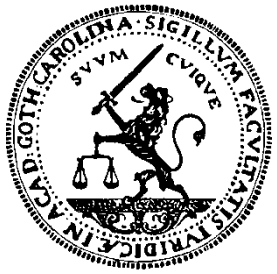

FACULTY OF LAW

Lund University

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Commercially Confidential Information

A Reviewed Understanding of the European Disclosure Regime for Medicinal Products

JURM02 Graduate Thesis

Graduate Thesis, Master of Laws Program

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Table of Content

Summary

Over the last couple of decades, the European Union has enacted several pieces of legislation to improve insight into its agencies and institutions. This trend has been particularly significant for the pharmaceutical industry, as documents submitted to the EMA in order to have medicinal products approved have been increasingly subjected to public access requirements.

Most recently, the 2014 regulation on clinical trials was enacted, which mandates the EMA to set up an online database and proactively publish data from clinical trials. It is expected to become applicable in 2019. The EMA, in an attempt to prepare itself for this paradigm shift, has vastly modified its policies on transparency: More documents than ever before are to be released upon requested access. This thesis studies the legality of these policies and asks whether the EMA exceeds its discretion.

The analysis is enabled by the three cases adjudicated by the General Court of the European Union in February 2018, which constitutes the most significant legal source for this thesis. These cases affirmed that the EMA has been correctly applying the old legislation on public access when granting third-party access to toxicology studies, clinical study reports for orphan medicinal products, and CHMP reports on similarity and clinical superiority; the court furthermore implies that this is the correct application of the CTR (once it becomes applicable).

Several conclusions can be drawn from the greenlighting of the EMA policies: i) the EMA is correct in assessing requests on a case-by-case basis rather than, as it previously did, presume that access requests to the documents concerned are to be denied; ii) even though none of these documents were treated in their entirety, the General Court has stated that future documents may be, provided that the compilation of publicly accessible and non-publicly accessible information constitutes an “inventive strategy which bequeaths added value to science.” However, such a treatment will most likely be a rarely used exception; iii) the exception for commercially confidential information is to be given a rather narrow interpretation even when taking into account protection of trade secrets in accordance with art. 39 of the TRIPS Agreement.

Sammanfattning

Under de två senaste decennierna har den Europeiska Unionen stiftat ett flertal lagar för att förbättra allmänhetens insyn i unionens offentliga organ. Denna trend har varit särskilt tydlig inom den medicinska industrin: Alltfler dokument som skickas till EMA för att få nya medicinska produkter godkända kan nu begäras ut av tredje parter.

Den nya förordningen angående kliniska prövningar förpliktigar EMA att skapa en europeisk databas och proaktivt publicera data från kliniska studier. Förordningen förväntas börja tillämpas under 2019. För att förbereda sig inför detta paradigmskifte har EMA radikalt förändrat sitt förhållningssätt till transparens: Fler dokument än någonsin förr kommer att släppas till tredje parter som begär tillgång till materialet. Denna uppsats studerar huruvida EMA:s tillämpning av lagar angående offentlighet är lagenlig.

Analysen är möjliggjord av tre nyligen publicerade rättsfall som EU:s lägre domstolsinstans avgjorde i februari 2018. Dessa utgör den viktigaste juridiska källan för diskussionsavsnittet. För att summera bekräftade dessa mål att EMA har tillämpat EU:s lagar om offentlighet på ett korrekt sätt när de har accepterat tredje parters begäran om tillgång till toxikologistudier, kliniska studier om sällsynta sjukdomar och CHMP rapporter angående likhet och klinisk överlägsenhet; vidare antyder domstolen att detta är en korrekt tillämpning av den nya förordningen angående kliniska prövningar (när den träder ikraft).

Ett flertal slutsatser kan dras från domstolens tillåtande inställning till EMA tillämpning: i) EMA har gjort rätt när de har studerat varje enskild begäran om tillgång, snarare än att anta att dokumenten inte är offentliga (som myndigheten gjorde förut); ii) trots att inga av dokumenten behandlades i sin helhet – som antingen fullständigt sekretessbelagda eller offentliga – har domstolen öppnat upp för möjligheten att göra det i framtiden, förutsatt att sammanställningen av offentligt tillgänglig och icke-offentligt tillgänglig information utgör en ”uppfinningsrik strategi, vilken medför mervärde för vetenskapen”. Sådana sammanställningar kommer sannolikt att vara ovanliga; iii) även med skyddet för företagshemligheter i art. 39 i TRIPS i åtanke, ska undantaget för kommersiellt konfidentiell information tolkas strikt.

Preface

Does anyone actually read the words
before the important chapters have started?
Paragraphs of gratitude, solitude, rectitude tendencies,
meant to be wholehearted

I don’t think anyone will read this
so I decided to do something strange
I wrote a poem about my writing
just to have some change

My supervisor, Timo, has been great
though busy he might seem
His research network takes a lot of his time
yet we still felt like a team

He helped me fix my intro and discussion
He helped me spell words right
Now I present to you my masterpiece
that no one will ever cite

It took so much time to write this
caused me a lot of pain
Turns out 23’000 words put down on paper
tends to melt your brain

Now my brain is liquid
you could drink it in a shake
not sure it would make you smarter
stay away for your own sake

Anyways, for proofreading, patience, and faith,
I extend my sincerest gratitude towards Chris, Hannes, Primus, mom, and dad. I greatly appreciate all the help I received. Thank you all so much!

Abbreviations

CCI	Commercially Confidential Information
CFR	Charter of Fundamental Rights [of the European Union]
CHMP	Committee for Medicinal Products for Human Use
CJEU	Court of Justice of the European Union
CSR	Clinical Study Report
CT	Clinical Trial
CTD	Clinical Trials Data
CTR	Clinical Trials Regulation
EC	European Commission
ECHA	European Chemicals Agency
ECHR	European Convention of Human Rights
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EMEA	European Medicines Evaluation Agency
EO	European Ombudsman
EP	European Parliament
EPC	European Patent Convention
EU	European Union
IP	Intellectual Property
IPD	Individual Patient Data
IPR	Intellectual Property Right
MA	Marketing Authorization
MS	Member State [of the European Union]
R&D	Research and Development
ROI	Return on Investment
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union

TRIPS	[Agreement on] Trade-Related Aspects of Intellectual Property Rights
TSD	Trade Secrets Directive
WTO	World Trade Organization

1. Introduction

1.1 Background

In 1961 it became apparent that a medicinal product containing the ingredient thalidomide, which was used to alleviate morning sickness and nausea during pregnancies,[1] had caused thousands of birth defects and deaths among German children. Following the thalidomide tragedy, the absence of a system for approving medicinal products as well as lacking insight into clinical trials (CT) was blamed.[2] Half a century later, the EU has well established procedures for regulatory approval through so called marketing authorizations (MA), requiring pharmaceutical undertakings to submit extensive amounts of material to have medicinal products approved.[3] The recent trend towards greater insight and transparency is supported by the U.S., the Word Medical Association, and the UN.[4] Yet the extent to which transparency should prevail for the documents submitted through this procedure remains heavily debated in the political as well as the judicial branches.

Balancing the right to access public documents and the private sector's interest in secrecy has become an important legal issue for the pharmaceutical industry. On the one hand, transparency guarantees insight in the day-to-day tasks as executed by the European institutions and is, particularly in the pharmaceutical industry, important to ensure that limited resources for research and development (R&D) are spent efficiently.[5] On the other hand, it is of severe importance for the companies operating in a patent intense and highly competitive pharmaceutical industry that commercial information is not disclosed easily to eager competitors.[6]

Over the previous couple of decades, the pharmaceutical industry has been subjected to a soaring number of new legislation, demanding increased transparency. The European Ombudsman (EO), in an attempt to contextualize recent trends, has described it as a "paradigm shift on public access to clinical study data."[7] Meanwhile, the EU is still committed to protecting commercial interests against disclosure, e.g. through the TRIPS

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[1] Miller, 1991, p. 649–674.
[2] Schneider, 2014, p. 159-160.
[3] See Regulation No. 726/2004 in particular.
[4] Schneider, 2017, p. 4-5; the Declaration of Helsinki.
[5] See EMA policy EMA/240810/2013, p. 1-2.
[6] Kim, 2017, p. 458-459
[7] European Ombudsman, case OI/3/2014/FOR, p. 71.

Agreement's (art. 39(3)) and the recently enacted Trade Secrets Directive's ((TSD) Directive No 2016/943) protection of private information against unfair commercial use. This contradiction between public and private interests becomes relevant for the pharmaceutical sector as companies are required to submit vast amounts of information to have new medicinal products approved by the EMA. Those documents, containing data retrieved through costly and time-consuming clinical trials, can subsequently be requested by competitors.[8]

The structural changes concerning the right to public access, in particular through Regulation No 1049/2001 regarding access to public documents, has been an attempt to increase transparency, while balancing the private interest in confidentiality. This regulation constituted the first part of a sequence of modernizing laws and policies, which aims to improve transparency. Most recently, the radical regulation on clinical trials has obligated the EMA to establish and maintain a European database to which vast amounts of information is to be published proactively. Subsequently, the EMA has implemented several policies to apply the public access regulations; these generally place a heavy burden on the party which desires to restrict access.[9] Through its policies, the EMA has gradually allowed for more documents to be released to competitors, e.g. clinical study reports (CSRs) submitted to it in MA applications, which are required for approval of new medicinal products.[10] The question that arises is whether the EMA has exceeded its discretion.

This strikes the core of this thesis, as it involves the definition of "commercially confidential information", the legality of recent policies when understood in conjunction with the right to secrecy, and the outcome of the inherent contradictions captured in the aforementioned laws and policies.

1.2 Purpose & Research Questions

The purpose of this thesis is to clarify the current state of the law concerning transparency requirements for the pharmaceutical industry. In particular, the balancing of private and public interests and the listed exception for commercially confidential information (CCI), as well as its relation to the protection of IP (e.g. trade secrets) will be examined thoroughly. As

[8] Choi, 2015, p. 521-522.
[9] Kim, 2017, p. 460-462.
[10] See EMA policy EMA/240810/2013, p. 6-8.

recent case law is studied, a number of interpretive issues will be brought up, e.g. CCI's relation to the TSD, general presumptions, overriding public interests, and the legal validity of EMA policies on public access. The explicit question that will be investigated is:

- How should the limitation of the transparency requirement in Regulation No 1049/2001 and the Clinical Trials Regulation for CCI be understood for documents submitted as a part of the MA application process for medicinal products?

Despite being a rather brief question, a full understanding requires this thesis to take into account recent changes by the EMA, the contradictory interests at stake, and how the past understanding of the notion relates to the new case law. This thesis will discuss the state of the law as understood by the EMA and address the private sector concerns arising from that understanding. An updated understanding of how the systematics of the right to public access relates to the pharmaceutical industry's private interest in secrecy will be provided,[11] as well as the implication that it has for the entry into applicability of the new regulation on clinical trials (CTR).

1.3 Limitation

Considering that this thesis is meant to be read primarily by lawyers, it will be assumed that the reader is knowledgeable of the fundamentals of EU law, e.g. the hierarchy of laws and courts.

On the contrary, information regarding life sciences can be confusing. However, it has become apparent that their terminology is unavoidable to fulfill the purpose of this thesis. Bearing that fact in mind, one subchapter of this introduction is dedicated to explaining pharmaceutical terminology (see chapter 1.6).

There are several legal areas that become relevant indirectly through the fact that the information that constitutes CCI is affected or entirely constituted by them. However, not all information that might be considered confidential deserves an entire subchapter. For instance, various intellectual property rights (IPRs) will be assessed very briefly and orphan medicinal

[11] Sandgren, 2005, p. 297.

products, which become relevant in one analyzed case (see chapter 4.1) will only be discussed in that case. Furthermore, despite fundamental rights being brought up in one of the cases analyzed in chapter 4, it had to be excluded from this thesis to properly focus on the more relevant issues.

Moreover, Regulation No 1049/2001 is the general regulation on public access to documents held by EU institutions and agencies. Thus, it affects transparency requirements to documents concerning agricultural and chemical products as well. But the research question only relates to the documents submitted to the EMA through the MA application process and the policies that the EMA uses to apply the regulation. Factoring in that the considerations for the documents concerned are usually different, few analogies can be made.

The definition of "trade secrets" in TSD is the same as the one in TRIPS. But art. 39 of the TRIPS Agreement is not incorporated in its entirety. The EU's exclusive external competence – to conclude binding agreements with superiority over secondary law – is a vast legal area. But as it does not directly relate to the reserach question and does not constitute a controversial topic, the extent to which it will be discussed is kept to a minimum.

Finally, Regulation No 1049/2001 has several exceptions in its 4th article. One in particular, the limitation for personal data (art. 4(1)(b)), has been subjected to radical changes since the adoption of the General Data Protection Regulation (GDPR). Regardless of how intriguing it is to speculate on the consequences of these changes, the limitation for CCI is a sufficiently demanding topic and thus the only one included in the purpose for this thesis. The same exclusion applies to other limitations listed in art. 4, e.g. for public interest, court proceedings and legal advice.

1.4 Methodology and Material

To provide an answer to the research question and fulfill the purpose of this thesis, the methodology and material discussed in this chapter will be used. In order to contribute to the legal academic discourse, this thesis attempts to systematize information from various sources to clarify what the law is.[12] The most efficient way to do so is to apply legal dogmatics on the important hierarchical levels of the law to discover and explain in a descriptive manner.[13]

[12] Sandgren, 2005, p. 323.
[13] Pierce, 2016, p. 44.

However, considering that the connection that CCI has to microeconomics[14], as the safeguard of private interests, it is justified to suggest that complementary perspectives can be useful in this particular area of legal science.[15]

The disposition (see chapter 1.7) is constructed to guide the reader through the various arguments for a broad or narrow interpretation of the CCI exception. Considering that the principles of public access and its exceptions are essential to understanding what documents are to be disclosed, the public access legislation and EMA policies will be in the 2nd chapter. This chapter also deals with summarizing the public interest in extensive transparency. The subsequent chapter handles the arguments in favor of exempting documents in MA application dossiers, i.e. they handle the private interests involved in the current public disclosure regime. Finally, the three new cases on CCI will be analyzed in a descriptive manner to determine how the General Court of the European Union understand the limitation of public access in art. 4(2) of Regulation No 1049/2001.

Bearing the research question in mind, a methodological concern is the fact that most relevant policies of the EMA as well as relevant case law, is still quite recent. Therefore, the lack of clarifying answers to controversial questions may be a cause of concern. However, it is evident that the essential parts are sufficiently clarified in EU legislation on access to public documents and trade secrets, EMA policies, the academic discourse, and recent case law on the application of the CCI exception. In particular, the three cases adjudicated by the General Court in February 2018 provides several useful clarifications on the legality of EMA policies and will thus be considered the primary source for determining the meaning of "CCI." Under current circumstances they are the most recently updated source, thus making a lot of academic research and older case law obsolete. Nevertheless, EMA policies and legal research offers clarification in areas where the court is yet to do so, while simultaneously providing an informative background to the conflicts that have arisen in the court proceedings.

Moreover, it should be noted that the CJEU is yet to rule on the legality of the EMA's recent policies and their relation to trade secrets and other private interests. Therefore, it is entirely possible that the highest court of the EU will have a completely different understanding on the

[14] Dixit, 2014, p. 86-89.
[15] Pierce, 2016, p. 45-49.

notion of CCI. Two of the cases (PTC and Intervet) have been appealed. The cases analyzed in chapter 4 will be assessed descriptively, i.e. important principles deriving from the cases will be assessed and subsequently analyzed in chapter 5 (discussion). In this regard, this thesis prioritizes the evaluation of what the law is (*de lege lata*). The last substantive chapter (concluding remarks) will partly summarize the noteworthy findings of this thesis and end with a final part in which a more prescriptive understanding of the law (*de lege ferenda*) can be addressed.[16] Despite its dominant descriptive side, the law can still be understood in a normative manner and allows for perspectives to shape the understanding of it. Thus, the final subchapter puts the narrow research topic of CCI in a broader context and discusses the future of CCI.

1.5 Other Research

The notion of CCI applied of medicinal products has been the subject of extensive academic research. However, due to the radical changes implemented in the recent EMA policies and the fact that no previous case law has concerned the legality of those changes, the academic discourse is at this point merely speculative and barely as strong as its argumentation. Nevertheless, the legal science still fills the purpose of clarifying the issues not yet tackled by the European courts and providing assistance in understanding the precedent set by the General Court. To fully comprehend the inherent contradiction between public and private interest for documents submitted for regulatory approval of medicinal products, this thesis studies the research material of prominent legal scholars, e.g. Giulia Schneider, Korkea-Aho and Leino.

1.6 A Lawyer's Introduction to Life Science Terminology

Clinical Study:

Any investigation which has the objective to ascertain the safety and/or efficacy of a medicinal product and is intended e.g. to discover or verify the effects of it.[17]

Hybrid Medicinal Product:

Medicines, for which the authorization partly depends on the results of tests on a reference

[16] Eng, 2000, p. 236-260.
[17] Regulation No 536/2014, art. 2(2)(1)

medicinal product and partly on new data from clinical trials, i.e. a hybrid medicine is always a form of generic medicine. Such a product may only be authorized after the period of data and market exclusivity is passed for the reference medicinal product (typically 10 years after the authorization).[18]

Marketing Authorization (MA):
The approval to market a medicinal product, obtained by successfully applying to the EMA. A MA must be renewed after five years and, if approved then, lasts for an unlimited period.[19]

Orphan Medicinal Product:
A medicine for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition that is rare (affecting not more than five in 10,000 people in the European Union) or where the medicine is unlikely to generate sufficient profit to justify research and development costs.[20]

1.7 Disposition

Chapter 2 concerns *Public Access*: In order to provide an understanding of what the current state of the law is concerning public access to private document, this chapter provides the relevant articles in European primary and secondary law as well as the important policies implemented by the EMA. Regarded to have significant importance in this chapter is the notion of CCI, the attempts by public institutions to define it, and the public interests in a narrow definition of CCI. Subsequently, chapter 3 brings up the topic of *Intellectual Property*: To understand the private interests and legal arguments related to the discussion of CCI, this chapter explains the various defenses used by pharmaceutical undertakings to avoid public disclosure. The focus is mostly on the role that IP, including the new directive on trade secrets, has in the European disclosure regime. It is also important to explain what the options for the judicial system are, i.e. if CCI is interpreted narrowly, what other protection exists for the obtainment and use of the disclosed information.

Chapter 4 assesses *Recent Case Law*: In order to clarify the current understanding of CCI in European administrative law, the three cases that have been adjudicated by the court since the

[18] EMA document EMA/393905/2006 Rev. 2, p. 1-3.
[19] Regulation No 726/2004, art. 14(2) and (3).
[20] Regulation No 141/2000, art. 3.

implementation of its 2010 policy on access will be studied. This chapter is essentially descriptive to provide the reader with an as unbiased understanding as possible of the General Court's interpretation. The subsequent 5th chapter is the *Discussion*, which aims to provide an answer to the research question. This chapter analyzes how information in the previous chapters interrelates and attempts to systematize information, while establishing the current state of the law for disclosure of CCI and its relation to the entry into applicability of the CTR.

This thesis ends with the 6th chapter, *Concluding Remarks:* To provide a summation of the findings of this thesis and conclude on a more normative note, a few final comments will be made in this chapter. Subjectivity permeates this chapter to a much higher degree than any previous ones. Particularly the last subchapter, which is an attempt to put the conclusions in a greater societal context.

2. Public Access

2.1 EU Legislation on the Right to Public Access

2.1.1 Primary Law

The role of European primary law, while negligible for providing detailed answers on the interpretation of relevant terms in this thesis, still maintains its presence for the right to public access. In particular, the Lisbon Treaty contains the acknowledgement of the interest in empowering natural and legal persons to access public documents. The legislation mentioned in subsequent subchapters derives from these provisions.[21]

The Treaty on the Functioning of the European Union (TFEU) establishes, through art. 15(3), the right to access public documents of the EU. Limitations may be enacted by the legislature to protect public or private interest. Moreover, the Charter of Fundamental Rights of the European Union (CFR) protects the right to, *inter alia*, documents of the European Commission (EC). Both of these rights belong to natural or legal persons residing or having its registered office within the Union.

As a fundamental right, acknowledged by the charter, the general principles laid out in CFR art. 52 applies on all limitations, i.e. restrictions on the right to public access must be proportional, have a genuine objective, and not go beyond what is necessary to achieve that objective.

2.1.2 Secondary Law

Despite the previously inadequate protection of the right to public access in directives and regulations, the European courts understood early that the role of public institutions demand a high degree of transparency. Thus, case law of the rather activist courts carried the main responsibility for the early development of the right of European citizens to access documents of the EU institutions. The efforts of the courts to push the trend in this direction would eventually lead to a call for action by the legislature and the subsequent enactment of

[21] E.g. see recital 17 of Regulation No 1049/2001 on the constitutional legitimacy of the legislation.

Regulation No 1049/2001 regarding public access to EP, Council and Commission documents and, later on, the inclusion of aforementioned articles in the Lisbon Treaty.[22]

Once implemented, the 2001 regulation on public access established a modernized legal instrument with the purpose to enforce "the fullest possible effect to the right of public access."[23] The structure, i.e. the implied methodology, of the regulation is that the general principle of public access (art. 2) is presumed to apply but can be overridden if an exception applies (art. 4). All exceptions are listed in art. 4 and include e.g. public security, international relations, integrity of the individual, and the exception that is most relevant for this thesis (art. 4(2)): "Commercial interests of a natural or legal person, including IP."

For the particular limitation concerning commercial interests the methodology has a third step: The legislature acknowledged that even in situations when a commercial interest ought to be protected, there may potentially be another interest in the disclosure of the document that must be considered to supersede the interest in confidentiality. Thus, documents that normally would be entitled to protection because of their commercial nature are disclosed due to an "overriding public interest" (art. 4(2)).

Following the construction of general principles through Regulation No 1049/2001, several *lex specialis* articles are being added through Regulation No 536/2014 on clinical trials for medicinal products for human use (hence, the Clinical Trials Regulation or "CTR").[24] As the title suggests, the primary object of the regulation is to harmonize the rules on clinical trials. However, also found in this regulation are modernized rules on public access to clinical trials data (CTD), obligating researchers to register clinical studies prior to conducting them.[25] Furthermore, the EMA is to establish and maintain an EU database, which researchers are to submit all their CTD to (art. 81). This "EU portal" may become the most significant step in the digitalization of public access to research once the regulation is being fully applied, which is expected to happen in 2019.[26] Similarly but not identical to the current regulation on public access, "commercially confidential information" is protected from disclosure (art. 81(4(b))) unless there is an overriding public interest.

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[22] Curtin and Meijer, 2006, p. 113.
[23] Recital 4 of Regulation No 1049/2001
[24] Kim, 2017, p. 457
[25] Recital 1 and 67 of CTR.
[26] Curtin and Meijer, 2006, p. 113-115; Schneider, 2017, p. 5.

Other than this specific regulation on pharmaceutical products, Regulation No 726/2004 on the procedures for authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, also ought to be mentioned in this context. Unlike the Clinical Trials Regulation, which harmonizes research procedures, Regulation No 726/2004 concerns the process of obtaining approval for effective and safe medicinal products. To clarify the process of having a medicinal product approved: When researchers have proved the efficacy and safety of a new drugs in accordance with CTR, the documentation of that medicine and other supplementing information is sent to the EMA in order to obtain marketing authorization (MA). Provided that the EMA decides to grant the MA, the undertaking is allowed to market the medicine for five years and, if renewed, for an unlimited period of time (art. 14(2) and (3)). It is explicitly incumbent upon the EMA to publish parts of the MA such as the assessment report from the Committee for Medicinal Products for Human Use (CHMP) on the medicine concerned and draw up a European Public Assessment Report (EPAR) understandable for the public (art. 13(3)).

The new Clinical Trials Regulation supplements by stating that the applicant has to submit the clinical study report (CSR), for all clinical trials, within 30 days after MA has been granted (art. 37(4)) or within one year of the termination of the clinical trial.[27] The Regulation also affirms that the general disclosure rules in Regulation No 1049/2001 applies to all documents held by the agency (art. 73). Once the EU portal is ready and the Clinical Trials Regulation becomes fully applicable, the EMA will be obligated to proactively publish CTD submitted in the MA application process. This has sparked the development of new EMA policies discussed in 2.2: The EMA is preparing itself to publish the adequate amount of information, i.e. sufficient to grant the public its right to access, while also protecting the submitting undertaking's commercially confidential information and patients' right to secrecy.[28]

The issue of transparency for CTD is of utmost importance as medicinal innovation conventionally requires high investments in R&D. Access to all concluded clinical studies allows for duplicative research to be kept at a minimum, which in turn allows for limited resources to be spent more efficiently, avoidable injuries caused by mistaken assumptions not be repeated and for scientific knowledge to advance at an even greater pace.[29] Transparency

[27] Fortunato et. al, 2018, p. 2.
[28] Schneider, 2017, p. 5-7.
[29] Kim, 2017, p. 457-458; Choi, p 521-522; Schneider, 2014, p.155-156.

also allows for non-profit organizations and other third parties to subject the CTD to independent review, thus potentially discovering hidden side effects or false data, while also inspecting the EMA's process for regulatory approval.[30] However, the trend towards greater transparency has not been uncontroversial. Pharmaceutical companies, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA), has pointed out that the Clinical Trials Regulation requires them to release information of commercial nature, allowing competitors to freeride on the efforts of others.[31] Additionally, the pharmaceutical industry has pointed out a risk of increased data sharing related to potential misuse in follow-up papers – in particular by non-EU competitors and unserious actors on the market.[32] Though it ought to be recalled that all CTD is not to be published, e.g. "commercially confidential information" (CCI) will remain undisclosed unless there is an overriding public interest (art. 81(4)(b))).

2.2 EMA Policies

Even the most expeditious and surface-leveled comparison between the Swedish legislation on transparency (Offentlighets- och sekretesslagen) and Regulation No 1049/2001 would serve to demonstrate how the former is extensive and specific, while the pan-European is more general and contains a lot of ambiguity.[33] For that reason it has been deemed necessary by the EMA to adopt policies on the implementation, clarifying how it is to be applied. The same conclusion was reached by the legislators in Regulation No 726/2004 in which the preamble states that the agency is crucial for establishing legal certainty by defining responsibilities related to transparency (recital 28).

After initial carefulness, the Management Board of the EMA adopted its first major policy on publishing and transparency in 2006 and it has since then been reviewed and supplemented by new policies on a yearly basis.[34]

The EMA policies have over time become increasingly pro-transparency.[35] The 2010 policy on access to documents (related to medicinal products for human and veterinary use) states in

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[30] Schneider, 2014, p.165.
[31] Choi, 2015, p. 536-537; Schneider, 2014, p.155.
[32] Fortunato et. al, 2018, p. 2-3 and 6.
[33] Offentlighets- och sekretesslagen has 44 chapters as opposed to Regulation No. 1049/2001 which has merely 1 with a total of 19 articles.
[34] Korkea-Aho and Leino, 2017, p. 1073-1074.
[35] European Ombudsman, case OI/3/2014/FOR, p. 71.

its introduction that all documents held by EU institutions and agencies in principle are accessible to the public unless certain public or private interests apply.[36] Furthermore, it had the drastic implication of effectively abolishing the presumption of confidentiality that used to apply to several submitted documents. Rather, undertakings are to supplement submitted documents with a list of suggested redactions, which the EMA analyzes and potentially complies with.[37]

The role that the EO has had in criticizing EMA application of secondary law cannot be understated as it undoubtedly has affected the direction of recent case law, policy trends and potentially even legislation.[38] The 2015 policy, which supplements the 2010 policy, also contains several radical changes in how the EMA is to conduct its tasks. It is the first policy to be implemented subsequent to the enactment of the Clinical Trials Regulation.[39] Thus, it tackles the issue of proactively publishing data from all conducted clinical studies.[40]

The EMA has been influential in shaping the direction of transparency law. It has been especially active on one particular topic of relevance for this thesis: Clarifying the limitation of public access that concerns information of commercial nature. As mentioned in 2.1 Regulation No 1049/2001 protects information of "commercial interest" (art. 4(2)), while the more recent legislation, CTR and Regulation No 726/2004, uses the terminology "commercially confidential information." As no one benefits on legal uncertainty – it merely leads to more know-how and finances invested into the legal procedure instead of more important areas – the issue of terminological discrepancies and ambiguities in the pharmaceutical sector has been identified as an issue and the EMA has attempted to solve it.[41]

However, the fact that CCI has become the preferred terminology does not bring closure to the understanding of the term itself. Defining "CCI" has turned out to be quite a winding path. Clinical studies remain the most controversial topic in this area.[42] In accordance with the EMA publication policies, CTD is not considered to fall within the scope of the CCI-exception except in limited circumstances.[43] These modifications of the EMA's application of

[36] EMA policy EMA/110196/2006, p. 30.
[37] Korkea-Aho and Leino, 2017, 1073-1074.
[38] Kim, 2017, p. 462; Choi, 2015, p. 536; Schneider, 2014, p.155; Stefanini, 2017, p. 1; Schneider, 2017, p. 5.
[39] Kim, 2017, p. 462-464.
[40] EMA policy EMA/240810/2013, p. 6-8.
[41] Kim, 2017, p. 466-467.
[42] Ibid, p. 460.
[43] EMA policy EMA/240810/2013, p. 4-6.

Regulation No 1049/2001 has sparked a significant reaction from the pharmaceutical industry, which has led to a thickening of the case law on the area (see chapter 4).[44] The General Court has furthermore acknowledged the imminent threats of disclosure by, on a fairly consistent basis, issuing interim measures "to prevent serious and irreparable harm to the applicants interests."[45]

An early attempt to provide a satisfying definition of CCI was part of a 2007 document on "principles to be applied for the deletion of CCI for the disclosure of EMEA documents," in which it was attempted to contextualize the concept by dividing CCI into two categories:[46] 1) Confidential intellectual property, know-how and trade secrets (including e.g. formulas, programs, process or information contained or embodied in a product, unpublished aspects of trade marks, patents etc.)" and 2) "commercial confidences (e.g. structures and development plans of a company)."[47] The 2010 publication policy includes additional guidance by equating CCI to "any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information."[48] Finally, the 2015 policy mostly contains a minor adjustment by re-stating a similar definition to the one mentioned in the 2010 policy, adding that it applies to the disclosure of clinical reports submitted to the agency and that the economic interest at stake has to be "legitimate."[49]

The EMA has taken the liberty of approaching the topic of CCI. Unlike the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA), it has attempted to fill the legal voids by deriving guidance from EU legislation and case law from various areas of the legal framework (competition, environmental, and public access law, etc.).[50] It is possible that the EMA is able to participate in the process of shaping the law to a higher extent than its equivalents in other legal areas due to the fact that it deals with fewer legislated

[44] Kim, 2017, p. 460-462.
[45] Case T-235/15 R Pari Pharma v EMA, para 58; Case T-718/15 R PTC Therapeutics International v EMA para 122; Case T-44/13R AbbVie v EMA para 48; Case T-73/13R InterMune v EMA para 37.
[46] Korreka-Ahi and Leino, 2017, p. 1073-1074.
[47] EMA document EMEA/45422/2006, p. 2-3; also notice that this policy, despite not being mentioned in the cases mentioned in footnote 32, still remains relevant for the EMA, e.g. in 2016 Work instructions (WIN/V/4035), p. 9.
[48] EMA/110196/2006, p. 4.
[49] EMA/240810/2013, p. 2-3.
[50] Korreka-Ahi and Leino, 2017, p. 1073-1074.

presumptions of transparency and that new legislation has been added on a frequent basis, requiring the EMA to adapt at a rapid pace.[51]

After gathering and summarizing all information in these policies the EMA released a document in 2016, on external guidance on the EMA's publication of clinical data for medicinal products for human use. This document was created to provide guidance to pharmaceutical companies when justifying redactions of CTD, though the document clarifies early on that it has the ambition to create consistency in the interpretation of CCI and should be read in conjunction with the 2010 and 2015 policies.[52] The external guidance places a heavy burden on the applicant to justify redactions, i.e. the process of redaction starts with a pharmaceutical company submitting their clinical reports and, alongside it, a list of allegedly confidential information and its reasoning behind why the information ought to remain undisclosed.[53] The EMA then anonymizes individual patient data (IPD) and studies the grounds for redaction of CCI to determine whether or not the information ultimately should be redacted.[54]

The 2016 document undoubtedly derives its core principles from the previous policies, e.g. the definition of CCI as stated in the 2015 policy.[55] However, unlike its predecessors the 2016 external guidance, in an attempt to disseminate the practicalities of public access limitations, adds specificities on how the EMA will apply the limitations. It also provides a better understanding for the sort of information that is not considered to be CCI.[56]

Five categories of, so called, rejection codes were added to the 2016 external guidance to simplify the type of information that will not be considered as CCI.

1. Information already in the public domain or publicly available, i.e. information that the EMA can find through, mostly, digitalized sources such as the undertaking's or the EMA's website, scientific literature, etc.[57]
2. Information that does not bear any innovative features, i.e. even if certain types of information is not publicly available, it should not be considered to require secrecy. The

[51] Korreka-Ahi and Leino, 2017, p. 1078-1080; EMA/110196/2006, p. 4.
[52] EMA document EMA/90915/2016, p. 49-50.
[53] EMA/90915/2016, p. 23-24 and 49-51.
[54] Kim, 2017, p. 466; EMA/90915/2016, p. 7.
[55] EMA/90915/2016, p. 56.
[56] Kim, 2017, p. 466-467.
[57] EMA/90915/2016, p. 52

document points out that clinical reports contain, to a high extent, description of methodologies and compilations of studies which do not reveal any "novel elements of any regulatory or scientific nature," but rather are compiled in accordance with "logic and common sense." If no innovative features are pointed out, those figures and texts will not be considered to be CCI.[58]

3. Additional information, the disclosure of which would be in the public interest, i.e. information that ought to be released in the interest of accountability and public health. For this rejection code the EMA has bundled group of information that will in principle be disclosed: 1) The conduct of clinical studies, 2) the reliability and validity of the data/research findings, 3) the safety and efficacy profile of the product, and 4) the reasoning underpinning the company claims and the opinion adopted by the Committee for Medicinal Products for Human Use (CHMP).[59]

4. Information lacking sufficient justification, i.e. a complete justification must include certain features: It has to distinctly identify the information concerned, describe its innovative features in relation to the specific scientific area, and explain how disclosure would undermine a legitimate economic interest or the competitive position of the undertaking.[60]

5. Information lacking relevant justification, i.e. if the undertaking fails to provide a satisfying explanation of how disclosure undermines its economic interest or competitive position, the EMA will reject it. The fourth and fifth rejection codes affirms the conclusion that the heavy burden of justifying redactions falls on the applicant, according to the EMA.[61]

It is not clear whether the EMA intended for the 2016 external guidance to be the exhaustive use of the public interest-doctrine. Art. 4(2) of Regulation No 1049/2001 stipulates that even CCI is to be disclosed provided that it relates to an "overriding public interest." Similar to CCI, this term is not further clarified within the regulation itself or any other regulation. Furthermore, the term is not used in the EMA policy documents and the only attempted clarification in the external guidance, as stated previously, can be found in third rejection code, which does not mention "overriding public interest" but merely "public interest." [62]

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[58] EMA/90915/2016, p. 52-53.
[59] Ibid, p. 53-56.
[60] Ibid, p. 56.
[61] Kim, 2017, p. 466-467.
[62] EMA/90915/2016, p. 53-56.

This limitation in Regulation No 1049/2001 has been the cause of case law, though not on the topic of pharmaceutical products. In Sweden and Turco v Council it was clarified that "overriding public interest" must be "applied in the light of the principles underlying [the regulation]," i.e. the interests mentioned in the preamble e.g. the right of citizens to scrutinize documents that led up to legislative acts and the legislative process itself.[63] In this regard, the case focused on the democratic intentions of the Regulation, but as far as medicinal products are concerned the assistance provided is limited. However, the EO has been a persistent participant in pushing for a more inclusive definition of the concept, stating that when the issue has implication for the health of individuals "such as information on the efficacy of a medicine"[64] the overriding public interest will supersede the CCI-doctrine and that the same applies for information that can result in improved products.[65] The significantly more extensive understanding of the public interest-doctrine – as presented by the EO – essentially implies that public health, in a wide sense of that term, legitimizes the subversion of commercial interest in non-disclosure.[66] In addition, guidance on the topic of "overriding public interest" can be found in the more recent case law, which will be discussed in chapter 4.

2.3 Summary

The inherent vagueness of Regulation No 1049/2001 has resulted in over a decade of attempts to create legal certainty. Of particular importance and relevance for this thesis is the limitation of the right to public access for CCI found in art. 4(2). Such information may exist in the information gathered in clinical studies, which must be submitted to the EMA after the trial is terminated or the data is used as part of an MA application for a new medicinal product. Once the EU portal is ready, which is expected to happen in 2019, the EMA will proactively publish the information submitted to it as part of the MA application process unless it is considered to fall under the exceptions in art. 4(2). This raises the stakes concerning the legality of EMA policies significantly.

The EMA has attempted to find a functional definition for practical purposes and currently uses the definition that information is considered to be CCI if disclosure would "undermine a

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[63] Case C-39/05 P, Sweden and Turco v Council, para 67 and 73-74.
[64] European Ombudsman, case OI/3/2014/FOR, p.62-71.
[65] Kim, 2017, p. 482.
[66] Ibid, p. 480-482.

legitimate economic interest or the competitive position" of the undertaking. The external guidance document of 2016 contributed with more practical instructions for the companies that need to suggest redactions of documents in its MA application dossiers. The guidance document suggests that for information to be categorized as CCI, it must fulfill 5 criteria: Information must 1) not already be in the public domain or publicly available, 2) bear innovative features, 3) have no overriding public interest in disclosure, 4) lack sufficient justification for disclosure, and 5) lack relevant justification.

3. Intellectual Property and Trade Secrets

3.1 Intellectual Property

The topic of right to public access to information applied on clinical studies cannot be separated from IP law.[67] As CTD becomes public to any legal person within the entire pharmaceutical industry, the questions of what information belongs to who and for what purposes it may be used arises. In addition to that, the disclosure of information, which has been kept under strict secrecy by undertakings, is by itself also a topic related to IP-rights (IPRs), which are protected by the European Charter of Fundamental Rights (CFR) (art. 17(2)).[68] The relationship between IP and public access to CTD has a convoluted nature: the prevalent ambition of IP law is to safeguard and incentivize innovation, while the disclosure of information traditionally regarded as trade secrets within the pharmaceutical sector may facilitate and strengthen the efficiency of medicinal innovation.[69]

This subchapter studies the relationship between the protection of trade secrets in WTO and EU law and the transparency requirements discussed in the previous chapter. Moreover, other IP rights will be discussed to establish a better understanding of how copyright and patents fit in to the topic discussed in this thesis.

3.1.1 Trade Secrets

Historically, the integration of trade secrets into the IP spectrum of rights has not happened effortlessly. The right of companies to have internally kept information remain secret has only recently been incorporated into pan-European immaterial rights.[70] This has led to some scholars addressing it as the "stepchild" of IP law:[71] Because despite being a part of EU law since the union's accession to the TRIPS Agreement in 1994, the legislation of the member states has varied excessively.[72]

The EU has only recently committed to harmonization of trade secret legislation by enacting Directive No 2016/943 on the protection of undisclosed know-how and business information

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[67] Case Case T-718/15, PTC v EMA, para 27-29.
[68] Art. 39 of TRIPS recognizes trade secrets as a form of IP; Schneider, 2014, p.85.
[69] Schneider, 2014, p.92.
[70] Lemley, 2008, p. 315-316; Ullrich et al, 2016, p. 728.
[71] Ullrich et al, 2016, p. 725-726.
[72] Torremans, 2015, p. 29.

(trade secrets) against their unlawful acquisition, use and disclosure (hereafter known as the Trade Secrets Directive or TSD).[73] The increased attention trade secrets have received over the last few years can mostly be explained by espionage and technology theft correlating with the digitalization of information.[74] The most relevant issue for this thesis is the debated topic[75] of what extent the protection of trade secrets applies to CTD.

If trade secrets ends up having little impact on the European disclosure regime for medicinal products, it does not entail that CSRs completely lack protection. Following the approval of a medicinal product, CTD is granted at least eight years of data exclusivity.[76] The undertaking is thereby protected from generic competitors, who must conduct clinical trials of their own. This non-reliance obligation, derived from data exclusivity periods, is described as a *sui generis* form of IP and has even been described as the "data exclusivity regime."[77]

The threat of a too narrow interpretation of the trade secrets protection prominently consists of allowing requesting pharmaceutical companies and sponsors to access information that grants a competitive advantage because of its secrecy. For instance, it has been argued that generic competitors may be able to use others CSRs to produce similar products using the same active substance, which has been disputed by the EO.[78] Generic competitors are currently allowed to conduct clinical trials on the active substances in already MA approved drugs to produce similar products, but the argument is that the development process is significantly facilitated by the disclosure of CSRs.[79] Moreover, an identified risk is that competitors will use disclosed data to file applications in foreign jurisdiction for similar or even identical medicinal products, thus circumventing the 8 years of data protection and the 10 years of marketing protection in art. 14(11) of Regulation No 726/2004.[80] The EMA has acknowledged that risk and added in its user conditions for the 2015 policy that the party provided with access to a CSR may not use it to support an application for marketing authorization or any variation thereof anywhere in the world. The remedy for failure to follow

[73] Torremans, 2015, p. 27-28.
[74] Seville, 2016, p. 519.
[75] Schneider, 2014, p. 94.
[76] Directive 2001/83/EC, art. 10.
[77] Schneider, 2017, p. 10-11.
[78] Schneider, 2014, p.89 and 110-114.
[79] Ibid, p.120-121.
[80] Spina Ali, 2017 p. 37-38; Schneider, 2014, p.89; this was furthermore pointed out by the Advisory Group on Legal Aspects as an aspect that ought to be considered by the EMA before drafting its 2015 policy.

that condition is the revocation of the right to access and use the CSR in question.[81] Furthermore, the Clinical Trials Regulation permits the Commission to conduct controls in order to verify that general principles in Annex I to Directive No 2001/83/EC, on e.g. generic medicinal products, are complied with. However, that article appears to be directed towards the trial process, rather than MA applications (art. 79 and recital 65).

3.1.1.1 Trade Secrets Directive

Notwithstanding the notion that harmonization of civil law has an intrinsic value, the explicitly mentioned purposes of the TSD is to enable and improve collaborative research,[82] provide a consistent definition of the term "trade secret,"[83] and grant adequate protection of information, which by a lot of businesses is valued equally high or higher than other IPRs.[84] The most prominent value of trade secrets can be found in the fact that even information which grants a competitive edge but does not meet the criteria for other IPRs, still can be kept secret and provide this advantage, unlike most other IPRs, for an unlimited time.[85]

In the 2nd article of the TSD "trade secrets" are defined, in accordance with art. 39(2) of TRIPS, as information which meets the following cumulative criteria:
a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the type of information concerned;
b) has commercial value because it is secret, and
c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

Such information is protected against unlawful acquisition, use and disclosure (art. 1). However, it should be noted that the preamble primarily appears to have private individuals as subjects for the restraints, i.e. to harmonize rules on unlawful competition between private actors is the primary purpose. The preamble mentions that the directive is to be implemented without prejudice to rules, which obligate public authorities to collect and subsequently disclose information to the public.[86] Regulation No 1049/2001 is explicitly mentioned in

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[81] EMA/240810/2013, p. 11 and 14.
[82] TSD, recital 3.
[83] Ibid, recital 14.
[84] TSD, recital 1; Grassie, 2016, p. 577; Schneider, 2014, p.96.
[85] Grassie, 2016, p. 590-591.
[86] TSD, recital 11.

recital 11 as a regulation that should not be affected by the TSD. Furthermore, the same ambition mentioned in the preamble is implemented in art. 1(2(b)) and (c), which states that the directive should not affect Union or national law, requiring businesses to submit information for reasons of public interest to public institutions, or subsequently requiring the institutions to disclose the information. However, the conclusion that TSD bears no relevance for the disclosure of information submitted as part of the MA application process has been called into question: [87] The uncertainty of the exact effect that the TSD will have is based on recital 18, which states that EU institutions are not released from confidentiality obligations. Therefore, the relationship between the TSD and clinical studies is yet to be clarified.

The TSD entered into force in July 2016, i.e. after the cases discussed in chapter 4. A shallow evaluation of the TSD suggests that it completely lacks relevance for the topic of the CTD disclosure regime. Yet it was brought up in the recent case Pari Phama v EMA (analyzed in chapter 4).[88] The primary reason for the TSD being, at least indirectly, relevant in these cases is twofold: Firstly, the exception in art. 4(2) of Regulation No 1049/2001 relevant for this thesis is commercial interest "including intellectual property." Trade secrets are recognized as a *sui generis* form of IP and there is no doubt that CTD should be considered to fall within the definition in art. 2.[89] The data is thus, at the very least, protected against competitors' unlawful obtainment or use of it. Secondly, the TSD has a robust connection to the TRIPS Agreement considering, *inter alia*, that the definition of "trade secrets" in art. 2 of TSD is identical with TRIPS art. 39(2) and that the directive mentions TRIPS as a reason for the importance of harmonization (recital 5-6).

3.1.1.2 TRIPS

The EU entered into the TRIPS Agreement in 1994, i.e. the same year that the WTO, of which TRIPS constitutes a fundamental component, was established.[90] The agreement remains highly influential for the global protection of IPRs, yet it has taken almost 20 years for the EU to commit to harmonizing legislation on the area of trade secrets. This has led to trade secrets being addressed as the "stepchild" of not only the TRIPS Agreement, but IP law in general.[91]

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[87] Schneider, 2017, p. 10.
[88] Case T-235/15 R, Pari Pharma v EMA, para 63.
[89] TSD recital 1; Spina Ali, 2017 p. 46.
[90] Valentin Rehncrona, 2017, p. 16.
[91] Ullrich et al, 2016, p. 726-729.

The part of TRIPS that is relevant for this thesis can be found in section 7 and in particular the 39th article. As stated above, the definition of the term "trade secrets" is, following the implementation of the TSD, identical in EU law and art. 39(2) of TRIPS. When the discussion of a harmonizing directive on trade secrets surfaced, it was feared by organizations committed to the independent review of CSRs[92] and equally welcomed by the pharmaceutical industry.[93] The reason for the high anticipation of the directive can be explained by the fact that it was thought to become the comprehensive implementation of art. 39 in TRIPS, i.e. an implementation of rules that influences administrative rules on disclosure of information. Article 39(3) requires contracting parties to protect data submitted through regulatory procedures from "unfair commercial use." Information submitted in the process of having a medicinal product approved for marketing is explicitly listed as an example of data requiring protection from disclosure. Such information only enjoys protection against disclosure and unfair commercial use on the precondition that it was secret prior to the MA application.[94]

The role of international law in the EU legal order has been an enduring controversy. The monistic approach has been confirmed on a consistent basis and in current jurisprudence, it is no longer a controversial statement to suggest that the TRIPS Agreement is part of EU law:[95] Considering that the EU is a contracting party of the agreement and the legal area falls within the scope of the Union's exclusive external competence,[96] TRIPS constitutes an "integral part of community legal order."[97] However, the CJEU has concluded that WTO law is not to be used in the context of reviewing legality unless that intention is explicitly expressed by the EU legislature.[98]

Thus, despite the TRIPS Agreement not being implemented, EU law still must comply with art. 39(3). Studying the article more carefully, the protection of data which required a "considerable effort" to compile is central. The last sentence provides two exceptions when disclosure is acceptable: 1) when disclosure is necessary to protect the public, and 2) when steps are taken to ensure that the data are protected against unfair commercial use. In this

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[92] Non-Profit Organizations Press Release, 2013.
[93] EFPIA article, 2013.
[94] Schneider, 2014, p.107-108.
[95] Van Vooren, 2014, p. 298-300; TFEU, art. 218.
[96] See art. 3(1(e)), 206, 207 of TFEU which establishes the EU's exclusive competence over common commercial policy.
[97] Case C-181/73, Haegeman v Belgian State, para 4-5.
[98] Case C-149/96 Portugal v Council, para 47-50; Bart van Vooren, 2014, p. 298-300.

regard, art. 39(3) reminds of the current methodology used by the EMA: Data is protected due to its commercial value under the CCI-doctrine but may be disclosed due to its value for public health. Nevertheless, whether the EMA has gone too far in its commitment towards transparency and allowed EU law to drift away from compliance with the TRIPS Agreement has been subject for recent case law and will be discussed in chapter 4.[99] WTO case law and related literature provides little definitive guidance on the interpretation of "public health," which has been almost entirely left to the member states to interpret so far.[100]

As mentioned in 3.1.1.1, the TSD may have ended up falling short on the expectation that it would contain administrative law within its scope (art. 2(2) and (3)), which raises the question of what effect the discrepancy between TRIPS and TSD ought to have. The WTO has not been ignoring the issue of transparency to CTD: TRIPS art. 8 acknowledges the right of states to adopt "measures necessary to protect the public health (…) and to promote the public interests in sectors of vital importance to their socio-economic and technological development." Furthermore, the Doha Declaration included paragraphs stating that TRIPS should not prevent contracting parties from protecting public health and promoting access to "existing medicines and research and development into new medicines."[101]

The European courts will have to account for and assess the TRIPS Agreement in its understanding of the legal order. In addition, entertaining the thought that EU law is inconsistent with the agreement, a case can be brought to a WTO panel and subsequently to the appellate body of the WTO. Such a case is to be brought by another contracting party of the WTO.[102]

3.1.2 Other Intellectual Property Rights

The exception for commercial interests in art. 4 of Regulation No 1049/2001 directly references IP as requiring protection from disclosure to not be undermined. The exact meaning of the phrasing and the impact that disclosure has on immaterial rights has been a topic for the academic discourse.[103] Undoubtedly, the legislators have allowed a certain

[99] See PTC, Pari Pharma, and Intervet cases in chapter 4.
[100] Schneider, 2014, p.113-115.
[101] Doha Declaration, 2001, p. 4-5 and 17; Schneider, 2017, p. 13.
[102] Dispute on Rules and Procedures Governing the Settlement of Disputes (Annex 2 of the WTO agreement), art. 2 and 17.
[103] Minssen and Nicholson Prize, 2015, p. 685-686; Korkea-Aho and Leino, 2017, p. 1064-1066.

degree of discretion for the courts to elaborate on the role of IP by listing it as an example of a legal objective that is to be included in the balancing of public and private interests under art. 4(2).[104]

3.1.2.1 Copyright Law

Other than art. 4(2), the 16th article of Regulation No 1049/2001, on the reproduction of documents, states that the regulation shall be without prejudice to rules on copyright which "may limit a third party's right to reproduce or exploit released documents." Though not a part of the exceptions (listed in art. 4), art. 16 remains a legal challenge for the understanding of what CCI is and how it may be used.[105]

The contradictory objectives of copyright and public access legislation complicates the state of the law: Should copyrighted material be considered to have additional commercial value requiring confidentiality? And if the EMA are to release compiled data and grant public access to it, does it matter that the submitter of it maintains copyright over the compilation for its future use?[106] The exact meaning of art. 16, and the relation between copyright law and the right to public access, is yet to be elaborated upon by the European courts.[107] The EMA has also not provided any comprehensive clarifications.[108]

3.1.2.2 Patent Law

The special treatment that the pharmaceutical products have received in patent law can be explained by the important role that pharmaceutical innovation plays for public health[109] and the immense costs associated with the development of new medicinal products.[110]

To prepare a medicinal product for the market, the pharmaceutical company will generally apply for a patent at an early stage, subsequently produce a drug which can be tested in all required phases of a clinical study and finally use the CSR in its application for market

[104] Korkea-Aho and Leino, 2017, p. 1069.
[105] Korkea-Aho and Leino, 2017, p. 1084.
[106] Ibid, 2017, p. 1064-1066
[107] Ibid, 2017, p. 1069.
[108] Ibid, 2017, p. 1083.
[109] Seville, 2016, p. 111-113.
[110] Minssen, 2012, p. 4-5.

approval.[111] In this regard, the novelty of an pharmaceutical innovation will not be affected by disclosure following an MA application.[112]

Nevertheless, the innovative aspect of the pharmaceutical industry contains a more incremental part as well, i.e. finding new uses for already approved medicinal products. The academic discourse has pointed out the potential threat that disclosure poses to such innovation.[113] Despite the European Patent Convention (EPC) allowing for repurposing patents (art. 54(4) and (5), disclosure may be a cause of concern for the patent requirements of novelty and innovative step (art. 52 and 56); especially if the EMA fails to consider "secondary effects of unrecognized importance" to fall within the scope of CCI.[114] However, this potential consequence of the recent policies, could be viewed as being positive for public health considering that new uses of medicinal products might be found more rapidly.

3.2 Summary

To utilize the exception in art. 4(2) of Regulation No 1049/2001 and thus avoid disclosure of documents submitted as part of the regulatory approval process for medicinal products, various legal defenses can be used. This chapter attempts to explain the arguments that have been used in recent case law (see chapter 4).

Despite the new directive on the protection of trade secrets not including documents submitted to EU agencies for regulatory approval, the TRIPS Agreement still sets a minimum standard. Thus, art. 4(2) must be interpreted in the light of art. 39(3) in TRIPS. The exact outcome of such an interpretation will be discussed in the cases analyzed in chapter 4. Moreover, other IPRs have been used be used as an argument for a broader understanding of CCI (which includes CSR), e.g. the re-purposing of already patented and authorized products and copyright protection of compiled data. One of the biggest concerns related to disclosing CSR is the use of such data for regulatory approval in foreign jurisdictions.

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[111] EO Decision 2560/2007/BEH, para 77.
[112] Spina Ali, 2017 p. 36-37.
[113] Minssen and Nicholson Prize, 2015, p. 685.
[114] Ibid, p. 686.

4. Recent Case Law

The General Court has, through the three cases analyzed in this chapter, ruled on the EMA's application of public access legislation for the first time since the implementation of the 2010 policy. In all three cases the rulings were published on the 5th of February 2018. For the purposes of this and subsequent chapters, the cases will be referred to as the PTC-case (4.1), the Pari Pharma-case (4.2), and the Intervet-case (4.3). The subchapters are arranged to follow the order in which the court has structured its ruling.

Moreover, as the case law on interim measures lacks relevance for the research question of this thesis, it will not be assessed in a detailed manner. However, the reader should notice that in all three cases, such measures were ordered prior to the rulings on the substantive issues due to the risk of "serious and irreparable harm."[115] It should further be noted that the PTC-case and the Intervet-case have been appealed to the CJEU.

4.1 PTC-case

In October 2012, PTC Therapeutics International Ltd submitted an MA application for the medicinal product Translarna. The drug was authorized by the EMA on 31st of July 2014. Over a year later, PTC was informed by the EMA that another pharmaceutical undertaking had requested access to a CSR in the MA application dossier for Translarna, which the EMA had granted in accordance with its 2010 policy on access. PTC disputed the decision to disclose, thus initiating court proceedings.[116]

PTC relies on several pleas against disclosure, the most relevant being that the report was protected by a general presumption of confidentiality under art. 4(2) of Regulation No 1049/2001 or at least that the particular CSR in this case ought to be considered as CCI in its entirety. In addition, PTC argues that the EMA failed to properly conduct a balancing exercise as required by law.[117]

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[115] Case T-235/15 R, Pari Pharma v EMA, para 40; Case T-729/15 R, MSD Animal Health Innovation and Intervet international v EMA; Case C-513/16 P EMA v PTC Therapeutics International, para 141.
[116] Case T-718/15, PTC v EMA, para 1-5.
[117] Ibid, para 26.

4.1.1 General Presumption of Confidentiality

The reason for the proposed existence of a general presumption of confidentiality is based on several arguments. At this point it ought to be recalled that CSRs were protected by such a presumption until the implementation of the EMA's 2010 policy.[118] The argument in favor of a general presumption suggests that the EMA's application of art. 4 in Regulation No 1049/2001 lacks legality. In this case, PTC argues that art. 4(2) must be read in conjunction with the TRIPS Agreement, as well as Regulation Nos. 726/2004, 507/2006 (on conditional MAs), and 141/2000 (on orphan medicinal products, see chapter 1.6). The latter two becomes relevant in this case due to the fact that the requested document concerns data for an orphan medicinal product. To clarify: PTC argues that a specific disclosure regime exists for medicinal products that will be used by relatively few patients, considering that the expected return on investment (ROI) on those drugs is relatively low.[119] PTC also argues that the lack of a general presumption requires the EMA to go through a burdensome case-by-case analysis of each requested document and implies in all arguments that disclosure risks to undermine its commercial interests.[120]

The court initially concludes that all documents held by the agency – i.e. created or received by it and in its possession – are affected by the public access requirement in Regulation No 1049/2001 art. 2(3). However, the CJEU has recognized the possibility for institutions and agencies to establish general presumptions for certain categories of documents, provided that a set of criteria is fulfilled:[121]

1. The general presumptions must concern documents of the same nature for which considerations of a "generally similar kind" are likely to apply.[122]
2. General presumptions are to be "dictated by an overriding need to ensure that procedures operate correctly" and to guarantee that their objectives are not jeopardized.[123]
3. General presumptions of confidentiality have only been established for documents included in files related to ongoing administrative or judicial proceedings.

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[118] Kim, 2017, p. 462-463.
[119] Case T-718/15, PTC v EMA, para 28-29.
[120] Ibid, para 30.
[121] Case T-718/15, PTC v EMA, para 34-35; The criteria can be found in Case T-718/15, PTC v EMA, para 38-41.
[122] Case C-39/05 P, Sweden and Turco v Council, para 50.
[123] Also see the referenced Cases C-514/11 P and C-605/11 P LPN and Finland v Commission, para 66, 68, 74 and 76.

4. Specific legal provisions relating to objectives of the relevant document and the procedure for its creation must be considered.

In its application of principles from case law, the court puts emphasis on the fourth criteria. As mentioned, PTC argues that a different disclosure regime exists when reading Regulation No 1049/2001 in conjunction with the regulations on orphan medicinal products and the TRIPS Agreement. The court notes that Regulation No 141/2000 does not contain any rules on public access and that Regulation No 726/2004 prescribes that the general provisions on public access are to apply (art. 73). The view that the MA application process should be transparent is clearly indicated by the legislators (art. 11-12 and 36-37 of Regulation No 726/2004). Thus, a general presumption of confidentiality cannot be established for CSRs neither in general nor as a *lex specialis* disclosure regime for orphan medicinal products.[124]

The court goes on to address other arguments related to the existence of a general presumption. It concludes that the TRIPS Agreement is an integral part of the EU legal order and it is necessary to have an interpretation which "as far as possible" is consistent with it. However, that does not equate to the agreement having direct effect: Consequently, an interpretation that challenges the legality of the provisions in relevant regulations must be rejected. In this case, the court finds that establishing a general presumption of confidentiality by interpreting Regulations Nos 1049/2001, 726/2004, 141/2000, and 507/2006 in the light of art. 39(2) and (3) in the TRIPS Agreement, would disregard the balance between public and private interest as intended by the legislator and distort the disclosure mechanism. The court insinuates that such an interpretation would give the TRIPS Agreement "absolute precedence" over the disclosure regime, which must be rejected. Rather, the 8 years of data exclusivity, 10 years of marketing exclusivity, and the general protection of CCI applied to separate data in the MA application dossier is sufficient.[125] It is furthermore clarified that art. 16 of Regulation No 1049/2001 – stating that the regulation is without prejudice to copyright – does not allow the requestor to "use, reproduce, publish, disclose or otherwise exploit" the documents.[126]

The court acknowledges the risk of the requestor exploiting the accessed CSR reports by circumventing data exclusivity rules in breach of regulation Nos. 726/2004 and 1049/2001. Though its subsequent reasoning is consistent with the EMA's, i.e. if the risk of disclosed

[124] Case T-718/15, PTC v EMA, para 46-53.
[125] Ibid, para 61-65 and 71.
[126] Ibid, para 68.

documents being used in an unlawful manner would constitute grounds for refused access, "almost full paralysis" would ensue for the EMA's transparency related activities. Therefore, the court finds it difficult to reconcile the risk of circumvention of data exclusivity rules with public access and concludes that the interest in transparency must be prioritized higher in this case.[127] In addition, the court claims that though neither it nor the EMA can guarantee that the accessed data will be used lawfully, that fact does not by necessity prove that the unfairly used information is confidential or that the entire document ought to enjoy a presumption of confidentiality.[128]

Moreover, the argument that the lack of a general presumption becomes too administratively burdensome for the EMA is hastily rejected. The court interprets the argument as a claim that the EMA is being too thorough in its application of Regulation No 1049/2001 and it reminds the applicant (PTC) that the letter and spirit of that regulation contradicts such an understanding. Public access is the objective and confidentiality is the exception.[129]

In conclusion, no general presumption of confidentiality was found to derive from the CCI exception in art. 4(2) of Regulation No 1049/2001 for neither CSRs in general nor specifically for conditional MAs such as the MAs for orphan medicinal products.

4.1.2 Entirely Confidential

PTC's second plea claims that the report in its entirety should be considered as CCI. The fundamental premise of the plea is the belief that the report constitutes an "inseparable whole with economic value,"[130] which entails that the EMA is at fault for deconstructing the report rather than assessing it as one entity. PTC's argument is that the information in the report could be used by competitors as a roadmap to obtain MA for a related medicine, even if specific parts are redacted. In addition, PTC argues that the trial data, study design, analysis and presentation of non-clinical information in the report was gathered using an inventive strategy and that the EMA has failed to take necessary steps to protect that information from unfair commercial use (TRIPS art. 39(3)).[131]

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[127] Case T-718/15, PTC v EMA, para 68.
[128] Ibid, para 72.
[129] Ibid, para 68.
[130] Such an interpretation was presented by the court in the Pari Pharma case on interim measures, Case T 235/15 R, Pari Pharma v EMA, para 56.
[131] Case T-718/15, PTC v EMA, para 76.

The court examines the plea. It has been established in case law that for an EU institution to deny access to a document based on art. 4 of Regulation No 1049/2001, it must explain how disclosure may "specifically and actually" compromise the private interest concerned. The risk must be "reasonably foreseeable" and not "purely hypothetical."[132] The General Court explains that case law has acknowledged as commercially sensitive e.g. information revealing the undertaking's business strategies, commercial relations, or expertise.[133]

When assessing the claim that the document should be treated as one entity, the court studies how such a precedent would relate to the rejection of a general presumption of confidentiality, i.e. can the document at issue be treated in its entirety without establishing a *de facto* general presumption? Those notions are deemed difficult to reconcile. However, the court claims that it is potentially possible for a report to be treated as one unit, provided that the applicant can prove that the assembly of the publicly accessible and non-publicly accessible data constitutes a "commercially sensitive item of data."[134]

On that note, the court studies the claim that the report provides a "road map" for competitors in applying for MAs for competing products: The court claims that requesting competitors will not be provided with any "valuable insight" on clinical development strategies or study design after the EMA has redacted e.g. "batch numbers, materials and equipment, explanatory assays, quantitative and qualitative description of the method for drug concentration measurement."[135] It would therefore be necessary for accessing competitors to conduct studies and trials of their own and produce efficient and safe medicinal products. Even if the competitors were to do that, Translarna is still protected by a ten-year period of market exclusivity (art. 8(1) of Regulation No 141/2000). Thus, the court does not acknowledge that commercial interests are sufficiently undermined for the exception in art. 4(2) of Regulation No 1049/2001 to be activated.[136] In addition, the methodology used to gather the data is not deemed to represent a novel state-of-the-art strategy. On the contrary, it follows the

[132] Case T-718/15, PTC v EMA, para 82, applying principles derived from Case C-506/08 P, Sweden v MyTravel and Commission, para 76.
[133] Ibid, para 85, citing and applying the precedent from Case T-516/11, MasterCard and Others v Commission, para 82 to 84.
[134] Ibid, para 89.
[135] Ibid, para 90.
[136] Ibid, para 90-92.

recommended guidelines and processes widely accessible within the scientific community. For these reasons, the report cannot be treated as one unit.[137]

Despite the conclusion that all information in the document should not be treated as one unit that is either confidential or not confidential, the court can still find that all information in this specific report falls within the scope of art. 4(2). However, it was never a disputed that parts of the report were publicly available at the time of the request. For instance, the EPAR contains significant amounts of data derived directly from the report.[138]

Finally, the court tackles the risk that competitors could use the requested information to obtain MAs in third countries, thus circumventing EU legislation on data and marketing exclusivity. The court addresses the argument as "vague" and considers the non-redacted information to not facilitate for competing undertakings to obtain MAs in foreign jurisdictions. The court ends on the note that if disclosure of all studies were to be prevented in order to avoid having other jurisdictions grant market access to competitors, the European public would be denied its right to access as granted by the law.[139]

4.1.3 Proper Balancing Test

The final plea concerns the balancing of public and private interests. PTC claims that such a balancing exercise was wrongfully omitted by the EMA. This claim is partially based on a reading of art. 4(2) in conjunction with the TRIPS Agreement, the fundamental right to a proportionality assessment and the specific rules of Regulation No 726/2004 on access to documents submitted to the EMA for regulatory approval. Furthermore, PTC argues that the adequate amount of information regarding safety and efficacy already is made public through the EPAR and that if the information is disclosed to the extent that the EMA wants, the confidence that pharmaceutical undertakings' have in the MA procedure will be harmed.[140]

The court investigates the pleas. Initially, the structure and implied methodology of art. 4(2) is examined: The article states that a request for access to documents shall be denied if disclosure would undermine a commercial interest, unless there is an overriding public interest in disclosure. Thus, the court finds that the EMA only is under an obligation to

[137] Case T-718/15, PTC v EMA, para 90.
[138] Ibid, para 89.
[139] Ibid, para 94.
[140] Ibid, para 104 and 110.

conduct a balancing test when it is found that a commercial interest is at risk of being undermined. However, neither the EMA nor the court found that such a risk was prevalent for the report in its entirety. This does not imply that a balancing test is not to be conducted for contested individual data within the report where such a risk is deemed to exist.[141] Thereby, all pleas of PTC were rejected.

4.2 Pari Pharma-case

In July 2012, Pari Pharma GmbH submitted an MA application for its medicinal product, Vantobra. Due to the fact that Vantobra was designated for the same therapeutic indication as an already authorized orphan medicinal product, the TOBI Podhaler, it was crucial for the application that the EMA would consider Vantobra to be similar, yet clinically superior. In order to prove that, the relevant data was submitted and assessed by the Committee for Medicinal Products for Human Use (CHMP), which recommended that Vantobra should be granted derogation from the market exclusivity that TOBI Podhaler enjoyed. The MA was subsequently granted by the EMA.[142]

In 2015, the owner of TOBI Podhaler, Novartis Europharm Ltd, requested access to the CHMP assessment report on the similarity of Vantobra to TOBI Podhaler as well as the assessment report on Vantobra's clinical superiority. Before disclosing any information, the EMA asked the owner of the reports to propose redactions. Pari Pharma objected to having the CHMP reports disclosed, but the EMA found, after an individual and specific examination of the suggested redactions, that there was no legal reason for denying the requestor access.[143] The request was thus granted. Pari Pharma contested the decision to disclose the CHMP reports, which was subsequently brought to the General Court for adjudication.[144]

In support of its claim, Pair Pharma relies on four pleas: Firstly, that disclosure cannot be justified considering that a general presumption of confidentiality applies to CHMP reports. Secondly, that the EMA policies lacks support in primary and secondary law; and finally, that the EMA failed to redact several individual pieces of the CHMP reports which are confidential therefore should not be disclosed in accordance with art. 4(2).[145]

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[141] Case T-718/15, PTC v EMA, para 108-109 and 111-112.
[142] Case T-235/15, Pari Pharma v EMA, para 1-9.
[143] Ibid, para 24-25.
[144] Ibid, para 1-9.
[145] Ibid, para 33.

4.2.1 General Presumption of Confidentiality

Pari Pharma argues that the reports as a unit – containing proprietary raw data, publicly-accessible clinical data, and analysis of that compilation by third parties – presents an integrated line of arguments, which forms an inseparable whole with economic value. Furthermore, Pari Pharma argues that the CHMP reports are covered by a general presumption of confidentiality.[146]

The General Court begins by clarifying that art. 2 of Regulation No 1049/2001 establishes the general principle that the widest access possible is to be given to all documents held by the EMA,[147] unless an exception in art. 4 applies.[148] Considering that it is an exception, it must be interpreted and applied strictly.[149] It falls within the discretion of EU agencies and institutions to establish general presumptions of confidentiality for documents of the same nature. Case law presents several criteria for when general presumptions are accepted by the court. These are identical to the ones identified in the PTC-case (see chapter 4.1.1).[150]

Considering that this case concerns an orphan medicinal product, it is concluded by the court that the specific regulations for those (in particular Regulation Nos 141/2000 and 726/2004) do not in any way limit the access to specific files. This in contrast to case law where general presumptions have been established due to the explicit limitation of access to "parties concerned" or "complainants." The General Court also concludes that the documents do not relate to an ongoing judicial or administrative procedure, i.e. the MA application has already been approved for Vantobra.[151] Therefore, no general presumption was established.

4.2.2 Entirely Confidential

The applicant argues that the CHMP reports reveals their know-how, strategy for obtaining MAs, and other trade secrets protected by the TRIPS Agreement. Furthermore, the undertaking argues that the reports must be treated as one inseparable unit; that claim is based on the previous Pari Pharma case, on interim measures, in which the General Court stated that

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[146] Case T-235/15, Pari Pharma v EMA, para 36.
[147] Statement derived from Case C-365/12 P, Commission v EnBW, EU:C:2014:112, para 85.
[148] Case T-235/15, Pari Pharma v EMA, para 38-39.
[149] Ibid, para 68.
[150] Ibid, para 42-47.
[151] Ibid, para 50-52.

it could treat the documents as an inseparable whole with economic value if they were to reveal an "inventive strategy, which bequeaths added value to science."[152]

The General Court states that to have access refused the applicant must show how disclosure could "specifically and actually" undermine the interest protected by an exception in art. 4. Business strategies, commercial relations, and information revealing the undertaking's expertise are pointed out as particularly worthy of protection against disclosure.[153]

In this case, the court notes that the CHMP reports, which always concerns a hybrid medicinal product,[154] are bound to contain extensive amounts of already published data relating to the reference medicinal product (TOBI Podhaler). To prove that such a compilation is confidential, the burden lies on the applicant to show that it provides added value to science – e.g. "new scientific conclusions or considerations relating to an inventive strategy" – which grants Pari Pharma a commercial advantage over its competitors. The General Court concludes that Pari Pharma fails to show that. On the contrary, the data provided in response to its dialogue with the CHMP, extensively stem from sources that are well known within the pharmaceutical industry. Information that derives from publicly-accessible sources and Pari Pharma's own market surveys can furthermore easily be distinguished. In addition, IT tools significantly facilitates the compilation of the data, which also supports the conclusion that there is little risk that Pari Pharma's commercial interests will be undermined.[155]

Finally, the General Court rejects the argument that information concerning hybrid medicinal products, which lacks data and market exclusivity, should enjoy additional protection from disclosure. The General Court regards the issue of data and market exclusivity to be separate from the issue of public access and adds that art. 16 of Regulation No 1049/2001 implies that copyright rules, limiting the requestor's right to exploit or reproduce, still applies.[156]

4.2.3 Proper Balancing Test

Pari Pharma argues that disclosure of CHMP reports lacks public interest. Rather, the EPAR

[152] Case T-235/15 R, Pari Pharma v EMA, para 63 and 56.
[153] Ibid, para 69-72.
[154] See chapter 1.6.
[155] Case T-235/15, Pari Pharma v EMA, para 75-84.
[156] Ibid, para 88-89.

is the result of proper balancing between public and private interests in disclosure and confidentiality and contains all information necessary to make publicly accessible. [157]

The General Court implies that Pari Pharma has misunderstood the implied methodology of the exception for CCI. Public interests only become relevant when the disclosure of a document held by a public institution risks undermining the commercial interest of the undertaking concerned. Considering that such a risk did not exist for the majority of the CHMP reports, such an assessment was never necessary.[158]

Moreover, the EPAR is merely intended to be "practical for professionals and understandable for the general public." It is the "minimum information," which the EMA is required to proactively publish.[159] The intention of the legislators was never to rule out access to other documents.[160]

4.3 Intervet-case

In November 2012, Intervet International BV (Intervet) applied for MA for a veterinary medicinal product, Bravecto. The application was accepted in February 2014. A year later, the EMA informed Intervet that a third party had requested access to five toxicology test reports in the MA application dossier. Considering that the EMA would grant access to three of those reports (collectively addressed as "the batch 1 study reports"), it asked Intervet and the sponsor of the reports at issue (MSD GmbH) to propose redactions. The undertakings obliged to the extent that they proposed redactions, though they claimed that a general presumption of confidentiality applied to the documents. After declaring that no general presumption applies to the report, the EMA rejected a majority of the proposed redactions – except for information referencing future development plans as well as details on concentration range of the active substance and on the internal reference standard used for the analytical tests. The EMA decision was contested which subsequently lead up to the adjudication of the General Court presented in this chapter.[161]

The applicants (Intervet and MSD) relies on five pleas: i) a general presumption of confidentiality protects the batch 1 study reports from disclosure, ii) the reports constitute

[157] Case T-235/15, Pari Pharma v EMA, para 91.
[158] Ibid, para 93.
[159] Ibid, para 98.
[160] Ibid, para 99.
[161] Case T-729/15, Intervet & MSD v EMA, para 1-10.

CCI, iii) the reports are protected by art. 4(3) of Regulation No 1049/2001 (about undermining the EMA's decision-making process), iv) no balancing test was carried out to account for all relevant interests, and v) no proper balancing has been carried out in respect of competing interests.[162] The third plea lacks relevance for this thesis and will therefore not be assessed.

4.3.1 General Presumption

The applicants initially plea that the batch 1 study reports are protected by a general presumption of confidentiality. In support of the claim, it is argued that a specific disclosure regime exists for documents submitted as a part of the regulatory approval process, making it essential that the documents are protected under art. 4(2) of Reguation No 1049/2001; any other interpretation would allegedly be inconsistent with the TRIPS Agreement and the *effet utile* of Regulation No 726/2004. Furthermore, the reports at issue ought to enjoy greater protection against disclosure considering that they originate from the applicants themselves. Finally, the applicants question the overall legality of the EMA's decision to abolish the general presumption for reports of this nature.[163]

The General Court clarifies that documents held by EU institutions and agencies are to be made publicly accessible unless an exception in art. 4 of Regulation No 1049/2001 applies. To facilitate the work of public agencies, general presumptions may be established for documents that are likely to be subjected to the same rulings.[164] The four conditions mentioned are identical to the ones referenced in the previous two cases (see 4.1.1 and 4.1.2) and will thus not be repeated.[165]

Documents concerned in this case were submitted as a part of an MA application. That process ended in 2014, when the MA was granted for Bravecto. Thus, the reports do not relate to an "ongoing judicial or administrative proceeding," which means that a general presumption cannot be granted on the grounds that secrecy is necessary for a public procedure to operate properly.[166] In that regard, it is emphasized by the General Court that a relation to future proceedings permeates the EMA's redaction process, i.e. redacted from the batch 1 study reports is data which "do not relate to the already authorized indication, (…) reveal

[162] Case T-729/15, Intervet & MSD v EMA, para 17.
[163] Ibid, para 18.
[164] Ibid, para 21-23.
[165] Ibid, para 24-31.
[166] Ibid, para 31-32 and 45.

details that are specific to the ongoing application or future development plans and which do not appear in in a publicly-accessible document."[167]

Furthermore, there are no indications that the legislators intended to establish a specific disclosure regime for the documents submitted as part of the MA application process. On the contrary, the General Court states that Regulation No 726/2004 references the general rules on public accessibility in Regulation No 1049/2001. Rules obligating the EMA to draw up and publish documents such as the EPAR merely constitute the minimum requirements.[168] The fact that the documents are produced by the applicants themselves is irrelevant for the question of whether they are confidential.[169]

Moreover, the relationship between the reports at issue and the TRIPS Agreement is assessed. It is initially established that all parts of the WTO Agreement form an integral part of EU law and that legal interpretations shall, "as far as possible," be consistent with it.[170] Nevertheless, the agreements must not be given "absolute precedence." The idea that the reports in their entirety should be presumed to be confidential is thereby rejected; such an interpretation would neglect the balance intended by the legislator and *de facto* "challenges the legality of the disclosure mechanism."[171] IP-related issues are further discussed in the sense that data exclusivity in Directive 2001/82 grant certain protection for veterinary medicinal products, that art. 16 of Regulation No 1049/2001 means that normal rules of IPRs still apply to the disclosed documents, and that the EMA's proactive conditions on use of disclosed documents does not mean that it accepts responsibility for misuse of those documents.[172]

In conclusion, the plea claiming that a general presumption on confidentiality exists for the batch 1 study reports is rejected.

4.3.2 Entirely confidential

The second plea made by the applicants is that the batch 1 study reports are to be considered CCI in accordance with art. 4(2) of Regulation No 1049/2001 and therefore protected in their entirety. In support of their claim, the applicants argue that the reports contain information of

[167] Case T-729/15, Intervet & MSD v EMA, para 46.
[168] Ibid, para 33-38.
[169] Ibid, para 43.
[170] Ibid, para 47-48.
[171] Ibid, para 49-50.
[172] Ibid, para 51-55.

a commercially confidential nature, e.g. regulatory know-how, clinical assessment abilities and an innovative strategy on running safety studies and compiling information (both secret and from the public domain). The mentioned compilation now constitutes one "inseparable whole with economic value" and the inventive strategy used to compile it provides competitors with a blueprint on how to obtain MAs with the same active substance. Data exclusivity is deemed, by the applicants, to grant insufficient protection against unfair competition.[173]

The General Court finds that general principles relevant for this case are found in art. 15(3) TFEU read in conjunction with recital 4 and art. 1 of Regulation No 1049/2001, which establishes the right of European citizens to public access that is "as wide as possible."[174] The areas listed in art. 4 of Regulation No 1049/2001 are exceptions and must be subjugated to a strict interpretation, i.e. for the exceptions to apply, it is insufficient for the documents to merely "fall within an activity or an interest mentioned in art. 4."[175] This disclosure regime applies to MA application dossiers (art. 73 of Regulation No 726/2004). In addition, the General Court refers to the guidance provided in EMA 2010 policy documents which defines CCI as information which "is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner."[176]

Safety studies, such as the ones conducted to produce the batch 1 study reports, will almost by necessity be conducted to meet the regulatory requirements for MA applications for veterinary medicinal products. To provide guidance and transparency, the EMA has created and published guidelines in collaboration with Japan and the U.S., which now constitutes the global standard for clinical studies. The studies at issue were conducted in accordance with those guidelines.[177] In addition, the General Court does not find any non-redacted information that would reveal the applicants' overall strategy and development program.[178]

The General Court also analyzes the claim that the reports should be treated as an "inseparable whole with economic value."[179] Considering that parts of the reports are already

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[173] Case T-729/15, Intervet & MSD v EMA, para 59.
[174] Case T-729/15, Intervet & MSD v EMA, para 60; also see Case C514/11 P and C-605/11 P, LPN and Finland v Commission, para 40.
[175] Case T-729/15, Intervet & MSD v EMA, para 61-68.
[176] Ibid, para 65-67.
[177] Ibid, para 72-74.
[178] Ibid, para 75.
[179] Case T-729/15, Intervet & MSD v EMA, para 81; Case T-189/14 R, Deza v ECHA.

publicly accessible (for instance through the EPAR) it is up to the applicants to show that compilation of published and non-published data is a "commercially sensitive item (…) whose disclosure would undermine their commercial interests." However, the applicants are not regarded to have adequately shown the risk to their know-how and commercial secrets.[180]

Furthermore, the claim that the reports provide competitors with a blueprint (or "roadmap") is rejected, due to their "vague and unsubstantiated" nature. The burden of proof is therefore put on the applicants, who fails to contest the EMA claim that the reports, after the redactions, contain any information on the "composition or manufacturing of Bravecto."[181] Moreover, the General Court notes that any future MA applications by competitors will have to abide to existing rules on data exclusivity, who therefore must conduct clinical studies of their own. Furthermore, it is not proven that the redactions made are insufficient to prevent such attempts.[182] It is later on in the case stated by the court that there is no apparent risk, if the reports are disclosed, that undertakings will start to submit the minimum information possible in MA applications in a way that would undermine the process.[183] Thus, it is not self-evident that access to the reports at issue would allow competitors to faster obtain MAs of their own.[184]

In this regard, the possibility of competitors using the reports to access markets in third countries that allow such exploitative use is assessed: The General Court considers the claims to be "vague and imprecise" and does not find that the documents, subsequent to redactions (in particular of concentration range of the active substance and internal reference standards used for analytical tests), would facilitate for competitors to obtain MAs in third countries. No "specific arguments" are presented to show that the risk is real. The General Court concludes with the remark that denying requests to all reports of this nature to avoid third countries granting access to the products concerned would deprive the public of its lawfully granted right to access to documents about authorized medicinal products.[185]

4.3.3 Proper Balancing Test

The applicants claim that an overriding public interest in Regulation No 1049/2001, when

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[180] Case T-729/15, Intervet & MSD v EMA, para 81.
[181] Ibid, para 79-80.
[182] Ibid, para 86.
[183] Ibid, para 112-115.
[184] Ibid, para 84 and 88.
[185] Ibid, para 87.

read in conjunction with the TRIPS Agreement, can only exists when it is necessary to protect the public. Intervet and its sponsor claim that the interest in public health used by the EMA falls short on the grounds that the claim is general and unsubstantiated. In addition, the EMA allegedly failed to evaluate whether the interest in transparency was proportional to the harm inflicted upon the applicants' privacy and what alternatives existed to disclosure.[186]

Art. 4(2) of Regulation No 1049/2001 states that even in cases where disclosure could undermine commercial interests, the documents may be disclosed provided that an overriding public interest exist. In executing the last sentence of art. 4(2), all interests in favor and against disclosure must be taken into account.[187] However, in the present case the General Court found no applicable risk in art. 4(2) and therefore the EMA rightfully neglected to conduct a balancing exercise.[188] It is furthermore not required in Regulation No 1049/2001 to apply a proportionality test every time a document is requested by a third party, but merely when deciding to only grant partial access instead of disclosing a redacted document, which is not the case here.[189]

In conclusion, the General Court did not find that the EMA had failed to conduct a proper balancing exercise or that the European methodology was inconsistent with the TRIPS Agreement.

[186] Case T-729/15, Intervet & MSD v EMA, para 116.
[187] Case T-729/15, Intervet & MSD v EMA, para 119-120; also see Case T-439/08, Agapiou Joséphidés v Commission and EACEA, EU:T:2010:442, para 136.
[188] Case T-729/15, Intervet & MSD v EMA, para 122, 124-125, and 130.
[189] Ibid, para 131-132.

5. Discussion

This discussion argues that the EMA's interpretation of the European disclosure legislation, applied to documents submitted as part of the process for regulatory approval of medicinal products, is supported by hierarchically higher sources of law. The General Court has not in any way stated that the EMA policies lack legality. The EMA's interpretation is yet to be proven wrong in the European courts, i.e. it has so far adequately redacted the necessary amount of information from MA application dossiers e.g. detailed information regarding composition or manufacturing of the medicinal product or information revealing the undertakings' future development plans.

To support the thesis statement above, this chapter will be structured in the following way: The first subchapter analyzes the recent changes implemented by the EMA; subsequent chapters go through the arguments brought up in the General Court in the same order that the court assessed them. Finally, the practical implications for future requests will be analyzed.

5.1 The New Disclosure Regime

Following the harsh criticism of the lacking right to access public documents of EU institutions, the 21st century has brought with it radical changes increasing transparency for almost all of the Union's areas of activity. This thesis focuses on the impact this transitional phase has had for documents concerning medicinal products for human and veterinary use.

General rules on disclosure, found in Regulation No 1049/2001, were the first to be enacted. Subsequent medicinal regulations, though affecting and specifying more documents that must be submitted or disclosed, still refers to the general rules on disclosure. Regulation 726/2004 required the EMA to draw up and publish documents such as the EPAR; the more recent Clinical Trials Regulation (CTR) requires pharmaceutical undertakings to have all clinical trials registered before conducting them and to submit all clinical trials data (CTD) to the EMA. Both of these refers, explicitly or implicitly, to the general rules of disclosure (art. 73 and 81(4)) and have contributed with more requirements of transparency. Even though the EMA is yet to solve all issues surrounding the proactive publishing of CTD in the online portal (in particular anonymization of patient-level data), the agency has clearly already taken steps in preparing for the full applicability of CTR through e.g. the 2015 policy document.

The insistent referencing to the rules in of Regulation No 1049/2001 does not in itself provide clear answers, considering that the implied methodology of that regulation is inherently ambiguous. It is evident that the EMA has confidently approached this vagueness and allowed itself the liberty of establishing more legal certainty. The various policies enacted since 2006 has been consistent with the legislator's intention to allow transparency to weigh heavier on the balancing between public and private interests. In accordance with that conclusion, the most significant changes were implemented through the 2015 policy and the 2016 external guidance document, i.e. following the CTR's entry into force. The contradictory effects these documents (and the 2010 policy) have had are that they attempt to establish long-term legal certainty, but when the EMA started to disclose new parts of MA applications such as CSRs, sponsored safety studies and CHMP reports for hybrid medicinal products, the industry was uncertain about the extent to which these documents were to be disclosed. This sudden and immediate uncertainty has surfaced in the shape of undertakings proposing extensive redactions of requested documents, which the EMA has refused. Those contested decisions have subsequently been taken to the General Court of the European Union. This marks the milestone where the EMA policies are put to the test: Has the EMA gone too far in its attempt to increase transparency?

5.2 Case Law: General Presumptions

In all three cases observed in chapter 4, it is consistently argued by the applicants that the documents concerned – CSR for an orphan medicinal product, CHMP reports, and safety studies – are protected by a general presumption of confidentiality: To rephrase, all undertakings' plea that the EMA is at fault for no longer assuming that third party requests to these documents are to be denied but rather analyzes the documents in their entirety in accordance with the standard presumption of public accessibility in art. 2 of Regulation No 1049/2001. This application is a direct consequence of the EMA's recently implemented policies. Thus, the claim that a general presumption of confidentiality exists *de facto* challenges the legality of the EMA's recent policies to the extent that they require the documents at issue to be analyzed on a case-by-case basis. A general presumption of confidentiality, were it to exist, would instantly change how the disclosure legislation is to be applied and is therefore always analyzed first by the General Court.

5.2.1 Specific Disclosure Regime

Various arguments were laid out in favor of a general presumption. The most similar line of argument can be found in the PTC-case and the Intervet-case. In both it was argued that a specific disclosure regime existed for the relevant documents, which meant that those documents were to enjoy the protection of a general presumption. Though while PTC in essence argued that the regulations on orphan medicinal product implied that a more extensive protection against any form of competition was necessary, Intervet argued in the first place that all documents submitted as part of the regulatory approval process required protection against disclosure or at least documents produced by the applicant itself.

It was found in all cases that documents held by the EMA should generally be accessible in accordance with art. 2(3) of Regulation No 1049/2001, unless an exception in art. 4 applies. Those exceptions, such as the one protecting commercial interests, are to be interpreted strictly. The General Court, having studied patterns in case law, subsequently recalled four criteria for the establishment of a general presumption against public access. It was never a question in any of the cases that considerations of a "generally similar kind" were likely to apply or that a general presumption may help in ensuring that procedures operate correctly (two of the criteria). Rather, the General Court swiftly established that none of the documents at issue related to an ongoing judicial or administrative procedure, i.e. all documents were submitted as part of the undertakings' MA application processes which, by the time of the third-party requests, were completed.

Equally important in all cases was the court's findings about the criterion concerning specific legal provisions for the relevant documents: These findings were the court's answer to the argument that specific disclosure regimes should apply to documents relating to orphan medicinal products or safety studies. In the Intervet-case it was concluded that the legislator had no intention of limiting the access to toxicology studies no matter who produced the document or what medicinal product it concerned. On the contrary, the legislators had the intention to increase transparency with those regulations by declaring the minimum amount of information that must be published, e.g. the EPAR. In the PTC-case the General Court found that the specific regulations on orphan medicinal products never prescribe any restrictions on access, but rather refers to the general rules on disclosure in Regulation No 1049/2001. In both cases, the court emphasizes the fact that no specific regulations concerning CTD has phrases limiting access, *inter alia* to "parties concerned" or "complainants." Thus, the court

rejects any argument that general presumptions of confidentiality can implicitly exist: For instance, the more extensive protection of data and market exclusivity in the regulation for orphan medicinal does not have any inherent implications on disclosure rules. An identical line of reasoning was presented in the Pari Pharma-case.

In support of a specific disclosure regime, both PTC and Intervet argued that the European disclosure legislation must be understood in conjunction with the TRIPS Agreement. It was never disputed that the agreement constitutes an integral part of the EU legal order or that EU law must "as far as possible" be consistent with it. However, the General Court had a more restrictive understanding of the Agreement's impact. In both cases it was found that the agreement cannot be given absolute precedence or challenge the legality of EU law. A general presumption was found to distort the disclosure mechanism in contrast with the legislative intent, thus effectively challenging the legality in a way that WTO Law is unable to. The General Court furthermore recalled the fact that data exclusivity provides some protection and that normal rules on copyright still applies in accordance with art. 16 of Regulation No 1049/2001. Therefore, the court rejected the argument that the TRIPS agreement can be applied to establish a general presumption. In this way, the General Court has clarified the relationship that the MA application process has with IP, including copyrights, patents, and, most importantly, trade secrets. So far, the protection of trade secrets has had no impact on EU disclosure laws at all. Considering that the TSD became applicable after the requests, it is no surprise that the directive was not further discussed. However, since the definition in the TSD and TRIPS are identical, the court using those definitions interchangeably is an acknowledgement that the EU's definition is as wide as the one in WTO law. It is still unclear what the exact impact the TSD will have on the EMA's application, but after having analyzed the limitations of the directive's scope, it seems unlikely that it will be significant.

5.2.2 Third Countries

On a similar note, the critique brought up in the academic discourse about *ipso facto* access and use, was assessed in the cases. In the PTC-case as well as the Intervet-case it was argued that the lack of a general presumption will allow for competitors to obtain market authorization for identical or similar products in third countries where the origin of CTD is irrelevant or there is no requirement of regulatory approval for medicinal products. Such an effect would provide competitors with a commercial advantage and undermine the owners' legitimate economic interests. The answers provided by the General Court in the two cases are

similar: The court considers the claims to be “vague and imprecise” in the sense that there is little evidence to support that the risk is more than hypothetical. Moreover, the Court considers the information disclosed, after redactions, to insufficiently facilitate for the obtainment of MAs in non-EU states. Finally, in both cases it is found that refusing requests to access in order to avoid exploitative use would deny persons their lawful right to access. To this extent, the findings are identical in the cases.

However, there is a significant difference between the two cases in one important area: In the PTC-case’s discussion about the documents being entirely confidential, it is acknowledged by the court that competitors may handle the disclosed data in breach of protection of data exclusivity laws. But the court goes on to say that the potential misuse does not necessarily require that documents in their entirety should be confidential. If the risk would be given too much influence, “almost full paralysis” would ensue for the EMA’s transparency related activities. This can only be interpreted to mean that even if the information is used in an unlawful manner to obtain MAs in third countries – which the EMA believes that it will not be – that trend will not make the EMA refuse access to entire documents. The court has therefore updated its understanding on the balancing of the various interests involved: the public interest in disclosing CSRs weighs heavier than the private interest in protecting the data from being used by competitors to obtain MAs in third countries. An important clarification in this regard is that the court has only ruled out the existence of a general presumption and having the documents concerned be treated as entirely confidential, i.e. if specific information is misused in third countries on a frequent basis, it is not unthinkable that such specific information can be redacted in the future.

On that note, the EMA policies in chapter 3.1 could be recalled, in which it is discussed how the EMA has prescribed in its 2015 policy that disclosed documents may not be used to support applications for regulatory approval in third countries. The remedy for failure to follow that condition is the revocation of the right to access and use the CSR in question, which has been criticized in the academic discourse for insufficiently disincentivizing exploitative use.

5.2.3 Administratively Burdensome

Finally, the court in the PTC-case analyzed the argument that the lack of a general presumption would by necessity put a heavy administrative burden on the EMA.

Undoubtedly, the task of going through every requested document on a case-by-case basis will entail a significantly increased workload for the EMA. However, the court states that PTC's interpretation is contrary to the *effet utile* of Regulation No 1049/2001. Thus, the court indicates that the EMA is correctly applying the regulation now that it analyzes the entirety of requested documents and only redacts specific information protected by the exceptions in art. 4. General presumptions are merely a tool to improve efficiency by being less thorough.

5.3 Case Law: Entirely Confidential

The relationship between a general presumption and considering the documents at issue to be entirely confidential is important. If the court were to be generous in declaring documents to be entirely confidential, it is a potential risk that such an application would develop into a *de facto* presumption of confidentiality. This issue is briefly addressed in the PTC-case. The distinction between the two notions is explained in the following way: A general presumption of confidentiality entails that the documents concerned would not be handled on a case-by-case basis by the EMA. Instead, third-party requests would be refused unless the requestor shows why the document in question does not enjoy the protection by being commercially sensitive. On the contrary, the question of whether the documents are entirely confidential concerns if the particular documents assessed should be treated as one economic unit and whether that unit enjoys protection under art. 4 of Regulation No 1049/2001.

In all three cases, the information in the reports are not entirely secret at the time of the requests. For instance, the EPARs have disclosed partial information and, in the case of the CHMP reports (Pari Pharma-case), extensive amounts of data originate from the reference medicinal product. Therefore, the only way to regard all information in the reports as confidential is by treating them as one economic entity. To do so, the applicants in all cases refer to the PTC-case on interim measures, in which the General Court stated that the report in the case could be treated as such if it were to reveal an inventive strategy which bequeaths added value to science. It is evident that all applicants have noticed the door that the General Court thereby opened, as they all argue that their compilations of information reveal innovative strategies. On a similar note, the General Court in the Intervet-case went on to further clarify this precedent, stating that it is up to the applicant to show that a compilation of publicly available and non-publicly available information constitutes a "commercially sensitive item whose disclosure would undermine its commercial interests."

It is unclear from the decisions what methodology the General Court considers to be an innovative strategy, which is an idea that is most likely derived from the EMA application documents' emphasis on the importance of innovative features. The conclusions that can be drawn from the three cases mostly concerns what is not considered as an innovative strategy. A significant common denominator is the origin of the methodology used to compile the information: In the PTC-case and the Pari Pharma-case it was pointed out that the strategy used to compile information followed the recommended guidelines, which are widely known in the scientific community. Furthermore, it was pointed out by the court that IT tools, such as search engines, facilitates the gathering process substantially. In the Intervet-case the court also emphasized that the guidelines for toxicology studies, drafted through international agreements, will generally follow a similar process to meet the safety requirements. In summation, the court stresses the inventiveness of the compilation process itself. If it is simply the standard process used for reports of the same nature, it will not be considered to represent an innovative strategy requiring to be treated as one economic unit. This precedent was also rephrased in the Pari Pharma-case in the following way: For a process to represent an innovative strategy, a determining factor is the amount of effort competitors would have to put in to gather the information by themselves: If the information is easily gathered, it cannot be argued that a commercial interest is being undermined if the report is not treated as one entity.

In addition, Intervet and PTC argued that the requested documents, if disclosed, would provide competitors with a roadmap to obtaining MAs for similar products. It is unclear as to where the applicants found support for the claim, but it is evident that the court considered them to be valid enough to be analyzed. For the toxicology studies, the court dismissed the claim as "vague and unsubstantiated." Emphasizes was mostly put on the fact that data exclusivity still applies and that redactions have excluded any information about the product's composition or manufacturing from disclosure. Similar to the court's reasoning on the risk of competitors filing applications in foreign jurisdictions, the court thus puts the heavy burden on the applicants to show that alleged risks of disclosure are more than just hypothetical. In contrast to the Intervet-case, for the CSRs in the PTC-case the court never labels the claims as "vague and unsubstantiated." However, the reasoning for its rejection of the claim is somewhat similar: the court concludes that no "valuable insight on clinical development or study design" is disclosed after the redactions made by the EMA. In conclusion, the court finds that there is no reason to treat neither safety studies nor CSRs for orphan medicinal

products in their entirety. The cases rather suggest that emphasis should be put on how much information is necessary to redact to prevent competitors from gaining insight to clinical development.

Similarly, Pari Pharma argued that disclosure of CHMP reports would allow competitors to produce products for the same therapeutic indication. Though Pari Pharma's argument was built around the notion that the reports were trade secrets protected by the TRIPS Agreement. Therefore, the General Court rather discussed if the information and sources used were "generally known" among people who normally deal with that kind of information (TRIPS art. 39(2) and TSD art. 2), which it was in this case. However, it is important to notice the court's reasoning following that conclusion, whereby it is stated that even if that information was not generally known, the compilation does not provide added value or reveal its "commercial strategy, know-how or expertise." The last sentence seems to suggest that the EMA's interpretation in this particular case was not inconsistent with the TRIPS Agreement, but even if it that was the case, the EMA still should not treat the CHMP reports as one economic unit. Rather, if some information in the reports are trade secrets, as defined in TRIPS and TSD, merely that particular part of the report should be redacted.

The role IPRs have for the disclosure regime was also discussed. The fact that data exclusivity exists and that orphan medicinal products are protected by 10 years of market exclusivity was used to support the case that the documents can be disclosed, i.e. certain information is already protected against unfair use. Therefore, it is redundant to provide additional protection against disclosure. In addition, the General Court helped in clarifying art. 16 of Regulation No 1049/2001, which states that the regulation is without prejudice to copyright law. The court understood the article to mean that despite the reports becoming publicly accessible, the creator still enjoys exclusive rights over its use and distribution.

5.4 Case Law: Balancing of Public and Private Interests

It was argued by Intervet and PTC that a reading of art. 4(2) of Regulation No 1049/2001 in conjunction with the TRIPS Agreement means that the EMA application lacks balancing of public and private interest and that the institution is at fault for not conducting a proportionality test. Pari Pharma, though not mentioning TRIPS, argues that disclosure lacks public interest. These arguments all defy the structure of art. 4(2) in which an overriding public interest only can be used to justify the disclosure of information if such an action

would undermine a commercial interest. The legal support for the applicants' claims can be found in art. 39(3) of TRIPS. That article states that information submitted for regulatory approval of medicinal products can only be justified by being "necessary to protect the public," or when steps are taken to ensure that "the data are protected against unfair commercial use." It would thus be necessary for a public interest to exist in order to release any documents submitted through the MA application process, unless required steps are taken to protect the information.

The court did not make any effort reasoning about which methodology should be used, but it can be assumed that the General Court, in accordance with its previous line of reasoning, did not entertain the idea that WTO law can challenge the legality of EU law. Therefore, when a conflict arises between the TRIPS Agreement and European secondary law, as is the case here, European law will prevail. The outcome in these cases was that the implied methodology of Regulation No 1049/2001 was applied, and the court never discussed whether a public interest existed in disclosure. Another thinkable justification of the General Court's application is that it already finds that necessary "steps are taken" to protect the disclosed information. The difference between the two understandings of the precedent set in these three cases is that the court either believes that EU law already is consistent with the TRIPS Agreement or simply decides to give the agreement a negligible impact.

Because the General Court chose to apply the methodology found in Regulation No 1049/2001, it was never forced to further clarify the implications of the exception for "overriding public interests." However, it was commented on in the final part of the Pari Pharma-case, where it was argued that specific pieces of the CHMP reports were confidential. The General Court pointed out that an overriding interest exists in the publication of CHMP-reports. Most likely, CHMP reports have a special standing in this regard considering that the product they concern will derogate from already authorized medicinal products. Thus, it is important for third parties to access the reason as to why the products concerned are deemed to be similar yet clinically superior. Other than this conclusion, little information is provided on the application of the exception for overriding public interests.

It was furthermore argued by PTC that the amount of information already being published is sufficient. This ought to be viewed as a supplementing argument to Pari Pharma's claim that the EPAR contains all information necessary to make public and is the result of the legislator's balancing between public and private interests. This argument was rejected by the

General Court, which clarified that the EPAR is merely intended to be "practical for professionals and understandable for the general public." It was never intended to constitute the maximum amount of information that the EMA could publish.

5.5 Practical Implications for Future Requests

Through these three cases, the court has for the first time ruled on the legality, and thus greenlighted, the EMA's 2010 policy. Undoubtedly, it is a red line throughout the three rulings that the EMA has been correct in its application of the exception for CCI. The General Court did not once protect any additional information outside of the parts that were already redacted by the EMA. These cases provide significant assistance for when the EU portal is completed and the CTR thus becomes fully applicable, considering that the 2015 implementation policy derives a substantial part of its principles from the now approved 2010 policy.

For future concerns, it is confirmed that the EMA has acted within its rights when abolishing the general presumption of confidentiality for CSRs, toxicology studies and CHMP reports on similarity and clinical superiority. Thus, those reports will continue to be analyzed on a case-by-case basis. Nevertheless, the court has kept the option to treat such reports as one entity. Even if that was not the case for the documents at issue, the General Court stated that documents may be treated in its entirety if they were to present an inventive strategy, providing added value to science. From a practical perspective, it is not yet clear what methodology would be regarded as such, but the court somewhat clarified in the Pari Pharma-case: The compilation of publicly available and non-publicly available information in the reports must provide "new scientific conclusions or considerations relating to an inventive strategy," which provides the undertaking with a commercial advantage over its competitors.

From the various rejected claims in the cases, it can be concluded that the General Court has placed a heavy burden on applicants to show how disclosure could "specifically and actually" risk undermining the applicant's commercial interests. It was thereby rejected that competitors may use the requested documents to file MA applications in foreign jurisdictions or as roadmap to produce competing products within the EU. On the contrary, the General Court considers data and marketing exclusivity rules to constitute sufficient protection against those risks. It was repeated throughout the cases that the claims were "vague and unsubstantiated" and that applicants were required to show how the risks were more than just

"purely hypothetical." Thus, a heavy burden has been put on applicants to provide evidence for the alleged risks to its commercial interests. This is consistent with the 2016 EMA guidance document.

The General Court did not go into exact details on what would constitute redactable information, and therefore it is possible that the most comprehensive and accurate legal source for future redaction processes is the EMA's policies. Most of the conclusions that the General Court reaches, can be found in the 2016 EMA guidance document: It discusses the impact of innovative features and novelty in compilations, public accessibility of information, and the burden of applicants to show that the alleged risks exists. All of which were mentioned in an affirmative manner by the General Court. The General Court furthermore comments on the information redacted by the EMA, in a way that summarizes the type of data it has in mind for future redactions: the relationship that the redaction process have with future proceedings is important, i.e. information that is not already publicly accessible and which relate to future development plans or ongoing applications should usually be redacted.

It could be noticed that the General Court on a consistent basis discussed whether "commercial interests" are being undermined, i.e. in accordance with the terminology found in Regulation No 1049/2001. It seldom refers to the EMA policies, including the term "CCI." However, as it is clear that the General Court never rejects the outcome of the EMA application, it seems irrelevant whether the two have adopted an identical terminology. Furthermore, once CTR practically becomes the *lex specialis* rule for disclosure of data from clinical trials, the discrepancy will be effectively removed. For future concerns, it is more important that the arguments for proactively publishing of CTD were not rejected. Once all issues surrounding the EU portal (art. 81 of CTR) have been solved and the EMA will, in accordance with its 2015 policy, start to proactively publish extensive amounts of information, these cases provide a clear indication that the EMA will redact the adequate amount.

6. Concluding Remarks

6.1 The Findings of this Thesis

In its preparation for the new regulation on clinical trials, the EMA has implemented new policies which have increased transparency significantly. The three recent cases analyzed in this thesis represents the defining moment where the legality of the EMA's interpretation was put to the test and, as has been shown in the 5th chapter, it passed with flying colors.

The precedent of most significant importance is that toxicology reports, CSRs, and CHMP reports no longer enjoys the protection of a general presumption of confidentiality. While the General Court has left the door ajar for treating such reports as one entity – which is either fully confidential or disclosed – that option is still left unused. For future disclosure requests, the inventive strategy used to compile public and non-public information will be the determining factor for how the compilation is treated. It is likely that reports only will be treated as one entity in exceptional cases: The three cases affirm the EMA's conclusion that a heavy burden lies on the applicants to show that alleged risks to commercial interests exist.

The General Court discussed the possibility of treating the reports as confidential due to risks associated with disclosure. For instance, the risk of competitors using the reports as a roadmap to obtain MAs within or outside the EU was pointed out but dismissed as "vague and unsubstantiated." Furthermore, the TRIPS Agreement was given minimal impact on the legal methodology used by the Court. Therefore, no proportionality test or balancing between public and private interest will be conducted unless it follows from the structure of art. 4 of Regulation No 1049/2001.

All mentioned findings so far are without prejudice to the fact that individual pieces of information within the reports may be confidential. The General Court implied that information revealing anything related to future development plans or ongoing applications should not be disclosed. While that sentence may be of some guidance, the EMA policies probably provides the most detailed directions that the pharmaceutical industry currently has.

These conclusions represent a reviewed understanding of the term "CCI," which will become even more significant once the EU portal is ready and the EMA will proactively publish CTD in accordance with the new regulation on clinical trials.

6.2 Normative Considerations

Placing the findings of this thesis in a greater societal context, it is evident that the cases of February 2018 marks the greenlighting of significantly increased transparency. The current state of the law for disclosure of documents submitted as part of the MA application process brings heavier weight to the public interests involved than has ever been the case before. Surely, this will allow for duplicative research to be kept at a minimum and negative side effects to be found even more efficiently than under the previous disclosure regimes. Those consequences ought to be kept in mind at all times when assessing this issue: More documents can now be subjected to independent review and the legitimacy of EMA as a public institution is strengthened. When that is combined with the full entry into applicability of CTR, transparency will to some extent permeate practically the entire process of manufacturing a new medicinal product.

CTR is a regulation which cannot be ignored in this circumstance. The EMA has prepared itself for the radical changes that an online database in an easily searchable format entails. In the end, the cases analyzed in this thesis tackles a lot more than merely issues about general presumptions. The EMA has essentially been defining the MA application process without real contestation since the implementation of its 2010 policy. These cases prove that the agency is rightfully obligating all submitting undertakings to suggest redactions and subsequently analyzes those on a case-by-case basis; the EMA is also correct in its somewhat restrictive approach to limiting circumstances for disclosure. Once the EU portal is completed, not only will more information than ever before be disclosed, but it will also be more easily accessible. Redundant duplicative research should thus become an even smaller issue than it currently is, and the limited resources invested into R&D for medicinal products can be spent even more efficiently.

Furthermore, it is interesting to consider the potentially enabling implications that the CTR will have on the phenomenon of "collective inventions,"[190] i.e. the concept of generic competition is institutionalized within the pharmaceutical industry; generic competitors rely on producing generic medicinal products by using other undertakings' already authorized products as a reference. To that extent, the pharmaceutical industry already operates under the assumption that data and market exclusivity will expire and that patents may not cover all

[190] Meyer, P. B., 2003, p. 27-28.

indications. Thus, the full use of a pharmaceutical innovation may always become the result of contributions from various competing sources. This is made possible by the enabling institutional structure of European laws on transparency and limitations on data and marketing exclusivity. It could even be argued that the regulations encourage it. The EU portal, applied in accordance with the analyzed cases, will most likely facilitate that trend.

Notwithstanding the positive effects that increased transparency has, disclosing extensive amounts of material may have a severely negative impact on the pharmaceutical industry. It is for this reason that it is more protected against competition through special rules on patents for medicinal products and disclosure rules. Some risks have been pointed out in this thesis and dismissed by the court as "vague and unsubstantiated." The heavy burden that has been put on applicants to show that risks are more than purely hypothetical has been proven to be difficult at this early stage. The extensively varying levels of prior research necessary to have medicinal products authorized in non-EU jurisdictions may pose a threat to the European pharmaceutical industry's commercial interests. It has been concluded by the General Court that the reports are sufficiently redacted to prevent that from becoming a reality and even if they are not, the risk should not allow the entire disclosure mechanism to be distorted. However, if the risks turn out to be more than merely hypothetical and the magnitude is significant, the court may have to reconsider its stance. That does not entail that the reports must enjoy the protection of a general presumption or be treated in their entirety, but merely may be of consequence for individual pieces of information within the reports. A disclaiming note is warranted for this paragraph: It is far beyond my understanding to conclude what the non-redacted information can be used for; according to the General Court and the EMA there is no risk of the information undermining commercial interests – but clearly it is a contentious issue when considering the pleas and articles of the pharmaceutical industry and parts of the academic discourse (see 3.1.1). The reason so much effort has been put on this issue is that if the disclosed information allows competitors to obtain MAs in foreign jurisdictions, the magnitude of the threat to commercial interests is potentially unneglectable as it largely circumvents the data exclusivity regime, i.e. the most significant acknowledged IP protection that CTD enjoys subsequent to its disclosure.

Another controversy of more pressing concern is the appropriate impact that the TRIPS Agreement ought to have on EU secondary law. Precedent set through case law has determined that the TRIPS Agreement should not challenge the legality of EU legislation,

despite constituting an integral part of the EU legal order. The General Court concluded throughout the Intervet and PTC-cases that if the TRIPS Agreement were to create a disclosure regime, it would *de facto* challenge the legality of the European disclosure mechanism. It is justified to rephrase this conclusion as TRIPS being unable to declare reports of any kind as entirely confidential or establishing a general presumption. In addition, TRIPS cannot alter the methodology used by the court (from Regulation No 1049/2001), i.e. public interest is only discussed in the last stage and only to have information published despite being of a commercially sensitive nature. This conclusion ought to be considered somewhat controversial. WTO-law generally is a conundrum for any jurisdiction: The EU does not want to be at a disadvantage by giving international law a greater impact than other WTO members, yet the agreement at issue is part of EU law and it is an obligation for the Union to abide by it.

Following that sentiment, it could be discussed whether there is a middle ground between barely giving the TRIPS Agreement any impact whatsoever and establishing a modified disclosure regime where the EMA is no longer allowed to assess reports on a case-by-case basis. Though perhaps that middle ground is already reached: Through the data exclusivity regime's marketing exclusivity and non-reliance obligation, the EU has already taken steps in protecting the disclosed documents in accordance with art. 39.3 of TRIPS. Such an interpretation is also supported by the Doha Declaration and art. 8 of TRIPS, which constitutes the WTO's acknowledgement of the interest in public health.

On that note it should be reemphasized that the General Court is not the hierarchically highest institution within the EU legal order. The PTC-case and the Intervet-case have been appealed. Therefore, it is not entirely certain whether the General Court has applied the laws correctly and the answers provided in this thesis are not definitive. In a way, the General Court has chosen the path of least resistance by simply siding with the EMA, the only exception being the use of a terminology that is closer to secondary law than EMA policies (e.g. "CCI" was barely referred to). The EMA's policies are furthermore partly the result of criticism from the European Ombudsman. This makes the interpretation chosen by the General Court far from unsupported in the legal discourse or even particularly controversial. However, that does not entail that a degree of vigilance for the appearance of concrete evidence of commercial interests being undermined would be paranoid or that all interpretive legal questions have now been solved. For instance, some concerns raised in the academic discourse about issues such

as re-purposing of patents were never raised. In addition, the TSD had not entered into force at the time of the requests. It is not entirely impossible that it will shed new light on the relationship between trade secrets and the current disclosure regime.

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