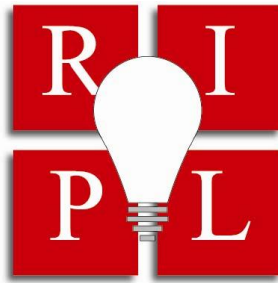


THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



PROTECTING TRADE SECRETS UNDER INTERNATIONAL INVESTMENT LAW: WHAT SECRETS INVESTORS SHOULD NOT TELL STATES

DARIA KIM

ABSTRACT

The article addresses specifics of trade secret protection under international investment law. As a particular example, it analyzes protection of pharmaceutical regulatory data against the background of the growing public policy campaign for broader access to clinical trial data and the recent unprecedented practice of the European Medicines Agency of disclosing clinical dossiers submitted for drug marketing approval. Given the significant role of foreign direct investment in the global pharmaceutical industry and substantial, exponentially increasing costs incurred by drug originator companies in conducting clinical trials, the prospect of investor-state dispute over data disclosure does not appear purely hypothetical. The question is whether investor-state arbitration is an apt instrument to protect originators' data against disclosure by drug regulatory authorities. The analysis suggests that the application of standards of international investment protection depends on the specifics of information at issue, its value, and functions in investors' commercial operations. With regard to pharmaceutical test data, it is argued that the prospects of investor-state arbitration are rather unfavorable for the investor, when data is disclosed to support policy objectives in public healthcare and medical innovation.

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PROTECTING TRADE SECRETS UNDER INTERNATIONAL INVESTMENT LAW:
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DARIA KIM*

I. INTRODUCTION

“Same same but different.” This catchphrase derived from the title of Detlev Buck’s movie¹ can characterize the standing of trade secrets among other types of intellectual property (“IP”). Being protected under international law as a category of IP, trade secrets differ from other types of IP in several aspects. Most importantly, protection is not mandated in the form of exclusive rights. While there are no specific qualification requirements for protection, trade secrets can cover vastly diverse types of information in terms of substantive content, economic value and functions. Empirical studies show that, in some sectors, firms can rely on trade secrets equally as on patent protection as a means to appropriate returns on R&D investment, and, under some circumstances, even to a greater extent.² The drug industry is among such sectors.³

Foreign direct investment (“FDI”) has played a considerable role in shaping the global pharmaceutical industry.⁴ Particular prominence among factors considered to have the most relevance for attracting FDI, is attributed to the effective protection of intellectual property.⁵ Likewise, IP protection plays an important role in the domestic regulatory framework in the pharmaceutical sector. So far, the boundaries

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¹ SAME SAME BUT DIFFERENT (Boje Buck 2009) *Filmhandlung und Hintergrund*, KINO.de, <http://www.kino.de/film/same-same-but-different-2009/>.

² See generally Wesley M. Cohen & Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, NBER Working Papers 7552, National Bureau of Economic Research, Inc. (2000); Richard C. Levin & Alvin K. Klevorick & Richard R. Nelson & Sidney G. Winter, *Appropriating the Returns from Industrial Research and Development*, Brookings Papers on Economic Activity, Economic Studies Program, The Brookings Institution, vol. 18(3), 783-832 (1987).

³ Cohen *et al.*, *supra* note 2, tables 1, 2.

⁴ THE UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT, WORLD INVESTMENT REPORT 2014, 13-15 (2014) (reporting on restructuring trends and new market-seeking investments in the world-wide pharmaceutical industry). According to the UNCTAD, the global FDI in the pharmaceutical sector is mostly represented in cross-border merger and acquisition deals and greenfield FDI, the former reaching a peak in 2007 and the latter in 2009. A significant increase has been observed in cross-border merger and acquisition deals targeting developing and transition economies from less than four percent before 2006, to ten percent between 2010 and 2012, “jumping to more than eighteen percent in 2013.” *Id.* at xvii. The trend is projected to continue to grow. *Id.* at 14.

⁵ See *infra* note 54.

of two types of IP rights—trademarks⁶ and patents⁷—have been tested in investor-state arbitration demonstrating the complexity of issues that stretch beyond economic and industry matters.

This paper addresses protection of another category of IP—trade secrets—in the context of pharmaceutical FDI and international investment agreements. The enforcement of trade secret protection has been emphasized by the U.S. in the framework of the Trans-Pacific Partnership negotiations. In August 2013, the U.S. Chamber of Commerce released a report calling for “enhanced legal protections for trade secrets, including criminalization of willful misappropriation and unauthorized disclosure of trade secrets [to be] elevated on the TPP agenda.”⁸

The inclusion of the specific obligation with regard to trade secret protection into the investment treaty does not only mean raising the level of the enforcement standard under the national IP law (and, consequently, granting the same level of protection to all WTO Member states due to the national treatment obligation). Protection of IP within an investment bears another important implication; it allows the investor to challenge domestic regulations of a host state that might affect IP-based assets, including confidential business and commercial information, under investor-state arbitration.⁹

This article analyses the specifics of protection of clinical data, as a part of pharmaceutical FDI, in the context of the evolving international campaign for greater public disclosure of clinical trial reports submitted for regulatory review. Most recently, the idea of data sharing has been promoted by initiatives such as the 2015 policy of the European Medicines Agency (“EMA”),¹⁰ the 2014/2015 WHO public consultations,¹¹ and the 2015 Report of the Institute of Medicine of the National

⁶ Philip Morris Asia Limited v The Commonwealth of Australia, UNCITRAL, PCA Case No. 2012-12; Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v Oriental Republic of Uruguay, ICSID Case No. ARB/10/7.

⁷ *Eli Lilly and Company v The Government of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2.

⁸ THE US CHAMBER OF COMMERCE, *THE CASE FOR ENHANCED PROTECTION OF TRADE SECRETS IN THE TRANS-PACIFIC PARTNERSHIP AGREEMENT* 5 (2013).

⁹ See the Office of the United States Trade Representative, Summary of the Trans-Pacific Partnership Agreement, available at <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/october/summary-trans-pacific-partnership> (last visited Nov. 27, 2015) (stating that the agreement “provides for neutral and transparent international arbitration of investment disputes, with strong safeguards to prevent abusive and frivolous claims and ensure the right of governments to regulate in the public interest, including on health, safety, and environmental protection. The procedural safeguards include: transparent arbitral proceedings, amicus curiae submissions, non-disputing Party submissions; expedited review of frivolous claims and possible award of attorneys’ fees; review procedure for an interim award; binding joint interpretations by TPP Parties; time limits on bringing a claim; and rules to prevent a claimant pursuing the same claim in parallel proceedings.”).

¹⁰ The EMA, *The European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use*, EMA/240810/2013 (2014) available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf (last visited Nov. 30, 2015).

¹¹ The World Health Organization, *Call for public consultation: WHO Statement on Public Disclosure of Clinical Trial Results*, available at <http://www.who.int/ictrp/results/en/> (last visited Nov. 30, 2015).

Academies “Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk.”¹² In broad terms, benefits of clinical data sharing are associated with healthcare improvement and scientific progress: access to clinical dossiers can support various research-related activities, improve efficiency of drug R&D, contribute to greater transparency and accountability of drug authorities, and reduce the risk of publication bias in reporting trial results.¹³ Among policy initiatives,¹⁴ the EMA is the first drug regulatory authority to start to disclose clinical reports.¹⁵ As of January 2015, access to clinical dossiers submitted for regulatory review can be provided upon marketing approval of a corresponding drug without the authorization of and remuneration to data originators under the condition that the data is used for *scientific, non-commercial research purposes* and, explicitly, not for generic drug approval.¹⁶

From the scientific perspective, clinical data presents a unique source of pharmacological knowledge generated during clinical tests about the newly established effects of a drug on the human body. From the business perspective, clinical trials are the most investment-intensive and time-consuming stage of drug R&D. From the regulatory perspective, the submission of clinical trial results that prove efficiency, quality, and safety are requirements enforced by national drug authorities before a drug can be released on the market. From the legal perspective, there is much uncertainty regarding the legal status and substantive rights in various types of data that are comprised in clinical dossiers. Not surprisingly, public consultations preceding implementation of the 2015 EMA disclosure policy featured a heated debate between public interest groups, the scientific community and the research-based biopharmaceutical industry.¹⁷ The U.S. Chamber of Commerce followed EMA’s initiative with a study alleging that the EMA’s new policy starkly contrasted with existing international practices.¹⁸

The legal basis for the blanket clinical data disclosure is far from clear. Pharmaceutical regulatory data can be protected against disclosure under trade secrets, unfair competition, *sui generis* regime of data exclusivity, as well as

¹² The Institute of Medicine of the National Academies, *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk* (2015) available at <http://www.iom.edu/Reports/2015/Sharing-Clinical-Trial-Data.aspx> (last visited Nov. 10, 2015).

¹³ See *infra* notes 127-136.

¹⁴ For an overview of international calls for clinical trial data sharing, see, e.g., PC Gotzsche, *Why We Need Easy Access to All Data from All Clinical Trials and How to Accomplish It*, TRIALS, 12:249, at 9-11 (2011).

¹⁵ While the EMA earlier policy provided for the “reactive”, or request-based access, the 2015 initiative implements the “pro-active” access to clinical reports on-screen as well as in downloadable and searchable formats. See the EMA, *supra* note 10, ¶¶ 4.1, 4.2.1.

¹⁶ *Id.* Annex 1, ¶ 3, Annex 2, ¶ 3.

¹⁷ For an overview of the submissions, see the EMA, *Publication and access to clinical data: an inclusive development process* (2014) available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000556.jsp (last visited Nov. 27, 2015).

¹⁸ The U.S. Chamber of Commerce & Global Intellectual Property Center, *Heading in a Different Direction? The European Medicines Agency’s Policy on the Public Release of Clinical Trials Data*, at 2 (2014) available at <http://www.theglobalipcenter.com/wp-content/uploads/2014/05/EMA-Study-COMPLETE.pdf> (last visited Oct. 30, 2015).

administrative law.¹⁹ The Court of Justice of the European Union has recently considered two cases in which pharmaceutical companies—AbbVie and InterMune—objected to the EMA’s decisions to grant access to their clinical data upon request by a third party.²⁰ Protection of data confidentiality was claimed on the basis of Article 7 of the Charter of Fundamental Rights of the European Union, Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms, and Article 339 of the Treaty of the Foundation of the European Union. Interim injunctions against the EMA’s disclosure granted by the General Court of the European Union were, later on, overturned by the European Court’s Vice-President and referred back to the General Court to examine the possibility of partial access to the clinical study reports if applicants could establish “with a sufficient degree of probability” the likelihood of “serious and irreparable damage” by third parties’ access to some of the contents.²¹

The issue of data disclosure is particularly relevant in the context of pharmaceutical FDI. In many cases, the originator and holder of clinical data would be a pharmaceutical multinational company submitting reports on clinical studies for regulatory review on behalf of a local subsidiary. In a more generalized scenario—abstracting from the particular example of pharmaceutical test data—similar investment protection claims can arise when business-related information is submitted for regulatory clearance procedures, and such data is subsequently disclosed by a local authority on public interest grounds.²² In a broader perspective, issues analysed here pertain to the conflict between private interests in data confidentiality and public interests in access to information; ultimately raising the question of reconciling the two when the state exercises its right to regulate in matters of utmost public interest.

¹⁹ It is assumed that, in most jurisdictions, the submission of test data for a regulatory review for the purpose of marketing approval would not qualify as public disclosure, neither involve the transfer of originators’ rights in data.

²⁰ Case T-44/13, *AbbVie, Inc., AbbVie Ltd. v. EMA*, (C.J.E.U. 2014) (delivered July 17, 2014); *InterMune UK and Others v. EMA*, Case T-73/13, (C.J.E.U. 2013) (delivered April 25, 2013). Since 2010, the EMA has been granting access to clinical trial reports submitted for the EU marketing authorization on the request basis.

²¹ See Case C-389/13P(R), *European Medicines Agency (EMA) v. AbbVie Inc. and AbbVie Ltd.*, Order of the Vice-President of the Court, Nov. 28, 2013, ¶ 51; Case C-390/13P(R), *European Medicines Agency v. InterMune UK, et. al*, Order of the Vice-President of the Court, dated Nov. 28, 2013, ¶ 54. Upon the issuance of the Vice-President Orders, proceedings in both cases were discontinued pursuant to the applicants’ requests. See Case T-73/13, *InterMune UK, et. al v. European Medicines Agency*, Order of the President of the Forth Chamber of the General Court of June 29, 2015(1); see also Case T-44/13, *AbbVie Inc., v. European Medicines Agency*, Order of the President of the General Court, of April 8, 2014).

²² See Tony Harris, Diane Nicol, & Nicholas Gruen, *Pharmaceutical Patents Review Report 2013*, at 169 (2013) available at http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf (last visited Jan. 13, 2016) (recommending that the Australian “Government should actively contribute to the development of an internationally coordinated and harmonized system where data protection is provided in exchange for the publication of clinical trial data”). See also Tania Rabesandratana, *Europe’s food watchdog embraces transparency*, SCIENCE (Oct. 23, 2015), <http://www.sciencemag.org/content/350/6259/368.full> (last visited Nov. 30, 2015) (reporting a similar initiative announced by the European Food Safety Authority to make public the data submitted for food safety evaluation and highlighting industry concerns that “the openness—which will extend to detailed industry reports—could threaten trade secrets”).

Against this background, this paper analyses the prospects of a hypothetical dispute over the disclosure of clinical data by a drug regulatory authority in the context of investor-state arbitration.²³ In particular, it addresses the questions: Does clinical data qualify for protection as a foreign investment? What standards of protection under international investment law can the investor invoke, and what are the specifics of their application in a particular case of disclosure of clinical dossiers? How would public and private interests stack up, and how can the balancing of interests be approached? The analysis is structured as follows. Part II considers whether clinical data qualifies as the subject matter of protection under an international investment agreement (“IIA”). Part III analyzes how the standards of investment protection apply in a dispute over the regulatory disclosure of clinical dossiers and focuses on the standards of expropriation (drawing an analogy with compulsory licensing for patents) and fair and equitable treatment (reflecting on the notion of “legitimate expectations”). Part IV concludes.

II. CLINICAL DATA AS THE SUBJECT MATTER OF PROTECTION UNDER INVESTMENT LAW

A claim for investment protection shall be subject to the tribunal’s *ratione materiae* jurisdiction if the claimant made an investment in the host state: Do dossiers submitted for drug marketing approval qualify as protected subject matter under international investment law?

A. The Economic Characterization of Clinical Data as Foreign Investment

In the economic sense, foreign investment can be defined as a “commitment of resources to the economy of the host state . . . entailing the assumption of risk in expectation of a commercial return.”²⁴ Although there is no “legally binding

²³ One may wonder whether the investor-state arbitration is an apt instrument for the investor to protect regulatory data against disclosure. In the first place, the investor would probably seek to obtain injunctive relief as a remedy rather than the *ex post* disclosure compensation. Once the data are released into public domain, the consequences can be irreversible: the data originator cannot control or prohibit the subsequent use of third parties of the data disclosed by public authorities. Although investor-state tribunals usually grant relief in the form of monetary damages, the availability of injunctive relief is not excluded. See Article 47 of the ICSID Convention and Rule 39 of the ICSID Arbitration Rules; Article 26 of the UNCITRAL Arbitration Rules. See also Christoph Schreuer, *Non-Pecuniary Remedies in ICSID Arbitration*, 20 Arb. Int’l 325, 326 (2004) (noting that “the [ICSID] Convention’s drafting history indicates that an ICSID tribunal has the power not only to award monetary damages, but also to order a party to perform a specific act or to desist from a particular course of action”).

²⁴ ZACHARY DOUGLAS, *THE INTERNATIONAL LAW OF INVESTMENT CLAIMS*, 161 (Cambridge University Press, 2009). See Mahnaz Malik, *Recent Developments in the Definition of Investment in International Investment Agreements*, Second Annual Forum of Developing Country Investment Negotiators 3-4 at 6, (November 2008), available at http://www.iisd.org/pdf/2008/dci_recent_dev.pdf (last visited Oct. 30, 2015) (noting, with regard to intellectual property, that to qualify as an investment, intellectual property, like any other type of asset, “must have the characteristics of an investment, such as the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk”).

definition” of investment under international investment law,²⁵ several tribunals referred to the characteristics distinguished in the *Salini v Morocco* case.²⁶ Having admitted the lack of “real discussion” of the criteria for characterization of an investment in earlier cases,²⁷ the tribunal in *Salini* summarized that “the doctrine *generally* considers that investment infers: contributions, a *certain* duration of performance of the contract and a participation in the risks of the transaction.”²⁸ As an additional condition, contribution to the economic development of a host State was mentioned in relation to the Preamble of the ICSID Convention.²⁹ Furthermore, the tribunal held that, although “in reality, these various elements may be interdependent,” they “should be assessed globally.”³⁰ In that context, ‘globally’ could be interpreted as considered altogether, in their overall effect.

It is somewhat curious that, in subsequent decisions, tribunals referred to the abovementioned elements as the ‘*Salini test*.’³¹ The broad wording gives a general idea rather than stipulate a legal standard as a set of specific qualifying factors. These criteria can be seen as neither absolute nor binding.³² Under such a broad approach, clinical dossiers can be notionally recognized as part of a foreign investment, especially since many IIAs explicitly incorporate intangible assets into the definition of investment.³³ However, further questions arise: Does it matter that the R&D activity—i.e., clinical trials and drug development—took place in a country *other* than the host state and not necessarily for the purpose of obtaining marketing authorization in that particular host state? With respect to drugs, for which marketing approval is sought in a foreign jurisdiction, does it matter where such drugs were originally produced?

²⁵ YARASLAV KRYVOI, INTERNATIONAL CENTRE FOR SETTLEMENT OF INVESTMENT DISPUTES, 58 (Kluwer Law International 2010).

²⁶ *Salini Costruttori S.p.A. and Italstrade S.p.A. v. Kingdom of Morocco*, ICSID Case No. ARB/00/4, (September 25, 2000). Although the *Salini* factors were developed and mostly applied in the arbitration under the ICSID Convention, their application has not been limited to the ICSID arbitration. See, e.g., *Romak S.A. v. The Republic of Uzbekistan*, UNCITRAL, PCA Case No. AA280, Award, ¶¶ 190-195 (Nov. 26, 2009).

²⁷ *Salini et al v Morocco*, ICSID Case No. ARB/00/4, Decision on Jurisdiction, ¶ 52 (Jul. 23, 2001).

²⁸ *Id.*, ¶ 52 (emphasis added).

²⁹ *Id.*

³⁰ *Id.*

³¹ For an overview of tribunal decisions applying, interpreting and modifying the *Salini* criteria, see, e.g., Alex Grabowski, *The Definition of Investment under the ICSID Convention: A Defense of Salini*, CHICAGO JOURNAL OF INTERNATIONAL LAW 15 (1), (2014).

³² See, e.g., *Philip Morris Brands Sarl, et. al v. Oriental Republic of Uruguay*, ICSID Case No. ARB/10/7, Decision on Jurisdiction, ¶ 185, (July 2, 2013) (stating that “[t]he *Salini* criteria are not jurisdictional requirements. Most of the tribunals that have examined these criteria have used them as typical characteristics rather than as jurisdictional requirements”).

³³ For detailed guidelines on the accounting of drug development costs as intangible assets under international accounting standards IAS 38.8, see PWC, *International Financial Reporting Standards (IFRS) Issues and solutions for the pharmaceuticals and life sciences industries* (2012) available at http://www.pwc.nl/nl_NL/nl/assets/documents/pwc-ifs-issues-and-solutions-for-the-pharmaceutical-industry-july-2012-vol-1-and-2.pdf (last visited Nov. 26, 2015).

1. *The Apotex case*

Similar concerns were addressed by the tribunal in the *Apotex v. United States* case,³⁴ in which the Canadian pharmaceutical company contested the U.S. FDA's decisions that had rejected its applications for marketing authorisation for two generic drugs. The claimant alleged that it had “made substantial ‘investments,’ including, but not limited to, the expenditure of millions of dollars each year in preparing ANDAs³⁵ for filing in the United States, and formulating, developing, and manufacturing approved generic pharmaceutical products for sale in the United States and throughout the world;” this qualified as investment in the meaning of Article 1139 of the NAFTA Agreement.³⁶ The U.S. argued that Apotex's activities in the territory of the United States with respect to sales of the two generic products *in casu* were “those of an exporter, not an investor,” while the sales were made by the U.S.-based distributors.³⁷ The argument was upheld by the UNCITRAL tribunal which affirmed that the claimant's activities in relation to drug regulatory approval in the country of exportation did not qualify as “an ‘investment’ in and of itself, within the meaning and scope of NAFTA Article 1139.”³⁸ Consequently, the case was dismissed due to the tribunal's lack of jurisdiction.

According to one opinion, Apotex's “critical omission” was “its failure to develop a claim that its U.S. affiliate [Apotex Corp.] was independently a NAFTA investment.”³⁹ However, had Apotex submitted the claim on behalf of its U.S.-based affiliate, would it, in principle, change the nature of Apotex's business in the U.S.—i.e., sales through the affiliated agent and distributor?⁴⁰ At the end, the tribunal was “unpersuaded” that such affiliate independently qualified as investment of “an interest in an enterprise” for the purposes of NAFTA Art 1139(e).⁴¹

It is common that pharmaceutical multi-national corporations (“MNCs”) conduct the majority of clinical trials in one country and use essentially the same dataset to obtain marketing authorization in multiple jurisdictions.⁴² Such a situation is not unique to clinical data: technologies can be patented and commercially utilized in multiple jurisdictions irrespective of where the corresponding R&D was conducted.

³⁴ *Apotex Holdings Inc. and Apotex Inc. v. United States of America*, ICSID Case No. ARB(AF)/12/1 (August 25, 2014).

³⁵ ANDA stands for an Abbreviated New Drug Application – the term used by the U.S. Food and Drug Administration to refer to an application for a generic drug approval.

³⁶ *Apotex v. the United States of America*, Notice of Arbitration under Chapter 11 of the NAFTA, ¶ 111 (Jun. 4, 2009).

³⁷ *Apotex Inc. v United States of America*, Memorial on Objections to Jurisdiction of Respondent United States of America, May 16, 2011, ¶ 44-45 (citation omitted).

³⁸ *Apotex Inc. v the Government of the United States of America*, Award on Jurisdiction and Admissibility, ¶ 243-245 (Jun. 14, 2013).

³⁹ Julian D. Mortenson, *Apotex v United States: Narrowing NAFTA's Definition of 'Investment'*, Case comment, 16 JOURNAL OF WORLD INVESTMENT & Trade, 163, 168 (2015).

⁴⁰ Apotex (Award), *supra* note 38, ¶¶ 235-6.

⁴¹ Apotex (Award), *supra* note 38, ¶ 238, footnote 108 (noting that “there was no evidence that Apotex Corp was an “investment” of Apotex, or that Apotex had an interest in it, such as to satisfy NAFTA Chapter Eleven”).

⁴² There are ethical arguments against risk exposure of humans and animals if clinical trials had to be repeated for the same drug in each jurisdiction, where marketing authorization is sought. Some jurisdictions may require one to conduct a part of clinical trials on the local population.

Yet, patents are commonly recognized as a category of assets within the investment definition under IIAs.⁴³

The *Apotex* decision points out an important distinction between a foreign investment as the business activity, and investment as costs incurred to create a business asset. This suggests that, even though a certain asset can explicitly be mentioned under an IIA, its qualification for protection as an investment should be analysed in conjunction with the economic activity of a foreign entity. If the business activity of the clinical data-holder is recognized as a foreign investment, costs related to conducting clinical trials can be seen as related expenditures (akin to the notion of the “pre-investment” that enables business operations in a host state). However, the interests arising in relation to the investment as resources committed to a host state’s economy, rather than the recovery of the costs of creating a particular asset, would be subject to protection.⁴⁴

2. The issue of contribution to the economic development of a host state

Contribution to the economic development of a host country was mentioned in the *Salini* decision as an *additional* criterion. Indeed, the developmental dimension of international investment rulemaking has been addressed in terms of the prospective agenda rather than the actual state of affairs.⁴⁵ In more pragmatic

⁴³ See generally the United Nations Conference on Trade and Development, Intellectual Property Provisions in International Investment Agreements, IIA Monitor No. 1, UNCTAD/WEB/ITE/IIA/2007/1 (2007); Norway’s Draft Model Agreement for the Promotion and Protection of Investments, Art. 2(2) (2007); the U.S. Model BIT, Art. 1 (2004). See also The Organization for Economic Co-operation and Development, *The Multilateral Agreement on Investment Draft Consolidated Text*, DAF/MAI(98)7/REV1, at 7 (1998) (noting that “further work [was] necessary to clarify the relationship of the MAI [multilateral agreements on investment] to other international agreements that relate to intellectual property, particularly where these conventions might require standards of treatment which differ from the MAI or where these conventions provide for dispute settlement mechanisms”).

⁴⁴ See Douglas, *supra* note 24, at 187, 257 (arguing that “the notion of a ‘pre-investment’ is meaningless” while the decisive factors for the investment definition are (i) whether the expenditures in the host state related to the acquisition of a property right that has the characteristics of, at least, one of the categories of an investment as defined by the relevant investment agreement, and (ii) the economic characteristics of an investment have materialized for the purpose of committing resources to the host state’s economy, whereby the claimant bears a risk related to commercial returns).

⁴⁵ See, e.g., Omar E. García-Bolívar, *Defining an ICSID Investment: Why Economic Development Should be the Core Element* (2012) available at <https://www.iisd.org/itn/2012/04/13/defining-an-icsid-investment-why-economic-development-should-be-the-core-element/> (last visited Mar. 14, 2016) (highlighting the lack of the explicit textual reference between the treatment of investment and the goals to promote economic development in international investment agreements); see also The United Nations Conference on Trade and Development, *Development Implications of International Investment Agreements*, IIA Monitor No., UNCTAD/WEB/ITE/IIA/2007/2, at 7 (2007) (arguing that, “to the extent that the development dimension is addressed in international investment rulemaking, it is done in an indirect manner and in a primarily defensive mode, in order to shield contracting parties permanently or temporarily from assuming their full responsibilities under the agreement”); The United Nations Conference on Trade and Development, *Investment Promotion Provisions in International Investment Agreements* (2008) (suggesting that “[c]onsideration could be given to developing guidelines on corporate economic development contributions to specifically address economic development concerns”). See generally Stephan W. Schill, *International Investment Law as*

terms, one can see foreign investment as “essentially about the acquisition of a cross-border claim to income in the hope of getting a return in the future.”⁴⁶ At the same time, the developmental aspect of foreign investment cannot be completely ignored. Its importance can be seen in at least two aspects: as forming the interpretative context for international investment dispute resolution,⁴⁷ and as pertaining to the balance of commitments.⁴⁸ The latter can be considered as an inherent *quid pro quo* in relation to the host state’s motivation to ensure a favourable environment supporting investors’ businesses and protecting investments.

In the *Philip Morris v. Uruguay* dispute over tobacco plain packaging legislation, Uruguay objected to the tribunal jurisdiction for the reason, among others, that the alleged investment did not satisfy the contribution-to-development criterion of the *Salini* test. It was argued that the claimant’s activities imposed “huge costs” on Uruguay⁴⁹ and “the ‘net contributions’ to the economic development made by the Claimants’ interests and activities in Uruguay has been overwhelmingly negative.”⁵⁰ That argument was dismissed by the tribunal. First of all, it did not consider the *Salini* criteria as “jurisdictional requirements to the effect that the absence of one or the other of these elements would imply a lack of jurisdiction.”⁵¹ Furthermore, it held that the notion of “investment” under Article 25(1) of the ICSID Convention was intentionally unspecified to cover “a wide range of economic operations confirming the broad scope of its application.”⁵² However, the scope could not be stretched limitlessly and its “outer limits” would not encompass “a single commercial transaction, such as the mere delivery of goods against payment of the price.”⁵³

Suffice it to say, the developmental aspect has not been perceived by tribunals as a mandatory legal criterion for the purpose of investment definition and protection. Even if it were so, such requirement would not be problematic for IP-based assets. Contribution to socio-economic and technological development has

International Development Law, in YEARBOOK ON INTERNATIONAL INVESTMENT LAW AND POLICY 2012-2013, 327-356 (Bjorklund A.K., ed., 2014).

⁴⁶ Steffen Hindelang, *Balancing the Rights and Obligations of States and Investors by Marrying Foreign Investment Protection off to Sustainable Development?* Speaking Notes, 24th Meeting of the Energy Charter Conference – Nicosia/Cyprus, at 2 (Dec. 5, 2013) available at http://www.encharter.org/fileadmin/user_upload/Conferences/2013_Dec_5-6/4-3_Hindelang.pdf (last visited Oct. 22, 2015).

⁴⁷ The ICSID Convention, first Preamble, available at <https://icsid.worldbank.org/ICSID/StaticFiles/basicdoc/partA-preamble.htm> (“Considering the need for international cooperation for economic development, and the role of private international investment therein . . .”).

⁴⁸ These two aspects are interrelated. For instance, as highlighted in the *Malicorp v. Egypt* award, “the notion of investment must be understood from the perspective of the objectives sought by the Agreement and the ICSID Convention. They are there to ‘promote’ investments, that is to say, to create the conditions that will encourage foreign nationals to make contributions and provide services in the host country, but also, and to that end, to ‘protect’ the fruits of such contributions and services.” *Malicorp v. Egypt*, Award, ¶ 110 (February 7, 2011).

⁴⁹ *Philip Morris v. Uruguay*, *supra* note 32, ¶ 177.

⁵⁰ *Id.*, ¶ 182 (alleging that “[b]ased on the Claimants’ own inflated estimate, their combined contributions total around US \$ 29 million per year, more than offset just by the direct health care costs of US \$ 30 million”).

⁵¹ *Id.*, ¶ 206.

⁵² *Id.*, ¶ 200.

⁵³ *Id.*, ¶ 203.

been viewed as the main justification for establishing the international system for IP protection allowing WTO member states to benefit from greater FDI and technology transfer.⁵⁴ This discussion does not intend to contribute to the debate regarding the extent to which this proposition holds true in general, or insofar as trade secrets are concerned. It is worth mentioning, however, that the relationship between trade secrets and innovation is not formalized as, for instance, in the case of patent protection that is granted *vis-à-vis* public disclosure and dissemination of technical knowledge. The sole value of trade secrets subsists in confidentiality; their contents and value can vary substantially. There is no “trade secret office” that, akin to a patent office, would assess whether a certain piece of information meets the merits of protection justified by its contribution to innovation. If a trade secret covers technical know-how, its transfer to a local subsidiary under a confidentiality agreement can be viewed as a contribution to technological development.⁵⁵ As far as clinical data are concerned, one can argue that local partners can learn from the scientific data, methodology and know-how contained in clinical dossiers. In this sense, clinical trial data can be viewed as contributing to development of the technical capacity of local subsidiaries.⁵⁶

B. The legal characterization of clinical data as an investment

The legal characterization of a foreign investment—tangibles as well as intangibles—is contingent upon securing property rights as recognized under the domestic law of the host state.⁵⁷ Protection of trade secrets is perhaps the least harmonized area of IP law. Jurisdictions can vary substantially in defining the legal

⁵⁴ Studies, in general, find a positive relation between the growth of FDI and the strength of IP protection. For an overview of literature on this expansive subject. *See generally* The World Intellectual Property Organization, 2009 Report on International Patent System (2009); Keith E. Maskus, *The Role of Intellectual Property Rights for Technology Transfer in Encouraging Foreign Direct Investment and Technology Transfer*, 9 *Duke J. Comp. & Intern'l L.* 109 (1998); Branstetter *et al.*, *Intellectual Property Rights, Imitation, and Foreign Direct Investment: Theory and Evidence*, NBER Working Paper 13033 (2007).

⁵⁵ In *Salini*, for example, the tribunal held that the investors contributed to the economic development of the Moroccan State by providing the know-how in relation to the contracted work (*Salini*, *supra* note 27, ¶ 57). On the importance of partnerships with pharmaceutical MNCs as a source of local technological capacity building, *see, e.g.*, The United Nations Conference on Trade and Development, LOCAL PRODUCTION OF PHARMACEUTICALS AND RELATED TECHNOLOGY TRANSFER IN DEVELOPING COUNTRIES (2011) (reporting on the case studies of the pharmaceutical FDI in developing countries and highlighting the role of the FDI in establishing, improving and expanding the local pharmaceutical production capacity, as well as the role of the related technology transfer for technological upgrading of the local subsidiaries).

⁵⁶ The United Nations Conference on Trade and Development, LOCAL PRODUCTION OF PHARMACEUTICALS AND RELATED TECHNOLOGY TRANSFER IN DEVELOPING COUNTRIES (2011) at 243-4 (reporting on the influenza vaccine project implemented by the WHO in Thailand and stating that “technical know-how and access to regulatory dossiers may present more significant challenges than patent issues.” Within the framework of the project, clinical dossiers, alongside with research and production related materials were comprised within “one technology package [that could] enable technology transfer in a cost-effective and timely manner.”).

⁵⁷ Douglas, *supra* note 24, at 52.

status, substantive rights, type and scope of protection in confidential information.⁵⁸ As far as undisclosed information is concerned, the reference point under international IP law is Article 39 of the TRIPS Agreement⁵⁹ that, in contrast to other IP categories, does not obligate WTO member states to grant protection in the form of *exclusive* rights. Instead, the provision presents a peculiar combination of unfair competition, trade secret and *sui generis* regimes of protection. To claim investment protection of data in a host state, the law of that state should recognize a right *in rem* in clinical data.⁶⁰ The contents of a clinical dataset comprise a broad range of miscellaneous data: some might qualify as commercial information, some as technological know-how, while some might qualify as scientific findings.⁶¹ Substantive rights in clinical data might vary from jurisdiction to jurisdiction; their recognition and scope, and entitlement to ownership are less certain than in the case of patents, which are secured upon the formal acquisition of rights (again, there is no “office of trade secrets” that would assess “secrecy claims” and issue a certificate of entitlement to the exclusive right). While a patent application⁶² can confer on the applicant a property-type right to exclude third parties’ unauthorized use of the claimed subject matter, in the case of an application for drug marketing approval, the administrative decision does not confer an entitlement in property right in data. Hence, neither application for marketing authorization, nor the marketing authorization itself possesses the legal characterisation of investment. Likewise, in the *Apotex* case, the tribunal did not consider whether there were property rights in clinical data *as such*. However, as far as an application for marketing authorization was concerned, it was “not persuaded that an ANDA [Abbreviated New Drug Application] must be characterized as ‘property’ for the purposes of NAFTA Article

⁵⁸ For instance, in the U.S., the regulatory framework applicable to clinical data includes the Freedom of Information Act, regulations of the Federal Food, Drug and Cosmetics Act and the Federal Trade Secrets Act, state trade secret law, constitutional takings doctrine. See Mustafa Ünlü, *It Is Time: Why the FDA Should Start Disclosing Drug Trial Data*, 16 MICH. TELECOMM. TECH. L. REV. 511, 520 (2010) (concluding that such “confusing, complicated, and sometimes contradictory regime contributes to the creation of legal bottlenecks”). For differences among the EU countries, see The European Commission, *Study on Trade Secrets and Confidential Business Information in the Internal Market*, MARKT/2011/128/D (2013); see also The U.S. Chamber of Commerce, *supra* note 8, at 22-24 (reporting on wide variances among the countries of the Trans-Pacific Partnership in terms of trade secret protection, especially in the availability of criminal sanctions).

⁵⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights art. 39 (3), April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

⁶⁰ Douglas, *supra* note 24, at 161.

⁶¹ For the specification of the content and structure of clinical dossiers submitted for the regulatory review, see, e.g., International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, the Common Technical Document, <http://www.ich.org/products/ctd.html> (last visited Nov. 29, 2015) (comprising guidelines for drug quality, safety and efficacy reporting).

⁶² For a discussion concerning whether patent applications qualify as investment, see Bryan C. Mercurio, *Awakening the Sleeping Giant: Intellectual Property Rights in International Investment Agreements*, JOURNAL OF INTERNATIONAL ECONOMIC LAW 15(3), 871, 876-880 (2012) (concluding that “it is extremely likely that an application for certain IPRs would normally be included within the scope of IIAs”).

1139(g) because it contain[ed] ‘confidential data and information.’⁶³ Notably, the tribunal held that

Apotex may have a right under U.S. law to have its disclosures to the FDA kept confidential, but there is no basis for this to transform *the inherent nature* of the ANDA itself, from an application for permission to *export* goods into the United States, into some form of investment within the scope of NAFTA Article 1139(g).⁶⁴

This statement suggests that, for the purpose of assessing whether an individual asset qualifies as an investment, the nature of the business activity would prevail over the legal status of the asset at issue. An investment agreement can explicitly incorporate intellectual property into the investment definition.⁶⁵ However, in the event of a dispute, a particular IP asset should be analysed in relation to the claimant’s economic activity in a host state. In *Philip Morris v Uruguay*, for instance, the tribunal did not analyse trademark rights affected by the contested regulatory measure in isolation from other assets specified by the claimant as its investment, but awarded jurisdiction based on the overall assessment of the claimant’s activities in Uruguay.⁶⁶

For the purpose of further analysis, we assume that the claimant would not be engaged merely in exporting activity but would carry out drug development and manufacturing in a country that adopts data disclosure policy after the investment was made. In this sense, clinical dossiers would form a part of a foreign investment, as they would enable an enterprise to obtain marketing authorization and perform business operations in a host state.⁶⁷

III. THE APPLICABLE STANDARD OF PROTECTION

There are substantive differences in the nature and scope of protection between international investment and IP law. Currently, 161 WTO member states are bound by the TRIPS Agreement to implement minimum standards of IP protection. In many cases, multilateral free trade agreements (“FTAs”) stipulate higher protection

⁶³ *Apotex v United States*, *supra* note 38, ¶ 219.

⁶⁴ *Id.* (emphasis added).

⁶⁵ For an overview of investment agreements that incorporate intellectual property as investment, see, e.g., Liberti, L., *Intellectual Property Rights in International Investment Agreements: An Overview*, OECD Working Papers on International Investment (2010); R.A. Lavery, *Coverage of Intellectual Property Rights in International Investment Agreements: An Empirical Analysis of Definitions in a Sample of Bilateral Investment Treaties and Free Trade Agreements*, 2 TRANSNATIONAL DISPUTE MANAGEMENT (2009).

⁶⁶ *Philip Morris v. Uruguay*, *supra* note 32, ¶¶ 221-235. Besides trademarks, assets claimed by Philip Morris as its investment included manufacturing facilities, shares in an enterprise, rights to royalty payments. *Id.*, ¶ 183.

⁶⁷ M SORNARAJAH, THE INTERNATIONAL LAW ON FOREIGN INVESTMENT 7 (2004) (defining that foreign investment “involves the transfer of tangible or intangible assets from one country into another for the purpose of their use in that country to generate wealth under the total or partial control of the owner of the assets”).

standards for IP.⁶⁸ In this regard, clarification might be needed on the relationship between investment and IP protection: do investors obtain new rights in their IP assets under investment agreements, in addition to protection under IP law? In contrast to IP rights, which are absolute, under an IIA the investor does not acquire a new right *in rem*, but a contractual right to enforce obligations under the respective agreement. Protection of IP within a foreign investment shifts protection claim into another legal paradigm and renders a different enforcement scenario. While IP protection targets infringement by users,⁶⁹ investment protection can be invoked in disputes against state policy measures. For instance, in the two above-mentioned IP-related disputes, Philip Morris sought the suspension of the legislation and compensation alleging the loss of the commercial value of its trademarks, and Eli Lilly contested patentability requirements under Canadian patent law.

The rest of this section analyses how the standards of expropriation and fair and equitable treatment (FET) can apply to investment claims against regulatory disclosure of clinical data. Other investment protection standards that deal with the arbitrary treatment of investors are not considered here, as it is assumed that, in principle, data disclosure policy is not directed at foreign companies or a particular investor but applies to all holders of drug marketing authorization.⁷⁰

A. *The assessment under the Expropriation Standard*

As mentioned, the legal status of and substantive rights in clinical data can vary from jurisdiction to jurisdiction. However, irrespective of how legal title in clinical data is determined, data disclosure by a drug authority, in principle, does not involve the transfer of ownership to the government or a third party, nor does it create a

⁶⁸ For recent statistics on the IP-related pharmaceutical provisions in trade agreements, see Raymundo Valdés & Maegan McCann, *Intellectual Property Provisions in Regional Trade Agreements: Revision and Update*, World Trade Organization, Economic Research and Statistics Division (2014) available at <http://www10.iadb.org/intal/intalcdi/PE/2014/14788.pdf> (last visited Nov. 26, 2015) (examining the sample of 245 regional trade agreements [RTAs] notified to the WTO and in force by February 2014. The statistical analysis accounts for the increase in RTAs with provisions related to pharmaceuticals including patent linkage and clinical data protection which “would be even more apparent if the agreements establishing the EEC, EFTA and the Andean Community were excluded from the count as initially they did not contain significant pharma-related provisions as such but rather established the legal frameworks within which such provisions were subsequently introduced.”). For a comprehensive coverage of the adoption of TRIPS-plus standards via bilateral and regional free trade agreements, see generally DAVID VIVAS EUGUL, REGIONAL AND BILATERAL AGREEMENTS AND A TRIPS-PLUS WORLD: THE FREE TRADE AREA OF THE AMERICAS (FTAA) (2003); Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT’L L. 79 (2004); Peter Drahos, *BITs and BIPs: Bilateralism in Intellectual Property*, 4 J. WORLD INTELL. PROP. 791 (2001); Richard E. Feinberg, *The Political Economy of United States’ Free Trade Arrangements*, 26 WORLD ECON. 1019 (2003); Ruth L. Okediji, *Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection*, 1 U. OTTAWA L. & TECH. J. 127 (2004).

⁶⁹ See TRIPS Agreement art. 43-47, 50 (stipulating obligations to provide for remedies against third party’s unauthorized acts).

⁷⁰ For instance, in the case of the EMA, any applicant’s data submitted for the EMA’s review can be subject to disclosure upon the grant of the EU marketing authorization, irrespective of the country of domicile of the applicant.

limitation on the use or withdrawal of marketing authorization issued on the basis of the submitted data. Hence, there is no direct expropriation. What appears less certain is whether the disclosure of data for experimental use interferes with the investor's business activity to an extent that it can amount to investment (indirect) expropriation.

In the *Apotex* case, the pharmaceutical company argued that the U.S. breached its obligation under NAFTA Article 1110 by interfering with and expropriating Apotex's property rights in applications for generic drug approval, in particular, by (i) "delaying Apotex's eligibility for final approval and timely entry into the generic pravastatin market" and, thus, "substantially depriving Apotex of the benefits of its investments in its generic pravastatin ANDA," and (ii) by "unlawfully redistributing the financial benefits of Apotex's investment" to its competitors.⁷¹ It challenged administrative and judicial decisions regarding Apotex's ANDAs issued based on the U.S. rules and procedures for generic marketing approval. Damages were claimed in the amount of \$8,000,000.⁷² In response, the U.S. argued that Apotex's claims under NAFTA Article 1110 were "without merit" as, first, the applications for generic approval did not constitute an "investment" under NAFTA Article 1139, and second, Apotex did not provide support "for its assertion that any of the various administrative and judicial decisions taken by U.S. federal courts and FDA were tantamount to an expropriation."⁷³ The question of whether the effect of the enforcement of the drug approval regulation on Apotex's ability to enter the market indeed amounted to expropriation was not decided by the tribunal, as all claims were subsequently dismissed due to the tribunal's lack of jurisdiction *ratione materiae* and *ratione temporis*.⁷⁴

To support the expropriation claim, an investor would need to prove the impairing effect of a contested regulatory measure on the investment. When raising the expropriation argument, Apotex could relate the U.S. FDA's decision not to grant marketing authorization with the commercialization of its products. In the case of clinical data, the causal relationship between the regulatory measure enabling data disclosure for non-commercial, public interest purposes and the impairment to commercial viability of investment appears less evident. Does clinical data disclosure hinder the investor's ability to utilize the data as an asset, or deprive the investor from benefits accruing from its own use of data?

The tribunal would need to determine whether the contested policy measure affects the value of data to an extent that it causes a loss to the investor's business or impairs enterprise operations. In the tobacco packaging dispute, Philip Morris alleged that the effect of Australia's plain packaging legislation amounted to expropriation as it deprives the company of "the value of its shares, which is heavily *dependent* upon the ability to use the *intellectual property* on or in relation to tobacco products,"⁷⁵ and that the interference of Uruguay's regulation with the exercise of trademark rights resulted "in a substantial reduction of the value" of the investor's

⁷¹ *Apotex v. the United States*, Notice of Arbitration under Chapter 11 of the NAFTA, ¶ 75 (Jun. 4, 2009).

⁷² *Apotex v. United States*, supra note 38, ¶ 133.

⁷³ *Apotex v. United States*, Statement of Defense, ¶ 44, (March 15, 2011).

⁷⁴ *Apotex v. United States*, supra note 38, ¶ 337.

⁷⁵ *Philip Morris Asia Limited v. The Commonwealth of Australia*, Notice of Arbitration, UNCITRAL, PCA Case No. 2012-12, ¶ 7.3 (a) (Nov. 21, 2011) (emphasis added).

enterprise and deprived it “of substantial revenue and profit.”⁷⁶ In the case of clinical data disclosure, it might be hard for an investor to defend an analogous argument. The imposed limitation on the commercial use of trademark rights can objectively interfere with the profitability of an enterprise.⁷⁷ Clinical data does not have a comparable commercial use—the primary function of clinical dossiers is to support an application for drug marketing approval. Thereafter, clinical reports are not used in the course of drug production, in a way that such use would add value to the product and contribute to a firm’s profits.

One can draw an analogy between the “forced” disclosure of regulatory data and compulsory licensing of patents. The issuance of a compulsory license can interfere with the patent holder’s interests and exercise of rights, while the validity and ownership of patent rights remain intact. Regulatory disclosure involves limitation of the investor’s discretion over clinical data (the EMA, for instance, grants access without authorization of or compensation to the data originator). The main difference between the two is that, in the case of compulsory licensing of patents, the detrimental impact on enterprise profitability by the limitation of exclusive rights is more evident than in the case of data disclosure for non-commercial use. Unlike a patented technology, clinical data does not have a “productive use” in a sense that the exclusion of competitors from such use in drug manufacturing would contribute to the data holder’s market power.⁷⁸

Within the public interest rationale for clinical data disclosure, one can distinguish between the purpose of protecting public health and that of promoting follow-on drug R&D.⁷⁹ The former refers to situations when an authorised drug can raise safety concerns.⁸⁰ That would be perhaps a *prima facie* case when a regulatory

⁷⁶ Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay, ICSID Case No. ARB/10/7, Request for Arbitration, ¶ 87 (Feb. 19, 2010).

⁷⁷ Studies find a positive relation between the use of trademark, brand recognition and loyalty, and profitability. See, e.g., The World Intellectual Property Organization, 2013 World Intellectual Property Report Brands—Reputation and Image in the Global Marketplace *available at* http://www.wipo.int/edocs/pubdocs/en/intproperty/944/wipo_pub_944_2013.pdf (last visited Oct. 31, 2015) (summarizing that “while evidence generally supports a complementary relationship between branding and advertising, in certain situations companies may find it more profitable to differentiate themselves through image rather than through product innovation”). See generally C. J. Simon & M.W. Sullivan, *The Measurement and Determinants of Brand Equity: A financial Approach*, 12 *MARKETING SCIENCE*, 28-52 (1993); Cobb-Walgren, *et al.*, Brand Equity, Brand Preference, and Purchase Intent, 24 *JOURNAL OF ADVERTISING*, 25 (1995); *Brand Equity*, *ENCYCLOPEDIA OF STRATEGIC MANAGEMENT* (Mie Augier & David Teece, eds., 2015) (quoting John Stuart, co-founder of Quaker Oats saying “If this business were split up, I would give you the land and bricks and mortar, and I would take the brands and trademarks, and I would fare better than you”); P. Askenazy *et al.*, *Advertising and R&D: Theory and Evidence from France*, Working paper, Paris School of Economics (2010).

⁷⁸ Such effect is associated with the referential use of clinical dossiers for the purpose of generic drug approval.

⁷⁹ For instance, the EMA policy differentiates between the purpose of “public scrutiny” and that of the “application of new knowledge in future research.” See the EMA, *supra* note 10, at 3-4.

⁸⁰ Such concerns would normally be addressed under pharmacovigilance (post-marketing surveillance) regulation that would provide for access to clinical dossiers for independent investigators for the secondary analysis. See the WORLD HEALTH ORGANIZATION (WHO), *PHARMACEUTICAL LEGISLATION AND REGULATION IN MANAGING ACCESS TO MEDICINES AND HEALTH TECHNOLOGIES*, at 6.8-6.9 (2012) (defining pharmacovigilance as an indispensable element of a comprehensive drug law).

intervention and investor's loss caused by drug withdrawal from the market would be justified. Whether there is such a compelling overriding public policy reason in the case of disclosure of clinical dossiers to scientific purposes appears less clear. This argument is of a different nature and involves the private interests of potentially competing undertakings that can benefit from the use of data in their own drug R&D.

Access to particular parts of clinical dossiers can bear different implications for new drug development. For instance, 'raw' patient-level data represents newly established or specified pharmacological properties of tested chemical or biological substances. Such scientific knowledge can support various R&D activities of follow-on researchers such as discovery of new drug targets and molecules, formulation of original hypotheses, analysis and determination of potential effects of new drug candidates, their characterization in terms of therapeutic action and safety.⁸¹ Besides patient-level data, clinical trial dossiers submitted for marketing authorization can contain strategic and methodological documents related to product development, manufacturing and commercialization. For instance, when objecting to the disclosure of its clinical study reports by the EMA, AbbVie argued that

disclosure would undermine the protection of [AbbVie's] commercial interests [as] the applicants' competitors could use the disputed reports to improve their competitive position with (actually or *potentially*) competing products in the highly competitive class of TFN antagonists . . . [Clinical study] reports therefore provide a *very specific road map* for a company wishing to *develop* a TNF antagonist for the therapeutic use in question, by enabling it to develop a similar 'biologics/biosimilar' strategy in order to produce a *follow-on medicinal product* or to *add new therapeutic indications to an existing medicinal product*. The reports also provide information about some of the hurdles the applicants had to overcome, which could reduce the development process for a medicinal product by *two to three years*.⁸²

Thus, the difference between a compulsory license for patents and regulatory data disclosure can be seen in that, under a compulsory license, the patented subject matter would be used to *manufacture* and *commercialize* a generic product, while the disclosed clinical data are supposed to contribute to new drug *development*.⁸³ Such use is unlikely to cause an immediate impact on profits from sales of the drug for which the dataset was initially generated to support marketing authorization. The outcomes of 'experimental' use by third parties appear remote and probabilistic at the

⁸¹ See, e.g., Paul Nightingale & Surya Mahdi, *The Evolution of Pharmaceutical Innovation*, in KNOWLEDGE ACCUMULATION AND INDUSTRY EVOLUTION. THE CASE OF PHARMA-BIOTECH, 73-111, at 81 (Mariana Mazzucato & Giovanni Dosi, eds., 2006) (viewing the "problem of curing a disease [as] a hierarchy of increasingly specific sub-problems involving iterative cycles of testing, understanding, modifying, and retesting potential solutions", and deliberating that "[i]n each step, scientific knowledge can be used to guide problem-solving and reduce the number of experimental dead ends that are pursued"). See also *infra* notes 130-134.

⁸² Case T-44/13 R, *AbbVie, Inc. v. European Medicines Association*, Order of the President of the General Court, ¶ 60 (25 April 2013) (emphasis added).

⁸³ See the European Medicines Association Policy, *supra* note 10, ¶ 4.1 (stipulating that access to data is granted "to enable . . . application of new knowledge in future research").

point of data disclosure, and can depend on a particular research project and the period when data are utilized, e.g., at an early stage of research when an original hypothesis is formulated, or during the more mature, pre-market product development. It may take years until the results of the follow-on R&D activity can be commercialized.

In this regard, experimental use contrasts the so-called *referential* use of clinical data for the purpose of *generic* approval.⁸⁴ In case of the latter, the launch of a generic drug can offset the investor's share in the relevant market. The submission of clinical data is a regulatory requirement that enables market access; the grant of marketing authorization does not come with monopoly-type legal protection. High costs of data generation can serve as a *de facto* market barrier and potentially eliminate competition in a specific drug market. However, data disclosure for experimental purposes would not remove this barrier for potential competitors. Nor would it interfere with the commercialization of the investor's drug.

The investor can argue that the disclosure of clinical data can confer a competitive advantage on competitors and speed up development and commercialization of new drugs.⁸⁵ However, third parties' benefits resulting from the experimental use of data might not necessarily be offset by the data originator's loss. First, the use of data in drug R&D is non-rivalrous; clinical data can be used in parallel R&D activities, i.e., third parties' use would not impede the originator's R&D. Second, experimental use may or may not result in a new product. Even if it does, the new drug may or may not compete with the originator's drug in the future. Overall, probabilistic and remote prospects of the outcomes of research use of data do not provide a strong basis for a claim that the disclosure would impair the economic viability of the investor's business activity to an extent that it can amount to investment expropriation.

B. The assessment under the FET Standard

The implementation of the 2015 EMA disclosure policy took over two years and was preceded by public consultations; its conditions apply *vis-à-vis* all holders of marketing authorizations granted by the EMA. Executed in a transparent and consistent way, the disclosure measure lies outside of the core area of the FET principle that is associated with protection against arbitrariness and the denial of justice. However, recent developments in tribunal decisions brought some novelties

⁸⁴ That is, when a drug authority evaluates a generic application on the basis of the clinical trial reports submitted by the originator company for marketing approval of its product. To obtain marketing authorization, a generic company needs to prove bioequivalence with the originator drug, but it is exempted from conducting full-scale clinical trials to demonstrate drug efficacy and safety.

⁸⁵ The argument that access to clinical dossiers can provide a springboard in the developmental work for a competing product, for instance, was raised by AbbVie that objected to the disclosure of its clinical data by the EMA. See Case C-389/13 P(R), *European Medicines Agency v. AbbVie*, ¶ 18 (arguing that "clinical study reports describe the manner in which the AbbVie companies planned and implemented the clinical trials necessary in order to obtain the MA [marketing authorization] for that medicinal product for the indication of Crohn's disease and therefore provide a *very specific road map* for a company wishing to *develop a medicinal product in the very competitive field* of tumour necrosis factor (TNF) antagonists") (emphasis added).

in interpretation of the FET standard that can potentially broaden the scope of its application. Of particular interest is the notion of “legitimate expectations.”

In the aforementioned tobacco and trademark disputes, the claimants invoked the notion of legitimate expectations alleging violation of the FET standard.⁸⁶ It remains to be seen how this notion will be interpreted by tribunals when assessing IP-related investment claims.⁸⁷ In general, legitimate expectations can hardly be considered as a well-established legal doctrine adding a substantively new dimension to the content of the FET standard; nor has it been consistently applied in arbitral decisions.⁸⁸ Some tribunals recognize that investor’s legitimate expectations *can be* a relevant factor within the FET standard.⁸⁹ However, the meaning of “expectations” was mainly associated with protection against regulatory measures enforced by the host states in an arbitrary way.⁹⁰ The liability threshold was set considerably high—to constitute a violation, a state would need to “transform and alter the legal and business environment under which the investment was decided and made,”⁹¹ or “completely dismantle the very legal framework constructed to attract investors.”⁹² In some cases, tribunals interpreted the notion of expectations as being confined to expectations to earn returns on investment. For instance, in *El Paso* it was held that “a balance should be established between the *legitimate expectation* of the foreign investor to make a *fair return on its investment* and the right of the host State to

⁸⁶ *Eli Lilly and Company v. The Government of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2, Notice of Arbitration, ¶¶ 73, 76-77, 81 (Sep. 12, 2013); *Philip Morris v. Australia*, *supra* note 75, ¶ 7.7.

⁸⁷ At the time of submitting this article, the decision in the *Eli Lilly* case is still pending. See International Centre for Settlement of Investment Disputes (ICSID), Case Details, *Eli Lilly and Company v. Canada* (ICSID Case No. UNCT/14/2) available at <https://icsid.worldbank.org/apps/ICSIDWEB/cases/Pages/casedetail.aspx?CaseNo=UNCT/14/2> (last visited Jan. 15, 2016). As for the *Philip Morris v. Australia* case, the tribunal decision dismissing Philip Morris’ protection claim has been announced but not published. See Permanent Court of Arbitration, PCA Case Repository, Case View available at <http://www.pccases.com/web/view/5> (last visited Jan. 15, 2016).

⁸⁸ See Kenneth J. Vandeveld, *A Unified Theory of Fair and Equitable Treatment*, 43 INTERNATIONAL LAW AND POLITICS, 43, 67 (2010) (arguing that [t]o the extent that the phrase “legitimate expectations” refers to expectations created by host state promises or assurances, the phrase does not exhaust the meaning of the fair and equitable treatment standard because the standard embraces principles other than the security of expectations”); Michele Potestà, *Legitimate Expectations in Investment Treaty Law: Understanding the Roots and the Limits of a Controversial Concept*, 28 (1) ICSID REVIEW 88, 89 (2013) (pointing out “the lack of a rigorous analysis by arbitral tribunal supporting the use of legitimate expectations [that] characterizes the majority of investment treaty awards”).

⁸⁹ *Técnicas Medioambientales Tecmed, S.A. v. Mexico*, ICSID Case No. ARB (AF)/00/2, Award (May 29, 2003); *Saluka Investments BV v. Czech Republic*, UNCITRAL-PCA, Partial Award, ¶ 309 (Mar. 17, 2006); *LG&E Energy Corp. et al. v. Argentine Republic*, Decision on liability, ICSID Case No. ARB/02/1 (Oct. 3, 2006); *Alpha Projektholding v. Ukraine*, Award (Nov. 8, 2010); *Impregilo S.p.A. v. Argentine Republic*, ICSID Case No. ARB/07/17, Award (Jun. 21, 2011); *Spyridon Roussalis v. Romania*, ICSID Case No. ARB/06/1, Award (Dec. 7, 2011).

⁹⁰ *Alpha Projektholding*, *supra* note 89, ¶ 420.

⁹¹ *CMS Gas Transmission Company v. Argentina*, ICSID Case No. ARB/01/08, Award, ¶ 275 (May 12, 2005).

⁹² *LG&E Energy Corp et al. v. Argentina*, ICSID Case No. ARB/02/1, Decision on Liability, ¶ 139 (Oct. 3, 2006).

regulate its economy in the public interest.”⁹³ Such view appears in line with the concept of investment as a commitment of resources made with the assumption of risk and in the *expectation* of a commercial return.⁹⁴ In general, tribunals have been rather reluctant to recognize investors’ expectations that the regulatory framework can remain “frozen” after an IIA is signed.⁹⁵

The notion of expectations is inherently subjective and the legal standard of protection cannot possibly accommodate investors’ individual perceptions of how their investments should be treated.⁹⁶ Several qualifying factors have been advanced by the tribunals to set boundaries to the scope of protection against regulatory changes that may contradict investors’ expectations. In particular, legitimate expectations shall be analysed objectively, in light of the circumstances that could have induced such expectations,⁹⁷ while most weight should be given to precise and explicit assurances and representations provided to the investor by the host state.⁹⁸ Specific provisions within a regulatory framework should be of such material importance that the investor would need to *rely* on them when making investment decision.⁹⁹

⁹³ El Paso Energy International Company v. Argentina, ICSID Case No. ARB/03/15, Award, ¶ 358 (Oct. 31, 2011) (emphasis added).

⁹⁴ See, e.g., *Tecmed*, *supra* note 89, ¶ 149 (recognizing the claimant’s expectation “of a long-term investment relying on the recovery of its investment and the estimated return through the operation of the Landfill during its entire useful life”).

⁹⁵ *CME v. Czech Republic*, UNCITRAL, Partial Award, ¶ 356 (Sep. 13, 2001); *OEPC v. Ecuador*, UNCITRAL/LCIA Case No. UN 3467, Final Award, ¶ 191 (July 1, 2004); *CMS Gas Transmission Company v. Argentina*, ICSID Case No. ARB/01/08, Award, ¶ 274 (May 12, 2005); *Saluka*, *supra* note 89 ¶¶ 305, 351 (Mar. 17, 2006); *Continental Casualty Company v. Argentina*, ICSID Case No. ARB/03/9, Award, ¶ 258 (Sep. 5, 2008); *Total S.A. v. Argentina*, ICSID Case No. ARB/04/01, Decision on Liability, ¶ 115 (Dec. 27, 2010); *El Paso v. Argentina*, *supra* note 93, ¶ 352. See also *Potestà*, *supra* note 88, at 113 (concluding that “[i]f one attempts to piece together what emerges from the latest awards which have examined this topic, one can see that there has been a gradual limitation of the more far-reaching *dicta* found in the first generation cases seen above”).

⁹⁶ *Saluka*, *supra* note 89, ¶ 304 (holding that “the scope of the Treaty’s protection of foreign investment against unfair and inequitable treatment cannot exclusively be determined by foreign investors’ subjective motivations and considerations”).

⁹⁷ *El Paso v. Argentina*, *supra* note 93, ¶ 356. “FET can be linked to foreign investors’ legitimate and reasonable expectations, [however] these expectations, as well as their violation, have to be examined objectively”, and that “legitimate expectations cannot be solely the subjective expectations of the investor, but have to correspond to the objective expectations than can be deduced from the circumstances.” *Id.*, ¶ 358; *White Industries v. India*, Final Award, ¶ 5.2.20 (Nov. 30, 2011) (denying protection as there was “no specific representation to [the claimant] . . . and no reliance (let alone reasonable reliance) on any such representation”).

⁹⁸ *Continental Casualty v. Argentina*, *supra* note 95, ¶ 259; *Total S.A. v. Argentina*, ICSID Case No. ARB/04/01, Decision on Liability, ¶¶ 120-121 (Dec. 27, 2010); *Oostergetel, Laurentius v. Slovakia*, UNCITRAL, Final Award, ¶ 236 (Apr. 23, 2012). See *Potestà*, *supra* note 88, at 98-113 (identifying “patterns of governmental conduct which tribunals have found to be susceptible of generating legitimate expectations deemed worthy of protection” and distinguishing between contractual assurances, informal assurances and general regulatory framework as sources of investor’s expectations).

⁹⁹ See, e.g., *Joseph Charles Lemire v. Ukraine*, Decision on Jurisdiction and Liability, ¶ 264 (Jan. 14, 2010) (stating that “[t]he FET standard is thus closely tied to the notion of legitimate expectations—actions or omissions by Ukraine are contrary to the FET standard if they frustrate legitimate and reasonable expectations on which the investor relied at the time when he made the investment”).

To support a claim for protection under the FET principle, instead of the nebulous notion of legitimate expectations, an investor should invoke specific provisions under the respective IIA that could be interpreted as giving rise to the obligation to treat regulatory data in a particular way.¹⁰⁰ In the absence of explicit commitments or assurances to maintain the confidentiality of data upon regulatory review, the investor may try to identify provisions under the sectorial regulations applicable to clinical data, or legal norms generally applicable to confidential commercial information and trade secrets at the time of making an investment that would guarantee confidentiality protection.¹⁰¹ Administrative law might contain provisions stipulating that the data submitted for regulatory review shall not be disclosed to third parties. Furthermore, the investor can resort to the customary treatment of clinical reports: dossiers submitted for the purpose of drug marketing approval can be held by a drug authority upon the decision to grant or deny marketing authorization, but normally they are not disclosed to third parties.¹⁰²

1. International IP protection standards for pharmaceutical test data as a source of “legitimate expectations”

In trademark and patent related disputes, claimants invoke obligations under the TRIPS Agreement as a source of their expectations for investment protection.¹⁰³ Article 39(3) of the TRIPS Agreement (“TRIPS 39(3)”) applies to pharmaceutical test

¹⁰⁰ See the Clinical trial Advisory Group on Legal aspects (CTAG5), Advice to the European Medicines Agency, lines 217-223 (30 April 2013) available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/04/WC500142857.pdf (last visited Jan. 13, 2016) (mentioning among the arguments against the EMA proactive disclosure of clinical trial reports that “Bilateral agreements normally protect strategic partnerships in the development of know-how in research and development of the product and the underpinning technology. Such agreements usually contain a confidentiality clause upon the contracting parties that is actionable in case of breach. It is generally expected that the confidential nature of such information (particularly that concerning the manufacturing and control of the product and detailed pre-clinical testing data and clinical strategic plan) is respected by the competent authorities during the course of the regulatory review.”).

¹⁰¹ The determination of the legal status and substantive rights in data comprised in clinical reports can be complex and jurisdiction specific. In the U.S., for instance, the regulatory framework applicable to clinical data submitted to the Food and Drug Administration includes the Freedom of Information Act, regulations of the Federal Food, Drug and Cosmetics Act, the Federal Trade Secrets Act, state trade secret law, constitutional takings doctrine. See Mustafa Ünlü, *It Is Time: Why the FDA Should Start Disclosing Drug Trial Data*, 16 MICH. TELECOMM. TECH. L. REV. 511, 520 (2010) (concluding that such “confusing, complicated, and sometimes contradictory regime contributes to the creation of legal bottlenecks”). In the EU, there has been no CJEU decision that would provide “any useful indicators as to whether highly technical scientific documents, such as [clinical and non-clinical study] reports, should receive, by virtue of their very nature, confidential treatment”. See Case T-235/15 R, *Pari Pharma GmbH v. EMA*, Order of the President of the General Court, September 1, 2015, ¶ 61. Furthermore, the General Court concluded that “there is no case-law that would make it possible to give a ready answer to the questions of confidentiality that fall to be decided in the present case by the future judgment on the substance.” *Id.*, ¶ 62.

¹⁰² In this regard, the EMA 2015 disclosure policy sets a precedent, when a drug authority grants access to clinical dossiers submitted for the regulatory review to third parties.

¹⁰³ *Eli Lilly v. Canada*, *supra* note 86, ¶ 42; *Philip Morris v. Australia*, *supra* note 75, ¶ 6.6, 6.7; *Philip Morris v. Uruguay*, *supra* note 76, ¶ 85.

data submitted for the drug regulatory review as *lex specialis*. The provision stipulates the *sui generis* protection of data against unfair commercial use and against disclosure:

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.

Ironically, the provision on trade secrets appears a mystery and poses an interpretative challenge regarding the minimum international requirement for test data protection.¹⁰⁴ Protection obligation is conditioned on the equivocal notion of the “unfair commercial use” that, up-to-date, has not been interpreted in WTO jurisprudence.¹⁰⁵ The agreement’s *travaux préparatoires* suggest that, originally, protection was directed at the referential use of clinical data for the purpose of expedited generic drug approval.¹⁰⁶ This, however, does not necessarily mean that was the final result achieved during the TRIPS negotiations. Even if one assumes that “unfair commercial use” implies referential use for generic approval, the debateable issue is whether the TRIPS Agreement stipulates protection in the form

¹⁰⁴ It goes beyond the scope of this inquiry to review policy and academic debate regarding the question whether TRIPS 39(3) mandates the WTO member states to prohibit the referential use of data for the expedited generic approval. For such analysis, see, e.g., Aaron Xavier, *Secrecy, Monopoly and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPs Agreement*, 45 HARVARD INTERNATIONAL LAW JOURNAL 443-502 (2004); UNCTAD- ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT (2005); Lucas Arrivillaga, *An International Standard of Protection for Test Data Submitted to Authorities to Obtain Marketing Authorization for Drugs*, 6 J. WORLD INTELL. PROP. 139 (2005); Jean-Frédéric Morin, *Tripping Up TRIPS Debates: IP and Health in Bilateral Agreements*, 1 INT. J. INTELL. PROP. MGMT 37 (2006); Shamnad Basheer, *Protection of Regulatory Data under Article 39.3 of TRIPs: The Indian Context*, Intellectual Property Institute (2006); Charles Clift, *Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals*, INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES (A. Krattiger *et al.*, eds, 2007); Jerome Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1 (2009); Carlos M. Correa Correa, *Test Data Protection: Rights Conferred Under the TRIPS Agreement and Some Effects of TRIPS-plus Standards*, THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH 568 (Rochelle C. Dreyfuss & Katherine J. Strandburg, eds, 2011); NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENTS AND TEST DATA (2014).

¹⁰⁵ The World Trade Organization, WTO Analytical Index: TRIPS available at https://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_e.htm (last visited Jan. 13, 2016).

¹⁰⁶ Many jurisdictions allow the approval of a generic product based on the bioequivalence studies demonstrating interchangeability with the innovator drug, but not requiring to provide own clinical data proving safety, quality and efficacy of a generic product. For the definitions of bioequivalence, innovator, comparator and generic products, see THE WORLD HEALTH ORGANIZATION, MARKETING AUTHORIZATION OF PHARMACEUTICAL PRODUCTS WITH SPECIAL REFERENCE TO MULTISOURCE (GENERIC) PRODUCTS: A MANUAL FOR NATIONAL MEDICINES REGULATORY AUTHORITIES (NMRAS) 41 (2011).

of *data exclusivity* rule—i.e., not allowing generic approval based on the originator’s data without her authorisation, *or* in the form of the *liability* rule—i.e., allowing the approval of a generic product without the authorisation of but with compensation to the data originator.¹⁰⁷

Notwithstanding the requirement under the TRIPS Agreement, protection of pharmaceutical data in the mode of data exclusivity has been adopted by many countries due to obligations under FTAs. For instance, all of the U.S. FTAs, although differing in details, stipulate pharmaceutical test data protection of a minimum five year exclusivity that, essentially, mirrors protection under the U.S. law.¹⁰⁸ Notably, the U.S. Government itself seems uncertain as to whether the obligation under the U.S. FTAs equals or exceeds the minimum standard of protection under the TRIPS Agreement. In particular, the U.S. Government Accountability Office stated that

[w]hether FTA provisions on data exclusivity go beyond TRIPS is less clear There are different interpretations of the obligations under TRIPS 39(3), and exactly what practices can be considered a fulfilment of this obligation. One interpretation of TRIPS 39(3) requires members to grant the originator of the data a period of exclusive use *similar to that provided by data exclusivity laws in the United States*. Under this interpretation, FTA provisions do not go beyond TRIPS. Others do not believe that Article 39(3) of TRIPS confers exclusive rights, but instead simply requires countries to prevent third parties from using the originators’ data for unfair commercial purposes. This interpretation suggests that the FTA provision goes *beyond the TRIPS requirement*.¹⁰⁹

Under TRIPS 39(3), the protection obligation against data disclosure envisages two exceptions: “except where necessary to protect the public” or “unless steps are

¹⁰⁷ See Basheer, *supra* note 104, at 23-29 (2006) (discussing compensatory liability model as an alternative approach to data protection and an intermediate standard under TRIPS 39(3)); Aaron Xavier Fellmeth, *Secrecy, Monopoly and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPs Agreement*, 45 Harv. Int’l L.J. 443, 453 (2004) (proposing a “readjustable royalties model” based on the cost-sharing approach for regulating the use of test data as a possible solution to reconcile imperatives of public health and innovation); Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data, in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ INTELL. PROP. L. REV. 1, 65-66 (2009) (arguing that TRIPS 39(3) “does not prevent governments from authorizing the generic manufacture of bioequivalent products on the basis of foreign regulatory approvals and the relevant scientific literature. . . . If some form of compromise on the issue of clinical test data becomes unavoidable, developing country negotiators should stand firm on cost-sharing counter-proposals that would at least avoid barriers to entry for generic producers.”).

¹⁰⁸ See Valdés & McCann, *supra* note 68, Annex IV. For an overview of data exclusivity regimes in 44 jurisdictions, see INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURES AND ASSOCIATIONS (IFPMA), DATA EXCLUSIVITY: ENCOURAGING DEVELOPMENT OF NEW MEDICINES (2011) available at http://www.ifpma.org/fileadmin/content/Publication/IFPMA_2011_Data_Exclusivity_En_Web.pdf (last visited Jan. 13, 2016).

¹⁰⁹ See the U.S. Government Accountability Office, *U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification*, GAO Report 07-1198, 30-31 (2007) available at <http://www.gao.gov/new.items/d071198.pdf> (last visited Nov. 26, 2015) (emphasis added).

taken to ensure that the data are protected against unfair commercial use.”¹¹⁰ These two conditions are not cumulative and differ in the grounds for disclosure. Under the first condition, data can be disclosed if, for instance, there are health risk concerns over the safety of the marketed drug and access is needed for independent investigators to conduct secondary analysis of the results. The second condition is, again, contingent on the notion of “unfair commercial use.” If one assumes that it refers to use for generic approval, data disclosure should be allowed upon the expiration of the term of protection, either in data exclusivity or liability form. As pointed out before, the EMA disclosure policy explicitly precludes the use of data for the purpose of obtaining marketing authorization and only allows access for public scrutiny (that would be within the first exception under TRIPS 39(3)), or for the purpose of follow-on research.¹¹¹ It appears uncertain whether the so-called *experimental* or *scientific* use of test data for R&D purposes comes under the notion “unfair commercial use.”¹¹² The EMA equates research use with use for non-commercial purposes.¹¹³ An issue might be taken, however, with regard to the ‘non-commercial’ use of clinical data, as any activity in the course of drug R&D can be viewed as potentially directed at the subsequent commercialisation of a new drug. At the same time, the possible impact of third parties’ access to data for R&D purposes on investor’s profits, in terms of the prospective development and introduction of a new product, is hypothetical and can hardly be ascertained and evaluated at the time when access to clinical reports is granted.

Given much ambiguity regarding the requirement under TRIPS 39(3), compliance with international standard for test data protection can hardly form a strong basis for the investor’s reasonable and legitimate expectations in situations when data are disclosed for public interest reasons.¹¹⁴ Data disclosure policy can be an unwelcome surprise for pharmaceutical companies. However, the claim that the

¹¹⁰ TRIPS Agreement, Article 39(3).

¹¹¹ See the EMA Policy, *supra* note 10, ¶ 4.1 and Annex 1, ¶ 3 (stipulating that “[w]hen using the Clinical Reports, the User shall . . . not use [reports] . . . for any other purpose than general information and non-commercial purposes, including non-commercial research purposes”; and “the User may not use the Clinical Reports to support an application to obtain a marketing authorisation and any extensions or variations thereof for a product anywhere in the world”).

¹¹² On the proportionality and necessity test with regard to public interest exception provided under Article 39(3) of the TRIPS Agreement, see Trudo Lemmens & Candice Telfer, *Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency*, 1 AMERICAN JOURNAL OF LAW AND MEDICINE 38, 63-112, at 88-89 (2012) (arguing for the “disclosure-friendly” interpretation of the obligation under Article 39(3) of the TRIPS Agreement). See Daria Kim, *Enabling Access to Clinical Trial Data: When is Unfair Use Fair?* CHICAGO-KENT JOURNAL OF INTELLECTUAL PROPERTY 14:2 (2015) (arguing that access to clinical data for research purposes does not violate protection obligation TRIPS 39 (3), even if such use can confer commercial benefits on follow-on innovators).

¹¹³ See the EMA, *supra* note 10, ¶ 4.2.1, Annex 1, ¶ 3, Annex 2, ¶ 3.

¹¹⁴ Should the investor intend to challenge the compliance of the disclosure policy with the obligation under the TRIPS Agreement, it would need to persuade its own government to initiate dispute settlement proceedings in the WTO. See Christopher Gibson, *A Look at the Compulsory license in Investment Arbitration: The Case of Indirect Expropriation*, AMERICAN UNIVERSITY INTERNATIONAL LAW REVIEW 25 (3) 357, 401-417 (2010) (analyzing the application of expropriation standard in disputes involving compulsory licenses for patents, and comparing investor-state arbitration and WTO dispute settlement as potential options for the investor to enforce protection claims against a compulsory license).

investor *relied on* the confidentiality protection of clinical dossiers when making investment decisions appears disproportionate in relation to other factors of investment amortization such as market size and economic conditions of a recipient state.¹¹⁵ Regulatory measures can vary significantly in terms of the magnitude of a change, underlying policy objectives and the gravity of the impact on investment. Data disclosure for non-commercial purposes bears, by far, less impact on the investor's profits if compared with measures such as drug price regulation or policies promoting generic competition.

2. The proportionality test and balance of interests

Some tribunals, when assessing "legitimate expectations" claims, resorted to the proportionality test and balance of interests. In *El Paso*, for instance, the tribunal held that the notion of legitimate expectations itself is "the result of a balancing of interests and rights, and that it varies according to the context"¹¹⁶ and should be assessed "with due regard to the rights of the State."¹¹⁷ In *Oostergetel*, the tribunal agreed that "stability of the legal and business environment does not equate immutability of the legal framework and that legitimate expectations must be *measured* through a balancing test taking account of specific circumstances."¹¹⁸ Questions arise: In what sense is balancing a *measure* of the "legitimacy of expectations"? What is the relevance of correlating the legitimacy of investor's *ex ante* expectations for protection with an *ex post* regulatory act?

In *Saluka*, the tribunal hinted at the unenforceability of obligations under investment treaties that are "inappropriate and unrealistic" if interpreted "too literally."¹¹⁹ The tribunal also emphasized that "the scope of the Treaty's protection of foreign investment against unfair and inequitable treatment cannot exclusively be determined by foreign investors' subjective motivations and expectations", and "in order . . . to be protected, [expectations] must rise to the level of legitimacy and reasonableness *in light of the circumstances*."¹²⁰ While qualifiers such as "inappropriate and unrealistic" might be of little guidance for the assessment, this view suggests the application of a tentative rule of thumb to determine whether expectations for protection extend beyond the scope of the state's discretion to regulate in the areas of public concerns. As the tribunal in *S.D. Myers v. Canada* held, the determination of a breach of the investment protection obligation "must be made in light of the high measure of deference that international law generally

¹¹⁵ For factors bearing on the FDI decision making, *see, e.g.*, John H. Dunning, *Global Capitalism, FDI and Competitiveness* (2002); Nauro F. Campos & Yuko Kinoshita, *Why Does FDI Go Where it Goes? New Evidence from the Transition Economies*, International Monetary Fund Working Paper WP/03/228 (2003); Ashoka Mody & David Wheeler, *International Investment Location Decisions: the Case of U.S. Firms*, 33 (2) J. INT. ECON 57 (1992); Florence Jaumotte, *Foreign Direct Investment and Regional Trade Agreements: The Market Size Effect Revisited*, International Monetary Fund Working Paper WP/04/206 (2004).

¹¹⁶ *El Paso v. Argentina*, *supra* note 93, 356.

¹¹⁷ *Id.*, 358.

¹¹⁸ *Oostergetel*, *supra* note 98, ¶ 118 (emphasis added).

¹¹⁹ *Saluka*, *supra* note 89, ¶ 304.

¹²⁰ *Id.*

extends to the right of domestic authorities to regulate matters within their own borders.”¹²¹ In other words, investors should not expect too much.

Balancing can be applied in the arbitral analysis for different reasons. For instance, in the *El Paso* award, the tribunal, on the one hand, held that “the *determination of a breach* of the FET obligation . . . requires a *weighing* of the Claimant’s legitimate and reasonable expectations on the one hand and the Respondent’s legitimate regulatory interests on the other,”¹²² in other words, to determine whether the protection obligation was breached by a policy measure. On the other hand, it noted that “[i]n order to determine whether frustration of the foreign investor’s *expectations* was *justified* and reasonable, the host State’s legitimate right subsequently to regulate domestic matters in the public interest must be taken into consideration as well,”¹²³ i.e., using balancing at the defense stage.¹²⁴

The proportionality test asks the following question: Is the loss caused to investment proportionate to the benefits of the regulatory measure? In other words, were the means proportionate to the objectives? In this sense, the idea of proportionality is akin to the concept of the necessity defense under customary international law. In *Philip Morris v. the Government of Australia*, the tobacco company claimed that “the benefits of the legislation (if any) are entirely disproportionate to the harm it will cause to PM Asia’s investment; accordingly, the legislation is not fair and equitable in any sense.”¹²⁵ The question is how to find comparable values to measure costs and benefits and weigh up the harm to private interests of a single investor and potential benefits to the public? The two appear to be in different “weight categories.”

This article does not intend to analyse how the concept of proportionality should be implied in balancing the rights of investors and public interests.¹²⁶ For the purpose of this discussion, several possible arguments can be pointed out that can be raised in response to investor’s protection claim, either when determining whether protection obligation is breached by data disclosure, or whether the breach is justified.

From the policymaking perspective, access to clinical data can support a range of objectives. In the area of public health, it can improve drug safety and quality, contribute to the transparency in decision-making of drug authorities, and reduce the risk of publication bias in reporting trial results.¹²⁷ Clinical trials are subject to

¹²¹ S.D. Myers, Inc. v. Government of Canada, UNCITRAL, Partial Award, ¶ 263 (Nov. 13, 2000). See also, *Saluka*, supra note 89, ¶ 305; and *Joseph Charles Lemire*, supra note 99, ¶ 505 (both decisions upholding S.D. Myers on this point).

¹²² *El Paso*, supra note 93, ¶ 305 (emphasis added).

¹²³ *Id.*, ¶ 358 (emphasis added).

¹²⁴ Alec Stone Sweet, *Investor-State Arbitration: Proportionality’ New Frontier*, 4 (1) LAW & ETHICS OF HUMAN RIGHTS 47, 63 (2010) (arguing “that hindrance [to investment] may nonetheless be mitigated or justified to the extent that the measures taken were not arbitral, and were meant to serve a proper good”).

¹²⁵ *Philip Morris*, supra note 75, ¶ 45.

¹²⁶ For a comprehensive analysis, GEBHARD BÜCHELER, PROPORTIONALITY IN INVESTOR-STATE ARBITRATION (2015); Benedict Kingsbury & Stephan Schill, *Public Law Concepts to Balance Investor’s Rights with State Regulatory Actions in the Public Interest - the Concept of Proportionality*, INTERNATIONAL INVESTMENT LAW AND COMPARATIVE PUBLIC LAW (Stephan Schill, ed., 2010).

¹²⁷ See THE ROYAL SOCIETY, SCIENCE AS AN OPEN ENTERPRISE 43 (2012).

mandatory registration with the subsequent reporting of the results;¹²⁸ however, data disclosed voluntarily represent “the tip of the iceberg”—clinical trial dossiers submitted by drug sponsors for marketing authorization represent, by far, more detailed records than published synopses of trials' main findings.¹²⁹

From an innovation perspective, access to clinical data can lead to a superior product being developed and launched at a faster rate. As aspired to by the EMA, access to clinical trial dossiers allows groups to “avoid [the] duplication of clinical trials, foster innovation and encourage development of new medicines.”¹³⁰ One of the objectives behind the EMA’s disclosure policy is “to enable the wider scientific community to make use of detailed and high quality clinical trial data to develop new knowledge in the interest of public health.”¹³¹ Along the same lines, the European Commission,¹³² the WHO,¹³³ and the Institute of Medicine of the National

¹²⁸ See, e.g., EU Clinical Trials Register <https://www.clinicaltrialsregister.eu> (containing data on clinical trials conducted in the EU or the European Economic Area after May 1, 2004); the World Health Organization, International Clinical Trials Registry Platform <http://apps.who.int/trialsearch/> (last visited Nov. 27, 2015). While there is no binding obligation under international law regarding clinical trials registration and results reporting, international ethical standards of conducting clinical research are embedded in the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects (adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964). Paragraphs 35 and 36 of the Helsinki Declaration stipulate that “[r]esearchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. . . . Negative and inconclusive as well as positive results must be published or otherwise made publicly available.”

¹²⁹ On the selective and insufficient disclosure of clinical trial results, see Christopher W. Jones et al., *Non-publication of Large Randomized Clinical Trials: Cross Sectional Analysis*, *BMJ* 347: F6104 (2011) (reporting that “of 585 registered trials, 171 remained unpublished. These 171 unpublished trials had an estimated total enrollment of 299 763 study participants. The median time between study completion and the final literature search was 60 months for unpublished trials.”). On the problem of publication bias and selective reporting of clinical trial results, see generally Peter C. Gøtzsche, *Why We Need Easy Access to All Data from all Clinical Trials and How to Accomplish It*, 12 *TRIALS*, 249 (2011); MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* (2005); BEN GOLDACRE, *BAD PHARMA: HOW DRUG COMPANIES MISLEAD DOCTORS AND HARM PATIENTS* (2012).

¹³⁰ The EMA, *Publication of Clinical Data* http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000555.jsp (last visited Oct. 31, 2015).

¹³¹ The EMA Policy, *supra* note 10, at 4.

¹³² The European Parliament, the European Economic and Social Committee, *On Scientific Information in the Digital Age. Access, Dissemination and Preservation*, at 2 (2007) available at http://ec.europa.eu/research/science-society/document_library/pdf_06/communication-022007_en.pdf (last visited Nov. 30, 2015) (“All research builds on former work, and depends on scientists’ possibilities to access and share scientific publications and research data. The rapid and widespread dissemination of research results can help accelerate innovation and avoid duplication of research efforts, although some delay for the first use by researchers or for commercial purposes can be justified.”).

¹³³ The World Health Organisation, *WHO Statement on Public Disclosure of Clinical Trial Results*, at 3 (Nov. 26, 2015) available at http://www.who.int/ictrp/results/WHO_Statement_results_reporting_clinical_trials.pdf?ua=1 (last visited Oct. 30, 2015) (recognizing the importance of facilitating research through greater access to primary datasets and supporting the development of “an enabling environment to allow data sharing to maximise the value of health research data”).

Academies¹³⁴ emphasize that access to data can accelerate new drug development and maximize the socio-economic value of research data. Similarly, the U.S. Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry state that data sharing can “uncover new areas of research.”¹³⁵ The importance of facilitating drug research through greater access to primary data has also been emphasized by the World Health Organisation.¹³⁶

In this context, the policy for clinical data disclosure for public interest purposes can be viewed as a *bona fide* regulatory measure that can be justified on the grounds of efficiency in R&D resource allocation; benefits for public health; and advancement in science, technology and innovation. Data disclosure should withstand the test of necessity both in situations involving concerns over the safety of the approved drugs, and when access is required for follow-on R&D purposes. In the former case, clinical dossiers submitted for regulatory review would present a unique source of information for independent investigators to conduct secondary analysis. In the latter case, disclosure would allow groups to avoid conducting duplicative trials in order to test hypotheses that might have already been examined in earlier research. Such repetitive research efforts can be viewed as ethically and economically unjustifiable.

One of the primary rationales for investment protection is to provide conditions for generating returns on investment. For instance, as was held in *Malicorp v. Egypt*, the investment definition under the Egypt-United Kingdom bilateral investment treaty “does not so much stress the contributions made by the party acting, as the rights and assets that such contributions have generated for it.”¹³⁷ Furthermore, the tribunal emphasized that a protection obligation must be understood in light of the objectives of the Egypt-United Kingdom bilateral investment treaty and the ICSID, which are to “‘promote’ investment, [i.e.] to create the conditions that will encourage foreign nationals to make contributions [and], to

¹³⁴ The Institute of Medicine of the National Academies, *Sharing Clinical Trial Data. Maximizing Benefits, Minimizing Risk. Report Brief*, at 1, 4 available at <http://iom.nationalacademies.org/~media/Files/Report%20Files/2015/SharingData/DataSharingReportBrief.pdf> (last visited Jan. 13, 2016) (aspiring that [d]ata sharing could advance scientific discovery and improve clinical care by maximizing the knowledge gained from data collected in trials, stimulating new ideas for research, and avoiding unnecessarily duplicative trials. The ultimate goal of data sharing should be to increase scientific knowledge, leading to better therapies for patients. . . . Greater data sharing could enhance public well-being by accelerating the drug discovery and development process, reducing redundant research, and facilitating scientific innovation”).

¹³⁵ The U.S. Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry, *Policy on releasing and sharing data*, at 4 available at: <http://www.cdc.gov/maso/Policy/ReleasingData.pdf>.

¹³⁶ The World Health Organization, *WHO Statement on Public Disclosure of Clinical Trial Results*, available at http://www.who.int/ictrp/results/Draft_WHO_Statement_results_reporting_clinical_trials.pdf?ua=1 (stating that “[t]he benefit of sharing research data and the facilitation of research through greater access to primary datasets is a principle which WHO sees as important. . . . WHO will continue to engage with partners in support of an enabling environment to allow data sharing to *maximise the value* of health research data.”) (emphasis added).

¹³⁷ *Malicorp v. Egypt*, Award, ¶ 108, 7 February 2011. The referenced Article 1(a) of the Egypt-United Kingdom BIT provides for a standard, non-exhaustive list of assets that can qualify as investment.

that end, to ‘protect’ the *fruits of such contributions*.¹³⁸ In this view, when access to clinical data is allowed for non-commercial public policy reasons and does not interfere with the commercialization of investor’s drugs, access policy should not be viewed as violating investment protection obligations.

IV. THE CONCLUSION

To answer the question stated in the title, investors might be wary to disclose to state authorities, in the course of regulatory procedures, information that has potentially high public interest. Pharmaceutical companies can resort to international investment law to challenge domestic policies enabling disclosure of test data. However, in light of the specific characteristics of clinical data analysed above, the prospects of investor-state arbitration appear rather weak for the investor. Most challenging for the claimant would be to prove actual or potential financial loss caused by third parties’ ‘non-commercial’ use of data. This does not preclude investors from claiming protection under national trade secret law, though the remedies might be less attractive than those that could be obtained under IIAs.

In more abstract terms, a dispute over pharmaceutical test data disclosure explicates a conflict between private interests in confidentiality protection and public interests in access to information. Investment law—designed to regulate international economic relationships—is perhaps not meant to answer the normative question of under what circumstances certain type of information should be subject to disclosure. Trade secrets can cover information of highly diverse contents and economic value. In cases where confidentiality of data plays a crucial role for appropriating returns on investment, the investor might have a more convincing argument to challenge access-to-information public policies. Yet, it may still not outweigh the public interest justification.

¹³⁸ *Id.*, ¶ 110 (emphasis added).