PART I:
GENERAL RULES ON THE PATENTING PROCEDURE

Considering that this study mainly focuses on conducts taking place before the patent office, it is imperative in the first place to briefly explain how the procedure at the patent office looks like and, most importantly, analyse what kind of duties and responsibilities the established patent and procedural rules set upon the applicants. This analysis is of vital importance to identify not only what kind of specific abuses might actually come about at the patent office, but also the solutions offered by the patent system in the US and in Europe and the underlying policy considerations that drive said approaches. This should also pave the way for later understanding how competition law may arise as an alternative or additional remedy.

This part of the work, hence, is divided into two chapters. First, in Chapter II, it aims at providing a bird's eye view of the general structure and standard stages that characterise a typical procedure before a patent office. Next, in Chapter III, a detailed description of the duties and obligations of patent applicants is portrayed. In this regard, the legal frameworks of the United States and Europe are compared as representative samples of two diametrically different viewpoints from which the issue can be approached. Considering the particularities of the American approach, the chapter concludes by analysing whether it would be feasible and desirable for the European patent system to adjust the duties that are imposed upon patent applicants or for European courts to embrace an inequitable conduct defence or modify the way in which they should solve disputes involving patents that have been fraudulently obtained.

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Chapter II: The Procedure before the Patent Office

1. *General Framework*

At the outset, it is important to bear in mind that patent protection, in contrast to copyright or other intellectual property rights, is not granted automatically and an inventor must thus formulate a formal application before the patent office in order to obtain protection. In fact, as a general principle, a separate application must be filed before the patent office of every country in which protection is sought and each of those applications has to fulfil a number of formal and language requirements.[11] Furthermore, each of them is thoroughly studied by experts, within an examination process that ordinarily lasts several years, in order to test whether they meet all the substantive patentability requirements and whether their subject-matter is not excluded from patentability. The long and winding road that an inventor is expected to follow before the patent office in order to acquire a patent has become today a quite complex procedure. A quick glance at the Guidelines for Examination of the EPO[12] or at the Manual of Patent Examining Procedure of the USPTO[13] illustrates its complexity and the extent of burdens and details that a patent applicant—and the patent office itself—need to observe.

Much has actually changed since the times when the first patents were granted in Venice and in England, namely, at a time when these exclusive rights for inventions were issued as just one species—and a rather rare one—of the general genus of privileges, licenses and regulations.[14] In the first place, the requisites that an inventor must meet in order to obtain a patent have significantly matured since the early stages of the patent sys-

11 It should be borne in mind that more than 150 countries are currently members of the Patent Cooperation Treaty (PCT), which essentially allows inventors to file an international patent application and delay for up to thirty months the decision on whether to continue with the application and, if so, in which countries. See text at nn 146ff.

12 EPO, Guidelines for Examination in the European Patent Office (EPO November 2014) (EPO Guidelines).

13 USPTO, Manual of Patent Examining Procedure (9th edn, 2014) (US MPEP).

14 Neil Davenport, *The United Kingdom Patent System: A Brief History* (Mason 1979) 14.

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tem. From a time when patents were synonyms of discretionary concessions from the Crown, passing through a period of heightened controls prompted by the English Statute of Monopolies of 1624,[15] the system has slowly evolved from a discretionary prerogative of the sovereign to a bureaucratic procedure under the now universally recognised principle according to which only true inventors are entitled to get a patent.[16] Furthermore, as the system kept developing, complementary requirements arose. In the eighteenth century, for instance, the courts in England started requiring patentees to make sufficient descriptions of their inventions, which not only helped patent owners to prove infringement but also provided competitors with enough information to attack the validity of the patent.[17] As to the inventive step or non-obviousness requirement, US patent case law has recognised it since at least 1850,[18] although it was only statutorily codified many years later.[19] In any case, despite some minor exceptions,[20] the patentability requirements today are to a large extent harmonised in most parts of the world—particularly after the signing of the TRIPS Agreement, which acknowledged the widely recognised require-

15 William R Cornish, David Llewelyn and Tanya F Aplin, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (8th edn, Sweet & Maxwell 2013) para 3-05. The Statute of Monopolies was enacted by the English Parliament and imposed a general prohibition on the grant of patents by the Crown, except for those granted to 'a manner of new manufacture'. Lionel Bently and Brad Sherman, *Intellectual Property Law* (4th edn, OUP 2014) 377. The test in place during that period was that the grant should not seek to restrain the public of any freedom or liberty that they had before. E Wyndham Hulme, 'History of the Patent System under the Prerogative and at Common Law' (1896) 12 LQR 141, 153.

16 Fritz Machlup and Edith Penrose, 'The Patent Controversy in the Nineteenth Century' (1950) 10 J Econ Hist 1, 2. It should be borne in mind that, in most countries, the right to the patent lies with the first person to file the patent application, regardless of the date of actual invention.

17 Cornish, Llewelyn and Aplin (n 15) para 3-06.

18 In 1850, the Supreme Court of the US stated that, in order to obtain a patent, the inventor was required to show not only novelty, but also some 'ingenuity and skill'. *Hotchkiss v Greenwood* 52 US 248, 267 (1950).

19 The US Patent Act only included a specific provision on non-obviousness in 1952, under section 103. Janice M Mueller, *Patent Law* (4th edn, Wolters Kluwer 2013) 276.

20 Section 112 of the US Patent Act, for example, requires the patent specification to include a 'best mode' –a requirement which is expressly authorised by art 29(1) of the TRIPS Agreement.

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ments of novelty, inventive step, industrial applicability and sufficient disclosure.[21]

As the substantive requirements for obtaining a patent developed, the formal procedure for obtaining it evolved as well and experienced significant reforms and adjustments. In England, eg, the procedure was for a long time perceived as obscure and uncertain, until in the middle of the nineteenth century the patent system was reformed and clearer guidelines were drawn.[22] In order to make the system more approachable for all citizens, the UK experimented for a short period of time with a mere registration regime whereby, upon the mere submission of the specification, a patent was granted without any substantial examination as to the merits of the invention—or lack thereof.[23] In the United States, where the English legal tradition naturally had a particularly strong influence, a radically different approach was preferred since the early days. As early as 1836 the United States Patent Office was already assigned with the task of searching prior art and closely examining patent applications before their grant.[24] This examination regime is the one that, in the end, prevailed in most jurisdictions, including the UK,[25] Germany[26] and the EPO.[27] Such a regime naturally demands rules and guidelines that have gradually rendered the procedure into a tremendously sophisticated system and, as technology evolves, the complexity of the patenting process increases at a comparable pace.[28]

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21 TRIPS Agreement, arts 27(1) and 29(1). See also Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4th edn, Sweet & Maxwell 2012) 428-33.

22 Cornish, Llewelyn and Aplin (n 15) para 3-09. Interestingly, Charles Dickens has demonstrated through parodies the bureaucracy that surrounded the obtaining of a patent in England at that time. See Jeremy Phillips, *Charles Dickens and the 'Poor Man's Tale of a Patent'* (ESC 1984).

23 Cornish, Llewelyn and Aplin (n 15) para 3-09.

24 ibid para 3-10.

25 The Patent Office started performing a similar examination in the beginning of the twentieth century. Davenport (n 14) 48 (a decisive factor for implementing examination was a study by the Fry Committee in 1901, according to which 42 per cent of the patents registered at that time were wholly or partly anticipated).

26 Georg Benkard, *Patentgesetz* (Claus Dietrich Asendorf and others eds, 10th edn, Beck 2006) para 7.

27 Bently and Sherman (n 15) 421.

28 John R Allison and Mark A Lemley, 'The Growing Complexity of the United States Patent System' (2002) 82 Bost U L Rev 77, 134.

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2. Synopsis of the Patent Procedure in the USPTO and the EPO

The procedure to obtain a patent is in principle a national procedure, meaning that a patent application is to be filed in every single country in which protection is sought.[29] Each nation, hence, has in place its own patent office to independently receive patent applications and grant patents that will only be binding within the boundaries of its territory. In the case of Europe, however, a system exists within the framework of the European Patent Organisation[30] under which one single patent office, the EPO, is responsible for a unified granting procedure. Once a patent is granted by the EPO, it is automatically transformed into a bundle of national patents which will have exactly the same legal effects as those national patents granted by the national patent office of each Contracting State.[31] This system does not affect the simultaneous existence of national patent systems, as the EPO is only intended to supplement rather than replace them,[32] although statistics show that a great portion of the patent applications filed in Europe today are filed through the EPO.[33]

The way in which the examination procedure is conducted in every patent office remains mainly an issue to be defined independently by every jurisdiction, as most aspects have not been internationally harmonised.[34]

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29 Paris Convention, art 4bis(1).

30 It should be borne in mind that the European Patent Organisation is not legally bound to the EU. All Member States of the EU are members of the European Patent Organisation, but the latter also comprises many other members which are not themselves EU Member states.

31 EPC, arts 2(2) and 64(1).

32 Margarete Singer and Dieter Stauder (eds), *The European Patent Convention: A Commentary* (3rd edn, Sweet & Maxwell 2003) vol 1, 15.

33 In Germany, for example, out of the 569 196 patents that were in force in 2013, only 124 432 (ie, 21.9%) had been granted by the national patent office. Deutsches Patent- und Markenamt, 'Jahresbericht 2013' (Lex Lingua 2014) i. In the UK, out of the 397 100 patents where renewal fees were paid in 2013, only 57 900 (14.6%) corresponded to patents granted by the UKIPO, the national patent office. UKIPO, 'Facts and Figures: 2012 and 2013 Calendar Years' (UKIPO 2014) 18.

34 Efforts have been made to harmonise patent procedures, but so far with only limited success. The Patent Law Treaty, eg, constitutes an attempt to harmonise some very important aspects of the procedure by providing maximum sets of requirements that the patent offices of each member state may demand. It was concluded in 2000 and entered into force in 2005. Issues harmonized by this treaty include, among others, requirements for obtaining a filing date, requirements relating to PCT applications, requirements for submitting evidence, etc. The US and several EU countries have already ratified this treaty, although not yet Germany. For an

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In fact, a small number of countries still have in place registration systems and do not perform a substantial examination of the patent applications before their grant. Most countries of the world, however, have adopted examination regimes with a significant number of analogous features. This chapter is devoted to succinctly describe the general aspects that characterise the processes both under the EPO and the USPTO, although patenting procedures in most countries share many of their essential features.

A. *Examination Process: an Ex Parte Procedure*

Broadly speaking, the examination procedure is a procedure initiated by the patent applicant, who needs to fulfil a number of both formal and substantive requisites and often demands a considerable amount of time.[35] It constitutes, in a way, a negotiation between the applicant and the patent office examiner,[36] where the former strives to persuade the latter that all the patentability requirements have been met and that the invention actually deserves protection. Although the procedure is mostly *ex parte*, there are certain stages in which third parties are allowed to intervene.[37]

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updated list of the member states, see <http://www.wipo.int/treaties/en/ip/plt/> accessed 14 February 2018. The TRIPS Agreement, on the other hand, provides in arts 62(2) and (4) for general conditions that all patent procedures should meet, but mostly leaves the issue to the member states' discretion.

35 In the United States, for example, the USPTO takes, on average, around 3 years to examine each patent application, although in some high technology fields the whole examination proceedings can actually take between 5 and 8 years. Warren K Mabey Jr, 'Deconstructing the Patent Application Backlog' (2010) 92 J Pat & Trademark Off Soc'y 208, 218. In Europe, the EPO takes around 3 years and 3 months to examine each application, but once the patent is granted third parties are entitled to file oppositions which may call for several additional years of procedure. Communication from the Commission, Pharmaceutical Sector Inquiry: Final Report (8 July 2009) paras 270-77 <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry> accessed 14 February 2018 (Pharma Sector Inquiry).

36 *Rohm and Haas Co v Collag Ltd* [2001] EWCA Civ 1589, [2002] FSR 28 [42].

37 See text at nn 103ff and 113ff.

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B. Filing of a Patent Application. Description, Claims and Priority

A patent application can be filed by any person without restrictions as regards the nationality or residence.[38] Although under US law the applications are often filed in the name of the real inventors,[39] the application can be assigned to any third person (in most cases the employer) and the patent may later issue to the assignee of the inventor.[40] Today, both the EPO and the US operate on a first-to-file system, which essentially means that the patent is granted to the first person to submit the application to the patent office.[41] For many years and until not very long ago, however, the US operated under a first-to-invent system, where patents were granted to the first person to make the invention rather that to the first one to file the application.

As to its formal requirements, a patent application should essentially contain a written description of the invention accompanied by one or more claims which must clearly point out the scope and subject-matter of the invention.[42]

I. Description

The description is a very important part of the patent application. It is where the applicant explains in detail what the invention is about and can play a significant role in patent litigation, since it can be used to interpret the scope of the exclusive right.[43] On a more theoretical level, this is an essential element of the specification as it guarantees the information function of the patent system.[44]

The description of a patent normally begins with a description of the state of the art in the specific field of the invention, based on the relevant background art known to the applicant.[45] In most cases, the description will continue with a disclosure of the invention by explaining the technical aspects in such a clear and complete way as to enable any person skilled

38 EPC, art 58; § 111 US Patent Act.
39 See 37 CFR §§ 1.41-1.48.
40 Donald S Chisum, *Chisum on Patents* (LexisNexis) para 11.02[2][a].
41 EPC, art 60(2); § 102(a)(1) US Patent Act.
42 EPC, art 78(1); § 112(a) US Patent Act.
43 EPC, art 69(1); *Phillips v AWH Corp* 415 F 3d 1303, 1313 (Fed Cir 2005) (en banc).
44 Bently and Sherman (n 15) 409.
45 EPC, r 42(1)(b); 37 CFR § 1.71; US MPEP, para 608.01(c).

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in the art to replicate it and use it.[46] In the case of the EPO, the patent application is further expected to focus on the problem that the invention is trying to solve and the advantageous effects vis-à-vis the prior art.[47] Additionally, the description normally describes at least one way of carrying out the invention, which is typically done by disclosing and explaining in detail one or more practical examples,[48] and in the case of the US it is also expected to disclose the best mode known by the inventor for carrying out the invention.[49] Finally, the patent specification can contain drawings,[50] which together with the description can be used to interpret the claims.[51]

II. Claims

The claims are the core part of a patent specification, since they are the ones which mark out the exact matter for which protection is sought. They should hence delimitate as precisely as possible the scope of the invention and of the exclusive right.[52] Every patent should contain one or more claims[53] which can be categorised, broadly speaking, depending on whether they refer to products or processes,[54] although a range of hybrids also exist.[55] They must be clear and concise and must find support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to that description.[56]

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46 EPC, art 83; 37 CFR § 1.71(a); TRIPS Agreement, art 29(1).
47 EPC, r 42(1)(c).
48 EPC, r 42(1)(e); 37 CFR § 1.71(b).
49 § 112(a) US Patent Act. See also TRIPS Agreement, art 29(1). The consequences for an applicant who fails to include the best mode, however, have been strongly mitigated with the passing of the Leahy-Smith America Invents Act (AIA), which amended § 282 to state that 'the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable'. See Andrew T Robinson, 'The America Invents Act and the Best Mode Requirement: Where Do We Go From Here? (2012) 20 J Intell Prop L 179.
50 EPC, art 78(d); § 113 US Patent Act.
51 EPC, art 69(1); Chisum (n 40) para 11.02[1][b][iii].
52 EPC, arts 69 and 84; § 112(b) US Patent Act. See also EPC, 'Protocol on the Interpretation of Article 69 EPC'.
53 EPC, art 78(1)(c); § 112(b) US Patent Act.
54 Bently and Sherman (n 15) 412-13; Roger E Schechter and John R Thomas, *Principles of Patent Law* (Thomson/West 2004) 25.
55 See Bently and Sherman (n 15) 412-15.
56 EPC, art 84; 37 CFR § 1.75(d)(1).

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III. Other Formal Requirements. Inventors and Priority

Together with the customary information that is expected to be provided in any presentation before a governmental institution, a patent application should include information such as the identity of all the inventors, details of the applicant and, where applicable, the details of the professional legal representative.[57] Furthermore, if applications for the same invention have already been filed in other countries, a patent applicant can also include a priority claim.[58] The subject of priority claiming has been harmonised to a large extent by the Paris Convention,[59] which gives patent applicants twelve months from the filing of the first patent application to file other patent applications in other countries.[60] The main effect of such priority claim is that the subsequent filings cannot be invalidated by reason of any acts accomplished in the interval.[61]

Despite their predominantly formal nature, the requirements that are to accompany a patent application might become an important element in the context of this work, due to the significance of the information therein contained and the risks and easiness with which mistakes or misrepresentations can be made.

C. The Application Process

I. Formal and Substantive Examination, Publication and Office Actions

Once the patent application is filed, the patent office normally performs a prompt examination in order to determine whether it fulfils all formal requirements and whether it can be accorded a date of filing.[62] During the course of this examination, however, the office does not yet make any assessment as to the actual patentability of the invention.

Once it has been verified that all the formal requirements have been met, the patent office will ordinarily proceed to publish the patent application, which as a rule happens 18 months as of the date of filing unless the

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57 EPC, r 41; § 115(a) US Patent Act; 37 CFR § 1.31.
58 EPC, art 87; § 119(b)(1) US Patent Act.
59 See Georg H C Bodenhausen, *Guide to the Application of the Paris Convention* (BIRPI 1968) 13-14.
60 Paris Convention, art 4(C)(l) and (2).
61 Bodenhausen (n 59) 41.
62 EPC, art 90(1) and (3) and r 40; 37 CFR § 1.53.

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applicant requests an earlier publication.[63] Publication is an important stage in patent prosecution: it not only discloses the invention to the public but also enables third parties to file observations as to its patentability.[64] Moreover, if the patent is finally granted, it is as of the date of publication that the owner is entitled to sue for infringement and claim damages.[65]

In the EPO, a search report—the *European search report*—is generally drawn up before the publication of the patent application.[66] The main aim of this report is to point out the relevant prior art that has been found,[67] and it is further accompanied by a preliminary opinion on whether the application seems to meet the patentability requirements.[68] The European search report is to be transmitted to the applicant immediately after it has been drawn up[69] and also published, if possible together with the patent application.[70]

After the publication of the patent application, the patent office proceeds to what is probably the most important stage of the whole procedure: the substantive examination of the patent application.[71] Such examination is carried out automatically in the case of the USPTO,[72] but in the EPO it must be specifically requested by the applicant within six months after the publication of the application[73] and failure to do so leads to the application being deemed withdrawn.[74] The substantive examination con-

63 EPC, art 93; 37 CFR § 1.211(a). In the USPTO, however, an applicant can request the application not to be published provided that the invention has not been and will not be the subject of an application in another country other than the US. 37 CFR § 1.213(a).

64 EPC, art 115; 37 CFR § 1.291.

65 EPC, art 67; § 154(d) US Patent Act.

66 EPC, art 92.

67 EPC, r 61.

68 EPC, r 62.

69 EPC, r 65.

70 EPC, r 68(1). Such publication, however, should not include the preliminary opinion. EPC, r 62(2).

71 EPC, art 94; § 131 US Patent Act.

72 § 131 US Patent Act.

73 EPC, r 70.

74 EPC, art 94(2). It should be noted that other countries, like Germany, have a more pronounced system of 'deferred examination', where an application can be pending without examination for up to seven years from the filing date until the applicant or a third party asks for it. § 44(2) PatG (*Patentgesetz* or German Patent Act). This system helps filtering away unwanted patents without wasting resources on examination, but might also lead to a prolonged uncertainty. Cornish, Llewelyn and Aplin (n 15) para 4-18.

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sists of a thorough scrutiny by technical experts in the specific field of the invention in order to ensure that it fulfils all the patentability requirements.[75] This means in particular that the patent office ensures that the invention comprises patentable subject-matter, that it is new, inventive and industrially applicable, and also that it has been sufficiently disclosed and that its claims are clear and supported by the description.[76]

It should be noted that the prior art search that the patent offices carry out in order to assess the novelty and inventive step of an application is usually performed over large databases of patents and patent applications from major patenting countries and of the most important technical literature.[77] Yet despite its comprehensiveness, it is materially impossible for the search to be entirely exhaustive.[78] There may always be pieces of prior art beyond the reach of the examiners, such as remote publications, prior sales of the invention or oral disclosures at exhibitions or conferences, all of which are more commonly brought up by third parties by submitting observations, in opposition proceedings (in the case of the EPO) or later on by defendants during litigation.[79]

In any case, if the examination reveals that the application does not meet all the patentability requirements, the corresponding objections are submitted to the applicants, who are entitled to present within a certain period of time their own observations and any amendments they might wish to make.[80] This negotiation between the applicants and the examiner often extends for a long period of time, until the examiner arrives to a final opinion on whether all the requirements have been met and, hence, whether the patent is to be granted or rejected.[81]

II. Amendments

Applicants are allowed to amend their applications both before and after grant.[82] Amendments are justified in the belief that it would be unreasonable to expect applicants to be perfectly aware of all the relevant facts and

75 EPC, art 94(1); 37 CFR § 1.104.
76 Cornish, Llewelyn and Aplin (n 15) para 4-22.
77 ibid para 4-19; Mueller (n 19) 57.
78 EPO Guidelines (n 12) pt B(III) para 2(1).
79 EPO Guidelines (n 12) pt B(VI) para 2 and pt G(IV) para 7(1).
80 EPC, art 94(3); § 132(a) US Patent Act.
81 EPC, art 97; § 131 US Patent Act.
82 EPC, art 123(1); § 132 US Patent Act; 37 CFR §§ 1.115 and 1.116.

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circumstances surrounding the invention at the time of filing,[83] especially considering that a first-to-file system encourages inventors to submit their patent applications as early as possible. Those amendments, hence, are ordinarily made in order to take account of prior art, to better describe the invention or to correct or remove mistakes.[84] The amendments, however, cannot by any circumstance contain subject-matter extending beyond the content of the application as filed and, by the same token, may not extend the protection it confers.[85]

Before grant, the applicant is as a rule free to make amendments any time before the receipt of the first office action from the examiner.[86] After that, amendments are basically submitted in order to overcome the observations raised by the examiner.[87]

Amendments after grant are much less frequent.[88] In the EPO, a patent owner can request the limitation—or even the revocation—of a patent as long as it fulfils the general requirements for amendments, and the amendment applies to all Contracting States where the patent has been validated.[89] In the US, patentees can request a certificate of correction in case of, eg, typographical errors,[90] but if they consider that, because of an error, the patent is inoperative or invalid, they can also request the reissuance of the patent in an amended form.[91]

III. Divisional Applications and Unity of Invention

If a single patent application discloses more than one invention, or different aspects of a single invention, the patent application can be broken up through the filing of divisional patent applications.[92] Divisional patent applications cannot extend beyond the content of the earlier application and they are deemed to have been filed on the date of filing of the earlier application.[93]

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83 Bently and Sherman (n 15) 431.
84 Cornish, Llewelyn and Aplin (n 15) para 4-30.
85 EPC, art 123(2) and (3); 37 CFR § 1.53(b).
86 EPC, r 137(1), (2) and (3); 37 CFR § 1.115.
87 EPC, r 137(3); 37 CFR § 1.111.
88 Cornish, Llewelyn and Aplin (n 15) para 4-34.
89 EPC, arts 105a and 105b and rr 80 and 138.
90 § 254 US Patent Act.
91 § 251(a) US Patent Act.
92 EPC, r 36; § 121 US Patent Act.
93 EPC, art 76(1); 37 CFR § 1.53(d).

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There are two main reasons why a divisional application might be filed. The most common situation is that where the application is divided due to a lack of unity of the invention.[94] In this regard, every patent application must refer to one invention only—or to a group of inventions so linked as to form a single general inventive concept.[95] Therefore, if an application refers to more than one invention, the examiner can require the applicant to restrict the application to only one of the inventions and the applicant can file divisional applications for the rest.[96]

On the other hand, even if the application refers to one single invention, the applicant might have economical, procedural, or other reasons for having different aspects of the application divided.[97] A divisional application might be filed, eg, to exclude problematic aspects of the invention from the main application in order to pave the way for its prompt grant, while leaving the most debatable issues to a separate discussion.[98]

IV. Grant, Publication and National Validation

If after the prior art search, the substantive examination, the exchange of views with the applicant and the possible amendments, the examiners are of the opinion that the application meets all the patentability requirements, they will proceed to inform the applicant that they intend to grant the patent and, upon the payment of the corresponding fees, will proceed to issue and publish it at once.[99]

In the case of the EPO, the patent holders will additionally need to validate their patents in each Contracting State of their interest. Indeed, as the EPC system provides for a unified granting procedure, patent applicants are required to indicate the Contracting States where they would like their patents to be in effect.[100] Afterwards, upon the grant of the patent, the Contracting States that were designated may require from the patentee to

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94 Singer/Stauder (n 32) vol 1, 285; Schechter and Thomas (n 54) 229.
95 EPC, art 82; 37 CFR § 1.141(a).
96 EPC, r 36(1)(b); § 121 US Patent Act.
97 Singer/Stauder (n 32) vol 1, 285.
98 Richard Hacon, *Concise European Patent Law* (Richard Hacon and Jochen Pagenberg eds, 2nd edn, Wolters Kluwer 2008) 91.
99 EPC, arts 97(1) and 98 and r 71(3) (in the EPO, the applicants are also required to file a translation of the claims into the two other official languages); § 151 US Patent Act.
100 EPC, art 79.

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provide a translation of the patent into one of the official languages of that state provided that the patent granted by the EPO was not drawn in one of those languages[101] and will then proceed to the local publication of the patent.[102]

V. Third Party Observations

Although the procedure to obtain a patent is mainly an *ex-parte* procedure, there are certain circumstances under which third parties are also entitled to participate in the examination. At the early stages of the procedure, that involvement is often very limited,[103] but later on it can become much broader.[104]

During the on-going examination process and before the grant of the patent, both the EPC and US law only allow third parties to take part in it by filing observations and submitting to the patent office prior art and other references concerning the patentability of a specific invention.[105] These filings have to be duly taken into account by the examiners, but they do not transform those who file them into active parties to the proceedings. In particular, they have no right to appeal if, eg, the observations are ignored or disregarded by the examiners.[106]

D. Post Grant Procedures

After the patent is granted, there are still certain situations under which patent holders and third parties are permitted to submit specific pleads before the patent office, which may affect the scope or the term of the patent, or even its validity altogether.

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101 EPC, art 65(1).
102 EPC, art 65(2).
103 Other countries, however, do provide for the filing of oppositions *before* the patent is granted. See, Indian Patent Act, s 25.
104 See text in nn 112-122.
105 EPC, art 115; 37 CFR § 1.99.
106 EPC, art 115; 37 CFR § 1.99(f).

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I. Post-Grant Amendments, Ex Parte Reexamination and Supplemental Examination

Under US law, even after grant the patent holders can themselves cite relevant prior art that had not been considered by the USPTO and request a reexamination of said patent.[107] The USPTO should then determine whether a substantial new question of patentability is raised;[108] if yes, it should proceed to reexamine the patent under the same procedural rules established for initial examination.[109]

With the entering into force of the AIA, however, the patentees will probably be inclined to use alternative procedures.[110] Indeed, the new section 257 of the US Patent Act entitles patentees to request a Supplemental Examination in order to consider, reconsider, or correct information believed to be relevant to the patent, which at first sight appears to be more advantageous for the patent holder.[111]

In the EPO, on the other hand, the office cannot re-examine the patent once it has been granted and the opposition period has expired, although, as mentioned above, the EPC2000 has introduced a set of new provisions that allow patent owners to request for the limitation or revocation of the patent.[112]

II. Third Party Intervention after Grant. Oppositions, Post-Grant Reviews and Inter-Partes Reviews

After the grant of the patent, the EPO has historically permitted third parties to intervene before the patent office in a more active way, in order to get the patent revoked or its scope narrowed down. Under the US system, third party intervention has been traditionally much more limited, but the

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107 § 302 US Patent Act.

108 § 303(a) US Patent Act.

109 § 305 US Patent Act.

110 Dennis Crouch, 'Is the New Supplemental Examination a Complete Replacement for Owner Initiated Ex Parte Reexamination?' (*Patently-O*, 3 October 2012) <www.patentlyo.com/patent/2012/10/is-the-new-supplemental-examination-a-complete-replacement-for-owner-initiated-ex-parte-reexamination.html> accessed 14 February 2018.

111 ibid. Indeed, under the Supplemental Examination procedure, patentees may 'immunise' their patents against subsequent inequitable conduct attacks. See text at nn 280-281.

112 EPC, arts 105a, 105b and 105c.

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scenario seems to be gradually changing with the entering into force of the AIA.

Under the EPC regime, any person can file an opposition before the EPO within nine months of the publication of the mention of the grant of the patent.[113] And even after the opposition period has expired, assumed infringers can intervene in on-going opposition proceedings provided that infringement or non-infringement procedures have already been instituted.[114] Oppositions can be filed on the grounds that the invention is not patentable, or that it has not been disclosed in a sufficiently clear and complete manner, or that the subject-matter extends beyond the content of the application as filed.[115] If, after hearing the patent applicant and considering the possible amendments made, the Opposition Division is of the opinion that the application does not meet all the requirements, it proceeds to revoke the patent.[116] It should be borne in mind that the filing of the opposition does not impede the granted patent from becoming a bundle of national patents, but if the Opposition Division later decides to revoke the patent, such decision will have effects on all countries were that patent had become effective.[117]

Under US law, third parties were in the past permitted to intervene at the patent office after the grant of the patent in a rather limited fashion, under the figure of Inter-partes Re-examination, which has been replaced and expanded with the passing of the AIA with two different alternatives.[118] On the one hand, within the first nine months of grant, third parties are entitled to file a Post Grant Review petition before the patent office, so long as they have not already challenged the validity and enforceability of the patent in court.[119] The decision is appealable to the Federal Circuit[120] and if claims are upheld the third party is estopped from challenging the validity of those claims subsequently.[121] On the other hand, after the first nine months of the grant of the patent, third parties are al-

113 EPC, art 99(1).
114 EPC, art 105.
115 EPC, arts 99 and 100.
116 EPC, art 101.
117 EPC, art 99(2).
118 For a broader description of AIA, see 'Recent Legislation' (2012) 125 Harv L Rev 1290.
119 §§ 321(a) and (c) and 325(a)(1) US Patent Act.
120 § 329 US Patent Act.
121 § 325(e)(2) US Patent Act.

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lowed to request an Inter Partes Review, which can only rely on prior patents or printed publications.[122]

In addition to that, it is important to bear in mind that, both under the EPO regime and in the US, once the patent has been granted third parties are also entitled to challenge its validity in court.[123]

III. SPCs and Term Extensions

Although the standard duration of a patent is twenty years counted as of the date of filing of the application,[124] there are exceptional circumstances under which such term can be extended.

a. SPCs in the EU

In Europe, the EPC does not directly provide for any alternative to extend the term of a patent, but it does permit the Contracting States to do so under two specific circumstances: (i) in order to take account of a state of war or similar emergency conditions, or (ii) if the subject-matter of the patent refers to a product which has to undergo an administrative authorisation procedure before it can be put on the market.[125] Under these premises, the European Union has implemented the use of Supplementary Protection Certificates (SPCs), which allow for the extension of the patent term for medicinal and plant protection products as a compensation for delays in authorising the products to enter the market.[126] They were specifically introduced to encourage pharmaceutical and plant protection research, by

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122 § 311 US Patent Act.

123 EPC, art 138; § 81 PatG; UK Patents Act, s 72; § 282 US Patent Act. It should be noted that, as a patent granted by the EPO becomes a bundle of national patents, a third party interested in challenging their validity in court should do so separately in every designated Contracting State.

124 TRIPS Agreement, art 33; EPC, art 63; § 154(a)(2) US Patent Act.

125 EPC, art 63(2)(a) and (b).

126 SPCs for medicinal products were introduced by Council Regulation (EEC) 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products [1992] OJ L182/1, which was later repealed and replaced with a codified version: Regulation (EC) 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152/1 (SPC Regulation). SPCs for plant protection products were introduced by Regulation (EC) 1610/96 of 23 July 1996 concerning the creation of

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guaranteeing a minimum period of effective protection sufficient to cover the investments made and to generate the resources needed to maintain a high level of research.[127]

SPCs are to be lodged independently before the patent office of every Member State where the patent was granted and the extension is sought.[128] Each patent office shall then proceed to establish whether all the requirements have been met, although Member States are permitted to exempt them from verifying certain conditions.[129] If the certificate is granted, the patent term is extended based on the following formula:

> *X = date of first market authorisation — patent application filing date — 5 years*

where X cannot be higher than 5 years.[130] In principle, the scope of the SPC extends only to the product covered by the authorisation to place the corresponding product on the market and for any use of the product that has been authorised before the expiry of the certificate.[131] The CJEU, however, has interpreted that the SPC is sometimes capable of covering any of the forms enjoying the protection of the basic patent, even if not specifically mentioned in the authorisation.[132]

b. Patent Term Extensions in the US

Under US law, the term of a patent can also be extended for the delays incurred in the regulatory review before the marketing authorisation,[133] although it diverges from EU's SPC system in a number of significant aspects. Term extensions in the US due to delays in marketing authorisation

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a supplementary protection certificate for plant protection products [1996] OJ L198/30 (Plant SPC Regulation).

127 See Katarzyna Zbierska, *Application and Importance of Supplementary Protection Certificates for Medicinal Products in the European Union* (Shaker 2012) 27-32.

128 SPC Regulation 469/2009, art 9(1); Plant SPC Regulation 1610/96, art 9(1).

129 SPC Regulation 469/2009, art 10(5); Plant SPC Regulation 1610/96, art 10(5). This circumstance might be a very important factor when analysing the *AstraZeneca* decision and the impact it might have on different procedures before the patent office where a stricter scrutiny is observed.

130 SPC Regulation 469/2009, art 13(1) and (2); Plant SPC Regulation 1610/96, art 13(1) and (2).

131 SPC Regulation 469/2009, art 4; Plant SPC Regulation 1610/96, art 4.

132 Case C-392/97 *Farmitalia* [1999] ECR I-5553.

133 § 156 US Patent Act.

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are normally referred to as Patent Term Restorations and were first introduced by the Hatch-Waxman Act in 1984 for drug products, medical devices, food additives and colour additives.[134] A request for a patent term restoration is filed before the patent office, which is to verify—with the assistance of the relevant health and agriculture authorities, predominantly the Food and Drug Administration (FDA)—whether all the legal requirements have been met.[135]

In contrast with the EU, the patent term in the US is extended not only for the period of time required by the regulatory procedure after the filing of the marketing authorisation request (normally referred to as New Drug Application or NDA), but also for the time devoted to clinical trials prior to such filing.[136] Also, the calculation does not take into account the filing date of the patent application. Broadly speaking, the term can be adjusted based on the following formula:

> *X = [filing date of NDA – starting date of human clinical trials]/2 + date of marketing authorisation – date of NDA*

where X cannot be higher than 5 years or extend beyond 14 years from the product's approval date.

In addition to the alternative described above, US patent owners can also see the term of their patents extended as a result of the delays in which the patent office itself could have incurred during the examination of the application.[137] The Patent Term Guarantee Act of 1999 sets a number of deadlines to the USPTO and each day of delay beyond these limits gives rise to one additional day in the term of the patent.[138] The exact determination of the term adjustment is carried out by the USPTO and conceded automatically, without the need of the applicant to make a formal request.[139]

134 § 156(f)(1) US Patent Act. In 1988, a similar system was implemented for animal drugs by the Generic Animal Drug and Patent Term Restoration Act.
135 § 156(d)(1) and (2) US Patent Act.
136 § 156(g)(3)(B) US Patent Act.
137 § 154(b) US Patent Act.
138 Schechter and Thomas (n 54) 241.
139 § 154(b)(3) US Patent Act.

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IV. Patent Linkage and the Orange Book

Considering that many products, most importantly pharmaceuticals, need to be thoroughly examined in terms of safety and efficacy before they are able to enter the market, a number of countries around the world have put into practice a system normally referred to as patent linkage, whereby the public authority in charge of granting these permissions is restricted of doing so when the product is covered by a patent owned by a third party. Ordinarily, patent offices are not involved in this process.

In the US, such as system was introduced by the Hatch-Waxman Act in 1984. When applying to the FDA to commercialise a new drug in the country, hence, applicants are required to file information on any patent that might exist protecting the drug.[140] Information submitted by all patentees is then published by the FDA in a list commonly known as Orange Book.[141] If third parties later intend to obtain marketing approval for a drug equivalent to one already authorised, they can only do so if they submit a certification declaring that: (i) no patent information has been filed by the first applicant; (ii) such patent has expired; (iii) the date on which that patent will expire; or (iv) that such patent is invalid or will not be infringed.[142] In the latter case, the patent owner must be informed of such application before its approval and can block such procedure for a period of 30 months if it starts legal actions against the new applicant within 45 days.[143] In practice, it basically equates to obtaining an automatic preliminary injunction, since the administrative procedures at the FDA will be stayed and the new applicants cannot enter the market before getting the final authorisation. The USPTO is not involved in these proceedings, neither when the patentees list their patents in the Orange Book nor when third parties intend to obtain marketing approval for drugs already listed there.

In the case of Europe, no such patent linkage exists. In fact, EU law does not seem to allow it either, neither on a European nor on a national level. Both Regulation 726/2004 and Directive 2001/83/EC provide in this regard that authorisations for medicinal products cannot be refused but on the grounds expressly set out therein, and none of them include the existence

140 § 505(b) Federal Food, Drug, and Cosmetic Act.

141 The list is officially entitled Approved Drug Products with Therapeutic Equivalence Evaluations. § 505 Federal Food, Drug, and Cosmetic Act.

142 § 505(b)(2)(A) Federal Food, Drug, and Cosmetic Act.

143 § 505(c)(3)(C) Federal Food, Drug, and Cosmetic Act.

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of a patent or any other intellectual property right as a valid motive.[144] That being said, there are a few Member States which do provide for some kind of linkange in their internal laws, particularly Hungary, Italy, Portugal and Slovakia.[145]

E. Alternative Procedures. PCT, Patent Prosecution Highway and the Use of Results from other Patent Offices

In addition to the standard proceedings, many countries have in place alternative procedures available for the applicants which might add more complexity to the issue. Most significantly, a very large number of countries including the US and all members of the European Patent Organisation are members of the PCT.[146] This treaty essentially provides for the possibility to file an international application in any of the designated receiving offices,[147] and its main advantage is that it provides applicants the possibility to delay for up to thirty months the decision on whether to continue with the application and, if so, in which countries.

Once the international application is filed, the designated patent office performs an early, non-binding prior art International Search Report and an opinion on the patentability and further proceeds to make an international publication of the application.[148] After this stage, the patent applicant can also request for a nonbinding International Preliminary Examination[149] and should in any case continue with the procedure by entering the national or regional phases in the countries of her choice (as long as they are PCT Contracting States) within 30 months after the date of filing.[150]

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144 Regulation (EC) 726/2004 of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L136/1, art 81(2); Directive 2001/83/EC of of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311/67, art 126.

145 Filipe Fischmann, *«Reverse Payments» als Mittel zur Beilegung von Patentstreitigkeiten - Ein Verstoß gegen das Kartellrecht?* (Stämpfli Verlag 2016) 335-339.

146 For an updated list of Contracting States, see <www.wipo.int/pct/en/pct_contracting_states.html> accessed 14 February 2018.

147 PCT, art 10.

148 PCT, arts 15, 17(2) and 21.

149 PCT, arts 31 and 35.

150 PCT, art 22(1).

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In addition to the PCT, and in view of the fact that patent applications for the same invention are often filed in a range of different countries,[151] many patent offices have entered into collaboration arrangements with each other, and even mutual recognition systems, in order to save resources and avoid repetition of work.[152] And even in the absence of formal agreements, thanks to the considerable simplifications in communication, many patent offices are able to use the search results and examination reports that other patent offices have already issued for the same invention.[153] Some countries even provide for the use of such results expressly in their national laws, eg by waiving the requirements of novelty, inventive step and industrial application when an equivalent patent has already been granted abroad.[154]

F. The Role of Patent Agents

As a general principle, inventors are not required to appoint a professional representative to file the patent application and follow the proceedings before the patent office and can thus act on their own behalf.[155] In the EPO, only persons who are not residents and do not have their principal place of business in a Contracting State are compelled to hire a professional representative, ie a patent attorney duly qualified and admitted to practice before the EPO.[156]

Even if not mandatory, the complexity of the entire patenting process and the high risks that an inadequately drafted or prosecuted patent may entail in the future encourage inventors to hire patent attorneys to file and

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151 It is estimated that, within the 10 largest patent offices, around 34% of the applications are duplicate applications. London Economics, 'Economic Study on Patent Backlogs and System of Mutual Recognition: Final Report to the Intellectual Property Office' (2010) 80, available at <www.gov.uk/government/uploads/system/uploads/attachment_data/file/328678/p-backlog-report.pdf> accessed 14 February 2018.

152 Jürgen Schade, 'Synergies created by international cooperation in the patent area' in Wolrad Prinz zu Waldeck und Pyrmont and others (eds), *Patents and Technological Progress in a Globalized World* (Springer 2009) 783.

153 Peter Drahos, '"Trust Me": Patent Offices in Developing Countries' (2008) 34 Am J L & Med 151.

154 Martín Bensadon, *Ley de Patentes Comentada y Concordada con el ADPIC y el Convenio de Paris* (LexisNexis 2007) 252, fn 826.

155 EPC, art 133(1); 37 CFR § 1.31.

156 EPC, art 133(2).

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handle their patent applications on a regular basis.[157] Hence, in actual fact, the vast majority of patent applications, both in the US and in the EPO, are filed through patent attorneys or patent agents.

Under the EPC regime, all patent attorneys are bound to be members of the Institute of Professional Representatives before the European Patent Office (EPI) and are subject to the disciplinary rules determined by the Administrative Council.[158] In the case of the US, all patent attorneys engaged in practice before the USPTO are subject to its disciplinary jurisdiction.[159] In this light, the disciplinary frameworks implemented by EPI or the USPTO may also play an important role within the context of the present work.

157 Bently and Sherman (n 15) 418.

158 EPC, art 134(1); Regulation on the establishment of an Institute of professional representatives before the European Patent Office [1997] OJ EPO 350, art 5(1).

159 37 CFR § 11.19.

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Chapter III: The Responsibilities of the Patent Applicants before the Patent Office

1. *The Duties of the Patent Applicant under US Law*

As observed in the previous chapter, procedures to obtain patents from the EPO and from the USPTO resemble each other to a large extent. Decades of a mutual mimicry that has soared over the last years have made procedures before the patent offices substantially analogous on both sides of the Atlantic, although a few important differences still remain. One of the aspects in which they most strongly differ is precisely the role that the patent applicants are expected to play during the examination of the invention and the consequences that a lack of sufficient candour can have on the patent.[160] In this regard, patent applicants before the USPTO are expected to get involved and collaborate in the examination in a much more active way than in the EPO and strict duties and responsibilities are imposed upon them. The US Supreme Court long ago stated that 'the relationship of attorneys to the Patent Office requires the highest degree of candor and good faith'[161] and that this requirement comprises the duty to report to it all relevant facts underlying the patent application.[162] This kind of remarks

160 Gina M Bicknell, 'To Disclose or not to Disclose: Duty of Candor Obligations of the United States and Foreign Patent Offices' (2008) 83 Chi-Kent L Rev 425, 460; Jay Erstling, 'Patent Law and the Duty of Candor: Rethinking The Limits of Disclosure' (2011) 44 Creighton L Rev 329, 331 ('the United States is unique in requiring such breadth of candor and in linking failures to disclose with the threat of inequitable conduct and the sanction of unenforceability.'). See also Case T 2321/08 *Samsung Electronics* (decision of the EPO Technical Board of Appeal of 11 May 2009) para 7.3 ('the second part of Rule 27(1)(b) EPC 1973 does not put a stringent obligation on the applicant to cite documents reflecting prior art known to him already at the time of filing the application.').

161 *Kingsland v Dorsey* 338 US 318, 319 (1949).

162 *Precision Instrument Manufacturing Co v Automotive Maintenance Machinery Co* 324 US 806, 818 (1945). The Supreme Court also stated that 'the far reaching social and economic consequences of a patent … give the public a special interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.' Ibid 816.

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lit the fuse to the daunting burden that US case law gradually moulded upon patent applicants.[163]

The rules of conduct that determine US patent applicants' duties and responsibilities have been delineated in the course of several decades on the basis of two main pillars: (i) the inequitable conduct doctrine and (ii) the specific regulations of the USPTO that established the so-called duty of candour. The inequitable conduct doctrine is a judicially developed doctrine which enables a court to declare a patent unenforceable—even if valid—if it finds that the patent holder, when conducting the application procedure before the USTPO, engaged in some kind of improper conduct in order to obtain the patent.[164] The duty of candour, in its turn, finds its origin in specific regulations issued by the USPTO, which in fact have been delineated on the basis of the evolving case law on inequitable conduct in a seeming attempt to codify the duties of the applicants.[165] These regulations are commonly known as 'Rule 56' and expressly state that the patent applicant has a duty of good faith in dealing with the office that includes a duty to disclose all known information which might be relevant for the patentability of the application.[166] Although the inequitable conduct doctrine and the duty of candour imposed by the USPTO have been developed simultaneously and strongly influenced each other, the Federal Circuit has clearly stated that they remain independent sets of rules and that ultimately the inequitable conduct doctrine is not bound by the regulation set by the USPTO.[167] The inequitable conduct doctrine was actually born as an equitable defence[168] that stemmed from the long-established doctrine of unclean hands,[169] an axiom that basically proclaims that 'he

163 Erstling (n 160) 330.

164 Janice M Mueller, *Patent Law* (4th edn, Wolters Kluwer 2013) 550-51.

165 Kevin Mack, 'Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands' (2006) 21 Berkeley Tech L J 147, 154.

166 37 CFR § 1.56.

167 *Therasense Inc v Becton, Dickinson & Co* 649 F 3d 1276, 1294 (Fed Cir 2011) (en banc). See also R Carl Moy, 'The Effect of New Rule 56 on the Law of Inequitable Conduct' (1992) 74 J Pat & Trademark Off Soc'y 257, 260.

168 An equitable defence is, in general terms, a defence to an action on grounds which formerly was only available in a court of equity. *Black's Law Dictionary* (9th edn, 2009) 483. However, after the merger of law and equity, most equitable defences were incorporated into the common law. T Leigh Anenson, 'Treating Equity Like Law: A Post-Merger Justification of Unclean Hands' (2008) 45 Am Bus L J 455, 456.

169 *Precision v Automotive* (n 162) 819.

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who comes into equity must come with clean hands'.[170] It embodies, in a way, the *tu quoque* fallacy that precludes those guilty of wrongdoing from denouncing others performing similar or related wrongs.[171] In the context of patent litigation, this would imply that patent owners cannot expect to enforce their patent rights if they turn up with unclean hands due to their prior deceptive behaviour before the patent office.

The sternness that has come forth in the American patent system has been explained, in the first place, by the very nature of patents, which are affected with a public interest.[172] Furthermore, the *ex parte* nature of patent prosecution and the lack of sufficient intervention by third parties both during and after the examination process have been indicated as essential factors vindicating the strict behavioural regime.[173] It is also often emphasised that the patent applicant is more knowledgeable in the field of the invention and frequently has more relevant information at hand than the examiner.[174] Be that as it may, the specific scope of the patent applicant's duties under US law and the consequences for contravening them have been the subject of extensive debates among US courts, scholars, legislators and practitioners which still persist today.

In this light, the main purpose of this section is to describe the development and key features of the inequitable conduct doctrine and the duty of candour that patent applicants owe to the USPTO. It first analyses the origin and development of these concepts and subsequently studies the standards that have been established and the types of conducts that can be held inequitable in practice. By way of conclusion, it explores whether said conducts can also have disciplinary or criminal consequences for the appli-

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170 Zechariah Chafee Jr, 'Coming into Equity with Clean Hands' (1949) 47 Mich L Rev 877. It is generally considered that the doctrine of unclean hands serves two fundamental purposes: protecting judicial integrity and promoting justice. Anenson (n 168) 461.

171 Ori J Herstein, 'A Normative Theory of the Clean Hands Defense (2011) 17 Legal Theory 171, 172.

172 *Precision v Automotive* (n 162) 816 ('a patent is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope').

173 David O Taylor, 'Patent Fraud' (2010) 83 Temp L Rev 49, 54. See also Thomas F Cotter, 'An Economic Analysis of Patent Law's Inequitable Conduct Doctrine' (2011) 53 Az L Rev 735, 778.

174 *Abbott Laboratories v Sandoz Inc* 544 F 3d 1341, 1357 (Fed Cir 2008).

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cants. Successively, the following sections will describe how European patent practice deals with these questions and evaluate whether there are any lessons to be learnt based on the US experience.

A. *The Origin of the Inequitable Conduct Doctrine. A Stroll down Memory Lane*

Since the very first US Patent Act in 1790, each of the patent statutes passed in the US has always provided for some form of private remedy against the procurement of a patent by fraud.[175] The courts, however, were for a long time rather reluctant to apply them.[176] It was only by the mid-twentieth century that courts reconsidered the importance that they were giving to misleading behaviours at the patent office, a shift that might have occurred more due to a growing hostility to patents than to an authentic re-evaluation of the figure of fraud.[177] In that context, the US Supreme Court delivered a series of unprecedented decisions during the first half of the 20th century where it refused to enforce patents on the basis that the patent holders had engaged in fraud during the examination procedure.

In *Keystone Driller Co v General Excavator Co*, the first of this series of cases, the Supreme Court had to deal with a situation where the patent applicant—who later assigned the patent to a third party—had agreed with a prior user of the invention to keep secret and supress the evidence of the details of such prior use.[178] In *Hazel-Atlas Glass Co v Hartford-Empire Co*, the second of these cases, the patent holder's attorneys had arranged the publication of an article in a journal signed by an ostensibly disinterested expert praising the invention as a remarkable advance. That article had then been introduced into the record in the patent office and in the court proceedings in support of the patentability of the invention.[179] In both cases, the Supreme Court denied relief to the patent owners relying on the doctrine of unclean hands, although it mostly focused on the relevance

175 Mack (n 165) 150.
176 Robert J Goldman, 'Evolution of the Inequitable Conduct Defense in Patent Litigation' (1993) 7 Harv J L & Tech 37, 38.
177 ibid 39.
178 *Keystone Driller Co v General Excavator Co* 290 US 240, 243 (1933).
179 *Hazel-Atlas Glass Co v Hartford-Empire Co* 322 US 238, 240-241 (1944).

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that the fraudulent behaviour had had on the judicial proceedings rather than on the fraud to the USPTO itself.[180]

It was in *Precision Instrument Manufacturing Co v Automotive Maintenance Machinery Co*[181] that the Supreme Court focused for the first time on the issue of fraud at the patent office as such and recognised that the nondisclosure of relevant information can act as a bar to the enforcement of a patent, and in that way gave birth to the inequitable conduct doctrine.[182] In this case, Automotive and Mr Larson (officer and founder of Precision) had been involved in interference proceedings at the patent office in order to determine who had been the first inventor in the context of two conflicting patent applications.[183] During the interference procedure, Automotive found out that Larson had filed statements containing false information designed to appear as the first inventor. But instead of disclosing this falsehood, the parties settled the interference proceedings and Larson assigned the patent rights to Automotive without disclosing the inaccuracies that such application contained. Later on, Precision began to manufacture a new product and Automotive attempted to enforce its patents against it. The case made its way to the Supreme Court, where the infringement action was finally dismissed on the grounds that the patentee, by concealing information prejudicial to its patent, had not displayed the standard of conduct required for the maintenance of a suit in equity.[184] In so deciding, the Supreme Court stated that

> those who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an uncompromising duty to report to it all facts concerning possible fraud or inequitableness underlying the applications in issue.[185]

Relying on the doctrine of unclean hands, the Supreme Court highlighted the impact that the prior misleading behaviour shown by Automotive

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180 Raymond P Niro and J William Wigert Jr, 'Patents, Fraud and the Antitrust Laws' (1968) 37 Geo Wash L Rev 168, 170.

181 *Precision v Automotive* (n 162).

182 Katherine Nolan-Stevaux, 'Inequitable Conduct Claims in the 21st Century: Combating the Plague' (2005) 20 Berkeley Tech L J 147, 150.

183 It should be borne in mind that, under the prior US patent regime, patents were not awarded to the first one to file a patent application but to the first one to make the invention. Standards for determining who had actually been the first inventor were rather complex and were often resolved by the patent office in interference proceedings.

184 *Precision v Automotive* (n 162) 819.

185 ibid 818.

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could have in the later enforcement of the patent. The court pointed out in this regard that such doctrine 'closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant.'[186] In the specific context of patents, and considering the public interest at stake, the court emphasised that

> this doctrine assumes even wider and more significant proportions. For if an equity court properly uses the maxim to withhold its assistance in such a case, it not only prevents a wrongdoer from enjoying the fruits of his transgression, but averts an injury to the public.[187]

The court did recognise, however, that this does not require the plaintiffs to have absolutely flawless background or have led blameless lives, though 'it does require that they shall have acted fairly and without fraud or deceit as to the controversy in issue.'[188] The question on whether the patents were actually valid was not even considered.[189]

With this decision, hence, the grounds for the inequitable conduct doctrine were established. Which concrete behaviours could actually amount to inequitable conduct, however, remained an unclear issue, for the decision of the Supreme Court offered little guidance as to the specific scope of the patent applicants' duties.[190] The Patent Act in force at that time was also of little help: among the list of defences available to the defendant against infringement actions, it merely provided for a general defence based on falsehood of the patent document or surreptitious or unjust procurement of the patent right.[191]

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186 ibid 814.

187 ibid 815.

188 ibid 814-15.

189 *Precision Instrument Manufacturing Co v Automotive Maintenance Machinery Co* 143 F 2d 332, 339 (7th Cir 1944).

190 Sean M O'Connor, 'Defusing the Atomic Bomb of Patent Litigation: Avoiding and Defending Against Allegations of Inequitable Conduct after McKesson *Et Al*' (2009) 9 J Marshall Rev Intell Prop L 330, 339-40.

191 The Patent Statute stated that a defendant in an infringement action 'may prove on trial any one or more of the following special matters: First: That for the purpose of deceiving the public the description and specification filed by the patentee in the patent office was made to contain less than the whole truth relative to his invention or discovery, or more than is necessary to produce the desired effect; or, Second: That he had surreptitiously or unjustly obtained the patent for that which was in fact invented by another…' § 61 US Patent Act (1870).

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B. The Development of the Inequitable Conduct Doctrine and the Duty of Candour

In 1949, only a few years after the Supreme Court's *Precision v Automotive* decision, the US Patent Office issued the Rules of Practice in Patent Cases, which were incorporated into the Code of Federal Regulations under title 37. These rules simply provided under § 1.56—'Rule 56'—that any application fraudulently filed or in connection with which any fraud was practiced or attempted on the Patent Office could be stricken from the files.[192] What exactly constituted fraud was, again, not specified, and even though the rule was passed after the decisions of the US Supreme Court on inequitable conduct, the way they should interplay was not clarified. In the years that followed, it would become a task for the lower courts to define the exact scope of the inequitable conduct defence and to develop its standards.

The first decisions by the lower courts on inequitable conduct already acknowledged that, in order to successfully raise such a defence, the defendants would have to prove that the misconduct had been both culpable and material to patentability.[193] The exact definition of these requirements became the subject of intense debate and led the courts to experiment with many different standards.[194] Furthermore, as the doctrine evolved, it came to embrace not only flagrant affirmative misconducts clearly intended to deceive the Patent Office, as it did in its origins, but also omissions and concealments of information.[195]

Following this thread of decisions, in 1977 the USPTO amended Rule 56 in an attempt to codify the guidelines that had been drawn by the copious case law. The new version of Rule 56 represented a strong change compared to the earlier version, as it defined in a much more detailed way the scope of the duty of candour and the persons who were actually bound by it.[196] The new version, which preserved the jurisdiction of the USPTO to strike patent applications itself, expressly provided that the duty of candour entails for patent applicants a duty to disclose information they are aware of, which is material to the examination of the application and further offered a definition of materiality. Moreover, it provided that the duty

192 37 CFR (1949) § 1.56. This also entailed that the issue of fraud would not only be discussed in court, but also at the USPTO.
193 Goldman (n 176) 53-54.
194 See text at nn 222ff.
195 Goldman (n 176) 56-58.
196 Donald S Chisum, *Chisum on Patents* (LexisNexis) para 11.03[4][b][i].

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of candour not only lied upon the inventor, but also upon the patent attorneys and any other person substantially involved in the procedure. Despite a few succeeding amendments, this version of Rule 56 still constitutes the basic structure of the Rule 56 that is in force today.

In the years that followed, the lower courts interpreted Rule 56 as a mere codification of existing case law,[197] denoting that the same conduct that could prevent the enforcement of a patent due to inequitable conduct allowed the USPTO, if discovered before grant, to deny the issuance of the patent.[198] But regardless of this apparent harmony, headaches would emerge before long. The uncertainty generated by the variety of different standards employed by the courts and the easiness with which such a defence was asserted soon prompted concerns among judges, as they perceived that the focus in patent suits was shifting from core issues like validity or infringement to a secondary question like the morality of the patent owner.[199]

It was precisely during this period of time that the Federal Circuit was created, with the predominant purpose of increasing legal certainty and efficiency.[200] Having a more positive view of the patent system,[201] many expected that this new court would transform the inequitable conduct doctrine into a less reachable defence for the defendants, but this did not happen.[202] Quite on the contrary, the Federal Circuit adopted the inequitable conduct doctrine as a tool for fostering full disclosure to the patent of-

197 ibid para 11.03[4][b][ii].

198 *Norton v Curtiss* 433 F 2d 779, 792 (CCPA 1970).

199 *Re Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions* 538 F 2d 180, 196 (8th Cir 1976). This trend might have also been stimulated by district courts that, feeling uncomfortable with complex technical cases, preferred to solve them based on issues that they could more easily comprehend. Goldman (n 176) 67.

200 Rochelle C Dreyfuss, 'The Federal Circuit: A Case Study in Specialized Courts' (1989) 64 NYU L Rev 1, 3. See also Martin J Adelman, 'The New World of Patents Created by the Court of Appeals for the Federal Circuit' (1987) 20 U Mich J L Refom 979, 982 ('The Federal Circuit was not created solely because the patent system was so important that it merited its own court. Rather, the creation of the Federal Circuit was also an outgrowth of the dissatisfaction with the functioning of both the Supreme Court and the federal appellate courts.').

201 In one of its early decisions, the Federal Circuit acknowledged that the need to discourage dishonest conducts at the patent office needed to be balanced with the basic policies underlying the patent system, like encouraging the disclosure of inventions and stimulating investments on innovation. *Rohm & Haas Co v Crystal Chemical Co* 722 F 2d 1556, 1571 (Fed Cir 1983).

202 Goldman (n 176) 70.

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fice[203] and hence relaxed the degree of fault required and adopted a relatively lax definition of materiality.[204] What is more, it corroborated that a finding of inequitable conduct had severe consequences for the patent owner: it not only barred the enforcement of the claim under consideration, but also every other claim in the patent.[205] In fact, the Federal Circuit later extended the effects of unenforceability not only to the patent at issue, but also to other related patents in the same technology family.[206] All in all, the defence became an irresistible tool for defendants in infringement suits[207] due to the relatively low standard of proof and the immense reward in case of success.[208] Not surprisingly, one of the Judges of the Federal Circuit soon declared that 'the habit of charging inequitable conduct in almost every major patent case has become an absolute plague.'[209] The doctrine, indeed, had expanded into a much broader form than the very thin Supreme Court case law on which it was built.[210]

In this light, a few attempts were made to bring some order and control the proliferation of inequitable conduct accusations, like an *en banc* decision in 1988 addressing the intent standard.[211] That same year, the patent office announced that it would no longer investigate or reject patent applications on the basis of fraud,[212] emphasising that it was not the best forum in which to discuss these issues, particularly as to the 'intent to mislead' the examination.[213] Since then, the patent applicant's behaviour became an issue that can only be discussed before the courts. Soon after that, in 1992, the Patent Office also amended Rule 56, basically modifying the ma-

203 *American Hoist & Derrick Co v Sowa & Sons Inc* 725 F 2d 1350, 1363 (Fed Cir 1984).
204 Dreyfuss (n 200) 21-22.
205 *JP Stevens & Co Inc v Lex Tex Ltd* 747 F 2d 1553, 1561 (Fed Cir 1984).
206 *Consolidated Aluminum Corp v Foseco Int'l Ltd* 910 F 2d 804, 808-12 (Fed Cir 1990).
207 Nolan-Stevaux (n 182) 148.
208 Taylor (n 173) 65.
209 *Burlington Industries Inc v Dayco Corp* 849 F 2d 1418, 1422 (Fed Cir 1988).
210 Robert P Merges and John F Duffy, *Patent Law and Policy: Cases and Materials* (6th edn, LexisNexis 2013) 1057.
211 *Kingsdown Medical Consultants, Ltd v Hollister Inc* 863 F 2d 867 (Fed Cir 1988) (deciding that a finding that a particular conduct amounts to gross negligence does not of itself justify an inference of intent to deceive).
212 Notice, Patent and Trademark Office Implementation of 37 CFR 1.56 of 8 September 1988 (1095 USPTO Official Gazette 16, 11 October 1988).
213 Chisum (n 196) para 11.03[4][b][v].

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teriality standard, although its effect on the inequitable conduct doctrine remained unclear.[214]

Notwithstanding the above, allegations of inequitable conduct continued to rise in the following decades, albeit very rarely in a successful way.[215] As the number of inequitable conduct allegations increased, so did the concerned voices from courts, practitioners and academics due to the substantial strain it caused on the patent system and the high costs it entailed for the parties.[216] A large number of solutions were suggested, many of which advocated for a more economic or utilitarian approach, ie to use the defence as a tool to optimise the quantity and quality of information available to examiners.[217] In 2011, immersed within this intense debate, the Federal Circuit issued an *en banc* decision in the *Therasense* case with the clear aim of controlling the 'plague' and providing stricter standards of analysis.[218] Almost simultaneously, the US Congress passed the AIA, which included—among other significant amendments to the Patent Act—the introduction of a post grant procedure called 'Supplemental Examination',[219] with the same purpose of reducing the number of inequitable conduct-based challenges.[220] The effects that these new developments will have on future litigation remain to be seen.

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214 ibid.

215 Mack (n 165) 156 ('from 2000 to 2004, an inequitable conduct adjudication appeared in 16% to 35% of all reported patent opinions'); Christian E Mammen, 'Controlling the "Plague": Reforming the Doctrine of Inequitable Conduct' (2009) 24 Berkeley Tech L J 1329, 1358 (in 2008 inequitable conduct was pled as a defence in 40% of the patent cases litigated in the US, but it was rejected in 99.65% of them).

216 Nolan-Stevaux (n 182) 148.

217 See, among many others, Paul M Janicke, 'Do We Really Need So Many Mental and Emotional States in United States Patent Law?' (2000) 8 Tex Intell Prop L J 279; Mack (n 165); Mammen (n 215); Christopher A Cotropia, 'Modernizing Patent Law's Inequitable Conduct Doctrine' (2009) 24 Berkeley Tech L J 723; Cotter, 'An Economic Analysis of Inequitable Conduct' (n 173).

218 *Therasense* (n 167). Already before the decision, the Federal Circuit had been applying an inequitable conduct standard stricter than that applied by the lower tribunals it reviews. Lee Petherbridge, Jason Rantanen and Ali Mojibi, 'The Federal Circuit and Inequitable Conduct: An Empirical Assessment' (2011) 84 S Cal L Rev 1293, 1349.

219 § 257 US Patent Act. See text at nn 110-111 in ch 1.

220 Lisa A Dolak, 'America Invents the Supplemental Examination, but Retains the Duty of Candor: Questions and Implications' (2012) 6 Akron Intell Prop J 147, 148. This new procedure essentially allows patent owners to 'clean and polish' their patents before they go to court, as their patents may not be held unenforceable due to inequitable conduct if the pertinent information is considered dur-

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C. Standards for Finding Inequitable Conduct

Regardless of whether it constitutes an affirmative or a negative conduct, the case law has consistently required defendants to show two essential elements in order to make a case of inequitable conduct in a patent infringement suit, namely materiality and intent.[221] That is, a defendant who raises an inequitable conduct defence should demonstrate both that the patentee's conduct had a significant effect on the decision of the patent office and that the patentee had the specific purpose to mislead the patent office. The precise definition of these elements has been the subject of different interpretations since the very first decisions.

I. Intent

Already in 1945, with its seminal decision in *Precision v Automotive*, the US Supreme Court acknowledged that only wilful misbehaviours could furnish sufficient ground for an inequitable conduct defence,[222] suggesting therefore that the element of intent had a significant role to play. During the first years, this element was interpreted in a rather restrictive fashion and most decisions were inclined to allow good faith as sufficient justification, but in the early 1970s a shift in the overall perception of the public interest surrounding the patent system inspired a number of courts to reconsider this stance.[223] With the purpose of balancing the protection granted by a patent with other public policy considerations, such as the importance of having a patent procedure free from scams, courts began to recognise that gross negligence could in some cases constitute sufficient proof of intent.[224] Over time, most courts accepted gross negligence as the new standard of culpability,[225] some of them explicitly stating that subjective

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ing a Supplemental Examination. Dennis Crouch, 'Supplemental Examination: Inequitable Conduct Amnesty and Beyond' (*Patently-O*, 16 September 2012) <www.patentlyo.com/patent/2012/09/supplemental-examination-inequitable-conduct-amnesty-and-beyond.html> accessed 14 February 2018.

221 Roger E Schechter and John R Thomas, *Principles of Patent Law* (Thomson/West 2004) 258.

222 *Precision v Automotive* (n 162) 815.

223 Goldman (n 176) 54.

224 *Norton v Curtiss* (n 198) 796.

225 Chisum (n 196) para 19.03A[4][a].

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good faith of the patent counsel does not necessarily immunise the possibility of an inequitable conduct case.[226]

The Federal Circuit later recognised this breadth in the intent requirement as a decisive factor that had contributed to the frenetic proliferation of the defence, and in 1988 rendered an *en banc* decision in *Kingsdown* in an attempt to retrace the lax definition of culpability back to the vogue. In a unanimous decision, the Federal Circuit stated that gross negligence would not suffice and that the involved conduct 'must indicate sufficient culpability to require a finding of intent to deceive'.[227]

From then onwards, courts have consistently applied this standard, but time would show that this tuning on the intent standard alone was not able to reduce the exaggerated number of inequitable conduct allegations and that further adjustments were necessary.[228] The Federal Circuit in *Therasense* thus revised several elements of the inequitable conduct doctrine, although in the area of culpability it simply ratified the narrow definition of intent advocated by *Kingsdown* and clarified that, in case of omissions, the defendants should prove 'that the applicant knew of the reference, knew it was material, and made a deliberate decision to withhold it.'[229]

II. Materiality

Although the Supreme Court did not explicitly include a materiality requirement when it first coined the inequitable conduct defence, courts soon recognised it as an essential factor to take into account.[230] Yet considering the limited guidance offered by the earlier cases, different standards soon emerged.

Over time, courts have in fact developed at least three different criteria: (i) the subjective 'but for' standard; (ii) the objective 'but for' standard; and (iii) the 'but it may have' standard.[231] Under the subjective 'but for' standard, defendants are required to show that the misbehaviour caused the examiner to issue the patent and that she would not have done so other-

226 *Argus Chemical Corp v Fibre Glass-Evercoat Co Inc* 759 F 2d 10, 14 (Fed Cir 1985).
227 *Kingsdown v Hollister* (n 211) 876.
228 *Therasense* (n 167) 1291.
229 ibid 1290.
230 Taylor (n 173) 58.
231 *Am Hoist* (n 203) 1362.

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wise.[232] Under the objective 'but for' standard, on the other hand, courts would only find inequitable conduct in those cases where the patent not only *would* not have been issued but also *should* not have been issued.[233] Under this standard, thus, a defendant should not only show that the examiner would have refused the application if it had been aware of the truth, but also that said refusal would have been appropriate and that the application does not objectively meet the patentability requirements.[234] In other words, the inequitable conduct determination would be congruent with the validity determination: inequitable conduct would only exist if the patent can be invalidated by the courts. The 'but it may have' standard, finally, emerged some time later as an additional, more expansive test in search of imposing a higher duty of honesty upon applicants.[235] Based on this test, it would be sufficient for a defendant to demonstrate that the misbehaviour *might* have influenced the decision of the examiner.[236]

In addition to these court-developed criteria, the USPTO has also contributed with two different materiality standards when defining the duty of candour—and both have been occasionally cited by the courts. In 1977, when Rule 56 for the first time included a definition of materiality, it implemented a 'reasonable examiner' standard, albeit very similar to the 'but it may have' standard.[237] Based on that standard, information is material 'where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.'[238] But in 1992, when the USPTO amended Rule 56, it adopted yet a different standard, under which information is considered material when it establishes 'a prima facie case of unpatentability'.[239] Courts have recognised the standards given by the USPTO as additional standards for assessing inequitable conduct and considered it an appropriate starting point for any discussion of materiality, [240] which denotes that, altogether, they have dealt throughout time with at least five different criteria to define materiality.

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232 *Plastic Container Corp v Continental Plastics of Oklahoma Inc* 607 F 2d 885, 899 (10th Cir 1979).
233 ibid.
234 ibid.
235 Goldman (n 176) 60.
236 *Plastic Container* (n 232) 899.
237 *Am Hoist* (n 203) 1362.
238 37 CFR (1977) § 1.56.
239 37 CFR § 1.56(b)(1).
240 *Am Hoist* (n 203) 1362-63; *Digital Control Inc v Charles Machine Works* 437 F 3d 1309, 1316 (Fed Cir 2006).

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Whilst most lower court decisions dealing with inequitable conduct ended up adopting either the 'but it may have' standard or the 'reasonable examiner' test,[241] the variety of different standards and their unpredictable outcome led to a high level of legal uncertainty.[242] In 2011, thus, in a new attempt to control the overflow of inequitable conduct accusations, a majority of Federal Circuit judges delivered an *en banc* decision in the *Therasense* case,[243] which shed some light on the doctrine and, among other adjustments, recognised a unique definition of materiality. Not surprisingly, the majority favoured a narrow criterion and opted for the 'but-for' test as the governing materiality standard.[244] Hence, inequitable conduct should only exist if it can be proven that the USPTO would not have granted the patent had it been aware of all the facts. It is not entirely clear whether they intended to adopt an objective or a subjective 'but for' standard, as the judgment includes statements pointing in both directions,[245] but the language of the text seems slightly inclined towards the subjective criterion.[246] In any case, little doubt remains that it leans in the direction of a more restricted yardstick, hoping to result in less baseless inequitable conduct accusations in the future.

It should be noted, finally, that the new definition of materiality recognises one exception in cases of flagrant misbehaviours.[247] Indeed, in order to give more flexibility to the doctrine, and incorporating elements from the unclean hands doctrine from which it stems, the Federal Circuit stated that, in cases of affirmative egregious misconducts, the defendants do not need to show that the misbehaviour was but-for material.[248] Yet because this exception only applies to affirmative conducts, any omission of the applicant to submit information, eg on prior sales or relevant prior art—which represent the vast majority of inequitable conduct cases today—will always be measured under the but-for yardstick.

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241 Chisum (n 196) para 19.03A[3][a]; Mueller (n 164) 557.
242 Erstling (n 160) 343.
243 *Therasense* (n 167).
244 ibid 1291.
245 Cotter, 'An Economic Analysis of Inequitable Conduct' (n 173) 745.
246 *Therasense* (n 167) 1291 ('… even if a district court does not invalidate a claim based on a deliberately withheld reference, the reference may be material if it would have blocked patent issuance under the PTO's different evidentiary standards.').
247 *Therasense* (n 167) 1292.
248 ibid 1292-93.

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III. Burden of Proof and the 'Sliding Scale'

In view of the gravity that a charge for inequitable conduct entails, courts have traditionally imposed defendants a heavy burden of persuasion.[249] In this regard, case law has uniformly required proof of inequitable conduct—ie, proof of materiality and intent—to be clear and convincing.[250] That does not entail, however, that said conduct is to be proved directly and that no inferences can be made. On the contrary, courts have acknowledged that inequitable conduct—and particularly the intent element—is rarely provable by direct evidence and hence that circumstantial or indirect evidence can be equally suitable.[251]

Despite the high burden of proof imposed upon the defendants, courts had historically also recognised that, once both materiality and intent had been proven, it was possible for the judge to weigh these two elements together by performing some kind of 'sliding scale' exercise: the greater the relevance of the misconduct, the lesser the degree of intent that needed to be shown and vice versa.[252] In *Therasense*, however, the Federal Circuit has emphatically rejected the employment of any 'sliding scale' and further emphasised that evidence on intent is to be assessed independently from evidence on materiality.[253]

D. Types of Conducts that can be Held Inequitable

After having analysed the standards for finding inequitable conduct, it is important to examine at this point which of the many actions that the patent applicant carries out—or fails to carry out—during the prosecution of a patent application are the ones that can later render a patent unenforceable in practice. As a general principle, the inequitable conduct defence can be raised against acts executed by any person in any way associated with the filing and prosecution of a patent application.[254] This means that the conducts of inventors, patent attorneys, agents, or any individual

249 Chisum (n 196) para 19.03B[5][a].
250 *Norton v Curtiss* (n 198) 797; *Star Scientific Inc v RJ Reynolds Tobacco Co* 537 F 3d 1357, 1365 (Fed Cir 2008).
251 Schechter and Thomas (n 221) 263.
252 *JP Stevens* (n 205) 1560; *NV Akzo v EI DuPont de Nemours* 810 F 2d 1148, 1153 (Fed Cir 1987).
253 *Therasense* (n 167) 1290.
254 37 CFR § 1.56 (a).

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involved in the procedure before the patent office can equally become relevant when the inequitable conduct defence is raised.[255] Such conducts can take place either at the time of filing the patent application or in any other subsequent stage.

But which are the specific behaviours that can actually trigger the applicability of the inequitable conduct doctrine? In view of the enormous complexity of the patent procedure, the range of different conducts that can become relevant under this doctrine is extremely broad. Generally speaking, these misbehaviours can emerge by way of either a positive or a negative act (ie, commission or omission) and they are frequently sorted into three basic categories: (i) failure to disclose material information; (ii) submission of false material information, or (iii) affirmative misrepresentation of a material fact.[256] This catalogue might appear somehow arbitrary, as it can be difficult at times to draw a sharp line between them. Concealing material information when responding to an office action, eg, might be difficult to distinguish from an affirmative misrepresentation.[257] There are, in any case, specific scenarios that have traditionally attracted more concern than others and which have been in the eye of the storm in most inequitable conduct lawsuits. In this regard, the failure to disclose a prior public use of the invention, the failure to cite known relevant prior art and the submission of false information are probably the patterns of behaviour most frequently denounced and thus justify a closer glance.

I. Failure to Disclose the Prior Public Use of an Invention

As it was mentioned above, one of the pivotal requirements of patentability is the absolute novelty of the invention. This implies that, in principle, if an inventor or any third party in any way discloses the invention to the public before the date of filing of the application (eg by publishing, selling, or just publicly using it), the patent application must be rejected.[258]

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255 37 CFR § 1.56 (c). See also Chisum (n 196) para 19.03A[4][e].

256 *Molins PLC v Textron Inc* 48 F 3d 1172, 1178 (Fed Cir 1995); Mueller (n 164) 552-53.

257 Under the Restatement (Second) of Torts, the concealment of information is actually equated with affirmative misrepresentation in terms of common law fraud. *Restatement (2d) of Torts* (1977) para 550. See also *Therasense* (n 167) 1314, fn 3 (dissenting opinion by J Bryson and others).

258 Under US law, an exception exists in circumstances where the prior disclosures are made by the patent applicants themselves: in these cases, applicants are

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Applicants are required to file an oath stating that they believe themselves to be the original and first inventors and to disclose any material prior art they are aware of,[259] which evidently includes prior disclosures by the inventors themselves.[260]

Situations in which inventors bring their inventions to the market or present them in a catalogue before deciding to file for a patent are certainly not implausible. The inventor may, eg, realise too late about the value of the invention, or have difficulties procuring sufficient funding, or could just be negligent. Under these circumstances, it is not difficult to conceive a patent applicant attempting to hide the prior disclosure of the application to the patent office. The fact that this kind of public disclosures are less likely to be found by the examiner could act as a further inducement.[261]

It is not surprising, hence, that in a large number of cases courts have found patents unenforceable due to a failure to disclose relevant uses, such as prior sales or prior publications of the invention.[262] These conducts should naturally meet the minimum standards of materiality and intent like any other inequitable conduct case, but in practice that will rarely constitute a major issue once the prior disclosure is discovered. It will often be hard for patentees to argue that they were not aware of their own use or that their concealing did not affect the decision of the examiner. Some other situations, however, might present more controversial questions. An applicant could, eg, fail to disclose a prior use convinced that is was an experimental use which did not affect the patentability of the invention.[263]

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awarded a grace period of one year as of the date of said disclosure in order to file the application. § 102(b)(1) US Patent Act. The EPC also provides for an analogous exception, although with a much more limited scope, under art 55(1).

259 37 CFR § 1.63(a)(4) and (b)(3).

260 Chisum (n 196) para 19.03A[2][a].

261 ibid.

262 Joel Davidow, *Patent-Related Misconduct Issues in US Litigation* (OUP 2010) 27-28.

263 *Monolith Portland Midwest Co v Kaiser Aluminium & Chemical Corp* 407 F 2d 288 (9th Cir 1969). In this case, the court rejected the argument on the basis that, whatever beliefs the patentee could have had, it failed to disclose the facts to the patent office. Ibid 295. See also *Manville Sales Corp v Paramount Systems Inc* 917 F 2d 544 (Fed Cir 1990) (concluding that, even if the prior use was indeed experimental, such information should still be considered material and therefore the applicant has an obligation to disclose it).

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II. Failure to Cite Known Relevant Prior Art

During the early days of the inequitable conduct doctrine, courts were rather hesitant to admit the defence on the grounds of a mere failure to disclose relevant prior art references proceeding from third parties, such as an article in a scientific journal or someone else's patent application, except in those cases where they clearly and completely anticipated the invention.[264] Instead, the first cases were targeted against more flagrant misbehaviours and the first guidelines of the USPTO remained silent about it. A general understanding appeared to prevail that it was the patent office the one who was mainly responsible for searching prior art and verifying the novelty of the invention.[265]

By the late 1960s and early 1970s, however, courts began to interpret that, in addition to the examiners' duties to search for prior art, applicants' duties also comprised the duty to disclose relevant information of which they could be aware, even if emanating from a third party and even if it did not openly anticipate the invention, provided that it could be relevant for the assessment of non-obviousness.[266] This expanded view of the patent applicant's duties was then confirmed by the Court of Customs and Patent Appeals in *Norton v Curtiss*, where the court recognised the limitations of the patent office to examine the applications and the inescapable need to rely on the applicants, which justified the highest standards of honesty and candour.[267] Consistent with this trend of the courts, the patent office amended its Rule 56 in order to also incorporate the heightened standards,[268] and later on the Federal Circuit endorsed this interpretation as well.[269] Today, the disclosure of relevant prior art by patent applicants is a

264 Chisum (n 196) para 19.03A[2][b]. See also Goldman (n 176) 56. In 1957, eg, a court stated that the applicant should disclose prior art that describes the invention or comes so close that it clearly and obviously anticipates it. *United States v Standard Electric Time Co* 155 F Supp 949, 952 (D Mass 1957).

265 Chisum (n 196) para 19.03A[2][b][i].

266 ibid para 19.03(2)(b); Goldman (n 176) 58. This was probably connected to the introduction of the non-obviousness requirement in 1952. Goldman (n 176) 57.

267 *Norton v Curtiss* (n 198) 794.

268 37 CFR (1977) § 1.56.

269 *Am Hoist* (n 203) 1363 ('the PTO "standard" is an appropriate starting point for any discussion of materiality, for it appears to be the broadest, thus encompassing the others, and because that materiality boundary most closely aligns with how one ought to conduct business with the PTO.').

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standard step in the patenting procedure and is normally carried out by the submission of an information disclosure statement (IDS).[270]

Over time, failure to cite prior art has become the most recurrent type of behaviour discussed in inequitable conduct cases.[271] The most frequent categories of prior art references that applicants fail to cite are patent documents (which include both granted patents and patent applications) and publications in journals, brochures or other mediums.[272] The applicants, however, are expected to cite not only this 'traditional prior art' but also any other kind of information an examiner could consider relevant to allow a patent. In this regard, the failure to disclose prior art cited by foreign patent offices in parallel proceedings,[273] the submission of untranslated or partially translated foreign references,[274] the failure to disclose on-going litigation involving the patent application,[275] the failure to cite connected, co-pending applications at the USPTO[276] and even the failure to cite information important for enablement or best mode[277] have been considered by courts as relevant behaviours that can render the patents unenforceable. What is more, the concealment of a prior art document could amount to inequitable conduct even if the examiners later on find it by themselves during examination and nevertheless grant the patent.[278]

With regard to the timing of the disclosure, the Federal Circuit first appeared to suggest that the disclosure should be immediate and that any further disclosure, even if done before the patent office started examining the

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270 37 CFR §§ 1.97-1.98.

271 Schechter and Thomas (n 221) 258.

272 Davidow (n 262) 28.

273 *Molins v Textron* (n 256); USPTO, Manual of Patent Examining Procedure (9th edn, 2014) (US MPEP) para 2001.06(a).

274 David Hricik, 'Where The Bodies Are: Current Exemplars of Inequitable Conduct and How to Avoid Them' (2004) 12 Tex Intell Prop L J 287, 303-04.

275 *Critikon Inc v Becton Dickinson Vascular Access Inc* 120 F 3d 1253 (Fed Cir 1997); US MPEP, para 2001.06(c)

276 *Dayco Products Inc v Total Containment Inc* 329 F 3d 1358 (Fed Cir 2003); US MPEP, para 2001.06(b).

277 Davidow (n 262) 11-16.

278 *AB Dick Co v Burroughs Corp* 798 F 2d 1392, 1396-98 (Fed Cir 1986). Other decisions, however, have suggested that, when a reference is already before the examiner, a finding of inequitable conduct is improper. *Molins v Textron* (n 256). Along the same lines, see also Edwin S Flores and Sanford E Warren Jr, 'Inequitable Conduct, Fraud, and Your License to Practice before the United States Patent and Trademark Office' (2000) 8 Tex Intell Prop L J 299, 311.

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patent application, could not purge the behaviour.[279] With the entering into force of the AIA, however, it is clear that patentees are allowed to bring to the attention of the examiner prior art information even after the grant of the patent, via the Supplemental Examination procedure, that—if successful—immunises the patent against inequitable conduct attacks.[280] In any case, patent owners are not required to disclose information that comes to their attention after the patent issues.[281]

Finally, it should be borne in mind that courts have unanimously stated that patent applicants are not expected to cite prior art of which they have no knowledge, as the duty to disclose relevant prior art does not entail for them a duty to carry out a special prior art search themselves.[282] Furthermore, courts have also refused to find inequitable conduct in cases where the undisclosed prior art reference was merely cumulative to other references already available to the examiner.[283]

III. Submission of False Information

Instead of simply concealing relevant data from the patent office, applicants may also attempt to persuade the examiner of the merits of their inventions through affirmative, deceitful behaviours by, eg, submitting false material information or making misleading statements. The fact that the patent office will not normally have the ability to verify or challenge the data renders these behaviours particularly threatening.[284]

A typical example of such behaviour is the submission of data containing inaccurate results or revealing false benefits of an invention. In *Frazier v Roessel*,[285] eg, the applicant had claimed to have invented a new camera-lens and had submitted to the patent office a video-recording in an attempt to persuade the examiner about the advantages of the invention. The court, however, later learned that the recording had been shot with a different lens. It consequently judged that this behaviour constituted a case of in-

279 *Driscoll v Cebalo* 731 F 2d 878 (Fed Cir 1984); *FMC Corp v Hennessy Industries Inc* 836 F 2d 521 (Fed Cir 1987).
280 § 257(c)(1) US Patent Act.
281 Chisum (n 196) para 19.03A[2][b][iv].
282 See, eg, *Am Hoist* (n 203) 1362.
283 *JP Stevens* (n 205) 1560; See also 37 CFR § 1.56(b) (clarifying that information cumulative to date already available for the examiner is not considered material).
284 Chisum (n 196) para 19.03A[2][d]; Hricik (n 274) 306.
285 *Frazier v Roessel Cine Photo Tech Inc* 417 F 3d 1230 (Fed Cir 2005).

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equitable conduct and declared the patent unenforceable. Similarly, courts have also declared the unenforceability of patents in cases where the test data that had been submitted was incomplete and inaccurate,[286] where the conditions of the test had been manipulated[287] and where the provider of an affidavit had deceitfully been presented as independent.[288] In fact, one of the cases that gave birth to the inequitable conduct doctrine concerned a journal publication that had been made by an allegedly independent expert.[289] Even a misleading assertion in the patent specification itself can render the patent unenforceable, eg if it falsely implies that a test has been run showing the invention's increased efficacy or surprising results.[290]

Be that as it may, courts have also often counselled caution when dealing with allegedly misleading behaviours so as not to interfere with the duty of advocacy of the attorneys.[291] Indeed, the line between this duty and a misleading statement is sometimes blurry. Courts have repeatedly stated, eg, that disclosing prior art and then persuading the examiner about the inventiveness of the application, even if that involves mischaracterising the relevance of a prior art reference, should not be considered inequitable conduct as long as it is not misleading.[292]

IV. Other conducts

In addition to the more emblematical patterns of behaviour cited above, there are many other different sets of conducts before the patent office that can later lead to a patent being declared unenforceable. The length and

286 *Monsanto Co v Rohm & Haas Co* 456 F 2d 592 (3rd Cir 1972).
287 Davidow (n 262) 39.
288 ibid 40.
289 *Hazel-Atlas Glass v Hartford-Empire* (n 179).
290 *Purdue Pharma LP v Endo Pharmaceuticals Inc* 410 F 3d 690 (Fed. Cir. 2005).
291 *Mueller Brass Co v Reading Industries Inc* 352 F Supp. 1357, 1379-80 (ED Pa 1972) ('two conflicting principles tear at an attorney practicing before the patent office. One is that the proceeding is not adversary, so the attorney therefore owes a high duty of candor to the examiner. The second is that the attorney has a duty of advocacy to his client. One should not forget in this context that the examiner himself is or should be an advocate for the public interest and should not be too easily swayed by the applicant's attorney.').
292 *Gambro Lundia AB v Baxter Healthcare Corp* 110 F 3d 1573, 1581 (Fed Cir 1997); *Innogenetics, NV v Abbott Laboratories* 512 F 3d 1363, 1379 (Fed Cir 2008). See also Hricik (n 274) 302 (arguing that examiners are presumed to have studied the prior art and can decide its relevance for themselves).

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complexity of the patent application procedure require from the applicants the performance of an immense range of different acts and any of them can become a ticking bomb.

Courts have found, eg, that omitting an inventor[293] or declaring a false priority date[294] when filing a patent application can also render the patent unenforceable. Furthermore, even if applicants disclose all relevant prior art they are aware of, a court could find inequitable conduct if such disclosure is done in such a way that the relevant piece of prior art is submerged in a long list of less relevant references so that the examiner overlooks it.[295] In those cases, courts have stated, applicants have an additional duty to explain the relevance of the prior art.[296]

Other less significant behaviours have also been considered to render a patent unenforceable, even if they do not have any impact on the grant of the patent. In that sense, misrepresentations in order to pay reduced fees as a small entity[297] or a false statement in a Petition to Make Special[298] have been considered sufficiently material to render the patent unenforceable. It has been argued that even the deliberate delaying of the examination procedure could be considered a case for inequitable conduct.[299]

As a side note, courts in the past have also found inequitable conduct in circumstances where the applicant had failed to disclose the best mode to practice an invention.[300] This situation, however, is not likely to be seen in the future, since the AIA has eliminated the possibility to declare a patent unenforceable on the basis of a failure to disclose the best mode.[301]

Last, but certainly not least, it cannot be overlooked that the vast majority of cases cited in the preceding paragraphs were decided before the *en*

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293 *Frank's Casing Crew & Rental Tools Inc v PMR Technologies Inc* 292 F 3d 1363 (Fed Cir 2002). See also Davidow (n 262) 1, 4-6.

294 Davidow (n 262) 42.

295 *Penn Yan Boats Inc v Sea Lark Boats* 359 F Supp. 948 (SD Fla 1972), affd 479 F 2d 1328 (5th Cir 1973); *Molins v Textron* (n 256) 1184.

296 Chisum (n 196) para 19.03A[2][b][ii].

297 *Nilssen v Osram Sylvania Inc* 504 F 3d 1223, 1231 (Fed Cir 2007).

298 *Scanner Technologies Corp v Icos Vision Systems Corp NV* 528 F 3d 1365, 1375 (Fed Cir 2008). A Petition to Make Special is a request that an applicant can make to the USPTO to promptly examine the application if special circumstances are revealed. US MPEP, para 708.02.

299 Davidow (n 262) 43.

300 *Consolidated Aluminum* (n 206) 808.

301 Paul M Janicke, 'Overview of the New Patent Law of the United States' (2013) 21 Tex Intell Prop L J 63, 76.

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banc decision in *Therasense* and could thus be solved differently should they be referred to the courts today.

E. Disciplinary and Criminal Sanctions

Irrespective of the effects that an inappropriate conduct before the USPTO might have on the enforceability of a patent, such conduct can also have disciplinary or criminal consequences on the patent attorneys or agents—and in some cases even on the applicants themselves.[302]

With regard to the attorneys and agents, the USPTO Rules provide that all practitioners engaged in practice before the Office are subject to the disciplinary jurisdiction of the USPTO,[303] which in practice is predominantly a responsibility of the USPTO's Office of Enrollment and Discipline.[304] The USPTO Rules further provide for a specific set of Rules of Professional Conduct comprising a long list of instructions on how practitioners are expected to conduct themselves before the Office,[305] and contravening any of these can lead to a disciplinary measure.[306] These disciplinary rules include, inter alia, a reminder to comply with the duty of disclosure provisions (ie Rule 56),[307] a prohibition to make false statements[308] or to knowingly offer false evidence[309] and a ban on bringing frivolous claims,[310] as well as numerous other situations traditionally covered by ethical regulations, such as the missing of deadlines or conflicts of interests. The sanctions that the Office can impose upon the practitioners include an exclusion from practice, a suspension from practice and a reprimand or censure.[311]

As it seems that any case of inequitable conduct by a practitioner would also violate the Rules of Professional Conduct,[312] one could assume that every finding of inequitable conducts by the courts entails a disciplinary

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302 Chisum (n 196) para 19.03B[6][j].
303 37 CFR § 11.19(a); § 32 US Patent Act.
304 37 CFR § 11.2 (b).
305 ibid §§ 11.100-11.901.
306 ibid § 11.19(b)(1)(4).
307 ibid § 11.303(e).
308 ibid § 11.303(a)(1).
309 ibid § 11.303(a)(3).
310 ibid § 11.301.
311 ibid § 11.20.
312 *Jaskiewicz v Mossinghoff* 822 F 2d 1053, 1057 (Fed Cir 1987). See also Ian G McFarland, 'In the Wake of *Therasense* & *Nisus Corp*.: How Can Patent Attorneys

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sanction for the patent attorney. The figures from the Office of Enrollment and Discipline, however, reveal a different story: the disciplinary sanctions are extremely rare and clearly outnumbered by the inequitable conduct cases.[313] Such discrepancy might be explained by the fact that inequitable conduct can also be committed by the applicants themselves or other individuals who are not subject to the USPTO's disciplinary rules,[314] although a more plausible explanation might be that the ominous nature of the disciplinary proceedings has left them as a last resource only.[315]

In addition to the disciplinary sanctions, practitioners and even non-practitioners may also be subject to criminal sanctions for their conduct before the USPTO.[316] The Criminal Code of the US provides that whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch, knowingly and wilfully (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined or imprisoned not more than 5 years.[317] In practice, however, criminal prosecution for patent fraud has been extremely rare, and it seems that only egregious cases with outrageous factual misstatements could be the object of a criminal punishment.[318]

2. *The Duties of the Patent Applicant in Europe*

As stated above, although the procedures and requirements to obtain a patent in the EPC and USPTO are relatively similar in many aspects, a number of significant differences still exist between the two jurisdictions and the general legal framework that surrounds the responsibilities of patent applicants vis-à-vis the patent office constitutes one of the most no-

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Defend Themselves against Allegations of Inequitable Conduct?' (2011) 78 Tenn L Rev 487, 497.

313 See Flores and Warren (n 278) 315. Decisions of the Office of Enrollment and Discipline of the USPTO are available at <http://e-foia.uspto.gov/Foia/OEDReadingRoom.jsp> accessed 14 February 2018.

314 Cotropia (n 217) 765.

315 Flores and Warren (n 278) 315.

316 37 CFR §§ 1.4 and 11.18(b)(1).

317 18 USC § 1001(a).

318 Ralph D Clifford, 'Is it Time for a Rule 11 for the Patent Bar?' (2013) 53 IDEA 351, 360.

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table examples. In fact, the EPC itself does not contain any provision laying down general behavioural rules, let alone sanctions for conducting the procedure in a dishonest or deceitful way.[319] It does provide, however, that the whole procedure before the EPO is to be governed by the principles of procedural law generally recognised in the Contracting States,[320] which evidently comprise inter alia the principle of good faith.[321] Be that as it may, there can be little doubt about the strong differences that the United States and Europe show in this regard, particularly in two major points: (i) the extent of the patent applicant's duty to disclose relevant prior art, and (ii) the consequences that any dishonest conduct before the patent office can later have on the validity or enforceability of the patent.

This section, thus, focuses on these two specific facets. In the first place, it analyses the extent of the patent applicants' duties within the EPC regime. Subsequently, it evaluates whether the conduct exhibited by patent applicants during examination can have any effects during the enforcement of the patent. Since this issue is, for the most part, a question of national law, the legal regimes of the United Kingdom and Germany have been chosen as representative examples.

A. *Extent of Patent Applicants' Duties. Is there a Duty of Disclosure under the EPC?*

The way in which the EPO expects patent applicants to conduct their application procedures appears to strongly differ from the system in place in the United States. There are, it is true, a few undisputed bases which are present in every patent system. It is hardly conceivable, for instance, that the EPO could tolerate any affirmative misrepresentation or submission of

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319 The Boards of Appeal of the EPO, however, have taken into consideration the behaviour of the applicant, eg, when deciding on apportionment of costs. See Case T 0952/00 *Rokicki* (decision of the EPO Boards of Appeal of 27 November 2002) (where a granted patent was opposed by a third party and, since it was shown that the applicant had concealed evidence of relevant prior use and made false statements during the whole procedure, the Board of Appeal decided that the patentee should bear the costs incurred by the opponent).

320 EPC, art 125.

321 See, eg, Joined Cases G 5/88, G 7/88 and G 8/88 *Administrative Agreement/ MEDTRONIC* (decision of the EPO Enlarged Board of Appeal of 16 November 1990 [1991] EPO OJ 137) para 3.2; Margarete Singer and Dieter Stauder (eds), *The European Patent Convention: A Commentary* (3rd edn, Sweet & Maxwell 2003) vol 2, 525.

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false documents on the part of the patent applicants, considering the general principles of procedural law applicable to the EPO proceedings.[322] In the same vein, a duty of good faith presumably also comprises a responsibility to draw the attention of the examiner to own prior acts which may affect the patentability of the invention.[323] Yet other conditions are substantially different. Most importantly, the extent of the patent applicants' duty to disclose surrounding information on patentability, such as relevant patent documents or scientific publications, seems to be considerably narrower than in the United States.

It should be reminded at the outset that, although every patent system inherently requires some amount of disclosure, at least as regards to the substance of the invention,[324] the EPC does not explicitly provide for any affirmative duty to disclose prior art in the sense the US law does under Rule 56. It is generally recognised that, whereas in the US applicants have a stringent duty to collaborate with the examination process,[325] the EPC seems to rely less on the information provided by the applicants and to confer the examiners a more inquisitive role. In what appears to be a clear externalisation of this vision, art 114 (1) EPC stipulates that 'in proceedings before it, the European Patent Office shall examine the facts of its own motion; it shall not be restricted in this examination to the facts, evidence and arguments provided by the parties and the relief sought.'

I. Rule 42(1)(b) EPC as a Duty of Disclosure?

Interestingly, rule 42(1)(b) EPC does compel the applicant, when describing the invention in the patent specification, to 'indicate the background art which, as far as is known to the applicant, can be regarded as useful to understand the invention, draw up the European search report and examine the European patent application, and, preferably, cite the documents reflecting such art.' In view of this language, it would be possible to contend that the rule actually imposes some type of disclosure responsibilities upon the applicants, as it requires them to acknowledge and cite all relevant prior art information of which they could be aware.

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322 See, eg, § 124 PatG ('Im Verfahren vor dem Patentamt, dem Patentgericht und dem Bundesgerichtshof haben die Beteiligten ihre Erklärungen über tatsächliche Umstände vollständig und der Wahrheit gemäß abzugeben.').

323 *Hoechst Marion Roussel Ltd v Kirin-Amgen Inc* [2002] EWHC 471 (Patents) [134].

324 See, eg, EPC, art 83.

325 *Norton v Curtiss* (n 198) 794.

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There have been at least two cases at the EPO where the examining divisions have attempted to refuse patent applications on the grounds that the specifications had not acknowledged relevant prior art.[326] In both cases, relevant pieces of prior art which had not been disclosed by the applicants were found in the European search report. As the prior art references emanated precisely from the applicants themselves, the examining divisions interpreted that the requirements imposed by rule 42(1)(b) EPC had not been fulfilled. One of the examining divisions further pointed out to the fact that the German version of rule 42, unlike the English and French editions, does not include the conditioning term *preferably* when laying down the duty to cite the relevant documents, thus reinforcing the idea of a harsher responsibility upon the applicants.[327]

The Boards of Appeal of the EPO, however, forcefully discouraged such reading in both cases and interpreted instead that applicants of European patents do not have a rigorous duty to disclose relevant prior art.[328] Both Boards of Appeal indeed understood that rule 42(1)(b) EPC 'does not put a stringent obligation on the applicant to cite documents reflecting prior art known to him already at the time of filing the application.'[329] The Boards of Appeal further acknowledged that, in those cases where references to relevant prior art are missing from the specification as filed and only later noted by the examiners, said information can be later included in subsequent amendments without entailing any extension beyond the content of the application as filed, in the terms of art 123(2) EPC.[330] Rather than a duty to collaborate with the examiners in the search for prior art, thus, rule 42(1)(b) seems to be perceived as a tool for the informative purpose of the patent system, aimed at ensuring that patent specifications disclose sufficient information to the public about the invention and the surrounding prior art.

It is thus clear that, under the current legal framework at the EPO as interpreted by the Boards of Appeal, European patent applicants do not have

326 Case T 2321/08 *Samsung Electronics* (decision of the EPO Boards of Appeal of 11 May 2009) (*Samsung I*); Case T 1123/09 *Samsung Electronics* (decision of the EPO Boards of Appeal of 17 December 2009) (*Samsung II*).

327 The German version of rule 42(1)(b) oft he EPC reads, in its relevant part, as follows: '… es sollen auch die Fundstellen angegeben werden, aus denen sich dieser Stand der Technik ergibt.'

328 EPO Board of Appeals, T 2321/08 of 11.5.2009; EPO Board of Appeals, T 1123/09 of 17.12.2009.

329 *Samsung I* (n 326) para 7.3; *Samsung Electronics II* (n 326) para 3.

330 *Samsung I* (n 326) para 8.4; *Samsung Electronics II* (n 326) para 3.

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a duty to disclose information on relevant prior art.[331] The same can be said about applicants before the major European national patent offices, like the DPMA (Germany) and the UKIPO (United Kingdom),[332] although the DPMA is entitled to require applicants, under specific circumstances and on a case-by-case basis, to disclose the state of the art to the best of their knowledge and to incorporate it into the specification.[333]

II. The Duty of Disclosure in the Travaux Préparatoires

The negotiations for the EPC took place many years after the duty of candour concerns first arose in the US, and a few decisions by national courts of the negotiating members had actually insinuated in the past that patent applicants' failure to disclose relevant prior art of which they were aware could be contrary to the obligation of good faith.[334] The issue, however, does not appear to have been comprehensively discussed while drafting the EPC. Either way, a glance at the *Travaux Préparatoires* might still offer some guidance for interpreting the convention on this matter.[335]

In the first place, parts of the debate seem to emphasise the active and inquisitive role that the patent office must have when examining the application and disregard any burden to furnish the examiners with general information that would be anyway accessible to them, such as scientific publications or other patent applications. In this regard, the debates in the *Travaux Préparatoires* draw the attention to the fact that, unlike a first-to-invent system, the first-to-file system adopted by the EPC encourages applicants to file their applications without delay. For that reason, the patent office should not expect applicants to be able to detect all the background art

331 In the same lines, see also Nöel J Akers, 'The Referencing of Prior Art Documents in European Patents and Applications' (2000) 22 World Patent Information 309, 310 ('to date, this provision has not been interpreted as placing any obligation on the applicant or his representative to inform the European Patent Office of any prior art believed to be relevant.').

332 Jan Krauß, 'Equitable Doctrines in International Patent Laws' in Toshiki Takenaka (ed), *Intellectual Property in Common Law and Civil Law* (Edward Elgar 2013) 103.

333 § 34(7) PatG. See also Akers (n 331) 310.

334 See, eg, *Re Clevite Corporation's Patent* [1966] RPC 199, 204 (Lloyd-Jacob J)

335 Vienna Convention on the Law of Treaties, art 31(2)(b).

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surrounding their inventions; this should rather be the examiners' responsibility when later studying their patentability.[336]

Additionally, it might be interesting to point out that, when the British Delegation discussed the implementation of the opposition proceedings, it suggested that they enable competitors to seek the revocation of a patent on the basis of information which could have been beyond the reach of the examiners during the application proceedings, such as the applicant's own prior use.[337] Such language seems to imply that the delegations were aware that applicants' withholding of relevant information constitutes a concrete risk that can lead to the unjustified grant of a patent. But, at the same time, they appear to suggest that an opposition procedure after the grant of the patent constitutes an adequate remedy thereto.

III. Rule 141 EPC and the Limited Duty of Disclosure

Although it is submitted that the EPC does not provide for a duty of disclosure in the sense the US does, it does envisage a number of circumstances where the applicants might nonetheless be required to submit specific types of information to the examiners, particularly in relation to search reports produced by foreign patent offices.

Firstly, although the general principle is that there is no obligation to inform the EPO about what other patent offices assess in parallel cases,[338] the EPC expressly allows EPO examiners to invite applicants, on a case-by-case basis, to provide information on prior art taken into consideration in

336 Travaux Preparatoires EPC 1973, BR/45 e/70 (Brussels, 16 December 1970), Additional Observations on the First Preliminary Draft Convention made by the Non-Governmental Organisations: Report by FICPI of 24 August 1970, para 7.

337 Travaux Préparatoires EPC 1973, BR/89 e/71 (Brussels, 18 March 1971), Reports from the Delegations to Working Party I of the Inter-Governmental Conference on the Activities of that Working Party: Report by the British Delegation, para 74; Travaux Preparatoires EPC 1973 (Luxembourg, 20-28 April 1971), Reports on Amendments and Additions to the First Preliminary Draft of a Convention Appearing in the Second Preliminary Draft: Report by the UK Delegation, para 63.

338 OLG Düsseldorf, decision of 6 June 2013, case I-2 U 60/11 [99] (in reference to European patent applications) ('Eine Verpflichtung zur Vorlage von Stellungnahmen anderer Erteilungsbehörden besteht grundsätzlich nicht, da das vorliegende Patenterteilungsverfahren von den Eintragungs- und Erteilungsverfahren anderer Schutzrechte unabhängig ist.').

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national or regional patent proceedings.[339] A failure to reply in due time results in the patent application being deemed withdrawn.[340]

Most importantly, when the Implementing Rules of the EPO were amended in 2009, they introduced for the first time an affirmative duty to spontaneously disclose that information in certain circumstances. Indeed, according to the amended version of rule 141(1) EPC, every patent applicant claiming priority on a foreign application 'shall file a copy of the results of any search carried out by the authority with which the previous application was filed.' In other words, all patent applications claiming priority rights (and there are certainly many of them) have a duty to inform the EPO about what transpired in that first filing, and for that reason some have argued that the amendment has actually introduced a limited duty of candour in the EPO.[341] The information is to be filed together with the European application, or without delay after such results have been made available to the applicant.[342] If applicants fail to do so, they receive an invitation from the EPO to provide them, and if they fail to reply in due time the application is deemed withdrawn.[343]

At first glance, this seems to be a relatively strict duty. According to rule 141(2) EPC, however, applicants can be exempted from such duty if the search results are available to the EPO under certain specified conditions. Several patent offices around the world have committed themselves to automatically make available to the EPO the search reports they prepare and thus applicants do not have a duty to file them if the office of first fil-

339 EPC, art 124(1) and r 141(3).

340 EPC, art 124(2).

341 Bradley W Crawford and James V DeGiulio, 'New (Limited) Duty of Candor in the EPO (Amended European Rule 141)' (2010) 8[4] MBHB Snippets 13 (2010), available at <www.mbhb.com/snippets> accessed 14 February 2018. Practitioners have labelled this rule 'European IDS', after its US' equivalent. Krauß (n 332) 105.

342 EPC, r 141(1).

343 EPC, r 70b.

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ing has been the US, the UK, Japan,[344] Austria,[345] South Korea,[346] or in those cases where the EPO itself prepared the search report on behalf of a third country—as is the case with France, Italy or the Netherlands—or in the framework of the PCT.[347] In practice, thus, there is a large number of cases in which applicants are exempted from this duty.

In any case, amended rule 141 does introduce additional responsibilities upon the applicants, even though in most cases the information it relates to would be easily accessible for the EPO through alternative, simpler ways, thanks to the technological developments in communication and the growing cooperation among major patent offices around the world. Furthermore, the language of rule 141(1) EPC and the adoption of different exceptions under rule 141(2) EPC is also likely to bring legal uncertainty among applicants as to the extent of their duty. For this reason, the amendment has been the subject of criticism and accused of making the patent procedure more complex without any apparent benefits.[348] The objective of the amendment, indeed, could probably have been achieved in a more efficient way by further forging the ties between the patent offices rather than creating new duties upon applicants.[349] If in most cases the search results would be easily available for examiners without the assistance of the applicant, it could have been more sensible to approach those specific cases separately rather than to impose an all-embracing duty that will prove superfluous most of the times. For the very rare cases where the search results of the first receiving office are not otherwise available, the

344 Decision of the President of the EPO dated 9 December 2010 exempting applicants claiming the priority of a first filing made in Japan, the United Kingdom or the United States of America from filing a copy of the search results under Rule 141(1) EPC – utilisation scheme [2011] OJ EPO 62.

345 Decision of the President of the EPO dated 19 September 2012 exempting applicants claiming the priority of a first filing made in Austria from filing a copy of the search results under Rule 141(1) EPC – utilisation scheme [2012] OJ EPO 540.

346 Decision of the President of the EPO dated 27 February 2013 exempting applicants claiming the priority of a first filing made in the Republic of Korea from filing a copy of the search results under Rule 141(1) EPC – utilisation scheme [2013] OJ EPO 216.

347 Decision of the President of the EPO dated 5 October 2010 on the filing of copies of search results under Rule 141(1) EPC – utilisation scheme [2010] OJ EPO 600.

348 David Brophy, 'Rule 141 and further EPO obstructions' (*IP Kat*, 12 August 2010) <http://ipkitten.blogspot.de/2010/08/rule-141-and-further-epo-obstructions.html> accessed 14 February 2018.

349 ibid.

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mechanism already offered in the past by rule 141(3), whereby the examiners explicitly invite the applicants to submit the information they need, was probably sufficient.

IV. The impact of AstraZeneca

Beside the limited disclosure duties that the European patent scheme impels today upon patent applicants, it has been stated that the decision of the CJEU in the *AstraZeneca*[350] case might have as a by-product an amplification of said duties, at least for determined firms enjoying a dominant position in the market.[351] This issue is analysed in depth in part II of this work.

B. Legal Consequences of a Deceitful Conduct before the Patent Office

In addition to the differences as to the scope of duties that rest upon patent applicants, the European patent system also differs from US law on the consequences that an inadmissible behaviour at the patent office can have on the patentees and on the enforceability of the patents that they might have obtained thereby.

In the first place, and unlike US law, a dishonest conduct from the patent applicant before the EPO does not provide sufficient grounds for the examining division to refuse the patent application. According to the text of the EPC, an application can only be rejected when it does not fulfil the patentability requirements,[352] but not merely because the applicant shows a reprehensible behaviour.

Most importantly, once the patent has been granted, the manner in which the patent applicant conducted the procedure before the EPO does not seem to have any impact on the validity or enforceability of the patent either. As to patent validity, it should be noted that the EPC provides a limited list of grounds under which national courts may revoke a European patent.[353] This list does not include fraud or false statements made by the

350 Case C-457/10 P *AstraZeneca v Commission* (CJEU, 6 December 2012, ECLI:EU:C:2012:770).
351 See text at n 1107 in ch 5.
352 EPC, art 97.
353 EPC, art 138.

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applicant and does not seem to leave any margin of discretion to the Member States. Hence, it would be difficult for Member States to contend that they can admit said conduct as a further ground for invalidity. With regard to enforceability, it should be reminded at this point that the EPC only constitutes a uniform system for the grant of patents but not for their enforcement, which for the most part remains a national concern.[354] This implies that, in order to analyse the impact that the behaviour of the applicant might have on the later enforcement of the granted patent, it is necessary to look into the practice of the different national courts with jurisdiction on these issues. This section specifically analyses how German and British legislators and courts have dealt with situations of patent fraud, since these two jurisdictions seem to be good representative examples of the two major legal traditions in Europe and both have considerable experience on patent disputes.

Unlike their peers in the US, the national courts of the EU Member States do not seem to have developed an inequitable conduct doctrine or any other doctrine of the sort. In fact, courts in the EU seem to devote little attention to the prosecution history and what the applicants could have said or done in the process for obtaining their patents; they rather adhere to a more straightforward investigation of the core legal issues.[355] This is evidenced, eg, by the fact that most EU courts do not embrace a *file-wrapper estoppel* doctrine to interpret the scope of the patents in the way the US courts do.[356] Courts in Germany, the UK and France have emphatically ad-

354 It should be noted, however, that some issues of patent litigation are partly harmonised, either through the EPC itself (which in art 138 provides for the only grounds under which national courts can revoke a European patent) or through EU law, such as Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights [2004] OJ L 195/16 (Enforcement Directive) with regard to remedies and taking of evidence. It should also be noted that most EU countries signed in 2015 an Agreement on a Unified Patent Court (UPC) which has not yet entered into force. It proposes a common patent court that will hear both infringement and patent revocation cases.

355 Paul Cole, 'Patents and Scientific Integrity' [2008(5)] CIPAJ 2, 10.

356 This doctrine, which derives from the *venire contra factum proprium* principle, refers to a rule of patent construction which requires that the claims of a patent be interpreted in light of the statements or amendments made by the applicant during the application process. *Festo Corp v Shoketsu Kinzoku Kogyo Kabushiki Co Ltd* 535 US 722, 733 (2002).

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vised against its use,[357] although a few precedents have admitted its usefulness under limited circumstances.[358]

I. Germany

In the case of Germany, courts in principle do not take into consideration the circumstances under which the patent has been obtained. In this regard, a defence based on surreptitiously obtained patents would only be admissible in extremely exceptional cases, in analogy to the situation where a party obtains a court judgment in a manner contrary to public policy along the lines of § 826 BGB (*Bürgerliches Gesetzbuch* or German Civil Code) and is later impeded to execute it.[359] The defence, which is normally referred to as *Patenterschleichung*, had gained some recognition in the past due to the fact that, before its amendment in 1941, the German Patent Act provided for a statute of limitations of five year for challenging the va-

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357 In Germany: BGH [2002] GRUR 511, 513 – *Kunststoffrohrteil* (The BGH stated that, for determining the socpe of a patent, art 69 EPC refers exclusively to the claims, the description and the drawings; it neither refers to the proceedings that preceded the grant of the patent nor is it necessary to revert to them from a practical perspective). In the UK: *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2004] UKHL 46, [2005] RPC 9 [35]-[39] ('The courts of the United Kingdom, the Netherlands and Germany certainly discourage, if they do not actually prohibit, use of the patent office file in aid of construction. There are good reasons: the meaning of the patent should not change according to whether or not the person skilled in the art has access to the file and in any case life is too short for the limited assistance which it can provide.'). In France: CA Paris, 11 October 1990 *Dolle v Emsens*, PIBD [1991] 491 III 2. For a summary of the problems associated with this doctrine, see *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1998] EWHC Patents 300, [1999] RPC 253 [52].

358 See, in Germany: BGH [2006] GRUR 923 – *Luftabscheider für Milchsammelanlage*. In the UK: *Rohm and Haas Co v Collag Ltd* [2001] EWCA Civ 1589, [2002] FSR 28 [42]; *Actavis UK Ltd v Eli Lilly & Co* [2014] EWHC 1511 (Pat) [108]-[112]. An exception to the general EU trend against the file-wrapper estoppel doctrine can be observed in the Netherlands, where in 2006 the Dutch Supreme Court decided that it can be invoked in order to narrow down the scope of a claim. *Dijkstra v Saier*, decision of the Supreme Court of the Netherlands of 22 December 2006, No. C05/200HR. An unofficial English translation is available at <www.ie-forum.nl/backoffice/uploads/file/IEForum/Book9.nl/Dijkstra%20vs_%20Saier.pdf> accessed 14 February 2018.

359 Peter Mes, *Patentgesetz, Gebrauchmustergesetz* (3rd edn, Beck 2011) para 104; Georg Benkard, *Patentgesetz* (Claus Dietrich Asendorf and others eds, 10th edn, Beck 2006) para 70.

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lidity of a patent.[360] Hence, once those five years lapsed, defendants in patent infringement cases found themselves barred from disputing the validity of the patent, which led them to search for alternative defensive strategies such as the allegation of patent fraud.[361] In 1941, however, said limitation period was abolished and the BGH suggested that there was no need to admit the defences based on patent fraud any more,[362] although the predominant legal doctrine still considers that it should remain admissible, albeit for exceptional circumstances.[363]

Germany has in place today a bifurcation system, wherein claims on patent infringement and claims on patent validity follow different paths and are handled by different courts: the former by the Regional Civil Courts (*Zivilkammern der Landgerichte*) and the latter by the Federal Patent Court (*Bundespatentgericht*).[364] As a claim on patent fraud allegation could be attempted, hypothetically, under both scenarios, ie, as a defence in patent infringement cases or as an argument against validity in cases where the patent is challenged, it is interesting to analyse how both courts have handled this issue.

Firstly, courts dealing with infringement cases are inclined to disapprove such defences because of the special features of the bifurcation system itself. In this regard, it has been stated that defences based on patent fraud are inadmissible if the underlying facts are also capable of underpinning an opposition or an invalidity action, because in such cases it would be the DPMA or the Federal Patent Court—who deal with oppositions and validity issues, respectively—who would have jurisdiction over these

360 Rudolf Kraßer and Wolfgang Bernhardt, *Patentrecht* (6th edn, Beck 2009) para 35(VII).

361 Benkard (n 359) para 70.

362 BGH [1954] GRUR 107 *Rechtsmittel* [46] ('…der Tatbestand der Erschleichung eines Patents durch bewußtes Verschweigen des Standes der Technik ist nur dann erfüllt, wenn die Offenlegung des Standes der Technik zur Versagung des Patents hätte führen müssen. Aus diesem Grunde ist im übrigen nach Wegfall der Präklusivfrist des früheren § 13 Abs. 3 PatG hinsichtlich der dort behandelten Vorwegnahmen kein Bedürfnis mehr vorhanden, den Tatbestand der Patenterschleichung durch bewußtes Verschweigen des Standes der Technik als besonderen Nichtigkeitsgrund zuzulassen, da bei Neuheitsschädlichkeit des verschwiegenen Standes der Technik schon die sich auf diesen erstreckende Neuheitsprüfung zur Vernichtung des Patents führen muß..').

363 Benkard (n 359) para 70.

364 §§ 65 and 143 PatG.

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questions.[365] In those cases, the infringement courts could, at the most, decide to stay the proceedings, but not reject a complaint on these grounds only. On the other hand, in those cases where the misbehaviour would not avail an invalidity action (eg, if the fraud was irrelevant for the examiner in granting the patent, or if it was committed to obtain the reinstatement of a valid patent), it has been argued that such conduct cannot constitute the basis of a defence in a patent infringement suit either, although on different grounds: in those cases, it could be interpreted that the restricted list of grounds for invalidation provided by the law encompasses a decision from the legislator in favour of all other patents, even if theoretically objectionable on different grounds.[366]

As far as the invalidity procedures are concerned, it should be reminded that the EPC does not allow courts to revoke a European patent based on the behaviour of a patent applicant itself.[367] Similarly, the PatG does not provide for such ground of invalidity for national patents.[368] The BGH itself had left the question open in an old decision,[369] but today it is generally understood that the plaintiff challenging the validity of the patent cannot ground its action on omissions or misrepresentations from the patentee during prosecution.[370] The BGH actually suggested in a later decision that it would be hard to imagine a situation where the culpability of the patentee could play any significant role in invalidity proceedings, since a decision on whether a patent meets all the requirements provided by the law does not need to look into the subjective state of its owner.[371]

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365 OLG Düsseldorf, decision of 14 June 2007, case I-2 U 135/05, [2008] GRUR-RR 333; OLG Düsseldorf, decision of 26 June 2008, case I-2 U 130/06; OLG Düsseldorf, decision of 6 June 2013, case I-2 U 60/11 [67].

366 Benkard (n 359) para 70.

367 EPC, art 138.

368 § 21 PatG.

369 *BGH Rechtsmittel* (n 362) 111 ('Auf die umstrittene Frage, ob überhaupt der Tatbestand der Patenterschleichung einen Nichtigkeitsgrund abgeben kann, braucht daher im vorliegenden Falle nicht eingegangen zu werden.') (citations omitted).

370 Kraßer and Bernhardt (n 360) para 35(VII)(8). In this regard, the Higher Regional Court of Düsseldorf stated that, in invalidity procedures, it is not admissible to argue that the examiner would not have granted the patent if it had been aware of the misconduct, as long as these factors do not objectively invalidate the patent. OLG Düsseldorf, decision of 14 June 2007, case I-2 U 135/05, [2008] GRUR-RR 333.

371 BGH [1965] GRUR 231, 234 *Zierfalten* ('…es ist kaum denkbar, daß die Frage des Verschuldens des Patentinhabers wegen Kennens oder fahrlässigen Nichtkennens schädlicher Entgegenhaltungen in einem Nichtigkeitsstreit

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Notwithstanding the above, German scholars have debated whether patentees can be held liable for damages under § 826 BGB if they hold and defend a patent knowing that it is invalid, either because of fraud or because of information they learnt about after grant. There is no case law addressing this issue[372] and it has been argued that, since an invalidity action does not constitute a re-examination of the patent, but only a verification of its validity against the specific arguments raised by the plaintiff, the mere defending of the patent cannot be considered illegal.[373] However, if patentees falsely state or deliberately imply that they are not aware of any relevant prior art, the alleged infringers could later be entitled to claim for compensation from the patentees for the damages they suffered.[374]

II. United Kingdom

In the past, UK law specifically allowed to challenge the validity of an exclusive right based on a deceptive behaviour before the patent office. Indeed, before its last substantial amendment in 1977, the UK Patents Act specifically provided for a ground of objection to the validity of a patent based on the fact that 'the patent was obtained on a false suggestion or representation'.[375] The raison d'être of this ground of objection goes back to the birth of patents as royal grants, which as such were subject to be repealed by the king under specific circumstances. Such circumstances comprised, among others, finding that the grant had been obtained on 'false suggestion'.[376] That notwithstanding, when the Patent Act was amended

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überhaupt eine Rolle spielen könnte, weil bei der Entscheidung der Frage der Schutzschädlichkeit von Entgegenhaltungen der subjektive Tatbestand ohne Bedeutung ist. Selbst bei Behauptung einer offenkundigen Vorbenutzung würde im Nichtigkeitsstreit die Frage der Kenntnis oder fahrlässigen Unkenntnis von den sie rechtfertigenden Umständen keine Rolle spielen').

372 Kraßer and Bernhardt (n 360) para 35(VII)(8).

373 Rudolf Kraßer, 'Verpflichtung des Patentanmelders oder –inhabers zu Angaben über den Stand der Technik' in Karl Bruchhausen and others (eds), *Festschrift Für Rudolf Nirk zum 70. Geburtstag* (Beck 1992) 537.

374 Krauß (n 332) 117.

375 UK Patents Act 1949, s 32(1)(j). See also Neil Davenport, *The United Kingdom Patent System: A Brief History* (Mason 1979) 35-36.

376 *Prestige Group (Australia) v Dart Industries*, [1992] FSR 143, 164 (Federal Court of Australia). Indeed, as royal grants, patents had to fulfil a number of fundamental requirements, namely that the grant be: (a) within the law; (b) not to the prejudice of existing rights; (c) certain; (d) not in contradiction of the sovereign's in-

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and brought into harmony with the rest of the European patent system, the grounds of revocation were amended and redrafted with a view on the prescriptions of the EPC, which entailed dropping some of the grounds of the previous act.[377]

Before its removal from the Patents Act, courts had interpreted this provision to require the false suggestions or representations to have been material for the granting of the patent, ie of such materiality that it could be said that the Crown had been deceived.[378] The types of cases that courts had to deal with in this regard were basically divided into two groups: those where the false suggestion or representation constituted a promise in the specification—usually by misstating or exaggerating the benefits of an invention—and those where the falsehood was extraneous to the specification.[379] Almost all the cases heard by UK courts concerned exaggerations or false statements in the specification about the alleged advantages of the invention,[380] and in most cases these objections overlapped with challenges on patentability.[381] Other challenges based on, eg, false statements or omissions as to prior art, priority or inventorship—which are the predominant allegations in inequitable conduct cases in the US—have been rarely alleged and there seems to be no instance of patents held invalid on such grounds.[382] Either way, cases dealing with false suggestions in any form were rather unusual,[383] and they are not conceivable in the present context, since neither a European patent nor a national UK patent can be invalidated today on the grounds of fraud or misstatements during the application procedure.[384]

Despite not having the capacity to render the patent invalid, it would be interesting to consider whether the fraud at the patent office could in any way affect the enforceability of the patent in court. It is worth recalling that the inequitable conduct doctrine developed in the US stems from the traditional equitable principle of unclean hands, a concept that actually derives from old English case law and which courts in the UK have historical-

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tention; (e) free from any false consideration or suggestion; and (f) free from any false recital. Davenport (n 375) 34.

377 Edward Armitage, 'The New British Patent Legislation' (1978) 9 IIC 207, 213.

378 *Valensi v British Radio Corp* [1973] RPC 337, 381 (Court of Appeal).

379 Thomas A Blanco White, *Patents for Inventions and the Protection of Industrial Designs* (5th edn, Stevens & Sons 1983) para 4-1001.

380 ibid para 4-1002.

381 ibid para 4-1001.

382 ibid para 4-1002.

383 *Re Chevron Research Company's Extension* [1975] FSR 1, 4 (Chancery Division).

384 EPC, art 138; UK Patents Act, s 72.

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ly recognised.[385] English courts have indeed applied this principle even when dealing with intellectual property issues, eg by preventing trademark holders from enforcing their right on the grounds that their business was fraudulent.[386] But despite the fact that courts had acknowledged that patent applicants' deliberate withholding prior art could be contrary to the obligation of good faith,[387] no court in the UK seems to have applied the unclean hands maxim as a response against a deceptive behaviour at the patent office. Under current UK law, the only stage where a dishonest behaviour before the patent office might have some relevance in court is probably at the time when the judge has to determine whether to award costs to one of the parties.[388]

III. Disciplinary and Criminal Sanctions

In connection to the sanctions that patent attorneys are subjected to for improperly conducting the application procedure entrusted to them, the differences between the US system and the disciplinary framework in force in Europe do not appear to be as sharp. Indeed, both under the structure of the EPO and under national laws, sanctions can be imposed upon patent attorneys for dishonest or misleading behaviour in a similar fashion to the disciplinary procedures before the USPTO.

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385 *Dering v Earl of Winchelsea* (1787) 1 Cox 318, 319 ('… a man must come into a Court of Equity with clean hands; but when this is said, it does not mean a general depravity; it must have an immediate and necessary relation to the equity sued for …').

386 See, eg, *Chocosuisse Union Des Fabricants Suisses De Chocolat v Cadbury Ltd* [1997] EWHC 360 (Pat) [72]-[75] (Citing *Newman v Pinto* [1887] RPC 508 (Court of Appeals), emphasising that 'a plaintiff should fail in the action only in those cases where the court concludes that, in all the circumstances, it is unconscionable for him to be given the relief he would otherwise be entitled to' and concluding that, where the plaintiff has engaged in misleading activities, the closeness of those activities to the right that is being enforced is an essential factor to consider).

387 *Re Clevite* (n 334) 204 (Lloyd-Jacob J).

388 UK Patents Act, s 106(1). Furthermore, where a patent is declared partially valid or when the patent owner amends the specification and claims damages for infringements that took place before such amendment, courts could not award damages, costs or expenses to the patentee if it is shown that the original specification had not been framed in good faith. UK Patents Act, ss 62(3)(b) and 63(2)(b).

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Within the European Patent Organisation, the Administrative Council has adopted a set of rules of professional conduct which governs the disciplinary power of the EPI and of the EPO on professional representatives.[389] Among other duties, patent attorneys are required to 'exercise their profession conscientiously and in a manner appropriate to its dignity', and in particular to 'not knowingly make any false or misleading statement'.[390] If they violate these rules, they are subject to disciplinary sanctions, which comprise warnings, reprimands, fines and a temporary or permanent deletion from the list of professional representatives.[391] These sanctions may be imposed by the Disciplinary Committee of the EPI or by the Disciplinary Board of the EPO,[392] and in both cases the decision is appealable to the Disciplinary Board of Appeal of the EPO.[393] However, the number of disciplinary sanctions appears to be quite low so far. In practice, most of the cases under the jurisdiction of the Disciplinary Board of Appeals relate to disputes over the European qualifying examination—where normally candidates challenge the marks awarded—rather than to matters of professional misconduct.[394]

In a similar way, German patent attorneys are also bound to conduct the application procedures candidly and truthfully before the DPMA,[395] and a violation of their duties can result in a sanction such as a warning, a reprimand, a fine or an exclusion from the register.[396] By the same token, in the UK the Rules of Conduct for Patent Attorneys issued by the Chartered Institute of Patent Attorneys provide for a wide catalogue of duties including integrity and to act in the interest of justice,[397] and a violation of said duties can lead to a great variety of sanctions that go from a public no-

389 Regulation of the Administrative Council of the EPO on discipline for professional representatives [1978] OJ EPO 91, [2008] OJ EPO 14. This regulation was adopted under the power conferred by art 134a(1)(c) of the EPC.

390 ibid art 1(1).

391 ibid art 4(1).

392 ibid arts 6 and 7.

393 ibid art. 8. See also Additional Rules of Procedure of the Disciplinary Board of Appeal [1980] OJ EPO 176 and 188.

394 'EPO Round up: Part 2' (*IP Kat*, 7 June 2005) <http://ipkitten.blogspot.de/2005/06/epo-round-up-part-2.html> accessed 14 February 2018.

395 § 124 PatG.

396 § 96 PatAnwO (*Patentanwaltsordnung* or German Patent Attorneys' Regulation).

397 UK Intellectual Property Regulation Board, Rules of Conduct for Patent Attorneys, Trade Mark Attorneys and Other Regulated Persons, rr 5 and 14.

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tice, warning or reprimand to a fine, a suspension or removal from the register and even an order to undertake further training.[398]

On a different note, it should not be overlooked that a wilful misrepresentation to the patent office—or to any other department of the government—could also have criminal consequences under the German Criminal Code,[399] as well as under the UK Perjury Act.[400]

3. *Ruminations on the US Experience. What can European Courts and Legislators Learn from it?*

Ultimately, the strict onus that US courts and legislators impose upon patent applicants seems to derive from a combination of traditional equitable principles and a perception of the applicants and their attorneys as sheer collaborators of the examination process. Both the broad scope of the duties—particularly the duty of disclosure—and the lethal consequences for falling foul of any of them position the US as a rather unique case among the different patent offices around the world.[401] An increasing number of patent offices admittedly require applicants to disclose certain information under specific circumstances, primarily prior art references cited by foreign patent offices in parallel examinations, and nearly always upon a case-by-case request from the examiner.[402] None of them, however, seems to impose such a strict, all-embracing obligation of disclosure as the US does. Moreover, the declaration of unenforceability that US courts have developed as a remedy against improper patent prosecution does not appear to have an equivalent figure among the European patent courts either.[403]

Having described in detail the scenario in the US and contrasted it with the very different state of affairs observed in Europe, there is an interrogative that inescapably arises: are European courts and authorities getting it wrong? Is there anything Europe can learn or replicate from the approach taken in the United States? Or is it rather the other way round?

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398 UK Intellectual Property Regulation Board, Disciplinary Procedure Rules, rule 14.

399 § 263 StGB (*Strafgesetzbuch* or German Criminal Code).

400 UK Perjury Act 1911, ss 2 and 5.

401 Janicke, 'Mental and Emotional States' (n 217) 291.

402 Bicknell (n 160) 457-63.

403 Janicke, 'Mental and Emotional States' (n 217) 292. See also *Les Laboratoires Servier v Apotex Inc* [2008] EWCA Civ 445 [9]-[10].

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The question has not been the object of intensive research yet, although a few voices—the loudest stemming from the generic pharmaceutical industry—have suggested that the European patent system should indeed implement an extended duty of candour resembling the one in place in the United States.[404] A more stringent duty of disclosure, they contend, could contribute to increase the quality of the patents that the EPO and other national patent offices issue. The predominant opinion, however, seems to be diametrically opposed to adjusting the law in this course. On the one hand, it is argued, it could only skyrocket the costs of litigation without any perceptible benefits.[405] On the other hand, certain specific features of the European patent system, such as the existence of a post-grant opposition procedure and the imposition of attorneys' fees to the losing party in litigation, might render unnecessary, or even counter-productive, any amendment of the law.[406] In any case, it is a question certainly worth asking.

At heart, there are seemingly not one but two issues that should be addressed at this point and which, although extremely intertwined and generally treated together, deserve to be broken down into independent questions. The first question refers to the scope of the duties that are laid upon the patent applicants, the role they are expected to play during examination and in particular the extent to which they are required to disclose information relevant to patentability. The second question is concerned with the legal implications that an improper behaviour of the patent applicant could have on the later enforcement of the patent. It seems more sensible, thus, to treat both questions independently, as it is theoretically possible to

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404 European Generic Medicines Association, 'Patent-Related Barriers to Market Entry for Generic Medicines in the European Union: A Review of Weaknesses in the Current European Patent System and their Impact on the Market Access of Generic Medicines' (2008) 10 and 27 <www.medicinesforeurope.com/wp-content/uploads/2009/06/EGA-IP_Barriers_web.pdf> accessed 14 February 2018. See also Giuseppe Scellato and others, 'Study on the Quality of the Patent System in Europe' (Report for the European Commission, DG Internal Market, 2011) 91-94 <http://ec.europa.eu/internal_market/indprop/docs/patent/patqual02032011_en.pdf> accessed 14 February 2018 (listing the duty of disclosure as a possible tool for increasing patent quality but also acknowledging that there might be arguments against its implementation).

405 Robin Jacob, 'Patents and Pharmaceuticals: A Paper given on 29th November at the Presentation of the Directorate-General of Competition's Preliminary Report of the Pharma-Sector Inquiry' in Hugh C Hansen (ed), *Intellectual Property Law and Policy: Volume 12* (Hart 2013) 653; Cole (n 355) 6.

406 Cotter, 'An Economic Analysis of Inequitable Conduct' (n 173) 777-78; Janicke, 'Mental and Emotional States' (n 217) 292.

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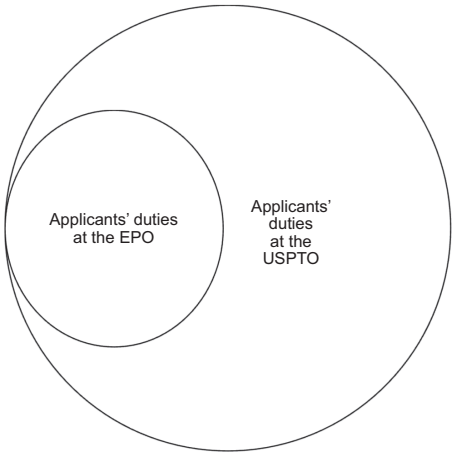
conceive one without the other, eg by broadening the applicant's disclosure duties while at the same time restricting the monitoring of such duties to the jurisdiction of the patent office or by solely imposing disciplinary sanctions.

A. *Extent of Patent Applicants' Duties*

As explained above, patent applicants at the USPTO have a strict duty of candour which derives from both Rule 56 and the case law developed around the inequitable conduct doctrine.[407] Patent applicants in Europe naturally have a duty of good faith as well, which requires from them an honest and transparent conducting of the procedure. The scope of this burden, however, seems to be considerably less harsh, particularly with regard to the prior art information that they are expected to disclose. If the extent of duties in each patent office had to be represented graphically, the graph would probably look like the following:



In the first place, thus, it would be opportune to evaluate whether a stricter code of conduct, and particularly an extended duty of disclosure, could deliver any benefits to the European patent system. No one would challenge at this point that, in order to get high quality patents, the examination pro-

407 37 CFR § 1.56; *Therasense* (n 167) 1287.

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cedure and the decision to grant should be as transparent and informed as possible. The question is whether an extended duty of candour can contribute in this respect or, to the contrary, whether the remedy would end up being worse than the illness.[408]

From a theoretical point of view, the idea of an extended duty of candour looks quite appealing at first sight. It is submitted that, with today's vast sources of information, the patent office's search for prior art cannot always be 100% complete.[409] In certain cases, applicants may possess more and better information surrounding the invention than the patent office,[410] leading to a situation of information asymmetry.[411] Although competitors or third parties might be equally versed on the subject, their involvement in the examination process is relatively limited until the patent is granted. Moreover, in certain fields of technology the quality of prior art identification by examiners might be particularly vulnerable.[412] Hence, requiring patent applicants to collaborate with the prior art search and examination by furnishing the patent office with all the information they are aware of might seem like a reasonable proposal that could ameliorate the information asymmetry, particularly bearing in mind the far-reaching social and economic impact of patents. This is, indeed, the basic idea behind the stringent duty of disclosure still in force in the United States,[413] and the main argument raised by those advocating the implementation of a similar obligation in Europe.[414] From a practical perspective, however, imposing such a burden on patent applicants might pose a number of unexpected pitfalls, not only due to the complexities in its implementation but also because the benefits for the patent system might be much scarcer than

408 Janicke, 'Mental and Emotional States' (n 217) 292. In a similar vein, but with far-reaching conclusions, Mark Lemley argues that strengthening the examination procedure might not always be cost effective, basically arguing that very few patents are actually litigated or licensed. Mark A Lemley, 'Rational Ignorance at the Patent Office' (2001) 95 Northwest U L Rev 1495.

409 EPO, Guidelines for Examination in the European Patent Office (EPO November 2014) (EPO Guidelines) pt B(III) para 2(1).

410 Taylor (n 173) 54.

411 ibid 52.

412 Bhaven N Sampat, 'Examining Patent Examination: An Analysis of Examiner and Applicant Generated Prior Art' (Dphil thesis, University of Michigan 2004) 33-34 ('the quality of issued patents, is likely to be worse in fields where a substantial portion of the relevant prior art is embodied in sources other than U.S. patents, including the scientific and technical literature.').

413 *Norton v Curtiss* (n 198) 794.

414 European Generic Medicines Association (n 404) 10 and 27; Scellato (n 404) 91-94.

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imagined,[415] or even backfire and undermine the patent office's examination process altogether. It should not be forgotten, in this regard, that no empirical studies seem to reveal a direct link between increased duties upon the applicants and higher quality of patents. In fact, the prevailing opinion appears to be that the average quality of the patents granted by the EPO is markedly higher than that of the patents granted by the USPTO,[416] and it has been suggested that the existence of a strict duty of disclosure in the latter might in fact be one of the determining factors.[417]

The following paragraphs appraise some of the major concerns that the introduction of such a duty could haul, most of which seem to tip the scales against the implementation of a strict duty of disclosure.

I. Defining the Scope of the Obligation

In the first place, it would be extremely challenging to delineate the duty in a clear way. It should be borne in mind that, based on the general principle of good faith, applicants at the EPO are already expected to reveal information they hold which plainly and unmistakably affects the patentability of their applications, such as their own prior uses or exhibitions. The EPO further requires applicants, under certain circumstances, to submit search reports produced by foreign patent offices, a burden which has already caused some stir among practitioners.[418] But if applicants are expected to put on the table the entirety of the information that the examiner needs for the assessment of the application's inventiveness, such as third parties' patents or scientific publications, severe difficulties could arise.

Firstly, it would be tremendously challenging to delineate the duty in a clear way and to precisely define the range of information that applicants are required to bring forward. In this regard, the legislator should basically

415 Jacob, 'Patents and Pharmaceuticals' (n 405) 653.

416 Bruno van Pottelsberghe de la Potterie, 'The Quality Factor in Patent Systems' (2011) 20 Industrial and Corporate Change 1755. *See also* Susana Borrás, 'The Governance of the European Patent System: Effective and Legitimate?' (2006) 35 Economy and Society 594, 601; Matthis de Saint-Georges and Bruno van Pottelsberghe de la Potterie, 'A Quality Index for Patent Systems' (2013) 42 Research Policy 704, 719 (patents granted by the USPTO are listed among the ones with lowest quality).

417 Bruno van Pottelsberghe de la Potterie (n 416) 1769.

418 Brophy (n 348).

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choose between confining the duty to prior art effectively known to the applicants, much like US practice today, or requiring them to disclose the entirety of the existing prior art—regardless of whether they are aware of it or not. In the first case, such a duty could result in applicants adopting an ostrich-like approach,[419] whereby they avoid performing any patentability searches and remain intentionally oblivious, striving to know as little as possible about the surrounding prior art,[420] which could lead to unjustified applications. In the second case, the duty would require applicants to become absolute experts before filing, which seems extremely far-reaching as it would entail immense costs—and delay of applications—that most applicants would not be able to bear.[421] In any case, such a duty would not spare the patent office the need to carry out its own prior art search.

More importantly, if the duty is confined to prior art actually known by applicants, the supervision of such a duty could become a great headache in practice. Indeed, authorities in that event would need determine in every individual case whether the applicants were aware of the relevant-but-undisclosed pieces of prior art—an investigation that has proven to be extremely burdensome in the US.[422]

Finally, it would also be troublesome for applicants to decide which specific pieces of prior art to disclose in each case. Faced with such burden, they would probably be inclined to err on the side of over-disclosure, just to be on the safe side,[423] or in the worst cases even 'bury' highly material references by blurring them inside a long list of less relevant information.[424] Either way, applicant intervention in those cases might thwart rather than ease the job of the examiner.

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419 Bicknell (n 160) 471.

420 Admittedly, authorities could in that case adopt a 'should have known' approach, although such a solution could result in endless discussions about what the applicants actually should have known, as it would bring negligence issues to the table. Hricik (n 274) 295.

421 Although some have actually argued that in the US the burden on the applicants should be heavier and that they should have a positive duty to search for prior art before filing and submit it to the USPTO. Thomas Schneck, 'The Duty to Search' (2005) 87 J Pat & Trademark Off Soc'y 689, 704.

422 Janicke, 'Mental and Emotional States' (n 217) 292.

423 Bicknell (n 160) 431; Taylor (n 173) 63; Erstling (n 160) 335.

424 Hricik (n 274) 301. It has been suggested that such risk could be alleviated by raising the costs for excessive disclosures. Cotter, 'An Economic Analysis of Inequitable Conduct' (n 173) 775. That proposal, however, might also be difficult to bring into practice.

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II. Practical Value

Even if a duty of disclosure were to be successfully implemented in Europe, it is not clear whether the information provided by the applicants would result in practice in higher quality patents,[425] or whether the examiner would take it into consideration at all for that matter. It has been suggested, in this regard, that an extensive duty of disclosure might in fact impede the quality of patent examination instead of furthering it.[426]

As the US has had a duty of disclosure in place for many years, it might be valuable to observe the impact that such duty has had on the examination procedure of the USPTO in practice. In this regard, a number of renowned patent law scholars have carried out an empirical study in order to test whether the USPTO really avails itself of the information submitted by the applicants.[427] The study reveals surprising outcomes, as it shows that patent examiners effectively disregard almost all applicant-submitted prior art, relying almost exclusively on prior art information they find themselves.[428]

The fact that examiners do not take into account prior art submitted by applicants might be explained in some cases by the weakness or irrelevance of the information they submit, although the major factors are probably connected to both information overload[429] and cognitive biases: examiners might just think more highly of their own searches.[430] Moreover, the limited amount of time that examiners can allocate to the study of each application and the large amounts of information that applicants might be inclined to disclose when faced with such a burden could also constitute relevant factors that explain why examiners tend to disregard such information.

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425 From an innovation policy perspective, a high quality patent should enable those persons having skill in the art to easily understand the invention. From social welfare perspective, a high quality patent would be a patent with little uncertainty over its validity and the breadth of the claims. Bronwyn H Hall and Dietmar Harhoff, 'Post-Grant Reviews in the U.S. Patent System Design Choices and Expected Impact' (2004) 19 Berkeley Tech L J 989, 991.

426 Erstling (n 160) 336.

427 Christopher A Cotropia, Mark A Lemley and Bhaven N Sampat, 'Do Applicant Patent Citations Matter?' (2013) 42 Research Policy 844.

428 ibid 853.

429 Jeffrey M Kuhn, 'Information Overload at the U.S. Patent and Trademark Office: Reframing the Duty of Disclosure in Patent Law as a Search and Filter Problem' (2010) 13 Yale J L and Tech 89, 92.

430 Cotropia, Lemley and Sampat (n 427) 851.

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It has further been stated that, even if a duty of disclosure was ever justified, it would not be any more, as the accessibility and power of computer-based prior art searching might render a duty of disclosure not cost-effective.[431] In this vein, it cannot be denied that the circumstances under which the duty of candour was first envisaged in the United States have drastically changed. As a result of the developments in access to information, communications and cooperation between the different patent offices, an obligation to disclose prior art might not make as much sense any longer.[432]

There might still be, it is true, certain situations where information might not be reachable by the examiner, eg in case of limited prior uses or remote and inaccessible public disclosures. Although in some of these cases it could be argued that applicants are already obliged to disclose such information under current laws on the basis of the principle of good faith, it is likely that such information will be known by competitors as well. Hence, EPC regulations on third party observations and oppositions might constitute an effective fall-back remedy. Indeed, under the EPC, third parties are entitled to bring relevant information on patentability to the patent office during the examination of the application via observations,[433] and most importantly, they can file an opposition to the patent within nine months after grant.[434]

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431 Cole (n 355) 6. See also Erstling (n 160) 357-63 (changes in technology, law and cooperation might make disclosure redundant).

432 As an illustrative example, the FTC carried out in 2003 a thorough evaluation on the duty of candour within the framework of a study on the proper balance of competition and patent law. Despite some voices urging for an expanded duty of candour, the FTC concluded that there is no sufficient evidence indicating that added responsibilities upon patent applicants would actually enrich the patenting procedure. FTC, 'To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy' (October 2003) ch 5, 11.

433 Although third parties do not formally become a party to the examination after submitting observations, examiners have a duty to take said observations into account by if they call into question the patentability of the invention. EPO Guidelines (n 409) pt E(V) para 3.

434 Scholars in the US had actually suggested –before the passing of the AIA– that one of the alternatives to improve the quality of information available to examiners would be to allow greater integration of third parties during prosecution. Robert P Merges, 'As Many as Six Impossible Patents before Breakfast: Property Rights for Business Concepts and Patent System Reform' (1999) 14 Berkeley Tech L J 577, 614; Hall and Harhoff (n 425) 1015. In the same vain, it has been argued that the benefits of an expansive burden upon applicants may be small or negative in a system in which post-grant oppositions are already common. Cotter, 'An Economic Analysis of Inequitable Conduct' (n 173) 778.

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III. Interest of Applicants Themselves to have All Prior Art Considered

Either if there is a duty to disclose relevant prior art or not, applicants might nonetheless be interested in having their patents examined against the closest prior art and hence inclined to disclose it on their own initiative, as it could positively affect the quality and value of the patent. In this regard, Caballero and Jaffe argue that 'omission of important references can be grounds for invalidation of the patent, giving the applicant an incentive to make sure that citations appear.'[435] Thus, applicants might be personally interested in disclosing themselves relevant prior art, because the more prior art references are considered and rejected by the examiner, the less likely it is that the patent will be later invalidated during litigation.[436] And even if the patent is not involved in litigation, a higher quality can give the owner a stronger bargaining position in case of opposition or licensing.[437] The incentive to disclose, however, might not be as strong in certain fields of technology where the number of patents of a determined portfolio matters much more than their quality.[438]

IV. Duty of Advocacy

Finally, it is also important to consider that patent attorneys have a duty to defend their clients' inventions and, therefore, should not be expected to provide every single argument to the examiners, who should reach their own conclusions.[439] An extensive duty of disclosure could thus fly on the face of the patent attorneys' duty of advocacy, especially if they are also required to opine on the relevance of every prior art reference, as it would place them in the uncomfortable position of having to first reveal a list of

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435 Ricardo J Caballero and Adam B Jaffe, 'How High Are the Giants' Shoulders: An Empirical Assessment of Knowledge Spillovers and Creative Destruction in a Model of Economic Growth' in Olivier Blanchard and Stanley Fischer (eds), *NBER Macroeconomics Annual 1993: Volume 8* (MIT Press 1993) 32, fn 22.

436 Erstling (n 160) 334, fn 36. See also Cotropia, Lemley and Sampat (n 427) 845 ('disclosure of prior art to the PTO can help "bulletproof" a patent in later litigation.').

437 Akers (n 331) 310.

438 Bhaven N Sampat, 'When Do Applicants Search for Prior Art?' (2010) 53 J L & Econ 399, 413 (in certain product fields, eg complex-product industries, where many patents cover a given product and the validity of any given patent is not as important, applicants are significantly less likely to contribute prior art).

439 Bicknell (n 160) 445.

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prior art and then rebut arguments that perhaps not even the examiner or competitors would have thought of.[440]

B. Legal Consequences of a Deceitful Conduct before the Patent Office

In addition to the question on the ideal breadth of the patent applicants' disclosure duties, a second, closely connected issue deserves to be tackled at this point, namely the legal implications that patent applicants' failure to comply with those duties could have on the later enforcement of the patent. It goes without saying that the relevance of this issue is strongly tied to the breadth of these duties. Yet even if the law of the EPC today, with its less stringent duties, were to remain the same, it is worth considering whether the patent applicants' failure to comply with their duties in the midst of examination, eg by making egregiously false statements, should have any impact at the enforcement stage.

As described above, US courts can hold a patent unenforceable if they find that the patent has been obtained through inequitable conduct—which traditionally consists of a failure to disclose relevant prior art or prior uses but can also occur when submitting false information or making misleading statements. The question at this point, hence, is whether European courts should adopt a similar approach and whether they would actually be enabled to do so by current EU and national laws.

I. Evaluation of the inequitable conduct doctrine in the US

Probably few American legal doctrines have been jeered and condemned as fiercely and passionately as the inequitable conduct defence. It has been called an 'absolute plague',[441] a 'formless liability',[442] the 'atomic bomb'

440 Goldman (n 176) 95. See also *General Tire & Rubber Co Ltd v Firestone Tyre & Rubber Co Ltd* [1975] RPC 203, 269 (Court of Appeal) ('It is, after all, the function of a patent agent to argue in honesty for the width of the application.'); *Hoechst v Kirin-Amgen* (n 323) [135] ('while the duty of candour on an applicant for a patent and its patent agent is undoubted and important, one should not carry it too far.').

441 *Burlington Ind* (n 209) 1422.

442 John F Lynch, 'An Argument for Eliminating the Defense of Patent Unenforceability Based on Inequitable Conduct' (1988) 16 Am Intell Prop L Asso Q J 7, 8.

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against patent enforcement,[443] and has been likened to enforcing traffic lights with nuclear weapons,[444] or to a death sentence for minor offences.[445] Surprisingly, however, the vast majority of the scholarship and courts seem to nevertheless endorse the underlying justifications of the doctrine and hardly any voice dares to censure its existence as such,[446] albeit the need for major or minor tweaks and adjustments is widely recognised.[447]

In should be reminded that the doctrine in the United States was originally born as a natural reaction to safeguard the transparency of the examining process,[448] strongly impregnated with ethical considerations.[449] It took the form of an unclean hands remedy, reinforced and tailored in consideration of the particular nature of the patent rights and its bearings on society. Without disparaging this moral trait, today many appear to behold it from a more utilitarian perspective, as a potentially valuable tool to induce efficient disclosure of information among patent applicants,[450] yet others are much more hesitant to see any practical benefits,[451] and some go as far as to say that the doctrine is not only failing to achieve its purpose but might even have a backfire effect, hampering rather than enhancing patent quality.[452]

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443 *Aventis Pharma SA v Amphastar Pharmaceuticals Inc* 525 F 3d 1334, 1349 (Fed Cir 2008) (Rader J, dissenting).

444 Joseph Farrell and Robert P Merges, 'Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help' (2004) 19 Berkeley Tech L J 943, 962.

445 Nicole M Murphy, 'Inequitable-Conduct Doctrine Reform: Is the Death Penalty for Patents Still Appropriate?' (2009) 93 Minn L Rev 2274.

446 See, eg, Merges and Duffy (n 210) 1065 ('a bitter pill indeed … but a necessary tonic in a system where applicants carry so much of the burden of disclosure'). Exceptions can be found in Lynch (n 442); National Research Council of the National Academies, *A Patent System for the 21st Century* (Stephen A Merrill, Richard C Levin and Mark B Myers eds, National Academies Press 2004) 121-23.

447 Lisa A Dolak, 'Inequitable Conduct: A Flawed Doctrine Worth Saving' (2010) 11 Wake Forest Intell Prop L J 1, 12.

448 *Precision v Automotive* (n 162) 816.

449 *Therasense* (n 167) 1285.

450 See, among many others, Cotter, 'An Economic Analysis of Inequitable Conduct' (n 173); Cotropia (n 217); Mack (n 165); Mammen (n 215).

451 Lynch (n 442) 9; Arti K Rai, 'Growing Pains in the Administrative State: The Patent Office's Troubled Quest for Managerial Control' (2009) 157 U Pa L Rev 2051, 2074-77; Janicke, 'Mental and Emotional States' (n 217) 292; Bicknell (n 160) 466.

452 Erstling (n 160) 365.

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The grounds on which the doctrine has been criticised are ostensibly heterogeneous. It is often stated, firstly, that the sanction it imposes is extremely severe and disproportionate, for if the court finds anything inappropriate in the conduct of the patentee during prosecution, there is only one remedy: unenforceability.[453] Furthermore, it might be a little unsettling that not only the claims to which the inequitable conduct relates are struck down, but rather the entire patent and potentially even further patents belonging to the same family—even if some of the claims were absolutely unrelated to the alleged fraud.[454]

Disapproving voices have also called the attention to the increased costs and complexity that disputes over inequitable conduct entail, as well as to the way they diverge attention from core issues like infringement and validity.[455] Moreover, the fact that the defence is raised excessively often—and in most cases frivolously—only exacerbates the problem.[456] The largest share of the high costs appear to derive from the subjective element, as it requires courts to dive into the internal sphere of every individual intervening in the process, making discovery proceedings particularly expensive[457] and often requiring attorney depositions with complex attorney-client privilege issues.[458]

Maybe more significantly, concerns have also pointed to the fact that the doctrine is applied at times with absolute disregard for the validity of the patent.[459] Indeed, a patent can be knocked down irrespective of whether it protects genuine—or even revolutionary—inventions, ie, even if all their claims are entirely valid and comply with all the patentability

453 Tun-Jen Chiang, 'The Upside Down Inequitable Conduct Defense' (2013) 107 Northwest U L Rev 1243, 1250-51.

454 Cotropia (n 217) 774-75.

455 ibid 740; Melissa Feeney Wasserman, 'Limiting the Inequitable Conduct Defense' (2008) 13(7) Va J L & Tech 14; Lynch (n 442) 16; Taylor (n 173) 65-66 (pointing out that it might even have a negative impact on reputation).

456 Mammen (n 215) 1344; Cotropia (n 217) 739-40; Wasserman (n 455) 14. It has been suggested, however, that imposing attorney fees against parties failing to prove inequitable conduct could somehow hold back the flood of groundless allegations. Mack (n 165) 172; Taylor (n 173) 91.

457 Wasserman (n 455) 14-15; *A Patent System for the 21st Century* (n 446) 122.

458 Cotropia (n 217) 740.

459 Friedrich-Karl Beier, 'Die Rechtsbehelfe des Patentanmelders und seiner Wettbewerber im Vergleich: Eine rechtsvergleichende Untersuchung zur Chancengleichheit im Patentverfahren [1989] GRUR Int 1, 6; Janicke, 'Mental and Emotional States' (n 217) 292.

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requirements.[460] This fact alone, it is argued, is sufficient to cast doubt on the overall benefits that an inequitable conduct doctrine can effectively deliver to social welfare.[461]

In view of these numerous concerns, the shrinking trend in which the doctrine is currently immersed—evidenced by the *Therasense* decision and the new Supplemental Examination procedure—does not come as a surprise. In fact, the stricter standard of proof implemented by the Federal Circuit and the decision of the Congress to allow patentees to 'cleanse' their patents before litigation openly speak of a more sceptical view towards inequitable conduct.[462] Yet the defence is far from disappearing and concerns might still endure, since the generous reward for a successful inequitable conduct plea has not been revised and imposing fees to defendants for groundless allegations remains rather exceptional. Therefore, the ultimate fate of this legal doctrine, and particularly whether it will finally be revamped into a more pragmatic instrument, still remains an open question.

II. Would it be advisable for European courts to implement a similar doctrine?

As highlighted above—and regardless of the intense critique—the grounds on which the inequitable conduct doctrine are founded are very seldom challenged within the American legal community. It is conventionally argued that the doctrine is in itself valuable and that defendants, in their role of 'watchdogs', in fact contribute to the integrity of patent examination.[463] Apocalyptic warnings are further made in the sense that excessively limiting the defence, or eliminating it altogether, would inevitably result in applicants reducing disclosure,[464] and even encourage them into deceptive conducts.[465] In Europe, however, where courts have not been persuaded into admitting a comparable defence, those threats have not been materi-

460 Considering that the decision of the Federal Circuit in *Therasense* has adopted a 'but-for' standard of materiality, most cases of inequitable conduct should entangle patents that are also invalid. *Therasense* (n 167) 1291. However, the same decision expressly stated that, in case of affirmative egregious misconducts, the question of whether the patent should have been granted or not becomes irrelevant. Ibid 1292-93.

461 Lynch (n 442) 9.

462 Dolak, 'America Invents the Supplemental Examination' (n 220) 164.

463 Merges and Duffy (n 210) 1058.

464 Cotter, 'An Economic Analysis of Inequitable Conduct' (n 173) 771.

465 Dolak (n 447) 17; Petherbridge, Rantanen and Mojibi (n 218) 1351.

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alised, as applicants at the EPO and other national patent offices do not seem to be particularly inclined towards dishonest behaviours. Moreover, despite the duty of disclosure in both offices being entirely different, nothing appears to suggest that, when deciding on any given patent application, examiners in the USPTO actually boast more relevant information on their tables in comparison to their EPO peers—or that they produce better quality patents at all for that matter.

Against this background, one is but strained to conjecture either (i) that the EPO has some kind of secret weapon which the USPTO lacks, or (ii) that the benefits that are normally attributed to the inequitable conduct doctrine are not as incontestable as assumed. Some legal authors in the United States who have addressed this question seem to prefer the first explanation, and they specifically draw the attention to the post-grant opposition process as the ace up the sleeve. Such a system, they contend, not only assists in the task of weeding out undesirable patents at an early stage, but also encourage efficient disclosure—both from the applicants themselves and from third parties.[466]

That the post-grant opposition process in place in the EPO—and in many other countries—plays a vital role in controlling patent quality can hardly be questioned.[467] What is yet to be established, though, is whether this process alone constitutes a substitute to the inequitable conduct doctrine as a matter of fact, and most importantly whether the latter really enjoys the prodigious effects that are to be expected from it. In other words, it would be opportune to determine whether—regardless of the positive effects that the post-grant opposition process can have—implementing a similar doctrine has the potential to further improve patent quality and impel more transparency into the European patenting procedure.[468] To explore the question, both the more ethical and the more utilitarian aspects

466 Cotter, 'An Economic Analysis of Inequitable Conduct' (n 173) 777-78 ('The fact that other countries have oppositions and not an inequitable conduct doctrine, as such, suggests the possibility that disclosure is adequate under such a combination...') ('the benefits of an expansive inequitable conduct doctrine may be small or negative in a system in which post-grant oppositions are common…'), Janicke, 'Mental and Emotional States' (n 217) 292; Becknell, at 466-67.

467 See, eg, Bronwyn H Hall and others, 'Prospects for Improving U.S. Patent Quality via Postgrant Opposition' in Adam B Jaffe, Josh Lerner and Scott Stern (eds), Innovation Policy and the Economy: Volume 4 (National Bureau of Economic Research 2004) 115.

468 What is more, considering that the AIA has meanwhile introduced a process that very much resembles the European post-grant oppositions, such line of reasoning could lead to the conclusion that the inequitable conduct doctrine has be-

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of the doctrine should be taken into consideration, although the latter is strongly dependant on the width of the applicants' disclosure duties—duties which remain fairly limited within the EPC.

In the main, and from a more ethical perspective, nothing seems to suggest that patent applicants' inadequate behaviour should automatically make their patents unworthy of any kind of legal aid. Admittedly, the unclean hands doctrine—on which the US' inequitable conduct defence is based—is also acknowledged in the United Kingdom,[469] and in a more limited fashion in Germany.[470] Yet such doctrine requires the misconduct to be directly related 'to the controversy immediately involved in the injunction suit' and 'of a character that renders the plaintiff's interests undeserving of injunctive protection'.[471] Hence, particularly if the invention meets all patentability requirements, an inappropriate conduct at the patent office might not necessarily justify ruling out the enforcement of the granted patent. This is not by any means to suggest that the conduct should remain unpunished, but rather that there might be alternative remedies, such as disciplinary or perhaps even criminal sanctions, which can deliver equally satisfactory results without necessarily bringing the discussion into the patent litigation ground.

Then again, even if not demanded by ethical principles—and even if that was not the purpose that the Supreme Court had in mind when giving birth to it—a doctrine of inequitable conduct might look appealing at first glance from a more utilitarian perspective, since it could function as a tool for attaining optimal amounts of information at the patent office—which should thus lead to better quality patents. Upon closer inspection, however, the benefits might be more ostensible than real.

Firstly, it may constitute in practice an inappropriate interference of the courts in the administrative process. In this regard, the patent office—just like any other administrative institution for the procedures under their authority—is probably in a much better position than the courts to regulate the degree of disclosure that should be demanded from applicants and the appropriate punishment, as nobody knows better than the agency what

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come obsolete. Before the AIA was passed, Cotter had actually warned that a post-grant opposition process coupled with an inequitable conduct doctrine could induce over-disclosure among US patent applicants. Cotter, 'An Economic Analysis of Inequitable Conduct' (n 173) 777.

469 *The Royal Bank of Scotland Plc v Highland Financial Partners LP* [2013] EWCA Civ 328, [2013] 1 CLC 596 [158].

470 BGH [1977] GRUR 494, 497 – *Dermatex*.

471 *Restatement (2d) of Torts* (1977) para 940.

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kind of information they need.[472] In this regard, the US Supreme Court had long ago suggested that the patent office should be the main responsible for supervising the behavioural duties of the patent applicants,[473] although the inequitable conduct doctrine as developed by the case law in that country rather conveys that authority to the courts. The introduction of the Supplemental Examination procedure by the AIA may thus represent an attempt from Congress to revert this trend and gradually reduce the role of the courts in this area.[474]

Furthermore, as referred above, the rewards of such a doctrine could be fairly narrow from the specific standpoint of the EPC, as its benefits would be eclipsed by the post-grant opposition procedure and could even result counterproductive.[475] But even in the absence of such an opposition process, the rewards of an inequitable conduct doctrine may be extremely slim.

It might be helpful, at this stage, to hypothetically set apart the two possible scenarios that can be envisaged if an inequitable conduct doctrine were to be implemented. On the one hand, there would be situations where the inappropriate conduct during prosecution misled the examiner into granting a patent which does not meet all patentability requirements, namely an invalid patent. On the other hand, there would be cases where, despite of the deceiving conduct of the applicant (e.g., by submitting a bogus affidavit aimed at reinforcing the inventiveness of the application), the invention meets all legal requisites and the patent that is granted is perfectly valid. In the first case, the patent should never have been granted, and it was only the deceptive behaviour of the applicant which convinced the patent office into allowing it. In the second set of cases, the misleading conduct might have had more or less influence on the decision of the patent office, but the patent nevertheless embodies a legitimate invention and the patent office was not mistaken in granting it.

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472 Merges and Duffy (n 210) 1058 (emphasising that, in other areas of law, agencies are held masters of their own procedures and courts show deference towards them); Rai (n 451) 2079.

473 *Kingsland v Dorsey* (n 161) 319-20 ('It was the Commissioner, not the courts, that Congress made primarily responsible for protecting the public from the evil consequences that might result if practitioners should betray their high trust.').

474 Merges and Duffy (n 210) 1068. See text at nn 110-111in ch 1.

475 Cotter seems to subscribe this opinion. Cotter, 'An Economic Analysis of Inequitable Conduct' (n 173) 778 ('the benefits of an expansive inequitable conduct doctrine could be small or negative in a system in which post-grant oppositions are common').

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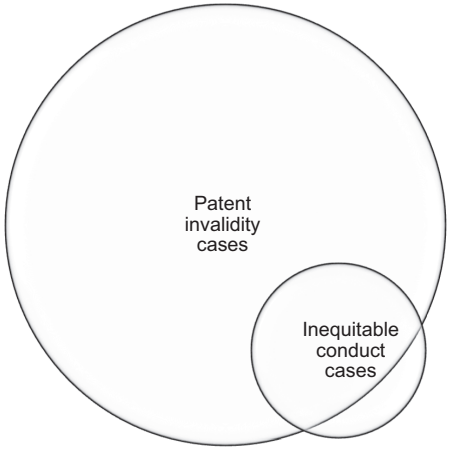
In the United States, the overwhelming majority of inequitable conduct cases discussed in court correspond to the first scenario. In fact, according to an empirical study carried out in 2005, in 89% of the cases where inequitable conduct was found, the claims at issue were also found invalid.[476] Since then, the Federal Circuit has hardened the materiality standards in *Therasense*,[477] meaning that this proportion is likely to be even higher today. If this universe of data had to be represented graphically, the result would probably look like the following:



For all those cases described in the first scenario (ie, where not only the patentee has engaged in inequitable conduct during patent prosecution but also the patent is invalid), the existence of a defence based on inequitable conduct seems somehow superfluous, since it would be just overlapping with the traditional invalidity defence. Such redundancy would not be a major concern if it were not because every inequitable conduct allegation exponentially increases the costs of litigation by diverging the discussion to complex and subjective elements, which frequently will have taken place long before and will be very difficult to prove. What is more, at least as it currently exists in the United States, an inequitable conduct defence most times does not relieve the courts from looking into the validity of the patent, since they still have to determine whether the patent could or should have been granted or not when analysing the materiality

476 Nolan-Stevaux (n 182) 163.
477 See text at nn 241-248.

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standard. Hence, for the largest part of inequitable conduct cases that can be conceived, the defence would be overlapping with the already existing invalidity defence without delivering any apparent added value. The outcome of those cases would be essentially the same whether the inequitable conduct defence existed or not, but in the latter event entailing much less costs and complications.[478] Perhaps the only differences would reside on the unenforceability 'contamination' of related patent claims (the appropriateness of which is at least debatable) and the award of legal fees—a remedy which is already widely available in Europe.

Be that as it may, the existence of such an inequitable conduct defence could be nevertheless justified for the second scenario, ie in those situations where the patent is valid but improperly procured. In these cases, the defendant would not have other alternative but to allege inequitable conduct, since the invalidity defence would be obviously unavailable. The number of cases where this situation might arise does not seem to be significant, and part of the scholarship has considered this reason enough to veto the doctrine.[479] But even disregarding the frequency with which such circumstances might arise, it is important to ask at this point whether it would be advisable at all to accept an inequitable conduct defence for this sort of cases. In other words: is it reasonable to refuse judicial relief to a patent that shields a legitimate invention for the sole reason that, during the application procedure and for whatever reason, the patentee showed a reproachable behaviour? The Federal Circuit in *Therasense* has expressly replied in the affirmative, stating that if such conduct amounts to affirmative egregious misconduct, inequitable conduct is still applicable, even if the patent is valid.

The approach of the Federal Circuit strikes as highly debatable. It is undisputed that such behaviour should not be tolerated by the law, but it is much less clear whether refusing to enforce the patent constitutes a reasonable remedy, since the invention is in fact new and inventive. Investi-

478 See Cole (n 355) (analysing many inequitable conduct cases in the United States, conjecturing how they would have been solved in the United Kingdom and concluding that all those cases would have been solved with an invalidity defence and attorney fees). See also, in the same line, Janicke, 'Mental and Emotional States' (n 217) 292.

479 Janicke, 'Mental and Emotional States' (n 217) 292 ('Under US patent law, it can be said that the inequitable conduct defense truly applies only where the patent is valid but was improperly procured. The number of these instances is bound to be small and does not seem to justify putting every patentee through the cost and jeopardy of a trial on inequitable conduct.').

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gating this behaviour is in fact extremely costly and diverts the attention from the core issues like validity and infringement. Most importantly, no matter how disagreeable or immoral the patentee might be, she may have made a valuable technological contribution—precisely what the patent system craves for. And if the conduct at the patent office was improper, it may well be more sensitive to entrust the patrol of that behaviour to spheres which are better prepared for that task, such as the patent office or the bar association through disciplinary sanctions, or even criminal courts in the most severe cases.

In the case of European patent litigation, it should be borne in mind that introducing an inequitable conduct type defence would not only lead to higher costs and longer litigation—a topic that cannot be overlooked—but also might give rise to additional concerns. In Germany and other countries having a bifurcated system in place, for instance, complications would probably emerge in the sense that these pleas would be somewhere halfway between both courts' jurisdiction. If the task were to be assigned to courts dealing with infringement, the whole notion of the bifurcation system would be futile, as those courts would be forced to look closely into validity issues when looking into the materiality of the misconduct. At the same time, it is not clear whether courts dealing with patent validity would have jurisdiction to deal with these pleas, since strictly speaking it would not be an issue of validity. In connection with the latter concern, it is also dubious whether the aggregate of legal instruments in force in the European Member States would permit their national courts to adopt a defence of this sort. Both the EPC and the national patent laws provide for limited lists of grounds under which courts may revoke a patent, and these lists do not include fraud or false statements made by the applicant. And if the patent is declared valid, a court does not seem to enjoy sufficient discretion to refuse its enforcement altogether.[480]

There is a final concern that might also be worth pointing out, not because of the frequency with which it would emerge but rather because it serves to highlight the potential that the inequitable conduct doctrine might have to breed uncertainty among the users of the patent system. An applicant could, in that regard, engage in inequitable conduct and later, after obtaining the patent, assign the right to an innocent third party. In that

480 According to art 13 of the Enforcement Directive, a national court cannot refuse to grant damages in case of infringement. In any event, it should be noted that the implementation by any European court of an inequitable conduct doctrine could have an impact on the whole EPO procedure which, if not followed by the other Member States, could result in a situation of extreme legal uncertainty.

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case, it would be necessary to determine whether the patent would remain 'infected' or whether the assignment would instead purge the patent. Either outcome would seem partly flawed. In the first case, which seems to be the solution adopted by US courts,[481] assignees would carry the burden of scrutinising the history of the patent to prevent surprises, and even in that case there might be unveiled risks impossible to detect in the course of standard due diligence searches. The alternative outcome, however, would probably contravene the principle *nemo dat quod non habet*, and the original patentees would find a way to avoid the consequences of their acts. Furthermore, the assignees in that case would have an incentive to bury their heads in the sand in order to know as little as possible about the patent's history so as to reduce risks of liability.

In view of the above considerations, it seems that the implementation of an inequitable conduct doctrine in Europe would be ill-advised. At the end of the day, it constitutes a doctrine whose raison d'être is still debated between pragmatism and an ethical instinct but whose advantages on any of both fronts are questionable at the very least.

In the United States, defendants appear to rely on this defence for a series of different reasons, including its power to tear down otherwise valid and enforceable patents, its impact on all the claims of the patent (and even other patents belonging to the same family) and the fact that it completely inverts the situation of the parties in litigation by removing the defendant from the hot seat and instead putting the patentee in the dock. None of these motives, however, seems heavy enough to justify altering the rules of litigation in Europe. An additional reason for its popularity in the United States is related to litigation costs: although inequitable conduct does not automatically make a case exceptional to grant attorney fees,[482] it is very often considered to be so,[483] hence departing from the general principle in American litigation. In Europe, where courts tend to impose attorney fees to the losing party as a rule,[484] this does not seem to be a major concern, although it would probably be reasonable for courts to take into account the conduct of the patentee as a relevant—and even aggravating—factor when deciding on the legal costs.

In summary, it seems that it would not be advisable for European courts to implement an inequitable conduct doctrine or otherwise refuse to en-

481 Chiang (n 453) 1293.
482 *Lighting World Inc v Birchwood Lighting Inc* 382 F 3d 1354, 1367 (Fed Cir 2004).
483 See, eg, *BRASSELER, USA I, LP v Stryker Sales Corp* 267 F 3d 1370, 1386 (Fed Cir 2001). See also Wasserman (n 455) 11, fn 80.
484 Enforcement Directive, art 14.

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force patent rights on the basis of what transpired before the patent office. Firstly, rather that high quality patents it would seem to warrant an increase in the costs of litigation and a distraction from important issues like infringement and validity. And more importantly, its contribution to the patent system would be either superfluous or indesirable. On the one hand, if a specific misconduct is tied to an invalid patent, the existence of an inequitable conduct would appear as clearly redundant and unnecessary, since challenging the validity of the patent is a much more straightforward defence which does not require delving into endless subjective matters. On the other hand, if the misconduct is tied to a patent that nevertheless meets all patentability requirements, it is not at all clear why a reproachable behaviour during prosecution should justify refusing the enforcement of a patent that protects a worthy invention and a valuable contribution to technical development.

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