supra,* 482.

scholars[646] and by the generic industry[647], underlining how it would on the contrary negatively affect the general pharmaceutical progress' pace, by not providing any targeted incentive for socially productive-research[648].

On the contrary, the essential rationale of the protection is to be found in the shielding research-based companies from economically inefficient free-riding practices[649] that would obstruct the innovation process leading to patentable outcomes[650]. Unlike ordinary intellectual property rights, data exclusivity is to be referred to the protection of the investment[651] necessary to generate an innovative product, or - better said- of the industrial know-how[652] entailed in the data portfolios handed out to regulatory agencies.

However, the data exclusivity regime, intended as an additional patent style defence for pharmaceuticals, leads to considerable externalities as regards the perpetuation of market power, by establishing financial barriers to market entry, substantially delaying competition by imitation mechanisms[653].

Indeed, the *proprietarisation* of information[654], extending the product monopoly already granted by the patent system to originators, delays

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[646] FELLMETH, *Secrecy, Monopoly, and access to pharmaceuticals in International Trade Law: protection of marketing approval data under the TRIPS agreement, supra,* 473. In the same direction REICHMAN, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation, supra,* 1772 ss., noticing the decrease of appeal of pharmaceutical patents, and of patentable pharmaceutical innovations.

[647] See JUNOD, *Drug Marketing Exclusivity in the United States & European Union Law, supra*, 483.

[648] *Ibid.*.

[649] See REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 40.

[650] However it has been underlined by literature that the free-riding practices that the data exclusivity provisions intend to avoid, are still very common, and form part of the normal competition information-interaction. See WEISSMAN, *Data Protection: Options for implementation,* in ROOFE-TANSEY-VIVAS-EUGUI, *Negotiating Health- Intellectual Property and access to Medicines, supra*, 151 ss.. Cf. also LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in an environmental health, and safety law, supra,* 466 ss..

[651] This position is shared by FACKELMAN, *Clinical data, data exclusivity and private investment production in Europe, supra,* 174-175.

[652] DODDS-SMITH, *Data protection under the European Pharmaceutical Legislation and under Federal Legislation in the USA, supra,* 30, citing the European Commission's statements concerning pharmaceutical industry's know-how, that has "an economic value equal to or greater than that of patents. (…)", being non patented results "a major determinant of firms' competitive advantage". See European Commission, *Treatment of know-how licensing under the competition rules,* published on the 14th February 2013, online available at http://aei.pitt.edu/39936/.

[653] LEMMENS-TELFER, *Access to Information and the Right to Health: the Human Rights Case for Clinical Trials Transparency, supra,* 85.

[654] HELLER, *The Gridlock Economy: How too much ownership wrecks markets, stops innovation, and costs lives,* New York, Basic Books, 2010, 45 ss.; REICHMAN, *Rethinking the role of clinical trials data in international*

generic entry, with overall implications in terms of access to medicines, and therefore on the level of public health generally assured[655], from both a quantity and a price perspective[656].

In fact, the effective exclusivity period generated by the data exclusivity regime results to be longer than the time during which the regulatory agency is bound by the non-reliance obligation, for one must consider also the time it will take regulatory authorities to approve the generic company's new application[657].

Moreover, data exclusivity protection could further strengthen pioneer pharmaceutical companies' dominant position, potentially leading to form of abuses of the dominant position itself, through the engagement of anticompetitive practices.

In this perspective, the European Court of Justice has defined as abuse of dominant position the delaying of generic entry through the misuse of marketing authorisations[658].

Yet, a more significant implication of data exclusivity is to be referred to the overall effect it has on the market structure[659]: indeed this sui generis

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intellectual property law: the case for a public goods approach, supra, 43.

[655] See CHAKRABARTI, *Need of Data exclusivity: Impact on Access to Medicine, supra,* 333. Cf. also YUNG-CHING YEH, *Pharmaceutical Data Protection Law and Policy, and their effects on the right to Medicines: a Comparative Analysis*, published on the 3rd October 2009, Theses and Dissertations, online available at http://digitalcommons.law.ggu.edu/cgi/viewcontent.cgi?article=1025&context=theses, *passim*. The issue will be later discussed *infra* chapter 3.

[656] Cf. CORREA, *Unfair competition under the TRIPs Agreement: Protection of Data submitted for the registration of Pharmaceuticals, supra,* 4.

[657] This is underlined by PUGATCH, *Intellectual Property and pharmaceutical data exclusivity in the context of information and market access, supra,* 12-13. It is on this basis that literature has underlined the sharp difference between data exclusivity and the other form of protection called market exclusivity, during which a generic applicant is allowed to make reference to the originator's registration file, in order to be able to enter the market as soon as the exclusivity period has expired. See THOMAS, *Proprietary Rights in Pharmaceutical Innovation: issues at the Intersection of Patents and Marketing exclusivities, supra,* 13 ss.; ID., *The Role of Patents and Regulatory Exclusivities in Pharmaceutical Innovation,* published on 7th January 2013, online available at http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/R42890_01072013.pdf, 4, noticing however how market exclusivity grants on the other side a higher standard of protection than data exclusivity, given that the former prevents a generic firm to enter the market, even if the evidence of the drug's safety and efficacy is shown through own clinical trials.

[658] AstraZeneca AB and Astrazeneca plc v European Commission (Case T-321/05) (2005/C 271/47). The court found two infringements of art. 102 TFEU, the first regarding misleading information in applications for supplementary protection (SPCs), provided by the pharmaceutical company before regulatory agencies from Germany, Belgium, Denmark and Norway; whereas the second consisted on the submission of requests for deregistration of the marketing authorisation from Losec, and the subsequent launch of the same product Losec in the form of tablets. Cf. NEGRINOTTI, *Abuse of Regulatory Procedures in the Intellectual Property Context- The AstraZeneca case, supra,* 146.

protection has important reflexes on the delay of scientific research, and at the same time on innovation development and competition interactions[660].

Also on this account, a comparison with the patent system is worthwhile. In fact, the patent system is shaped on the edge of a trade off between temporary monopoly protection and immediate disclosure of the invention. The transparency on which the patent system is build upon enables scientific research to move forward on the basis of the information newly disclosed, and permits therefore to similar, or improved products to enter the market as soon as the patent term has expired.

On the contrary, "data exclusivity offers no trade-off between protection and disclosure inherent to intellectual property rights"[661].

Indeed, the non-reliance obligation of the data exclusivity regime has been interpreted, despite the lack of any normative grounds, as strictly related to a non-disclosure requirement of the same test data. Some literature[662] has been arguing that the non-disclosure obligation of regulatory agencies is to be directly derived from the expressed non-reliance obligation, as well as from art. 287 EC Treaty[663], obliging all the institutions to keep secret the confidential information they obtain during execution of their duties secret[664].

According to this position, prohibition of disclosure to third parties, is indeed to be derived through interpretation of the rule embedded in art. 10 of the Directive, and is functional to the strengthening of the temporary

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659 DREXL, *The relationship between the Legal exclusivity and Economic Market Power- Links and Limits,* in GOVAERE-ULLRICH, *Intellectual Property, Market Power and the Public Interest, supra,* 13 ss..

660 On the issue see FLANAGAN-MONTAGNANI, *Intellectual Property and Social Justice: a Law and Economics approach, supra,* XI.

661 So FACKELMAN, *Clinical data, data exclusivity and private investment protection, supra,* 177.

662 See COTTIER- MEITINGER-MEITINGER, *The protection of Test Data submitted to Governmental Authorities: The impact of the TRIPs Agreement on EC law, supra,* 66.

663 Art. 287 EC Treaty: "The members of the institutions of the Union, the members of committees, and the officials and other servants of the Union shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components".

664 See COTTIER-MEITINGER-MEITINGER, *The protection of Test Data submitted to Governmental Authorities: The impact of the TRIPs Agreement on EC law, supra,* 66.

market predominance the data exclusivity regime intends to incentivise innovation[665].

However, positive law of the data exclusivity regime does not provide any expressed confidentiality requirements[666], and more specifically, no direct requirements of non-disclosure are found in it[667]: the cited interpretation is thus to be firmly rejected.

On the contrary, according to a second and more convincing position, clinical trials disclosure is totally consistent with the data exclusivity regime[668].

Indeed, as it has been shown above, data exclusivity protects clinical trials data from competitors in the realm of marketing authorization processes.

As far as the fulfilment of public health interests related to the spread of knowledge about drug's safety and efficacy characteristics is concerned, the data exclusivity provisions do not pose any obstacle to the implementation of transparency systems.

Indeed, given that the provision does not mention (non)disclosure at all, scholars have noticed how, once the protection against unfair commercial use is assured through the compliance with the non-reliance obligations, "nothing should prevent a regulator from disclosing those data to the wider public *without having to argue that disclosure is demonstrably necessary for public protection*"[669].

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[665] ADAMINI-MAARSE-VERSLUIS-LIGHT, *Policy making on Data exclusivity in the European Union: from industrial interests to legal realities, supra,* 1105; International Federation of Pharmaceutical Manufacturers and Associations, *Encouragement of new clinical drug development: the role of data exclusivity, supra,* 5. On the issue also LEMMENS, *Pharmaceutical knowledge governance: a human rights perspective, supra,* 165.

[666] JUNOD, *Drug Marketing Exclusivity in the United States & European Union Law, supra,* 506.

[667] Literature has however noticed how this lack of expressed confidentiality obligations does not mine the international requirements under the TRIPs Agreement, for, after the elapse of the exclusivity period, test data are not disclosed to third parties, but at the contrary only reliance upon the first applicant's data is made, therefore not compromising at all confidentiality obligations under TRIPs, COTTIER-MEITINGER-MEITINGER, *The protection of Test Data submitted to Governmental Authorities: The impact of the TRIPs Agreement on EC law, supra,* 68.

[668] COTTIER-MEITINGER-MEITINGER, 66. This is stressed also by LEMMENS-TELFER, *Access to Information and the Right to Health: the Human Rights Case for Clinical Trials Transparency, supra*, 86.

[669] LEMMENS-TELFER, *Access to Information and the Right to Health: the Human Rights Case for Clinical Trials Transparency, supra,* 85. Emphasis added.

6. Towards a systematic solution

In light of the above made considerations, another step forward can be done towards the core of the problem regarding the conflict between private commercial interests defended by research-based companies and public transparency goals, functional to the promotion of health and scientific research. Data protection and data exclusivity regimes have been successfully lobbied by the pharmaceutical industry as a means of amplifying market shares and recouping the costs of drug development[670].

This form of "back door intellectual property"[671] regarding clinical trials data, has been consequently invoked by research-based companies associations[672] as evidence of the fact that information embedded in the application protocols is commercially valuable and therefore falling under the exemptions to general transparency rules[673].

The commercially sensitiveness of clinical trials data is clearly shown by economic analysis and directly confirmed by the establishment of a legal and economic protection granted by the above examined regimes[674].

However through the analysis of both the international and supranational normative framework, shaping the adequate protection to this particular commercial asset, the issue of clinical trials data disclosure is addressed and substantially resolved.

Indeed, at the international level art. 39.3 TRIPs Agreement on the one hand defines the trade secret status of test data, on the other it provides a public health exemption for disclosure.

The perspective of this provision is therefore exactly the opposite of the one emerging from the recent European legislation: if the former poses the

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[670] See REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 4.
[671] *Ibid.*.
[672] See the statements contained in EGA, *Data exclusivity, a major obstacle for Innovation and Competition in the EU Pharmaceutical sector, supra,* 9.
[673] Cf. *supra* chapter 1.
[674] See *supra,* chapter 1.

general rule for non-disclosure, remaining disclosure an exemption, the latter, as it has been shown above, has the contrary approach.

Yet, the balance to be stricken remains the same, and no further, decisive, interpretative guidelines for the disclosure or concealment solution is to be found.

On the contrary, an accurate evaluation of the data exclusivity regime[675], criticised by literature for having raised the threshold of protection with reference to international obligations[676], offers a deeper understanding of the issue.

Indeed by purging competition through the isolation of a monopoly zone regarding marketing authorization, the commercial value of trials data is recognised and effectively secured.

The shield provided by the non-reliance obligation imposed on regulatory agencies, has thus the effect of neutralising the threats to research-companies' commercial interests given by disclosure.

Through the establishment of databases reporting the results of clinical trials as regards drug's safety and efficacy features, general access to information is granted with substantial benefits for scientific research, innovation, and progress[677].

Consumer ONGs and healthcare providers would in that way increase their conscience over drug's safety, whereas the research community and generic companies would gain knowledge of the arrival point of scientific development, in virtue of a mechanism that is similar to the transparency functions of patents.

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[675] Stressing the need for further research on the adequate duration of data exclusivity protection PUGATCH, *Intellectual Property and pharmaceutical data exclusivity in the context of information and market access, supra,* 25; JUNOD, *Drug Marketing Exclusivity in the United States & European Union Law, supra,* 510; FACKELMAN, *Clinical data, data exclusivity and private investment protection, supra,* 183.

[676] See in particular REICHMAN, R*ethinking the role of clinical trials data in international intellectual property law: the case for a public goods approach, supra,* 13 ss.; ID., *Undisclosed Clinical Trial Data under TRIPs Agreement and its Progeny: a broader perspective, supra*, 18.

[677] JUNOD, *Drug Marketing Exclusivity in the United States & European Union Law, supra,* 515-516, stating that disclosure would finally put an end of the "sitting" of drug agencies on "hoards of precious information".

Thus, under a data exclusivity regime, making clinical trials data publicly accessible has only positive effects from a public health and knowledge standpoint.

As in the patent system, no erosion of commercial interests is to be found as long as the law precludes the marketing of similar products on the basis of the so disclosed clinical trials data.

This said, it can be easily noticed how the *sui generis* form of intellectual property at stake, does not only *permit*- this meaning *not preventing*- clinical trials data disclosure, but is rather to be seen as a positive normative ground *for* disclosure[678].

Indeed, data shielded by exclusivity regimes are *de facto* protected against unfair commercial use[679].

The only use enabled by disclosure is thus the *fair use* for medical research and consumer consciousness enhancement.

Reflections on the fundamental rights to health, to the share of the benefits of scientific progress, and to information are therefore evident[680].

It is therefore in the realm of the intellectual property framework itself that disclosure of test data finds its legal justification and that the interpretational short circuit between general rules and exemptions is interrupted.

As illustrated above, the definition of what has to be factually considered commercially relevant information leads to substantial interpretative and therefore practical uncertainties.

Before addressing it on an interpretative level, the issue at stake has thus to be defined from a systemic perspective.

From this latter point of view, the normative framework concerning clinical trials data shows that protection of the commercial interests entailed in test data, is not to be regarded as an *exemption* to a general transparency rule- thus in a conflict perspective- but rather as a *rule* itself in the realm of the

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[678] In this direction LEMMES-TELFER, *Access to Information and the Right to Health: the Human Rights Case for Clinical Trials Transparency, supra,* 85, stating that "data and market exclusivity may be undesirable for other reasons, but exclusivity protection can clearly be invoked by those states that have entered into TRIPs+ agreements to defend the introduction of detailed trial registration and results reporting obligation".

[679] *Ibid.*.

[680] See *infra* Conclusions.

intellectual property discipline, that systematically interacts with other branches of the drugs' regulatory legislation.

Furthermore, as some literature has been stressing, the data exclusivity regime does not require exclusivity over clinical trials data, but rather over the marketing authorisation effect related to them[681].

This subtle specification of the object of protection underlines how disclosure, directly referring to the data itself, is not in any way prevented under data exclusivity regimes.

Thus, disclosure of pharmaceuticals' safety information does not affect the marketing authorisation exclusivity effect, which is protected in the realm of a separate body of law aiming at sheltering companies' industrial know-how. This purpose is achieved through the prohibition of the release of marketing authorisation for similar products, to be interpreted as a specification of the international obligation of protecting against the unfair use of clinical trials data.

Hence, data exclusivity rule is not in contrast with the drug regulatory disclosure provisions of the latest reforms. On the contrary, it supports them, providing a structural justification for disclosure. The latter is in fact systematically rationalized *on the condition that* commercial interests are generally protected.

In this perspective, it is the combined reading of consideration of different areas of clinical trials data's normative framework that addresses the evaluation, on the one side, of the demand to preserve economic incentives, and on the other, of the satisfaction of public interests, in a complementary, rather than in an exclusionary manner.

The interpretative creation of a non-disclosure obligation would unbearably alter this scheme. Indeed informational overprotection ends up mining pharmaceuticals' safety awareness, with important repercussions on public health's quality, and generating additional market failures caused by health risks[682].

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681 FACKELMAN, *Clinical data, data exclusivity and private investment protection, supra,* 173.

682 "economists and law makers have supported disclosure as a non-intrusive way to correct market failures that cause health and environmental risks and harms.48 Access facilitates an array of essential

Furthermore, also overall dynamic market efficiency[683] results to be affected, impacting on ultimate innovation and competition development[684].

Indeed, given that the economic arguments justifying the granting of certain kinds of market "immunities" in consideration of the intellectual efforts triggering industrial innovation, must be considered as an untouchable basis of every intellectual property analysis, it is exactly to these same arguments that one must refer in order to draw a line between what is worth of protection and what is not, and in order to define the desirable scope of the protection itself[685].

In this light if the non-reliance obligation deriving from the data exclusivity regime, appears to be perfectly compatible with intellectual property system's rationales[686], the legal consistency of non-disclosure obligations is on the contrary very weak.

Thus, it is only when the basic non-reliance protection expires that the demand to protect commercial interests gains again proper room, and must be satisfied through the evaluation of the exemption to the general disclosure rule.

Once having defined the structural weight of the data exclusivity regime, and hence the legal foundations of clinical trials disclosure, the effective scope of mandatory reporting practices can be defined by shifting the focus on the interpretational issue of the balancing of opposite interests[687].

For this purpose, important suggestions are to be derived from the human rights, consumer law and public goods perspective.

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social and market responses that depend upon information pro- duction and sharing". LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in an environmental health, and safety law, supra,* 483.

683 RAMELLO, *Incentives, Efficiency, and Social Justice: the Strange Case of Intellectual Property and Knowledge, supra,* 19 ss..

684 FACKELMAN, *Clinical data, data exclusivity and private investment protection, supra,* 175.

685 MUZAKA, *Politics of Intellectual Property and Access to Medicines, supra,* 20-21.

686 The peculiarities of this form of intellectual property must however be adequately evaluated. Cfr. BRAUN-PUGATCH, *The changing face of pharmaceutical industry and intellectual property rights,* in *The Journal of World Intellectual Property, supra,* 610.

687 Cf. LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in an environmental health, and safety law, supra,* 468, stating that "rather than balancing the two interests, the law should return to first principles and make it clear that EHS (Environmental, Health and Safety information) disclosure is the general rule. Only very limited nondisclosure privileges should be allowed to pro- tect new and emerging innovations".

7. Privacy restraints

Apart from the need to protect commercially confidential information, the second restraint that research-based companies have opposed in order to contrast the establishment of clinical trials reporting practices has been the confidentiality of volunteers' personal data[688].

Indeed, before and during the testing procedures, an enormous amount of volunteers' personal information is put together, sufficient to provide a detailed health profile of the individual being tested. On the basis of these personal data the relevant drugs' safety and efficacy information is produced[689]. The issue of personal health data collection becomes also more complex if one considers the growing importance of pharmacogenomics, based on the use of an individuals' entire genetic profile for the purposes of the development of personalized pharmaceutical products[690], in this way raising even deeper privacy concerns[691].

Hence, amongst the data obtained through testing, not only commercially valuable information is to be found, but also sensitive information regarding the health status of patients and their response to the new developed drug.

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688 LEMMENS, *Pharmaceutical Governance: a Human Rights Perspective, supra,* 181. For exampla, in its claim in front of the ECJ *InterMune* affirmed for grounds of disclosure the fact that information embedded in the clinical trials are protected by the fundamental right to private life under art. 8 of the ECHR. Cf. European Medicines Agency vs. InterMune, C-390/13 P(R), order of the Vice-President of the Court, 28 November 2013, *supra*

689 Cf. Italian Data Protection Authority, *Guidelines for data processing within the Framework of Clinical Drugs Trials- 24 July 2008,* online available at http://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/export/1671330, 1.

690 For an assessment of legal implications of personalized medicine from a regulatory standpoint see RILEY, *An Unfulfilled Promise: Changes Needed to the Drug Approval Process to make Personalized Medicine a Reality,* 70 Food & Drug Law Journal (2015), 289 ss., 300-305, stressing how in the development of a 'personalized' pharmaceutical product not only 'ordinary' clinical trials are needed, but also "patient experience data, combining claims and cost data, clinical data included in the electronic health record, and data reflecting patient behaviour and preferences which may be commercially owned by entities outside the pharmaceutical and health provider industries". The amount of personal data to be processed by pharmaceutical sponsors is thus bigger from both a quality standpoint-*i.e.* genetic information, that expresses the most intimate of individuals' features- and a quantity standpoint- *i.e.* the variety of information needed for the product being effectively personalized.

691 See GOLDMAN, *Pharmacogenomics: Privacy in the Era of Personalized Medicine,* 4 Nw. J. Tech. & Intell. Prop. (2005-2006), 83 ss., 91-96, stressing the discriminatory threats caused by the publication of genetic profiles in freely accessible databases. However the Author acknowledges also the high social gains that a rich genetic database would achieve, given the "increased opportunity for research to identify and isolate polymorphisms affecting drug metabolism".

This information has been referred by literature as "the most intimate, personal, and sensitive of any information maintained about an individual"[692].

The complexity of clinical trials protocols makes it difficult to clearly distinguish which piece of information is to be qualified as personal data or as commercial confidential information. It can be thus argued that this is a case of the ever growing overlapping of personal data and commercial confidential data qualification of a company's same informational asset[693].

The demand to protect patients' health information confidentiality has been stressed in the Declaration of Helsinki of 2003, underlining how "every precaution must be taken to protect the privacy of research subjects, and the confidentiality of their personal information"[694]. The same declaration stresses the "right of research subjects to safeguard their integrity" and acknowledge how "every precaution should be taken to respect the privacy of the subject, the confidentiality of patients' information and to minimize the impact of the study on the subjects' physical and mental integrity and on the personality of the subject"[695]. Also the Council for International Organizations of Medical Science's International Ethical Guidelines has recognised the need for the trials investigators to "establish secure safeguards of the confidentiality of subjects' research data", and that "subjects should be told the limits, legal or other, to the investigators' ability to safeguard confidentiality and the possible consequences of braches of confidentiality"[696].

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[692] GOSTIN, *Health Information Privacy,* 80 CORNELL L. REV. (1995) 451. Also case law about health information has stressed the "highly private and personal" nature of health information, as the Canadian Supreme Court confirmed in the controversy *McInerney v. MacDonald,* cited by LEMMENS, *Pharmaceutical knowledge governance: a human rights perspective, supra,* 168.

[693] For a general assessment see European Data Protection Supervisor, *Privacy and Competitiveness in the age of big data: the interplay between Data Protection, Competition law and Consumer Protection in the digital Economy,* March 2014, online available at https://secure.edps.europa.eu/EDPSWEB/webdav/shared/Documents/Consultation/Opinions/2014/14-03-26_competitition_law_big_data_EN.pdf, 26.

[694] Cf. *Declaration of Helsinki- Ethical Principles for Medical research involving Human subjects*, *supra,* par. 23.

[695] *Ibid.*.

[696] International Organizations of Medical Science, *International Ethical Guidelines for Biomedical Research involving Human Subjects*, Geneva, 2002, online available at http://www.cioms.ch/publications/layout_guide2002.pdf, par. 18.

Privacy concerns have been thus internalized by the European Clinical Trials Regulation, underlining how the record, process, handling, and storage of clinical trials data must be carried out in accordance "with the applicable law on personal data protection"[697] and that the "EU database shall be publicly accessible unless, for all or part of the data and information contained therein, confidentiality is justified" on the grounds of "protecting personal data in accordance with Regulation EC n. 45/2001"[698].

The scope of this second exemption to the general disclosure rule has thus to be better evaluated in light of the provisions of the European data protection framework: indeed it is evident how the need to protect subjects' personal data can substantially impact on the effectiveness of legal transparency requirements.

In this perspective, clinical trials disclosure is to be located on the edge of another trade off between public and private interests: information, scientific research, and therefore health demands face in this case the restraints suggested by the preservation of individuals' right to dignity[699]. More generally, the fostering of health research through mandatory publication of data also falling under the scope of data protection rules, seems to reach the very core of what some scholars have defined the "privacy-innovation *conundrum*"[700].

In the course of pharmaceutical product development, threats to research subjects' personal data are firstly to be found at a stage precedent to the granting of a marketing authorisation.

Indeed, during the conduction of the testing, the health information of research subjects is accessed by the medical staff, and in second instance by the sponsor itself, often collaborating with other entities such as analysis laboratories or research organizations working on a contractual basis

[697] Art. 56 of Regulation EU n. 536/2014, of the European Parliament ad of the Council, of 16 April 2014, on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, *supra*.

[698] Art. 81.4 of Regulation EU n. 536/2014, *supra.*

[699] GOSTIN, *Health Information Privacy, supra,* 490.

[700] Quoting ZARSKY, *The privacy-innovation Conundrum,* 19 Lewis & Clark L. Rev. (2015), 115 ss..

(CRO), in most cases located outside the EU. The continuous information exchanges so derived pose substantial threats to personal data's confidentiality, therefore raising the need, acknowledged by some strand of literature, of raising a high standard of protection in order to "prevent specific risks from affecting data subjects" [701]. More specifically, it must be recalled how the Directive 96/45/EC imposes an explicit ban as regards the transfer of personal data from EU Member States to other non EU countries, where the legal regime does not assure an adequate level of privacy protection[702]: these provisions could indeed pose some problems for multinational pharmaceutical companies [703], considered that the collection of the trials information is carried out in CRO mostly located outside the European Union[704].

Additional, and equally challenging privacy issues emerge from the establishment of reporting platforms regarding clinical study reports, and thus directly concerning the personal information embedded in them.

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[701] Italian Data Protection Authority, *Guidelines for data processing within the Framework of Clinical Drugs Trials- 24 July 2008, supra,* 2, underlining that "the collection, dissemination and large scale retention (partly in third countries), of multifarious information items related to the health and, in some cases, the sex life of individuals enrolled in clinical trials are fraught with several criticalities in terms of personal data protection; accordingly, a high standard of protection is required in order to prevent specific risks from affecting data subjects".

[702] Cf. art. 25 of the Directive 96/45/EC of the European Parliament and the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data, affirming that "The Member States shall provide that the transfer to a third country of personal data which are undergoing processing or are intended for processing after transfer may take place only if, without prejudice to compliance with the national provisions adopted pursuant to the other provisions of this Directive, the third country in question ensures an adequate level of protection; The adequacy of the level of protection afforded by a third country shall be assessed in the light of all the circumstances surrounding a data transfer operation or set of data transfer operations; particular consideration shall be given to the nature of the data, the purpose and duration of the proposed processing operation or operations, the country of origin and country of final destination, the rules of law, both general and sectoral, in force in the third country in question and the professional rules and security measures which are complied with in that country".

[703] SCHULZE STEINEN-BOHN, *Data Protection in Clinical Studies- Implications of the new EU General Data Protection Regulation,* published on 19th June 2012, online available at http://www.klgates.com/files/Publication/54c52880-824b-4c9c-a3bd-284f8b774c77/Presentation/PublicationAttachment/8ed5a350-8281-473d-8bf2 1d6b2f9e6c75/Alert_DataProtection_june2012.pdf, 4.

[704] *Ibid.*.

Indeed, the systematic disclosure of personally sensitive information clearly raises a risk of massive personal data's distortive and discriminatory misuse, traditionally related to health information recording systems[705].
However, a closer analysis of the European Data Protection framework shows how disclosure of trials subjects' personal data collected in the context of clinical research experiences, is not radically prevented, and with that how the threats posed to the effectiveness of Clinical Trials Regulation's mandatory disclosure provision by the cited privacy exemption, are actually of little significance.

7.1 Transparency in clinical key-coded personal data: in search for regulatory gaps

Against this backdrop, three are the data protection tools to be examined for our purposes: first, interesting insights are to be derived from the de-identification techniques used to process the collected data; secondly, informed consent conditions to treatment are to be considered of particular relevance for the inclusion of scientific research purposes amongst the legitimate uses of personal data; finally, the same data protection provisions take into consideration scientific research needs through specific exemptions to ordinary data protection rules.

As far as the first point is concerned, data collected through testing procedures undergo a process of de-identification[706]: indeed, in accordance to the good clinical practice guidelines established by the Clinical Trials

[705] "The systems also have the potential to process more data in new context and to make them more readily available to a wider circle of recipients than before, thereby changing the whole scale of possible misuse of medical information about individual patients". Art. 29 Data Protection Working Party, *Working Document on the processing of personal data relating to Health in Electronic Health Records (EHR),* Adopted on 15 February 2007, online available at http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2007/wp131_en.pdf. On the issue see also RYNNING, *Public Trust and Privacy in Shared Electronic Health Records,* in *European Journal of Health Law,* 14 (2007), 105-112. See also BANZI-BERTELE'-GARATTINI, *Accessibilità dei dati sui farmaci: Le nuove norme EMA,* in *Giornale Italiano di Farmacoeconomia e Farmacoutilizzazione,* 2014, 6, 11-12.
[706] Cf. World Health Organization, *Handbook for Good Clinical Research Practice (GCP) for trials on pharmaceutical products*, Geneva, 2002, online available at http://apps.who.int/prequal/info_general/documents/gcp/gcp1.pdf, 103-106.

Directive[707] and the Good Clinical Practice Directive[708], participants in clinical trials are given a unique identification number[709], with the purpose of carrying out the testing procedures under anonymity[710]. The collected data are thus key-coded, or better said, pseudonymized[711].

It is on the basis of these de-identification mechanisms that the European Ombudsman has negatively resolved the problem of the protection of personal data embedded in clinical trials protocols, by stating that due to the difficulty of re-identification, no privacy obstacles were to be found for disclosure[712].

However this position provides a simplistic insight on the issue, given that these mechanisms are not irreversible[713]: on the contrary the same Good

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[707] Directive 2001/20/EC, of the European Parliament and of the Council, of 4 April 2001, on the approximation of the laws, regulations and administrative provisions of Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, *supra.*

[708] Directive 2005/28/EC of 8 April 2005, laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufactoring or importation of such products, *supra.*

[709] European Medicines Agency, Guideline for Good Clinical Practice, Note for Guidance on Good Clinical Trials Practice, July 2002, online available at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf, stating that "a unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial related data". European Medicines Agency- Heads of Medicines Agency, *Guidance document on the identification of commercially confidential information and personal data within the structure of the marketing authorisation (MA) application- Release of information after the granting of a marketing authorisation, supra,* 2.

[710] Cf. Health Action International, *Protecting citizens' Health: Transparency of Clinical Trial Data on Medicines in the Eu, supra,* 4-5.

[711] On the issue, LASTIC, *Are Clinical Trials Data Transparency and Patient Privacy mutually exclusive?,* Conference Paper, 2013 CDSC International Exchange, Bethesda, online available at https://www.researchgate.net/publication/259923557_Are_Clinical_Trials_Data_Transparency_and_Patient_Privacy_mutually_exclusive; SETHI, *The Promotion of Data Sharing in Pharmacoepidemiology,* in *European Journal of Health Law,* 21 (2014), 271 ss., 282, underlining the benefits of pseudonymization, to be seen as "one mechanism which does enable traceability whilst alleviating some concerns around using identifiable data", and as "one of several mechanisms which speak to current flexibilities around conducting data linkage". The Author stresses the difference between pseudonymisation and anonymisation techniques, stressing the advantages of the former. *Contra* see CAVOUKIAN-EMAM, *Dispelling the Myth Surrounding de-identification: Anonymization Remains a Strong Tool for Protecting Privacy,* June 2011, online available at https://www.ipc.on.ca/images/Resources/anonymization.pdf.

[712] This point has already been discussed in chapter 1 paragr. 2.2.2.

[713] Cf. Article 29 Working Party on anonymization techniques, online available at http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2014/wp216_en.pdf, 5, stressing that as a consequence of anonymization techniques, "the data must be stripped of sufficient elements, such that the data subject can no longer be identified. More precisely, thet data must be processed in such a way that it can no longer be used to identify a natural person by using "all the means likely reasonably to be used" by either the controller or a third party. An important factor is that the processing must be irreversible". Directive 95/46/EC, *supra,* does however not clarify how such a de-identification process should or could be performed. *Contra* see OHM, *Broken Promises of Privacy: Responding to the surprising failure of anonymization,* 57 UCLA LAW REV. (2010), 1701 ss., presenting interesting re-identification examples.

Clinical Practices expressly require that the personal information must be key-coded in a way that can allow the sponsor, through the investigator, to retrieve the data subject[714].

In practice, trials centres own a list where the codes are matched with patients' identification. This list should theoretically remain confidential, but in fact sponsors gain knowledge of it through their own study monitors visiting the trials centres in order to verify the observance of the relevant protocol.

In this light, it is evident how personal data collected through testing processes, are subject to a considerably higher number of exposure threats, compared to 'ordinary' health data.

Indeed, health data are generally fully protected by healthcare providers' confidentiality obligation[715]. Under the duty of confidentiality, practitioners must not use or disclose information in a way that disappoints "reasonable expectations of privacy"[716].

To the contrary, during the trials, the confidentiality obligation of physicians is weakened by the fact that for the effectiveness of their controls, sponsors must have access to all information protocols, including non-coded source documents[717]. For example, sponsors can access the list

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[714] SCHULZE STEINEN-BOHN, *Data Protection in Clinical Studies- Implications of the new EU General Data Protection Regulation, supra*, 3.

[715] Cf. Art. 81,1 comma lett. a) of the Proposal for a Data Protection Regulation, mentioning "the obligation of professional secrecy" and the "obligation of confidentiality", weighing on health professional subjects. Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), voted on the 15th December 2015, online available at http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf. On the issue see TAYLOR, *Confidential Patient Information For Public Health: Distinguishing Between Health Protection and Health Improvement,* in *Medical Law Rev.,* 23, 3, 348 ss, stressing how the duty "to protect *identifiable* patient data is rooted in professional ethics as well as common law". CALLENS, *The Privacy Directive and the Use of Medical Data for Research Purposes,* in *European Journal of Health Law,* 2, 1995, 309 ss., stating how "the physician has the obligation not to disclose confidential patient information which he learns in the course of his professional practice. Together with the individual interest, the general interest is at the root of the general secrecy rule. This means that it is in the interest of everyone that the physician, in the course of his professional practice, does not betray a patient's confidence".

[716] TAYLOR, *Confidential Patient Information For Public Health: Distinguishing Between Health Protection and Health Improvement, supra,* 353, citing the relevant English case law, that has widely been affirming how "information that can identify individual patients, must not be used or disclosed for purposes other than healthcare without the individual's explicit consent, some other legal basis, or where there is a robust public interest or legal justification to do so".

[717] VAN QUATHEM, *Controlling Personal Data- The case of Clinical Trials,* Data Protection Compliance Advisor, Covington and Burling, 2005, online available at https://www.cov.com/~/media/files/corporate/publications/2005/10/oid64167.ashx.

of the names in the realm of the controls of the procedures aimed at obtaining research subjects' informed consent[718]. In this regard it has been noticed how the practitioner of clinical trials bears a real conflict of interest related to his dual role of both physician and researcher appointed by enterprises[719].

Secondly, through the trials procedures, the same data subject undergoes various phases of testing, every of which generating data that will be further processed for the necessary product safety assessments within analytics that comprehend all the data collected through the whole testing by all the volunteers involved[720]. With this regards, scholars have noticed how each same set of test data has different sources, related to the various testing phases, this leading in return to a higher identification hazard[721].

Literature has stressed how the greater possibility to identify key-coded data is directly functional to a better achievement of the research purposes intended to be achieved through the clinical studies, in relation for example to the need to monitor the patients' response to a tested product also after the phases of the ordinary testing have been carried out[722]. In this regard, it has been significantly argued that "data can be either useful or perfectly anonymous but never both"[723].

The fact that volunteers' data are key coded must be better assessed in light of the European data protection provisions. Indeed the Data Protection Directive 95/46/EC regards as personal information every information related to a person that is *indirectly* identifiable through an identification number[724]. Also Art. 29 Data Protection Working Party has underlined the

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[718] Italian Data Protection Authority, *Guidelines for data processing within the Framework of Clinical Drugs Trials- 24 July 2008, supra,* 4.

[719] Cf. TERRY, *Protecting Patient Data in the age of Big Data,* 81 UMKC L. Rev. (2012-2013), 385 ss., 410.

[720] MCGRAW et al., *Privacy and Confidentiality in pragmatic clinical trials,* in *Clinical Trials Journal,* 12, 5, 520 ss., online available at http://ctj.sagepub.com/content/12/5/520.full.pdf+html.

[721] *Ibid.*, 524. On these same issues, see also SETHI, *The Promotion of Data Sharing in Pharmacoepidemiology, supra,* 288.

[722] It is the case of the monitoring of long term adverse events. Cf. VAN QUATHEM, *Controlling Personal Data- The case of Clinical Trials, supra,* 3.

[723] OHM, *Broken Promises of Privacy: Responding to the surprising failure of anonymization, supra,* 1703-1704.

[724] According to Art. 2 (a) of Directive 95/46/EC, *supra,* "personal data shall mean any information relating to an identified or identifiable natural person (data subject); identifiable person is one who

relevance as personal data of every piece of information deriving from the combination of different items, and allowing the identification of a data subject[725]. Specifically referring to key coded data, the Working Party has underlined how such data "constitutes information relating to *identifiable* natural persons for all parties that might be involved in the possible identification, and *should be subject to the rules of data protection legislation*"[726]. Hence, under the current European approach, literature has underlined how *identifiable* data gain the same status of *identified* data[727].

The very broad notion of personal data adopted by the European Union[728] is thus perfectly capable of comprehending key-coded data that are, as shown above, very easy to decode.

In this perspective, the trials' sponsor, *i.e.* the research-based company, is to be considered data controller, as it is the sponsor itself that initiates the trials and determines the purpose and means of the processing of the collected data[729]. The role of the data controller can be also held by the contract research organization responsible for the conducting of the trials in the cases the organization itself takes over the ordinary functions of the sponsor[730]. Moreover pharmaceutical companies are to be considered also data processors, for they being the very first 'centre of administration' of the trials protocols before the handing out of trials portfolios to the regulatory agency.

Under these premises, if also key-coded data are to be fully considered as personal information, then it is evident that data protection provisions must

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can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity".

[725]For example through the matching of a patient's initial with his birth date. Article 29 Data Protection Working Party, Opinion n. 4/2007 on the concept of personal data, online available at http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2007/wp136_en.pdf.

[726] *Ibid.*. Emphasis added.

[727] SCHWARTZ-SOLOVE, *Reconciling Personal Information in the United States and European Union,* 102 California Law Rev. (2014), 877 ss., online available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2271442, 895-896. Emphasis added.

[728]*Id.*, focusing on the difference between American and European notion of personal data, being the former narrower due to a direct identification requirement.

[729] GILLON, *"Fully" informed consent, clinical trials, and the boundaries of therapeutic discretion,* in DOYAL-TOBIAS, *Informed Consent in Medical Research,* London, BMJ Books, 2001, 257 ss., 262.

[730] SCHULZE STEINEN-BOHN, *Data Protection in Clinical Studies- Implications of the new EU General Data Protection Regulation, supra,* 2-3.

be fully applied, with all the related obligations imposed by the law[731], such as limits on information use and restrictions on information disclosure[732].

Such a high privacy threshold protection may however lead to an overprotection of these data that are very unlikely to be identified for various reasons, because of the difficulty of de-codification of the same data[733], or because of the difficulty to retrieve the data subject[734].

Some scholars have for example mentioned the scenario in which the data controller maintains encrypted keys along with strong institutional safeguards to prevent access to key-coded data unless specifically defined events occur, affirming how "the party who accesses the data but not the keys, handles information that is functionally *nonpersonal information for that party*" and concluding that "in certain circumstances, therefore, the possibility of identification may be highly remote for the party who has access only to key-coded data"[735]. According to this viewpoint, greater attention to "the risk level associated with potential identification" is to be given, with the consequence that information that is merely identifiable *should not be treated "as fully equivalent to identified information"*[736].

To the contrary, it is argued, the European data protection rules are shaped so as to increase the level of protection in a manner that is disproportionate to the effective risks connected to data use, in that way blocking "socially productive uses of analytics that do not raise significant risks of individual privacy harms"[737]. Echoing this reasoning, also from the lines of civil law scholars it has been acknowledged, through a much more theoretical argument, how the processing of sensitive health data for research purposes is substantially different from the use of these same data for purposes that

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731 VAN QUATHEM, *Controlling Personal Data- The case of Clinical Trials, supra,* 3.
732 SCHWARTZ-SOLOVE, *Reconciling Personal Information in the United States and European Union, supra,* 910. Cf. SETHI, *The Promotion of Data Sharing in Pharmacoepidemiology, supra,* 272.
733 For example, if the matching documents from which the name of the data subject is to be derived, gets lost, or there is a proof of destruction.
734 MCCHARTHY-PORTER, *Confidentiality: the Protection of Personal Data in Epidemiological and Clinical Research Trials,* 19 L. Med. & Health Care 1991, 238.
735 SCHWARTZ-SOLOVE, *Reconciling Personal Information in the United States and European Union, supra,* 896. Emphasis added.
736 *Ibid.*, 909. Emphasis added.
737 *Ibid.,* 910.

are strictly and solely related to the data subject: medical research is indeed not interested in the individual as such, but rather in a group of persons[738].

These positions propose interesting insights as regards the need to find possible ways of converging privacy with scientific research burdens, opening up to solutions that could be of great interest as regards the interpretation of European data protection rules.

More importantly, the underlying intent is the one of heading towards a modulated approach as regards the notion of personal data for scientific research purposes. Such an approach, in return, could be decisive for a mediation between the 'inclusive' European attitude and the 'exclusive' American trends, according to which the qualification of personal data is to be given only to *identified* data[739].

In this regards, the statements contained in the latest EU-US Privacy Shield regarding the move of personal data from the European Union to the United States, are of particular interest: the Shield seems in fact to adopt a European approach as far as the definition of personal data is concerned[740]. In this way, in case of data transfer, the risk of total loss of protection of those data that are only *identifiable*, and thus protected only under EU law, is prevented.

The basic scheme adopted by the Shield is that in cases of transfer of personal data, "EU Member State law applies to the collection of the personal data and to any processing that takes place prior to the transfer to the United States", whereas "the Privacy Shield Principles apply to the data once they have been transferred to the United States"[741].

Moving from the general considerations deeper into specific sectorial branches of regulation, the framework principles issued by the US

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[738] CALLENS, *The Privacy Directive and the Use of Medical Data for Research Purposes, supra,* 324, interestingly noticing how "the fact that there is no mention of misuse ot complaints would confirm the assertion that the invasion of the right to privacy is non-existent or very remote".

[739] This is in fact the definition of personal data to be generally found in a very fragmented and sectorial American data protection framework. See SCHWARTZ-SOLOVE, *Reconciling Personal Information in the United States and European Union, supra,* 891.

[740] "'Personal data" and "personal information" are data about an *identified* or *identifiable* individual". EU-US Privacy Shield Framework Principles Issued by the US Department of Commerce, Annex II, released on the 29th February 2016, online available at http://ec.europa.eu/justice/data-protection/files/privacy-shield-adequacy-decision-annex-2_en.pdf, 3.

[741] *Ibid.*.

Department of Commerce state, with specific regards to clinical trials data, that "personal data developed in specific medical or pharmaceutical research studies often play a valuable role in future scientific research", and that therefore "pharmaceutical and medical device companies are allowed to provide personal data from clinical trials conducted in the EU to regulators in the United States for regulatory and supervision purposes"[742]. Hence, in light of the above mentioned declarations, the move of trials subjects' personal information is not only allowed, but the personal data themselves would receive, according to the rules of the Privacy Shield to be applied after the transfer has been carried out, a European styled protection.

However, a deeper look in the technicalities of the issued clinical trials data protection leads to radically opposite conclusions. Indeed, the framework principles explicitly refer to research key-coded data- that constitute, as it has been stated, the most, if not the entire, part of the personal data collected through pharmaceutical testing-, and affirm that "a transfer from the EU to the United States of data coded (…) *would not constitute a transfer of personal data that would be subject to the Privacy Shield Principles*"[743].

This statement leads to a few observations.

First, even if the text refers to data that are "uniquely key-coded at their origin by the principal investigator so as not to reveal the identity"[744], it has been illustrated above how sponsors in practice conduct a very deep monitoring over physicians' activities, weakening in this way the confidentiality duties of the same practitioners. It is thus in practice very unlikely- contrary to what the text affirms - that the trials sponsors, *i.e.* research companies, do not get in possession of the key. Indeed, it has been demonstrated above how clinical key coded data collected through trials are exposed to a very high identification risk, rendering these same data

[742] EU-US Privacy Shield Framework Principles Issued by the US Department of Commerce, Annex II, *supra*, 27, further stating "EU Member State law applies to the collection of the personal data and to any processing that takes place prior to the transfer to the United States. The Privacy Shield Principles apply to the data once they have been transferred to the United States".
[743] *Ibid.*, 28. Emphasis added.
[744] *Ibid.*.

absolutely *identifiable*, and thus, according to the principles and definitions adopted by the Shield itself, to be protected also after a transfer to the EU.
It is thus interesting to notice that the Privacy Shield adopts an opposite solution as regards pharmaceutical test data, that do not fall in the scope of personal data, and that can consequently be freely processed for research purposes. With this regards, the Privacy Shield seems to have perfectly internalized the increased attention given by American literature to the need to enhance analysis of large key coded data sets for healthcare research purposes[745]. Given that clinical trials data are substantially formed by coded personal data, it is clear that a narrower interpretation of the notion of personal data, like the one adopted in the United States and finally also by the Privacy Shield Framework Principles with specific regards to clinical trials data[746], removes obstacles to the processing of those data, and more precisely to publication of those same data in publicly accessible databases.

Coming back to the European framework, despite the critics coming from the lines of various scholars, calling for an adjustment of data protection rules to health research purposes[747], the European Union appears to include pseudonymised data within the scope of personal data. Things won't change with the enactment of the data protection Regulation, where it is remarked how on European ground "the principles of data protection should apply to any information concerning an identified or identifiable natural person"[748].

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[745] It has been in fact largely shown how information-based research has enabled very important discoveries, in that way shifting the centre of medical research itself, from traditional trialling to collected data analytics. Cfr. V.V. A.A., *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health through Research,* 2009, online available from the National Academy Press, http://www.nap.edu/catalog/12458.html, 112 ss..

[746] EU-US Privacy Shield Framework Principles Issued by the US Department of Commerce, Annex II, *supra,* 1.

[747] Cf. SETHI, *The Promotion of Data Sharing in Pharmacoepidemiology, supra,* 284, underlining how the current regulatory European patterns do not properly address the need of the promotion of scientific research, therefore concluding that "a regulatory approach which better promotes sharing data in appropriate circumstances is needed".

[748] Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), *supra*, recital 23, further stating that "*Data which has undergone pseudonymisation, which could be attributed to a natural person by the use of additional information, should be considered as information on an identifiable natural person.* To determine whether a person is identifiable, account should be taken of all the means reasonably likely to be used, such as singling out, either by the controller or by any other person to identify the individual directly or indirectly. To ascertain whether means are reasonable likely to be used to identify the individual, account should be taken of

In relation to the recent European transparency policies, it is clear that this large notion of personal data is likely to have a great impact, as it was with the case of commercial confidential data, on the effectiveness of the mandatory disclosure rule posed by art. 81(4) of the Clinical Trials Regulation. Indeed, as it has been noticed, a significant part of clinical trials protocols are exactly made up by personal health data of the volunteers that underwent the trials, falling therefore under the scope of the privacy exemption provided by the same normative provision.

However, in the lines of both past and future European data protection rules, the lawfulness of the processing for scientific innovation purposes of codified data qualified as personal sensitive data, such as health data, can still be justified in consideration of the gaps opened up by both informed consent determinations and the public interest exemptions contemplated by the same data protection provisions.

Indeed, in the management- that is to say collection and eventual release- of the volunteers' personal data a crucial role is played by the informed consent conditions to treatment[749].

It is important to recall how the conduction of medical experimentation without informed consent is explicitly considered as a human rights violation by art. 7 of the International Covenant on Civil and Political Rights[750].

As far as the informed consent is concerned, international guidelines as well as scholars have stressed how the consent forms, to be effective, must provide sufficient detail about the product being tested, its risks and its intended use[751]. The handing out of this information necessary for the

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all objective factors, such as the costs of and the amount of time required for identification, taking into consideration both available technology at the time of the processing and technological development". Emphasis added.

749 GILLON, *"Fully" informed consent, clinical trials, and the boundaries of therapeutic discretion, supra,* 263-264.

750 Art. 7 of the International Covenant on Civil and Political Rights, "(…) no one shall be subjected without his free consent to medical or scientific experimentation". Cf. LEMMENS, *Pharmaceutical Governance: a Human Rights Perspective, supra,* 170.

751 Cf. SETHI, *The Promotion of Data Sharing in Pharmacoepidemiology, supra,* 285, recalling the statements of the so called "Albrecht Report" for the Committee on Civil Liberties, Justice and Home Affairs, proposing in 2012 numerous amendments to the Proposed Data Protection Regulation, and underlining how the consent must be "specific, informed and explicit". Cf. also MCCHARTHY-

consent to become effectively informed, has been interestingly seen as a first disclosure occasion regarding drug's safety and efficacy data, that are transmitted through informed consent leaflets to clinicians, to patients, and finally also to research ethics committees[752].

However, a closer look to the practice shows how the information about the pharmaceutical product's features disclosed through informed consent forms, are not that detailed, and thus appear to be functional to satisfy the clinical trials sponsor's and conductor's interest in avoiding responsibility, rather than the patients' interests in the enrolment in effectively safe testing procedures[753].

The Clinical Trials Regulation provides a detailed framework for the informed consent that data subjects of trials conducted in the European Union must provide before participating in a trial[754]. In particular, art. 29 requires that "informed consent shall be written, dated and signed by the person performing the interview (…)".

The English Health Research Authority, coordinating ethical committees, has defined "practical steps to promote transparency, including (…) guidance in participant information sheets and consent form content to ensure consent is not a later barrier to data sharing"[755].

PORTER, *Confidentiality: the Protection of Personal Data in Epidemiological and Clinical Research Trials, supra*, 238; International Organizations of Medical Science, *International Ethical Guidelines for Biomedical Research involving Human Subjects, supra,* par. 18 and World Health Organization, *Handbook for Good Clinical Research Practice (GCP) for trials on pharmaceutical products*, *supra*, 106, "The informed consent document should describe (1) who will have access to personal data of the research participants, including medical records and biological samples; (2) the measures taken to ensure the confidentiality and security of research participants' personal information; and (3) the potential risks to subjects if such measures are breached (e.g., stigma, loss of reputation, potential loss of insurability, etc.)".

[752] LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 81.

[753] This is the assertion of CHALMERS-LINDLEY, *Double Standards in informed Consent,* in DOYAL-TOBIAS, *Informed Consent in Medical Research,* London, *supra*, 266 ss.. Stressing the point also FURNESS-NICHOLSON, *Obtaining Explicit Consent for the use of Archivial Tissue Samples: Practical Issues,* in *Journal of Medical Ethics,* 20 (2004), 561 ss., considering the difficulties and impracticalities of obtaining a consent that is to be regarded as effectively informed, and showing the divergences existing on this subject between theory and the practices carried out by trials' conductors.

[754] Cf. recitals 6, 27, 30, 31, 32, 33, 36 and Chapter V regarding protection of subjects and informed consent, artt. 28 ss., of Regulation EU n. 536/2014, *supra.* SCHULZE STEINEN-BOHN, *Data Protection in Clinical Studies- Implications of the new EU General Data Protection Regulation, supra,* 4.

[755] Cf. Health Research Authority, *The HRA Interest in Good Research Conduct, Transparent Research*, May 2013, online available at http://www.hra.nhs.uk/documents/2013/08/transparent-research-report.pdf, 2.

Informed consent to treatment should therefore encourage rather than pose obstacles to clinical trials data disclosure[756].

Indeed, if the explicit and legitimate purpose of the publication in mandatory scientific databases would be specified in the informed consent leaflet, and if the subject would be therefore allowed to subscribe the treatment of its personal data for the purposes of scientific transparency, no misuse of the sensitive information would be found in light of the relevance principle and the purpose-specification rule[757]. However, it must be stressed that consent must explicitly regard public release of the data, and not a generic scientific research purpose[758]. Indeed, as far as the research purposes are concerned, consent is generally given with regards to one specific study, and further uses are not covered[759]. Hence, only the consent given to public disclosure purposes would be capable of overcoming the problem of secondary and further uses of otherwise protected personal data[760]. With this regards however, the Proposed Data Protection Regulation overcomes the problem of the data processing for purposes that are different from the ones to which the subject has given consent to, by affirming that "the further processing for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes should be considered

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756 BANZI-BERTELE'-GARATTINI, *Accessibilità dei dati sui farmaci: Le nuove norme EMA, supra,* 12. Cf. also V.V.A.A., *A Proposal to protect Privacy of Health Information while accelerating Comparative Effectiveness Research,* in *Health Affairs,* November 2010, 29, 11, 2082 ss., online available at http://content.healthaffairs.org/content/29/11/2082.long, stating that "where consent is legally required, it should be easy and convenient for patients to volunteer their medical information for research. Studies indicate broad public willingness to participate in research if asked".

757 Cf. recital 28 of the Directive 95/46/EC, *supra*: "Whereas any processing of personal data must be lawful and fair to the individuals concerned; whereas, in particular, the data must be adequate, relevant and not excessive in relation to the purposes for which they are processed; whereas such purposes must be explicit and legitimate and must be determined at the time of collection of the data; whereas the purposes of processing further to collection shall not be incompatible with the purposes as they were originally specified". Art. 6: "Member States shall provide that personal data must be a) processed fairly and lawfully; b) collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes. Further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible provided that Member States provide appropriate safeguards; c) adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed (...)".

758 Cf. LASTIC, *Are Clinical Trials Data Transparency and Patient Privacy mutually exclusive, supra.*

759 *Ibid.*. On this issue also ZARSKY, *The Privacy-Innovation Conundrum*, *supra*, 141.

760 In this sense, THOMAS-WALPORT, *Data Sharing Review,* issued to the English Government on the 11th July 2008, online available at http://webarchive.nationalarchives.gov.uk/+/http:/www.justice.gov.uk/docs/data-sharing-review.pdf, 31-33.

as compatible lawful processing operations"[761]. Following these lines, also art. 5 of the same Regulation, specifically regarding the principles of data processing, after having affirmed the principle of "purpose limitation" of the given consent, specifies that "further processing of personal data for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes shall, in accordance with art. 83(1), not be considered incompatible with the initial purposes"[762].

Against this backdrop, one last and decisive remark can be made. Indeed, the peculiar public informational value of clinical trials protocols could justify the processing of the personal data at stake also in the absence of any specific consent expressed by the data subject. The examination of the proposal of a general Data Protection Regulation shows how areas of compatibility between information goals and the demands of protection for research-subjects' personal data could be expressly taken into consideration by law.

The proposal of the general Data Protection Regulation provides in fact precious grounds for the disclosure of clinical trials data, through the definition of specific cases in which an information practice is to be regarded as fair in a privacy perspective[763].

In this regard, art. 9 of the Proposal, concerning the prohibition of "the processing of (…) genetic data or data concerning health", defines an exemption to the general rule, when the "processing is necessary for the performance of a task carried out *in the public interest, on the basis of Union law*, or Member State law which shall provide for suitable measures to safeguard the data subject's legitimate interests"[764].

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[761] Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), *supra*, recital 40. Cfr. also art. 40, affirming that Derogating from the prohibition on processing sensitive categories of data should also be allowed (…)for health security, monitoring and alert purposes, the prevention or control of communicable diseases and other serious threats to health".

[762] *Ibid.,* art.5.

[763] GOSTIN, *Health Information Privacy, supra,* 456.

[764] Emphasis added.

Furthermore, Art. 81 of the same Proposal specified that the processing of health data is allowed in the cases it is necessary for "(…) b) reasons *of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety, inter alia for medicinal products or medical device*" [765]. It is interesting to notice that in the last agreed version of the text such provision has been erased, probably because it has been considered redundant in respect of the following general provision of art. 83.

Indeed, art. 83 provides a general exemption to the application of the data protection rules, in the cases of the processing of personal data for research purposes, if "these purposes cannot be otherwise fulfilled by processing data which does not permit or not any longer permit the identification of the data subject", and if data "enabling the attribution of information to an identified or identifiable data subject is kept separately from the other information as long as these purposes can be fulfilled in this manner".

These provisions would thus perfectly apply to the case of clinical trials disclosure systems related to the safeguarding of public health through the sharing of scientific knowledge about drug's quality and safety characteristics. Moreover, it must be bared in mind how the publication, and thus processing of clinical trials data for public interest purposes, although clearly constituting a derogation of ordinary data protection rules, still regards data assets that are key coded, and hence, not *actually* but only *potentially* identifiable, this still being an important factor to be considered when evaluating the *actual* harm suffered by the data subject.

In light of the above made considerations, the enactment of the Data Protection Regulation could constitute a great step forward towards the orienting of individuals' data protection instances to broader social scientific research demands[766].

Indeed, it must be noticed that Data Protection Directive 95/46/EC or Regulation 45/2001, regarding the "processing of personal data by the

[765] Emphasis added.

[766] This is what has been observed in literature by ZARSKY, *The privacy-innovation Conundrum,supra,* 120 ss..

Community institutions and bodies"[767], do not provide these specific exemptions from general data protection rules.

Yet, under the Data Protection Directive 95/46/EC, clinical trials transparency platforms could have been still justified in light of the exemption provided as regards the processing of personal data, when it is necessary to "reconcile the right to privacy with the rules governing freedom of expression"[768]. Indeed in the patients' right to information has been expressly linked to the freedom of expression, found at art. 10 of the European Convention on Human Rights, guaranteeing freedom of expression as defined by the "right to receive and impart information"[769]. Moreover also art. 8.3 of the same Directive mitigates the general prohibition as regards the processing of medical data, "where processing of medical data is required for the purposes of preventive medicine (…)"[770].

Pursuant to these provisions it is clear how the protection of research-subjects' personal data is hardly to be invoked as a direct obstacle for test data disclosure. On the contrary, the exemptions to ordinary privacy rules appear to override the privacy exemption posed by the Clinical Trials Regulation[771], in that way opening up the legal path to transparency practices.

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[767] Cf. art. 20 Regulation 45/2001/EC of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, *supra.*

[768] Art. 9 of Directive 95/46/EC, *supra.*

[769] Cf. also on the international level, art. 19.2 of the International Covenant on Civil and Political Rights, stating that "everyone should have the right to freedom of expression; this right shall include freedom to seek, *receive* and impart information (…)".Emphasis added. See *infra.*

[770] Critically commenting art. 8 of the Data Protection Directive, CALLENS, *The Privacy Directive and the Use of Medical Data for Research Purposes, supra,* 320 ss..

[771] Art. 81, 4 lett. a) of the Clinical Trials Regulation 536/2014, *supra.* It is interesting to notice that the privacy exemption does not have itself an overriding public interest exemption, such as the one provided by the exemption regarding the protection of commercially confidential information, in lett. b).

Conclusions

1. The public interest in scientific data's transparency

The examination of the controversies surrounding the issue of clinical trials data disclosure, together with the analysis of the exemptions to the general rule provided by art. 84, 4 par. *a)* and *b)* of the recent Clinical Trials Regulation[772], show how the concealment of drug's safety and efficacy information has been motivated on the basis of the companies' right to shield their commercially confidential information, and of the research subjects' right to see their personal data processed only for very limited and expressed purposes.

The systemic disclosure of these data through the establishment of a clinical trials protocols' database, that is publicly and commonly accessible, has been therefore opposed on the grounds that it would allegedly nullify the two cited rights.

In the controversy between the Cochrane Collaboration Research Group and the European Medicine Agency, the European Ombudsman has nonetheless stressed the need to protect the general right of the public to access official documents, functional to the satisfaction of the public's interest to access information about pharmaceutical products.

Accordingly, also the Clinical Trials Regulation expressly affirms that such database has the main purpose of enabling European citizens' to "have access to clinical information about medicinal products"[773].

In order to render the access to these data effective, it is further underlined how "all data held in the EU database shall be in an easily searchable format, all related data shall be grouped together by way of the EU trial

[772] Regulation EU n. 536/2014 of the European Parliament ad of the Council, of 16 April 2014, on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, *supra*.
[773] Art. 81, 2 Regulation 536/2014, *supra*

number, and hyperlinks shall be provided to link together related data and documents held on the EU database and other databases managed by the Agency"[774].

However, as it has been shown, the legal consistency of this right to access, to be mainly found in Regulation EC 1049/2001, and the Rules for implementation of the same Regulation, could appear at first sight quite weak in light of the intellectual property and privacy framework established for the protection of different aspects of information embedded in clinical trials protocols, that is to say on the one hand the "sweat of the brow"[775] of research-based companies, and on the other side the volunteers' personal health data.

It is only through a deeper analysis of the two disciplines that the so opposed legal barriers to disclosure appear to cripple: indeed the data exclusivity regime does not seem to prevent disclosure, but provides, on the contrary, legal conditions for it, raising a direct defence to the commercial use of confidential business information, and nullifying in that way the risks of potential misuse of it posed by the publication of clinical trials protocols; instead, as regards the privacy concerns, the recalled public interests exemptions specifically regarding the public health area, and the research purposes, mentioned by the Proposal for a general Data Protection Regulation, appear to be perfectly applicable for the case of the establishment of a European database regarding drug's safety and efficacy information.

This information is to be considered of great public value for its nature of risk information[776].

Disclosure of this information is thus essential for the satisfaction of the public interest.

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[774] *Ibid.*.

[775] Cf. REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: The case for a public goods approach, supra,* 43; See also ZAHL, *Pharmaceuticals and the Law: as Patent Laws converge, attention shifts to Data Protection,* 12 Metropolitan Corporate Counsel, February 2005, 2, 24 ss..

[776] See LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in environmental, health, and safety law, supra,* 509 ss..

However, once demonstrated that neither the intellectual property nor the privacy normative framework are capable of preventing disclosure, and shifting from a *denstruens* to a *construens* perspective, the public interest of transparency and accountability as regards clinical trials information, also recognised by an economic cost-benefit analysis[777], must be enquired on the interpretational level through the lenses of other legal paradigms[778].

Access to risk information regarding pharmaceuticals' safety appears essential to the protection of patients' health[779], and- strictly linked to this-, of consumers' interests in product safety[780]. Moreover societies' interests in a credible, accountable and public-safety oriented public research[781], and the need of social groups and institutions to be aware of risks in order to make relevant decisions[782], have to be taken into account.

On these premises, three are the legal interpretational tools that are to be considered relevant for the definition of the public interest underlying clinical trials disclosure: first the human right to health as defined by International Human Rights Treatises and the Human rights case law; second the doctrine related to the public goods dimension of research and knowledge production; and finally the consumer rights framework as defined by the correspondent European Directives.

1.1. The Human Rights to Health and Information as interpretative tools for transparency in clinical trials data

As far as the human rights standpoint is concerned, the establishment of appropriate health knowledge systems regarding clinical trials information-

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[777] Indeed it has been stated how "the secret's opportunity costs are likely to be greater on the risk management side, than are its benefits on the commercial side". LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in an environmental health, and safety law, supra,* 510. Cf. also LEVINE, *Secrecy and unaccountability: Trade Secrets in our Public Infrastructure,* 59 FLA. L. REV., 135, 2007, 157 ss..

[778] Cf. LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 99 ss..

[779] *Ibid.*.

[780] Cf. BENHÖR, *EU Consumer Law and Human Rights,* Oxford University Press, 2013, 72 ss..

[781] So ANDANDA, *Managing intellectual property rights over clinical trial data to promote access and benefit sharing in public health, supra,* 152.

[782] LYNDON, *Secrecy and access in an innovation intensive economy: reordering information privileges in environmental health, and safety law, supra,* 510.

as provided by the general disclosure rule at art. 84 of the Clinical Trials Regulation- is to be linked to the duty of states to assure an adequate level of public health[783]. This goal is in return to be achieved also through the creation of reliable information exchange platforms, detecting pre-market test results, as well as negative adverse drug reactions[784].

In this perspective, information and health are to be considered strictly related to each other, in line with a broad interpretation of the right to health, embracing a "variety of human rights as tools to deal with public health issues"[785], or, more technically speaking, with an understanding of the same right to health as "inclusive, incorporating a myriad of freedoms and entitlements"[786].

In this light art. 12 of the *International Covenant on Economic, Social and Cultural Rights* provides a definition of the right to health to be referred to the "highest attainable standard of physical and mental health"[787].

As it has been underlined, the right to health is to be determined by the two essential components of availability and accessibility[788].

An adequate consideration of accessibility as a key component to ensuring the right to health[789], includes also "reliable information about medicines (…) so (patients and health professionals) can take well informed decisions and use medicines safely"[790], being in that way drug regulation required to

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[783] LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 100 ss.; YUN-CHING YEH, *Pharmaceutical Data Protection Law and Policy and their Effects on the Right to Medicines: a Comparative Analysis, supra,* 152 ss..

[784] GIBSON-LEMMENS, *Niche Markets and Evidence Assessment in Transition: a critical Review of Proposed Drug Reforms,* in Medical Law Review, 22, 2, 200 ss.,

[785] LEMMENS, *Pharmaceutical Governance: a Human Rights Perspective, supra,* 166.

[786] LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 101, citing U.N. Special Rapporteur on the Right to Health Paul Hunt.

[787] For the various definitions of the right to health to be found on the international level, see SMITH, *Human Rights and Bioethics: Formulating a universal Right to Health, Health Care, or Health Protection?,* 38 Vand. J. Transnat'l L., 2005, 1295 ss., stressing definitional uncertainties surrounding the issue of the right to health.

[788] See U.N. Educational, Scientific and Cultural Organization, *General Comment 14: the Right to the Highest attainable Standard of Health,* 11 August 2000, online available at http://www.nesri.org/sites/default/files/Right_to_health_Comment_14.pdf, par. 12.

[789] On the issue see KINNEY, *The International Human Right to Health: what does this mean for our nation and world?,* in 34 Ind. L. Rev., 2000.1457 ss..

[790] U.N. General Assembly, *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health- Note by the Secretary General,* 10 August 2009, online available at http://www.refworld.org/docid/4aa762e30.html, 15. Cf. also U.N. Educational, Scientific and Cultural Organization, *General Comment 14: the Right to the Highest attainable Standard of Health, supra,* paragr. 12.

"ensure the safety, efficacy, and quality of medicines available (…) as well as the accuracy and appropriateness of medicine information"[791].

This position is also shared by the U.N. Committee on Economic, Social and Cultural rights in the general Comment 14, where it is underlined how the right to health is to be defined on the basis of the "underlying determinants of health", including "access to health-related education and information"[792].

Thus, according to this perspective, access to information about pharmaceuticals' safety features is to be considered as a fundamental determinant of the same right to health[793].

This approach is expressly recognized also by the *Human Rights Guidelines for Pharmaceutical Companies in relation to access to Medicines,* underlining the transparency responsibilities of pharmaceutical companies: it is here stated that "the principle of transparency not only requires that information be made publicly available, but also that the information be made available in a form that is accessible, manageable, and useful. In conjunction with other companies in the sector, a pharmaceutical company should agree to standard formats for the systematic disclosure of company information and data bearing upon access to medicines, thereby making it easier to evaluate the performance of one company against another, as well as the performance of the same company over time. This will enhance public accountability and investor confidence"[794].

Furthermore, the peculiar connection between the right to health, and the right to information as a component of it, has been stressed by the

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[791] U.N. General Assembly, *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health- Note by the Secretary General, supra,* 21.

[792] U.N. Educational, Scientific and Cultural Organization, *General Comment 14: the Right to the Highest attainable Standard of Health, supra*, par. 11.

[793] LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 101, stressing the "connection between the right to health and the need to develop appropriate knowledge systems". The Author argues that "access to critical information about those drugs, such as the information created through the scientific community's use of trial registries and result reporting, is also a key determinant to the right".

[794] See U.N. General Assembly, *The right to Health- Note by the Secretary General,* 11 August 2008, online available at http://www.who.int/medicines/areas/human_rights/A63_263.pdf, 15 ss., 17-18. On the issue cf. LEMMENS, *Pharmaceutical Knowledge Governance: A Human Rights Perspective, supra,* 172 and LEE-HUNT, *Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines,* in *Journal of Law, Medicine and Ethics,* 2012, 220 ss., 226-227.

European Court of Human Rights in the controversy *The Sunday Times v. The United Kingdom*[795] specifically regarding the publishing of clinical trials of a drug containing an ingredient known as thalidomide that had caused in 1961 a high number of women to give birth to children suffering from serious deformities[796]. The Sunday Times wanted to publish an article regarding the history of the testing, manufacture and marketing of the drug, but received an injunction on the grounds that the publication of this information would have resulted in a contempt of court[797].

The plenary European Court of Human Rights rejected the injunction to publish clinical trials data, on the assertion that the ban to publish the relevant health information would have violated art. 10 of the European Convention of Human Rights as regards freedom of expression, posing legal grounds for "the right of the public to be properly informed"[798]. In this light the Court stressed the need to satisfy the "vital interest" of "the families of numerous victims of the tragedy" in "knowing all the underlying facts"[799].

Literature commenting the case has considered the thalidomide tragedy as the direct result of the deficiency of the drug regulatory system and at the same time the lack of governmental insight as regards the establishment of solid knowledge systems based on transparent data[800].

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795 *The Sunday Times v. United Kingdom,* 30 Eur. Ct. H.R. (ser. A), 26 Aprile 1979, online available at http://hudoc.echr.coe.int/sites/eng/pages/search.aspx?i=001-57584#{"itemid":["001-57584"]}.

796 On the case see FINTEL-SAMARAS-CARIAS, *The Thalidomide Tragedy: Lessons for Drug Safety and Regulation,* published on the 28th July 2009, online available at https://helix.northwestern.edu/article/thalidomide-tragedy-lessons-drug-safety-and-regulation.

797 Cf. LEMMENS, *Pharmaceutical Governance: a Human Rights Perspective, supra,* 166.

798 *The Sunday Times v. United Kingdom, supra,* par. 66. Cf. art. 19.2 of the International Covenant on Civil and Political Rights, according to which "Everyone shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information (…)". Numerous are the cases of the European Court of Human Rights regarding the link between access to information and the freedom of expression. Cf. *Guerra and others v. Italy*, ECHR, 19 February 1989, commented by LEMMENS, *Pharmaceutical Governance: a Human Rights Perspective, supra,* 166-167.

799 *Ibid.*.

800 LEMMENS-TELFER, *Access to information and the right to health: the human rights case for clinical trials transparency, supra,* 103.

1.2 The Human Right to benefit from scientific research and progress as interpretative tool for transparency in clinical trials data

Following the human rights discourse, the rule of clinical trials disclosure is to be enforced also in light of another human rights-associated interest, namely the right to benefit from scientific research and progress, directly deriving from the public good dimension of scientific research[801].

The access to the fruits of the latest scientific research is indeed to be considered an essential precondition of the stimulation of follow-on research and is strictly functional to the guidance of better clinical practice[802].

In this light, the right to benefit from research results, has been recently recognized at art. 12 of the UNESCO Declaration on the Human Genome and Human Rights, declaring that "benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made freely available to all", and in art. 15 of the International Covenant on Economic, Social, and Cultural Rights, affirming that "states parties to the present Covenant recognize the right of everyone to (…) enjoy the benefits of scientific progress and its applications".

The sharing of direct research results entailed in clinical trials information is thus to be considered relevant from a general scientific progress perspective, from a double standpoint.

Indeed, on the one side, the monitoring of the benefits and risks of all centrally approved medicines[803] would provide researchers with a clear knowledge of the current scientific development level, that is an essential

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[801] This is the standpoint of REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: The case for a public goods approach, supra,* 51, affirming that "it seems clear that the information gleaned from the clinical testing of drugs and therapies is a public good in the sense that each individual citizen benefits from such information without reducing its value to others"; cf. LEMMENS, *Pharmaceutical Knowledge Governance: a Human Rights Perspective, supra,* 172.

[802] REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: The case for a public goods approach, supra,* 52.

[803] The sharing of information for the benefits of scientific progress, is particularly stressed by GØTZSCHE-JORGENSEN, *Getting access to unpublished clinical trials at the European Medicines Agency, supra, passim.*

precondition for effective and faster innovation enhancement[804]; on the other side, publicly accessible clinical trials information systems undoubtedly count as accountability mechanisms of pharmaceutical companies' responsibilities[805]. Some scholars have thus argued that this could in return function as an incentive for the increase of the standards of testing's accurateness, in virtue of the exposure to civil society's judgment and control[806].

The need to protect and enhance, through relevant information disclosure practices, the active role of the public opinion as a "social watchdog" over the creation of public health oriented science, can be derived from the reasoning of the European Court of Human Rights in another important controversy on the issue of the right to access information contained in official documents[807]. Although not directly related to clinical trials data disclosure[808], the declarations of the Court appear to be relevant for the present argumentation.

Indeed, on this occasion, the Court stressed the right of the public to receive information of general interest. The satisfaction of this right is to be considered as an essential tool for society to carry out its public control

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804 EISENBERG, *The role of the FDA in Innovation Policy, supra,* 383: "public availability of data from clinical trials would allow firms to learn from each other's experience so that they could design better products and conduct better trials in the future. (…)It would permit reanalysis of data by skeptical competitors in ways that might challenge the spin selected by the product's sponsor, and facilitate meta-analysis of aggregated data from multiple studies of related products". LEMMENS, *Pharmaceutical Knowledge Governance: a Human Rights Perspective, supra,* 169.

805 HUNT-KHOSLA, *Are Drug Companies living up to their Human Rights Responsibilities? The Perspective of the former United Nations Special Rapporteur (2002-2008),* in *Plos Medicine,* September 2010, 7, 9, 3.

806 ANDANDA, *Managing intellectual property rights over clinical trial data to promote access and benefit sharing in public health, supra,* 157. *Contra* REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: The case for a public goods approach, supra,* 50, affirming that "requiring mandatory disclosure of clinical trials will not eliminate the inherent conflict of interest underlying the commercial provision of drugs and medicine or the fundamental inefficiencies the current system promotes. So long as drug companies retain primary responsibility for conducting or funding clinical trials, they will be tempted to selectively disclose information and to avoid research programs that could reveal unfavourable outcomes. Nor would a disclosure requirement alone ensure that the stakeholding company will conduct all the tests deemed most beneficial to public safety".

807 *Társaság A Szabadságjogokért* (Hungarian Civil Liberties Union) v. Hungary, ECHR, 14 April 2009, Case n. 37374/05, online available at http://hudoc.echr.coe.int/sites/eng/Pages/search.aspx#{"fulltext":["Társaság"],"documentcollectionid2":["GRANDCHAMBER","CHAMBER"],"itemid":["001-92171"]}. Par. 36.

808 The case was however still related to drug regulation issues: in fact it concerned the request by the Hungarian Civil Liberties Union TASZ to Hungary's Constitutional Court to disclose a parliamentarian's complaint questioning the legality of new criminal legislation concerning drug-related offences. The Constitutional Court refused to release the information.

function in the areas of major public concern[809], such as health care and pharmaceutical industry performance.

In this light, free access to trials information is immediately functional to the increase of scientific community's awareness over the potential risks of marketed medicinal products, this reflecting itself, on the practical level, in a stronger degree of patients' protection.

Indeed, it has been underlined how the transparency of clinical trial results promotes medical practitioners' surer decisions "about the safety and therapeutic value of both single products and product groups"[810].

1.3 Consumer Rights as interpretative tools for transparency in clinical trials data

However, access to clinical trials data is not only relevant as regards the informed decisions of healthcare providers, but it appears to be of crucial importance also from a consumer protection perspective.

Hence, shifting from the collective perspective of the right to health and the right to the common enjoyment of research results, to the more particular dimension of consumer law, the rule of trials results disclosure can find here two further legal justifications.

Indeed, a consumer's right to be adequately informed as regards the features of the products used, is to be derived from the Directive on the Community code relating to Medicinal Products for Human use 2001/83/EC, intending to protect consumers' right to self-determination and to consent to therapy[811].

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[809] On this precise issue see *Joint Declaration of HAI Europe, ISDB, AIM, BEUC, Medicines in Europe Forum, Relevant Health Information for Empowered Citizens,* published on the 3rd October 2006, online available at http://www.isdbweb.org/documents/uploads/relevant_health_information_001.pdf.

[810] REICHMAN, *Rethinking the role of clinical trials data in international intellectual property law: The case for a public goods approach, supra,* 52.

[811] FAEH, *Pharmaceutical Information: Does the Directive 2001/83/EC Protect such a right for the End User?,* in *Amsterdam Law Forum,* 3, 1, 2011, 30 ss..

Important suggestions in this direction can be inferred from the rules on packaging and labelling of pharmaceuticals[812], requiring a first, although limited in scope, disclosure of information about the products' features[813].
Some scholars have thus affirmed how these specific rules concerning the informational aspects of drugs' marketing, provide strong interpretative grounds for a consumer's right to pertinent, correct, complete and understandable information[814], with which the establishment of mandatory test data reporting systems clearly comply.
The consumer protection standpoint provides however another important basis for the transparency of test data in light of the right to product safety deriving from Directive 2001/95/EC, which is to be considered a direct transposition of the human right to health in the consumer law dimension[815].
Indeed, recital 19 of the Directive acknowledges the obligation of the producer to "supply consumers with information enabling them to assess and prevent risks, to warn consumers of the risks posed by dangerous products already supplied to them"[816], whereas recital 27 states that "effective supervision of product safety requires the setting up at national and Community levels of a system of rapid exchange of information (…)".
Moreover, legal grounds for clinical trials' disclosure systems are to be more specifically found in recital 35 of the same Directive expressly affirming that "public access to the information available to the authorities on product safety should be ensured", and in art. 16, stating that "information available to the authorities of Member states or the Commission relating *to risks to consumer health and safety posed by products shall in general be available to the public, in*

812 *Ibid.,* 32 ss., for a comment on artt. 54 ss.. of the Directive 2001/83/EC.
813 EISENBERG, *The role of the FDA in Innovation Policy, supra,* 382-383, affirming that "some disclosure of data occurs in summary form through the required labelling that must accompany the product in the market. The audience to whom these disclosures are directed is clinical decision-making".
814 FAEH, *Pharmaceutical Information: Does the Directive 2001/83/EC Protect such a right for the End User?,* 43.
815 BENHÖHR, *EU Consumer Law and Human Rights, supra,* 73-74.
816 This is again stressed in art. 5 of the Directive, stating that "within the limits of their respective activities, producers shall provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks".

accordance with the requirements of transparency (…)"[817] and that "in particular the public shall have access to information on product identification, the nature of the risk and the measures taken".

1.4 Conclusionary remarks and suggestions for further research

This considered, it thus becomes clearer how "addressing information needs of patients and consumers is not only a matter of content but also of communication"[818].

Indeed, at a deeper understanding of the matter, there are different degrees of test data disclosure[819], and accordingly, different are the intersections with the mentioned fundamental right to the enjoyment of "a high level of human health protection", as recalled by art 35 of the Charter of Fundamental Rights of the European Union.

On the one side, given its informational value, disclosure of test data would directly satisfy the interests of individuals- patients and healthcare practitioners- and of society as a whole to be adequately informed of pharmaceutical products risks and hidden side effects.

Access to information about medicines' features is thus highly relevant in order to address public safety concerns.

However, on the other side, the consideration of the regulatory significance of trials information, shows how the systemic disclosure of it could have broader implications also as regards access to medicines[820].

Indeed, as it has been shown, disclosure of clinical trials data turns out to have direct effects also on competition and innovation mechanisms, enabling generic competitors to gain greater knowledge of pharmaceutical design's "state of the art", and fostering in that way generic products'

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[817] Emphasis added.

[818] *Joint Declaration of HAI Europe, ISDB, AIM, BEUC, Medicines in Europe Forum, Relevant Health Information for Empowered Citizens, supra,* 3.

[819] In this sense LIETZAN, *A new framework for assessing clinical data transparency initiatives, supra,* 12.

[820] Cf. YUN-CHING YEH, *Pharmaceutical Data Protection Law and Policy and their Effects on the Right to Medicines: a Comparative Analysis, supra,* 156-157.

market entrance, as soon as the period of data exclusivity has expired and the marketing license can be granted.

Also from this further standpoint, the interpretational tool of the right to health strongly supports the public interest of information disclosure, as a means to fulfil fundamental market freedoms, that are in return functional to the enjoyment of a higher standard of health.

Indeed, in the pharmaceutical sector, the connection between competition and health concerns is very strong, since the earlier generic companies enter the market, the sooner prices decreases, with clear gains in patients' welfare[821].

However, the consideration, through the lenses of the right to health protection demands, of the anticompetitive effects of the *sui generis* protection of data exclusivity assured to innovators' trials data could possibly lead to more drastic consequences.

Indeed, it is exactly from the data exclusivity regime that research-based companies have intended to derive a non-disclosure obligation regarding the same test data, as well as strategies to increase the degree of protection, both for patented and non-patented products, for the purpose of enforcing market predominance.

From this latter perspective, generics' entrance in the market is delayed in the more direct sense of blocking the entry of second comers through the barrier of a patent like protection regarding pharmaceuticals' information.

The anticompetitive outcomes of the data exclusivity regime have been stressed by literature[822], invoking legislative reforms, and proposing more public friendly layouts for a data protection still needed to shield originators' commercial investments from the threat of inefficient free-riding practices by competitors. Yet, it has also noticed how a change in the law is for now very difficult to envisage[823].

However, the evaluation of this *sui generis* intellectual property protection in light of the European fundamental right to health could possibly boost the

[821] See MUZAKA, *Politics of Intellectual Property and Access to Medicines, supra,* 35-36.
[822] Cf. *supra* chapter 2.
[823] FACKELMAN, *Clinical data, data exclusivity and private investment production in Europe, supra,* 181.

amendment process, by revealing the crippling "constitutional" legitimacy of such a strong form of safety information *propertization*.

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