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Patent Quality: does one-size-fit all?

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PATENT QUALITY: DOES ONE-SIZE-FIT ALL?

Summary

Lately, concerns about questionable patent quality are on a rise in Europe. It is agreed that sound policy considerations are urgently needed to optimize the existing European patent system. Nonetheless, any meaningful policy-oriented discussion about the patent quality problem in Europe may only start by being able to build a strong premise and clarity about the term ‘patent quality'. However, the varied meanings and perceptions that may be attributed to the patent quality show that the disharmony is quite loud, therefore, patent quality is often described as ‘quality in the eyes of the beholder' rather than a consensual definition. At the same time, when one is confused by the stakeholder-perceptions about patent quality, academic literature gives a more promising insight based on theories and reasoning than mere personal interests.

In this article a broad range on literature is analyzed to answer the question, what are the various meaning and contexts associated with the term "patent quality" and could there be one-size-fits-all definition for the term? The resulting paper facilitates choosing the factors of concern that influence the quality of patents in an innovation system, especially from a sound policy perspective.

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1 Introduction

The previous decades have witnessed rising concerns about patent quality. However, the issue of declining patent quality is neither new nor limited to the academic concerns. It is well admitted by various patent offices and many have already been taking steps to keep a check.[1] It is interesting to note that a substantial share of literature focusing on patent quality and related concerns comes from the U.S.A,[2] maybe because critics in the U.S.A. gauged the problem earlier than elsewhere. Interestingly, most of the earlier comparative studies on 'patent quality' resulted in concluding that EPO has been producing better quality patents (than the U.S.A.), however, the recent trends at the EPO suggest that the EPO has also been beguiled into the same trap of questionable 'patent quality'.[3]

However, any study on "quality" is an extremely difficult endeavour to achieve objectively. The subjectivity of the term exposes it to the crisis of being able to become the subject-matter of a study that could be regarded as comprehensive and non-prejudicial. Similarly, this proposition also applies to studies relating to patent quality and the issues surrounding it, creating an inherent uncertainty in defining and measuring patent quality.[4]

At the same time, any meaningful policy-oriented discussion about the patent quality problem in Europe may only start by being able to build a strong premise and clarity about the term

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[1] A Patent Quality Review Office (the U.S.A.) was created in 1974; in 2010 a Quality Metrics was introduced to gain more insight into measuring patent quality; 2015 USPTO Enhanced Patent Quality Initiative (EPQI) was taken. See, Tara Klamrowski, 'The USPTO'S EPQI and the Demand for Higher Patent Quality' (22 November 2016) <http://knowledge.reedtech.com/intellectual-property-all-posts/the-uspto-s-epqi-and-the-demand-for-higher-patent-quality> accessed 2 January 2018. The EPO states one of its aims as 'quality management' and is raising concerns about patent quality; In 2010, its report 'Raising the bar' focused on quality aspects of a patent followed by its first report on quality, published in 2016. See, EPO Quality Report, (2016) < http://documents.epo.org/projects/babylon/eponet.nsf/0/D4D30CF45FD00F51C125814C003C4B0D/$File/epo_quality_report_2016_en.pdf > accessed 20 January 2018.

[2] Dietmar Harhoff, 'Patent Quantity and Quality: Trends and Policy Implications' in Dominique Foray and Brian Kahin (eds), *Advancing Knowledge and The Knowledge Economy* (The MIT Press 2006) 332.

[3] The EPO also holds ISO 9001 certificate for the entire process, which is an internationally recognized standard for quality management systems. Everything seemed to be working well at achieving the highest quality if we rely on the constant reports and posts from the EPO and its President. However, an extra ordinary letter signed by 924 EPO examiners, addressed to the members of the Board of the Administrative Council stated that the "*quality of the EPO patents is endangered.*" See, EPO Examiners, '*Petition to the Administrative Council of the EPO'* (7 March 2018) < https://regmedia.co.uk/2018/03/14/epo-examiners-letters.pdf > accessed 3 June 2018. Over the years the EPO has centred its concerns on how to allocate work load and revenue, essentially overlooking their responsibility in upholding the main motive of the patent system. See, Dominique Guellec and Bruno van Pottelsberghe de la Potterie, *The Economics of the European Patent System: IP Policy for Innovation and Competition* (Oxford University Press 2007), 2.

[4] Colleen Chien, 'Comparative Patent Quality' (2016) Santa Clara Law Digital Commons <http://digitalcommons.law.scu.edu/facpubs/938/> accessed 6 December 2017; Giuseppe Scellato and others, 'Study on the Quality of the Patent System in Europe, PATQUAL: Tender MARKT/2009/11/D', 19 <http://ec.europa.eu/internal_market/indprop/docs/patent/patqual02032011_en.pdf> accessed 6 December 2017.

'patent quality'. However, this task is not easy as this exploration may never be unidirectional.[5] It may also depend upon who asks the question- "What is Patent Quality?''. Rather, the varied meanings and perceptions that may be attributed to the patent quality show that the disharmony is quite loud, therefore, patent quality is often described as 'quality in the eyes of the beholder' rather than a consensual definition.[6]

All the same, there is no deficiency of literature related to patent quality (in general) and related concerns. In this article, I provide a concise review of the scholarly contributions to the literature on patent quality. The literature is brought together, reviewed and synthesized in order to derive meaningful conclusions about characteristics/definition of a 'good quality patent' or factors that affect the quality of patents. This is done especially keeping in mind its relevance for a policy-oriented research.

2 Patent Quality: Parable of the blind men and an elephant

Every patent system is a complex interaction of various stakeholders and the perception about patent quality may also be motivated by the interest of these stakeholders.[7] (See diagram 2.1) For instance, patent attorney or a patent office may consider a well-written patent that clearly fulfils the statutory patentability conditions as a high-quality patent (legal validity).[8] For the engineer or inventor, the high-quality patent might be perceived as the one protecting a major invention rather than an incremental one (technologically advanced). Economists may want to test the quality of a patent by analyzing if it fulfils its basic function of incentivizing innovation and the costs involved (economic value).[9] For them, *"high-quality patent should cover only*

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[5] Sara-Jayne Adams, 'Quality is the Key to a Bright Patent Future' (2008) Intellect Asset Manage 55, 55 <http://www.oceantomo.com/pdf/studies/IAM_April_May_2008_Barney.pdf> accessed 24 May 2018.

[6] Gaétan de Rassenfosse, Adam B Jaffe and Elizabeth Webster, *Low-quality Patents in the Eye of the Beholder: Evidence from Multiple Examiners* (NBER Working Paper No 22244, 2016) <http://www.nber.org/papers/w22244> accessed 6 December 2017.

[7] Christi J Guerrini, 'Defining Patent Quality' (2014) 82 Fordham Law Review 3091. For her, the four important stakeholders whose perception of patent quality is relevant in formulating a definition are 1. the patent office, 2. the courts, 3. the patentee and 4. the public. Also see, Adams, 'Quality is the Key to a Bright Patent Future' compilation of interviews where a number of stakeholders and IP experts are approached in the patent community on behalf of IAM Magazine to understand their opinion on patent quality is an interesting read in this regard.

[8] Mariagrazia Squicciarini, Hélène Dernis and Chiara Criscuolo, *Measuring Patent Quality: Indicators of Technology and Economic Value* (OECD Science, Technology and Industry Working Paper No 2013/03, 2013) 7 <http://www.oecd-ilibrary.org/science-and-technology/measuring-patent-quality_5k4522wkw1r8-en > accessed 1 December 2017. Warren Woessner (Schwegman, Lundberg & Woessner) and Mike Lloy (Griffith Hack) opinions cited in Alexandra Sklan, 'Ask the Experts-Patent Quality' (2014) 3 Pharmaceutical Patent Analyst 17,18-19 <https://www.future-science.com/doi/pdf/10.4155/ppa.13.74> accessed 24 May 2018.

[9] Squicciarini, Dernis and Criscuolo, *Measuring Patent Quality: Indicators of Technology and Economic Value*; Bruno van Pottelsberghe de la Potterie (2011) argues that the economists' routine consists in overly simplifying the examination practice under abstract concepts such as patent "breadth" or "scope," which are nearly impossible for examiners to implement in practice. Therefore, he urges to achieve a fair balance between

those inventions that would not have been made without the incentive provided by the protection of the intellectual property right."[10] A patent owner's standpoint would depict patent quality necessarily as a function of value.[11] For him, the value would be linked to the likelihood of the successful enforceability of the patent in litigation and the amount of damages that could be obtained in case of his patent being infringed (and successfully keeping competitors at bay!).[12]

The public would perceive quality as maintaining an appropriate balance between monopolistic rights of the patentee and costs the public pays to use the invention. Lastly, the public also desires the efficient working of the judicial system (including both, invalidating patents that never should have issued and upholding patents that merit protection).[13]A good quality patent is considered to ultimately be commercialized and brings social, economic and/or environmental welfare.[14]

In this regard, some contend that the degree of patent quality is different for evaluators in different situations, for example, in patent trade (sold patents are of high quality), in patent litigation (patents that win lawsuits are of high quality), and in patent assignment (patents that have assignment processes are of high quality).[15]

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complexities and abstraction while studying the subject. See, Bruno van Pottelsberghe de la Potterie, 'The Quality Factor in Patent Systems' (2011) 20 Industrial and Corporate Change, 1756 <https://academic.oup.com/icc/article/20/6/1755/888713 > accessed 10 April 2018.

[10] See, Scellato and others, 'Study on the Quality of the Patent System in Europe, PATQUAL: Tender MARKT/2009/11/D', 19.

[11] See, Guerrini, 'Defining Patent Quality'.

[12] See, Jonathan Atkinson (Harrison Goddard Foote LLP) cited in Sklan, 'Ask the Experts-Patent Quality', 21.

[13] Guerrini, 'Defining Patent Quality', 3126.

[14] SONG Hefa and LI Zhenxing, 'Patent Quality and the Measuring Indicator System: Comparison among China Provinces and Key Countries', 4 <https://www.law.berkeley.edu/files/Song_Hefa_IPSC_paper_2014.pdf> accessed 25 November 2017.

[15] Amy JC C Trappey and others, 'A Patent Quality Analysis for Innovative Technology and Product Development' (2012) 26 Advanced Engineering Informatics 27 <https://www.sciencedirect.com/science/article/pii/S1474034611000486 > accessed 20 August 2018.

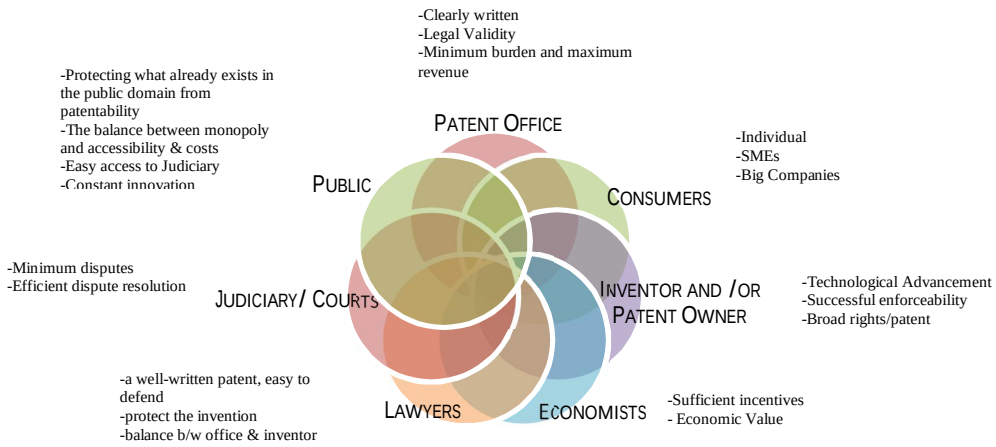

DIAGRAM 2.1: PATENT QUALITY: MIXED EXPECTATIONS

These varied notions of quality as perceived by its users have given rise to a wide array of definitions of patent quality and users have tried to formulate the indicators/definitions of patent quality most suited to them. Further, the complexity not only arises by virtue of the interaction of various actors but also because the patent systems are established at an interface of legal constraints, economic incentives, scientific and technological advances and business strategies.[16]

This reminds me of the parable of the blind men and an elephant (see diagram 2.2) and I see a number of aspects of the parable fit finely with the current perceptions about patent quality. The story goes like this; a group of blind men come across an elephant for the first time and start touching the elephant to conceptualize it. Their description of the elephant is then based on the one part of the elephant that they were in contact with and is different from each other. Hence, the resultant description is their absolute truth but based on their limited and subjective experience. In the case of patent quality, first, most of the stakeholders in a patent system perceive ‘patent quality' with some vested interest. Some are very much concerned about the private gains; others may possibly want to bring in the public-interest explanation for a patent system. However, ultimately everyone comes with some blindness (bias) - if not total, then partial- while having their own opinion about patent quality. To find out the whole truth, one must put parts together and should conceptualize the concept with open eyes!

[16] See, Potterie, 'The Quality Factor in Patent Systems'.

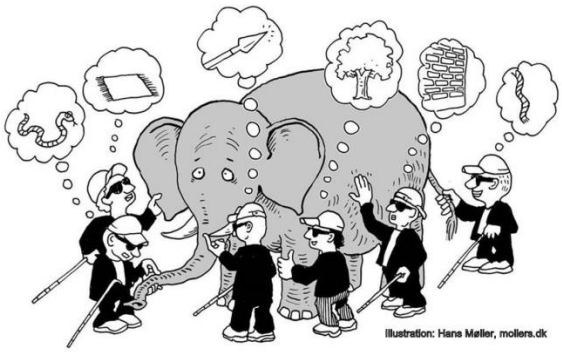

DIAGRAM 2.2: THE PARABLE OF THE BLIND MEN AND THE ELEPHANT[17]

3. Conceptualizing Patent Quality: A Look at the Academic Literature

Academic literature has also made plausible contribution to the subject and attempts have been made to define (wholly or partly) patent quality,[18] empirically measuring patent quality (or composing patent quality indicators),[19] assessing the factors affecting quality,[20] comparing patent quality across various jurisdictions[21] and so on. Rather, when one is confused by the stakeholder-perceptions about patent quality, academic literature gives a more promising insight based on theories and reasoning than mere personal interests.

Any academic discussion about patent quality must commence with the analysis of the legal quality of the patent.[22] Legal quality may simply be associated with the statutory standards of

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[17] Image Source: Hans Moller, mollers.dk. The image was downloaded from the following link: <https://caroline-smith.com/2016/07/14/truth-is-an-elephant-2/> accessed on 18 November 2018. Due permission from the illustrator has been sought to use the picture.

[18] For example, see, Guerrini, 'Defining Patent Quality'; Potterie, 'The Quality Factor in Patent Systems'; Hefa and Zhenxing, 'Patent Quality and the Measuring Indicator System: Comparison among China Provinces and Key Countries'; Ronald J Mann and Marian Underweiser, 'A New Look at Patent Quality: Relating Patent Prosecution to Validity' (2012) 9 Journal of Empirical Legal Studies 1 <https://pdfs.semanticscholar.org/1df5/e28df889032b81ecec639bb659d48702f9b0.pdf > accessed 28 November 2017.

[19] For example, see, Hefa and Zhenxing, 'Patent Quality and the Measuring Indicator System: Comparison among China Provinces and Key Countries'; Squicciarini, Dernis and Criscuolo, *Measuring Patent Quality: Indicators of Technology and Economic Value*; Jean O Lanjouw and Mark Schankerman, 'Patent Quality and Research Productivity: Measuring Innovation with Multiple Indicators' (2004) 114 The Economic Journal 441 <http://onlinelibrary.wiley.com/doi/10.1111/j.1468-0297.2004.00216.x/epdf > accessed 6 December 2017.

[20] For example, see, R. Polk Wagner, 'Understanding Patent-Quality Mechanisms' (2009) 157 University of Pennsylvania Law Review 2135 < https://www.law.upenn.edu/live/files/86-wagner157upalrev21352009pdf > accessed 6 December 2017; Scellato and others, 'Study on the Quality of the Patent System in Europe, PATQUAL: Tender MARKT/2009/11/D'; Gaétan de Rassenfosse and Adam B Jaffe, 'Are Patent Fees Effective at Weeding Out Low-Quality Patents?' (2018) 27 Journal of Economics and Management Strategies 134 <https://onlinelibrary.wiley.com/doi/epdf/10.1111/jems.12219 > accessed 27 March 2018.

[21], For example, see, Potterie, 'The Quality Factor in Patent Systems'; Chien, 'Comparative Patent Quality'.

[22] See, John R Thomas, 'The Responsibility of the RuleMaker: Comparative Approaches to Patent Administration Reform' (2002) 17 Berkeley Technology Law Journal, 730-31 <https://scholarship.law.georgetown.edu/cgi/viewcontent.cgi?article=1318&context=facpub > 24 July 2018. In author's opinion, *"…quality patents are, in short, valid patents. Such patents may be reliably enforced in court,*

patentability. Any invention can be granted a patent if it fulfils three basic conditions of (1) novelty; (2) inventive step and (3) capability of the industrial application.[23] Otherwise, in the first place, it cannot be patented, else, if the patent is granted, runs the risk of being invalid. Theoretically, these conditions of patentability may sound simple and clear but their interpretation and implementation is a matter of subjective assessment which may vary. Thereby, this may affect the (legal) quality of granted patent (that may mean that even grant of a patent does not ensure validity).[24]

While operationalize 'patent quality' as legal validity, scholars like Prof. Ronal J. Mann and Dr. Marian Underweiser (2012) have not only limit their analysis to traditional concept of validity (i.e. features apparent on the face of the patent-novelty, inventive step, patentable subject matter etc.) rather they build a robust insight into the features that might relate to validity, including, the textual features of the patent (including, claims and specifications) and information about prosecution history.[25] They analyze the validity of the patents as a function of three distinct steps: (i) the invention, (ii) The effort of the applicant and (iii) the effort of the examiner.

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consistently expected to surmount validity challenges, and dependably employed as a technology transfer tool. Quality patents fortify private rights by making their proprietary uses, and therefore their value, more predictable. They also clarify the extent to which others may approach the protected invention without infringing. These traits in tum strengthen the incentives of private actors to engage in value-maximizing activities such as innovation or commercial transactions..."

[23] A simple glance at how similar (but not identical) the USA and the Europe substantive requirements look can be tabulated as follows to notice that differences that may occur. Further, the definition, assessment criterion and interpretation of these substantive requirements may also vary.

TRIPS	**USA**	**EUROPE**
New	Novelty	Novelty
Inventive step	Non-obviousness	Inventive Step
Industrial application	Usefulness	Industrial Application
Any invention in all fields of technology [Exclusions: Art. 27 (2) and 27 (3), TRIPs]	machine, manufacture, composition of matter, or any improvement [judicial exceptions]	Any invention in all fields of technology [Exceptions: Art. 52 (2), EPC]
Sufficiently clear and complete disclosure	adequate disclosure	adequate disclosure

[24] This variation is not only across jurisdictions (for example, at EPO uses the problem-solution approach and the 'could-would' concept while evaluating Inventive step requirement. However, U.S.A.'s evaluation of non-obviousness is based on the tests of 'teaching-suggestion-motivation' and 'Graham Factor') but also within the same jurisdiction different assessment results of similar cases may be possible (For example, the expertise of the examiner, the time available for examination etc. may affect the decision, and hence quality).

[25] Mann and Underweiser, 'A New Look at Patent Quality: Relating Patent Prosecution to Validity', 2. Also see, Nefissa Chakroun, 'Improving Patent Information Quality: Development and the Disclosure Requirements' (2012) 15 The Journal of World Intellectual Property < http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2012.00438.x/pdf> 19 January 2018.

This is similar to the report submitted to the EU that aimed to provide evidence on the current quality of patents in Europe that studied two complementary perspectives: 1) quality of granted patent per se (compliance with fundamental requirements/substantive examination) and 2) quality of patent from a systematic perspective.[26] The authors did not only simply analyze the efficacy of the substantive examination process but also looked at other factors like costs for obtaining, managing and enforcing a patent.[27]

For Prof. Colleen Chien (2016), the quality of patents is a result of a set of three important decisions in a patent process: By the applicant: i) submission of a certain quality of patent application, ii) to renew the patent and by patent office and by the patent office: iii) to grant the patent or not.[28]

Dr. Gaetan de Rassenfosse et. al. (2016) interpret issuance of low-quality patents corresponding to two pathways based on the height of inventiveness: *"(i) the patent office may apply systematically a standard that is too lenient (low inventive step threshold); or (ii) the patent office may grant patents that are, in fact, below its own threshold (so-called 'weak' patents)."*[29] The existence of low standards that are applied consistently still generate valid patents.[30] Prof. Bruno van Pottelsberghe de la Potterie (2011) definition follows this line and he defines (legal) quality as "*the extent to which a patent system complies with its legal standards in a transparent way.*"[31] Prof. Song Hefa and LI Zhenxing (2014) added to this definition **"…***the degree of its specification meeting requirements of sufficient disclosure...*" as another aspect of patent quality.[32]

Scholars have also clearly distinguished patent quality from its value.[33] However, scholars like Dr. Paul F. Burke and Prof. Markus Reitzig (2007), include the techno - (economic) quality created by the patent's underlying invention as an important aspect of patent quality along with

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[26] Scellato and others, 'Study on the Quality of the Patent System in Europe, PATQUAL: Tender MARKT/2009/11/D', 7.
[27] Ibid, at 17.
[28] Chien, 'Comparative Patent Quality', 14.
[29] See, Rassenfosse, Jaffe and Webster, *Low-quality Patents in the Eye of the Beholder: Evidence from Multiple Examiners.*
[30] Ibid, at 3.
[31] See, Potterie, 'The Quality Factor in Patent Systems'.
[32] See, Hefa and Zhenxing, 'Patent Quality and the Measuring Indicator System: Comparison among China Provinces and Key Countries'.
[33] Wagner, 'Understanding Patent-Quality Mechanisms', 2138, A patent's value is dependent on factors like the size of the relevant market and the relationship between the patent's scope and a marketable good or service. He states that some of these factors may be related (directly or indirectly) to the quality, but these are factors much beyond the scope/concern of the patent law. See also, Rassenfosse and Jaffe, 'Are Patent Fees Effective at Weeding Out Low-Quality Patents?'.

the legal quality created by a patent's reliability as an enforceable property right.[34] They reframe the definition to link patent quality and patent assessment quality as follows: "*a patent office's consistent categorization of patents along a dimension of technological quality leading to sustainable property rights*".[35]

Prof. Dietmar Harhoff (2007) lists the characteristics of a high-quality patents as (i) having a high inventive step; (ii) clearly written with no intentional 'smoke and mirror'; (iii) not a minor variation of some other patent; (iv) considering all prior art while search/examination; (v) clearly delineated and non-overlapping with other patents; (vi) extent of patent protection commensurate to the contribution to the state of the art and most importantly (vii) legally robust; meaning thereby small likelihood of revocation in courts with low uncertainty for investment.[36]

Reading the aforementioned scholarly opinion about patent quality adequately makes me infer that though there exists versatility in approaches, the academic literature still largely concentrates on legal aspect (narrow or broad) for defining patent quality (with only some authors trying to add the techno-economic aspect of quality to the definition). And why should it not? If a patent can be readily invalidated, all of the other quality measures are without merit. Therefore, a patent that fails to meet the legal requirements for patentability can never be a quality patent, regardless of any other (technological or commercial or any other) perspective in determining quality. [37] It is agreed that patents with higher legal quality are usually more difficult to be challenged during examination or invalidation procedures.[38]

Further, for a policy-oriented research, it is important to choose '*one of these many concepts/perception*' of patent quality as this will definitely be the lead for any further research or discussion about the subject. So what should be a rational choice for deciding the characteristics of a good-quality patent be based on?

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[34] Paul F. Burke and Markus Reitzig, 'Measuring Patent Assessment Quality—Analyzing the Degree and Kind of (in)Consistency in Patent Offices' Decision Making' (2007) 36 Research Policy 1404 <https://www.sciencedirect.com/science/article/pii/S0048733307001369> ACCESSED 13 Aprile 2018.
[35] Ibid, at 1406.
[36] Dietmar Harhoff, 'Promoting Innovation – The Role of Patent Quality' (EUPACO-Towards a New European Patent System), 3 <http://eupaco.wdfiles.com/local--files/eupaco2/Dietmar%20Harhoff.pdf > accessed 11 October 2018.
[37] Brian Elias, 'Patent Quality: It's Now or Never' LexisNexis White Paper, 2 <https://www.lexisnexis.nl/db_images/white-papers/Whitepaper-patent-quality-no-or-never.pdf> accessed 20 December 2017.
[38] See, Hefa and Zhenxing, 'Patent Quality and the Measuring Indicator System: Comparison among China Provinces and Key Countries'.

3 Analysis and Conclusion

One may think that patent quality should be defined in a manner that it should take account of all the stakeholders involved in the system.[39] At the same time, more the number of stakeholders, more perspectives one may expect to lead to difficulties in formulating a 'one size fit all' definition of patent quality (or if the goal is not to define, it definitely leads to taking into consideration more indicators and concerns). The major risk that one may encounter here is that all these perspectives when studied together may not always be complementary and supplementary to each other. For example, a stronger patent may mean a broader patent (so that not just the one invention but also close substitutes are also excluded) for an investor or industry; but may be of counter-interest to the society.

Nonetheless, whatever be the different perceptions and expectations about patent quality, the guiding force while conceptualizing patent quality for policy suggestions has to be well-grounded theory keeping in mind the goal for which a patent system is created. This goal may be an economic one (i.e. promote innovation), at the same time it is regulated by a legal instrument (patent law) and the law has a societal function/purpose to fulfil. In conformity, academic literature summarized above seems well-reasoned than stakeholders-perception.

After a close scrutiny of the aforementioned ideas, the problem of patent quality can be studied in two different ways: i) analyzing the substantive legal standards (especially, novelty, inventive-step including PHOSITA, patentable subject-matter etc.) or/and ii) studying the interpretation and application of these standards, both by the applicant and the examiner. Choosing one of these paths will essentially set the boundaries of one's analysis.

The former i.e. revising the standards would require revisiting the theoretical justification for granting patents and observing if the present system needs re-alignment with the purpose for which it was created/ for which it exists. The economic welfare theory of patents suggests that granting of a patent involves a trade-off. A monopoly right should only be granted if it provides a true incentive for innovation. The law should then require a patentable invention to be really new/novel, non-obvious/inventive and capable of industrial application.[40] Further, social purpose of the system is the disclosure requirement that is also an important characteristic of a

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[39] *The OECD Innovation Strategy: Getting a Head Start on Tomorrow* (Organisation for Economic Co-Operation and Development (OECD) 2010) 148 < http://www.oecd-ilibrary.org/docserver/download/9210061e.pdf?expires=1516620458&id=id&accname=ocid177396&checksum=982312E56F59FCF1D3C854F68BC47F61 > 11 December 2018.

[40] Bronwyn H. Hall and others, *Prospects for Improving U.S Patent Quality via Post- Grant Opposition* (NBER Working Paper No 9731, 2003) 2 <http://www.nber.org/papers/w9731> accessed 2 December 2017.

"high-quality patent"- "*that it enables those "skilled in the art" to comprehend the invention well enough to use the patent document for implementation of the described invention*".[41] From a social welfare perspective, breadth of claim is also relevant. The utilitarian economic approach to justify the patent system sees patents not as a natural right that the inventor should have, but as a mere policy instrument adopted by the government to benefit the society.[42] Patents supplement the market forces in achieving a socially desirable level of innovation, hence patent should be granted only if they are beneficial to society.[43] Hence, this route of interpreting quality may be taken while revising the economic aim/expectation form a patent system. This is also relevant when comparing patent quality with the international standards or across various jurisdictions.

The other way is to accept the existing substantive law as it is and analyze how well a patent system complies with its own standards.[44] This is a more useful route of interpreting/defining quality when we one seeks policy suggestions to internally improve the patent system.

The process of patent prosecution starts with the applicant taking the first step by submitting a patent application at the patent office. Therefore, without a doubt, the applicant assumes control over quality aspects of the patent.[45] Once the application is submitted, the quality of the prosecution process will also determine the quality of the patent that is then finally granted.[46] This, of course, will include the quality of examination that also influences the quality of the patents.[47]

Furthermore, I agree with the opinion that any policy consideration would at least expect a system to produce a legally valid patent that complies with the statutory requirements of

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[41] Another criterion for a "high-quality patent". This dimension of patent quality, however, is less likely to be affected by post-grant opposition proceedings. See, ibid, at 3.

[42] See, Guellec and Potterie, *The Economics of the European Patent System: IP Policy for Innovation and Competition.*

[43] Dominique Guellec, 'Patent Design' in Dominique Guellec and Bruno van Pottelsberghe de la Potterie (eds), *The Economics of the European Patent System: IP Policy for Innovation and Competition* (The Economics of the European Patent System: IP Policy for Innovation and Competition, Oxford University Press 2007), 114.

[44] See, Potterie, 'The Quality Factor in Patent Systems'.

[45] Gene Quinn (founder, IPatchdog) is of the opinion that the quality of the output depends on the quality of input. In the case of patent quality, the applicant has the foremost role to play in determining the quality and consistency of the input as he drafts and defends the patent application. See, Brian Cronin, *The Quest for Patent Quality: European Inventive Step and US Obviousness* (2016).

[46] The quality of a patent is affected by the quality of the overall system in which it operates. This implies that the peculiarities of the European patent system (environment) need to be studied to determine the patent quality it produces. See, Scellato and others, 'Study on the Quality of the Patent System in Europe, PATQUAL: Tender MARKT/2009/11/D'.

[47] See, Bruno van Pottelsberghe de la Potterie (2011), Scellato G. et. al. (2011), Bhaven N. Sampat et. al. (2005).

patentability.[48] Many scholars have rightly extended their interpretation of the term patent quality beyond 'traditional' legal quality (compliance with statutory requirements of novelty, inventive step, capable of being industrially applied and patentable subject matter).[49] A robust insight of the features that may relate to validity (or at least influence the chances of patent being valid), include the textual features of the patent document (for example claims and specifications),[50] clear and sufficient disclose,[51] time & costs structures[52] and the ease of management of granted rights or ease of enforceability.[53] Legal certainty and reasonable costs are also considered important for business purposes.[54] It is also clear that if patent quality matters, the stakeholders/actors involved in the patent system must change/improve their ways.[55] A careful look at the previously cited works reveals that many scholars[56] have also followed a logical sequence to study the patent quality by broadly studying two phases of the patent process, namely, i. the quality of application as submitted by the applicant,[57] and ii. the quality of operational design.[58] To my understanding, it is meaningful to do a thorough analysis of the present patent system because to effectively fix the problem of sub-optimal patent quality

[48] See, Bruno van Pottelsberghe de la Potterie (2011), Gaétan de Rassenfosse and Adam B. Jaffe (2018), Scellato G. et. al. (2011), Gaetan de Rassenfosse et. al. (2016), Prof. R. Polk Wagner (2009), Prof. Colleen Chien (2016), Susan Walmsley Graf (2007), Paul F. Burke and Prof. Markus Reitzig (2007), Christi J. Guerrini (2014) and Song Hefa and LI Zhenxing (2014) have agreed to legal quality/validity as one of the dimensions (if not the only one) of overall patent quality.

[49] See, Ronal J. Mann and Marian Underweiser (2012).

[50] See, Ronal J. Mann and Marian Underweiser (2012), Susan Walmsley Graf (2007), Christi J. Guerrini (2014), George Matta, *A Renewed Focus on Patent Quality – Implications for Patent Owners* (Globe Business Media Group 2017) 50.

[51] See, Prof. R. Polk Wagner (2009), Prof. Colleen Chien (2016), Susan Walmsley Graf (2007), Christi J. Guerrini (2014), Song Hefa and LI Zhenxing (2014).

[52] Brian J. Love (2016), Scellato G. and others (2011).

[53] Scellato G. and others (2011).

[54] B. Pottelsberghe, 'Lost property: The European Patent System and Why it doesn't Work' Bruegel Blueprint Series 9, 4 <http://bruegel.org/wp-content/uploads/imported/publications/patents_BP_050609.pdf> accessed 6 December 2017.

[55] Thomas, 'The Responsibility of the RuleMaker: Comparative Approaches to Patent Administration Reform', at 741.

[56] Mann and Underweiser, 'A New Look at Patent Quality: Relating Patent Prosecution to Validity'; Bhaven N Sampat, 'Determinants of Patent Quality: An Empirical Analysis' <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.382.8290&rep=rep1&type=pdf> accessed 18 November 2017; Kevin Mack, 'Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands' (2006) 21 BERKELEY TECHNOLOGY LAW JOURNAL 147 <https://scholarship.law.berkeley.edu/btlj/vol21/iss1/9/> 5 April 2018; Susan Walmsley Graf, 'Improving Patent Quality Through Identification of Relevant Prior Art: Approaches to Increase Information Flow to the Patent Office ' (2007) 11 Lewis & Clark Law Review 495 <http://law.lclark.edu/live/files/9569-lcb112grafpdf> accessed 13 April 2018 ;Wagner, 'Understanding Patent-Quality Mechanisms'; Guerrini, 'Defining Patent Quality'.

[57] This includes the law/rules available for reference by the applicant to draft the patent application, the effort (in terms of time and money) that the applicant puts before filing a patent application and the various resources the applicant uses during this process. Rather some of the empirical results also found that the decisions and efforts of the applicant are of more relevance than any other factor. See, Chien, 'Comparative Patent Quality'.

[58] This may include examination quality, efforts by the examiner, interactions between examiner and applicant, third-party involvement, opposition proceedings etc.

in the system, policymakers first need to understand the root cause of the problem.[59] This is possible only with a solid guidance as to what features of the patent system are actually incentivizing the granting of the sub-optimal level of patent quality. Lastly, patent quality is also affected by the so-called 'non-traditional' use of the patent system (for example, firms adopting a high-volume, low-quality patenting/portfolio strategy, 'ever-greening' etc.).[60] A policy-oriented research has to delve deeper into all these concerns of patent quality to deliver meaningful suggestions.

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[59] Michael D. Frakes and Melissa F Wasserman, *Decreasing the Patent Office's Incentives to Grant Invalid Patents* (The Hamilton Project, 2017) 5 <https://www.brookings.edu/wp-content/uploads/2017/12/es_121317_decreasing_patent_office_incentives_grant_invalid_patents.pdf> accessed 19 March 2018.

[60] Prof. R. Polk Wagner (2009), Susan Walmsley Graf (2007), Song Hefa & LI Zhenxing (2014). Under such circumstance, the applicant does not desire a patent because the grant of such patent will incentivize the invention, however, has other considerations (for example, creating a monopoly over broad rights, avoiding competition etc.). This may make them less concerned about the quality of their patent.

Balancing the Quality of Patents with Effective Enforcement of Invalidity Claims in the Pharmaceutical Industry in Europe

Naina Khanna
Project: ESR8

Research Question

1. What are the factors influencing the quality of patents in the pharmaceutical sector in Europe?
2. Whether or not existing legal arrangement (including patent grant process and enforcement mechanisms) incentivizes the creation of optimal quality patents in the pharmaceutical sector in Europe?
3. Is it possible to balance the quality of patents with effective enforcement of invalidity claims in the pharmaceutical industry in Europe (specifically with the upcoming Unified Patent Court)? If yes, how?

Methodology

I envisage that I will be following an empirical approach for evaluating the legal arrangement (i.e. the patent system for my concern). 'Legal normative analysis' approach will be followed, 'what the patent system is' and 'what it ought to be' (for the Pharmaceutical sector in Europe). The aim is to identify the most critical aspects of the system and as well as the expectation of the major European Innovative Pharmaceutical companies from prospective reforms. Having done an analysis of the literature on patent quality to develop a theoretical framework for the subsequent thesis, broad factors influencing patent quality (these will be the focus of my subsequent study) will be analysed step-by-step. The subsequent study will then follow a methodology that will be a combination of desktop research and the observations that I will deduce from the time I spend interning at Hovione (either based on the field-note method or case-study method) and EFPIA (including the interviews/survey I will conduct). Also, I may point out that I expect that I will conduct a qualitative analysis of the data collected through interviews. Depending on the number of experts that will agree to be interviewed, I may also use the software- ATLAS.ti for a smooth qualitative analysis and coding of the data. In the next part of the thesis I will dwell on the second important aspect of the legal arrangement (i.e. the patent courts). This will entail a review of the literature. I will do a desk-research analysis aided by the views (collected after interviews) of the major innovative pharmaceutical companies regarding the expected effect of the upcoming Unified Patent Court.

Societal impact

Scholars have mutually agreed that there exists the problem of deteriorating patent quality in most of the prominent jurisdictions and Europe is no exception to this case. Low quality cannot be ignored especially for a business operating in patent-dense markets, and pharmaceutical business is one of those. This may not reflect real innovation taking place in the sector. Further, pharmaceutical inventions have a great role in public policy and public health; therefore, any decisions about patents or such monopolies should come more cautiously and accurately.

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