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Nanotechnology Inventions in U.S. Patent Law

Marko Schauwecker

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Stanford Law School
Crown Quadrangle
559 Nathan Abbott Way
Stanford, CA 94305-8610

University of Vienna School of Law
Department of Business Law
Schottenbastei 10-16
1010 Vienna, Austria

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About the Author

Marko Schauwecker is a Fellow of the Stanford-Vienna Transatlantic Technology Law Forum. His research work is also connected to the Europe Center at Stanford University's Freeman Spogli Institute for International Studies. Marko Schauwecker studied law and political science in Germany, France, Spain, and the U.S. He holds graduate degrees from the Free University Berlin and the University Paris I Pantheon-Sorbonne, obtained a PhD from the Ludwig-Maximilians-University Munich, and an LLM from the University of California at Berkeley School of Law (BerkeleyLaw). Marko Schauwecker spent two years as a research assistant at the Max Planck Institute for Intellectual Property, Competition and Tax Law in Munich, where he served as a member of the "European Max Planck Group for Conflict of Laws in Intellectual Property (CLIP)." In 2009, he joined the Patent Law Directorate of the European Patent Office in Munich as a lawyer. His research focuses on Patent Law and Conflict of Laws. He may be reached at m.schauwecker@web.de.

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Abstract

At least since the turn of the century, inventions in the field of nanotechnology have been expected to bring about the most promising and influential technologies of the future, with broad benefits to human life and the environment. Due to the innovative function of the patent system, whether and to what extent these predictions about nanotechnology will come true depends to a large extent on the way patent law is applied to inventions in this field. Against this background, this paper analyzes the interaction of nanotechnology with patent law in the U.S., where – contrary to Europe – the issue has already received some attention in theory as well as in administrative and judicial practice. This paper will show that the issue of "downsizing" as well as the unpredictability prevailing in the field of nanotechnology – even though raising important questions of patentability – are not unknown to the patent system. The only truly new challenge for the patent system derives from the cross-industry nature of nanotechnology. This study, however, finds that the patent system neither poses insurmountable hurdles, nor stricter requirements for the patentability of nanotechnology inventions than it imposes on inventions from other technological fields.

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A. Introduction

Nanotechnology is considered to be one of the 21st century's key technologies.[1] For the purposes of patent law,[2] the term "nanotechnology" relates to "an atomic, molecular, or macromolecular structure, that…[h]as at least one physical dimension of approximately 1-100 nm[3][,] and…[p]ossesses a special property, provides a special function, or produces a special effect that is uniquely attributable to the structure's nanoscale physical size".[4] With nanosize being the definitive criterion, nanotechnology inventions can be found in a wide variety of technical fields.[5] The use of nanostructures yields particular hope for improving the diagnosis and treatment of serious diseases like cancer, or in revolutionizing the science of solar technology, water treatment and the development of low emission automobiles.[6]

According to some predictions, the global market for nanotechnological goods and services might total 1 trillion USD by 2015, which would make it the fastest growing technology ever.[7] Policy initiatives focus on the economic promotion of

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[1] For a plain and accessible introduction to nanotechnology see, e.g., Richard D. Booker & Earl Boysen, Nanotechnology for Dummies (2005), as well as Mark. A. Ratner & Daniel Ratner, Nanotechnology: A Gentle Introduction to the Next Big Idea (2002). For a brief historical outline of the development of nanotechnology see Matthew J. Dowd et al., Nanotechnology and the Best Mode, 2 NANOLB 238, 240 (2005).

[2] For a definition from a natural science perspective, as well as various efforts of coming up with a narrower definition and the problems related thereto, see Nikolas J. Uhlir, Throwing a Wrench in the System: Size-Dependent Properties, Inherency, and Nanotech Patent Applications, 16 Fed. Cir. B.J. 327, 328 (2007).

[3] 1 nm corresponds to one part in a billion of a meter. Etymologically, nanotechnology is "dwarf technology."

[4] Definition of the USPTO; for a full description of nanotechnology class 977 visit http://uspto.gov/go/classification/uspc977/defs977.htm. The USPTO's definition to a great extent corresponds to the EPO's classification of nanotechnology inventions; see http://www.epo.org/topics/issues/nanotechnology.html. Regarding the definitions, see also Alexander Esslinger, Patenting Nanotechnology Inventions in Europe, 4 NANOLB 495, 496 (2007), as well as Blaise Mouttet, Nanotech and the U.S. Patent & Trademark Office: The Birth of a Patent Class, 2 NANOLB 260, 262 (2005).

[5] For an account of the interdisciplinary, cross-industry nature of nanotechnology see, e.g., Mark A. Lemley, Patenting Nanotechnology, 58 Stan. L. Rev. 601, 614 (2005).

[6] See in more detail (without author), Top Ten Ways Nanotechnology Will Impact Life in the Next Ten Years, 4 NANOLB 401 (2007).

[7] See Raj Bawa, Nanotechnology Patenting in the US, 1 NANOLB 31, 36. For figures on the predicted size of the nanotechnology market, investment and skilled labor demand see the annual reports of the National Science Foundation, available under http://www.nsf.gov/crssprgm/nano/reports/nsfnnireports.jsp.

nanotechnology;[8] and on the risks and ethical concerns associated with its development and use.[9] Legal doctrine on the other hand, analyzes the impact of the "nanotech revolution"[10] on patent law. As in biotechnology and information technologies, patent protection plays a crucial role in the development of nanotechnology, as only the prospect of harvesting the economic fruits of costly research incentivizes innovation and gives start-up companies access to venture capital.[11]

For this reason, experts predict an ever-increasing number of nanotech patent applications in the coming years. Patent offices have been active in preparing for this expected wave by creating a new patent class and training examiners for the technical challenges associated with nanotechnology.[12] So far, the number of nanotech patents has not even broken into the double-digits,[13] and those patents granted, in many cases, have not even led to any marketable products. Nonetheless, experts in the field agree that questions of nanotechnology will, together with biotechnology and computer-implemented inventions, comprise the

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[8] In this regard, see the Congress' "National Nanotechnology Initiative" of 2003 (http://www.nano.gov), as well as the "21st Century Nanotechnology Research and Development Act", 15 U.S.C. § 7501 (2004).

[9] For this important aspect of nanotechnology policy, which cannot be treated in this framework, see, e.g., Davis Baird & Tom Vogt, Societal and Ethical Interactions With Nanotechnology ("SEIN") – An Introduction, 1 NANOLB 391 (2004); Amber Hottes, Review of Nanoethics: The Ethical and Social Implications of Nanotechnolgy, 4 NANOLB 527 (2007), as well as the in-depth study of Geoffrey Hunt & Michael Mehta, Nanotechnology: Risk, Ethics and Law, 2006.

[10] Vgl. Douglas Sharrott & Lucian C. Chen, Patenting Nanotech Inventions, 1 Industrial Biotechnology 153 (2005).

[11] See in particular Albert P. Halluin & Lorelei P. Westin, Nanotechnology: The Importance of Intellectual Property Rights in an Emerging Technology, 86 J. Pat. & Trademark Off. Soc'y 220 (2004); see also Bawa, *supra* note 7, at 37; J. Steven Rutt et al., New Patent Rules Will Dramatically Impact Nanotechnology Patenting, 4 NANOLB 447, 448 (2007), as well as Laurie A. Axford, Patent Drafting Considerations for Nanotechnology Inventions, 3 NANOLB 305 (2006).

[12] For the USPTO see Halluin & Lorelei, *supra* note 11, at 227; Vivek Koppikar et al., Current Trends in Nanotech Patents: A View From Inside the Patent Office, 1 NANOLB 25, 27 et seq. (2004) as well as Mouttet, *supra* note 4, at 260 et seq. For the EPO visit http://www.epo.org/topics/issues/nanotechnology.html; see also Esslinger, *supra* note 4, at 495 et seq.

[13] For statistics see Mouttet, *supra* note 4, at 261; Blaise Mouttet, Nanotechnology and U.S. Patents – A Statistical Analysis, 3 NANOLB 309 (2006); Koppikar et al., *supra* note 12, at 25 et seq.; Lemley, *supra* note 5, at 602 et seq. (2005); as well as Thomas Heinze, Nanoscience and Nanotechnology in Europe: Analysis of Publications and Patent Applications Including Comparisons With the United States, 1 NANOLB 427 (2004).

top issues courts will have to deal with in the field of intellectual property in the next twenty years.[14]

The acknowledgment of nanotechnology's importance and patent laws' vital role in this development contrasts with the overwhelming lack of studies on the interplay between both fields in German[15] and European[16] legal writing. Contrarily, in the U.S, a journal specifically devoted to the social, business, and patent law aspects of nanotechnology, was launched in 2004.[17] Against this background, this paper aims to give an overview of the key patent law issues likely to arise in the field of nanotechnology. This paper considers the issues that have already been the subject of first nanotech-specific United States Patent and Trademark Office (USPTO) and court decisions. In addition, this article shall also serve as a catalyst for further studies devoted to European patent law(s) and nanotechnology.

[14] See the Honourable Judge Arthur J. Gajarsa of the Court of Appeals for the Federal Circuit (CAFC), Quo Vadis?, 6 Marq. Intell. Prop. L. Rev. 1, 4 et seq. (2002).

[15] So far, there seem to be only two law review articles on very specific aspects of nanotech patent law. See Stefan R. Huebner, Zur Neuheit von Erfindungen aus der Nanotechnologie [Novelty of Nanotech Inventions], 109 (10) Industrial Property and Copyright Law (GRUR) 839, as well as Ralf Uhrich & Herbert Zech, Patentierung von Nanomaschinen [Patentability of Nanocars], 110(9) GRUR 768 (noticing a "novercal treatment" of the topic).

[16] Slightly more scholarly writing can be found on the EPC, see Esslinger, *supra* note 4, at 495 et seq.; Christian Kallinger et al., Patenting Nanotechnology: A European Patent Office Perspective, 5 NANOLB 95 (2008), as well as Maurice Schellekens, Patenting Nanotechnology in Europe: Making a Good Start? An Analysis of Issues in Law and Regulation, TILT Law & Technology Working Paper No. 008/2008, 28 May 2008, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1139080 (acknowledging that the topic is to a large extent neglected in academic writing).

[17] Nanotechnology Law & Business (NANOLB). Also U.S. legal writing so far lacks a comprehensive study of the legal problems related to the patentability of nanotech inventions.

B. Key Issues Regarding the Patenting of Nanotech Inventions in the U.S.

The protection of nanotechnology inventions through patents presents legal intricacies to various extents with regard to all requirements of patentability under Title 35 of the United States Code (U.S.C.). The placement of nanotechnology in the larger framework of U.S. patent law therefore requires an in-depth analysis of patentable subject matter (Part I., *infra*), novelty (Part II., *infra*), nonobviousness (Part III., *infra*), utility (Part IV., *infra*), and disclosure requirements (Part V., *infra*) as they apply to inventions in the field of nanotechnology.

I. Patentable Subject Matter, 35 U.S.C. § 101

Despite the apparently broad wording of section 101,[18] titled "Inventions patentable," according to which "...[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title;" mere discoveries of natural phenomena[19] are not protectable under U.S. patent law.[20] Given the breadth and heterogeneity of fields in which nanotech inventions are susceptible to occur, their categorical exclusion from patentability for falling outside the scope of section 101 cannot be outright claimed. For the same reason, however, it cannot be ruled out

[18] For a discussion of whether the patentable subject matter test amounts to an independent patentability requirement, see Merges & Duffy, *supra* note 18, 67; clearly supporting this assumption, e.g., *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1372 (Fed. Cir. 1998), according to which section 101 is "the first door which must be opened on the difficult path to patentability".

[19] Georgios Zekos, Patenting Abstract Ideas in Nanotechnology, 9(1) The Journal of World IP 113 (2006) also brings up the category of abstract ideas which do not have access to patent protection. However, from the article it remains dubious how this notion could bar the patentability of nanotechnology inventions.

[20] See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972). For an in-depth analysis see Merges & Duffy, *supra* note 18, 67-130.

that nanotech inventions will, as a matter of principle, never raise questions of patentable subject matter. Carbon nanotubes, for example, have been argued not to be patentable subject matter as carbon tubular structures occurr abundantly in nature.[21] Without a doubt, such an objection cannot be raised against the patenting of processes for isolating or making carbon nanotubes in certain sizes, because those processes are neither laws of nature nor natural phenomena. Product claims relating to carbon nanotubes which are artificially made or obtained through sophisticated processes should survive a section 101 invalidity attack, as the purification or isolation makes them distinguishable from those structures occurring in nature and thereby erodes the natural phenomena argument.[22] With the jurisprudence on patentable subject matter still in flux,[23] one must wait and see how courts will handle the natural phenomena – isolation/purification dichotomy in the field of nanotech inventions.[24] In any case, it can be stated with certitude that section 101 is not the primary hurdle for nanotech inventions on the difficult path to patentability.

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[21] For more elaboration on this point see John C. Miller & Drew L. Harris, The Carbon Nanotube Patent Landscape, 3 NANOLB 427, 443 et seq. (2006).

[22] See Miller & Harris, *supra* note 21, at 434 (drawing an analogy to the patentability of isolated or purified gens as acknowledged, e.g., in *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 13 U.S.P.Q.2d 1737 (D. Mass. 1989)). Zekos, *supra* note 19, at 114 supports this reasoning with regards to fullerene inventions, arguing that those constitute implementations clearly differing from what can be found in nature. For this line of argument see also *in re Bergstrom*, 427 F.2d 1394, 1397 (C.C.P.A. 1970); *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd. and Genetics Institute, Inc.*, 927 F.2d 1200, 1203 (Fed. Cir. 1991), as well as *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.N.Y. 1911).

[23] See, lastly, regarding the patentability of computer-implemented inventions *in re Bernard L. Bilski and Rand R. Warsaw*, Decision 08/833,892, October 30, 2008, http://www.cafc.uscourts.gov/opinions/07-1130.pdf.

[24] See Miller & Harris, *supra* note 21, at 444.

II. Novelty, 35 U.S.C. § 102

The most basic requirement for the patentability of any invention is its novelty. According to § 102, "[a] person shall be entitled to a patent unless – (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent…"[25] A plea for lack of novelty (so-called anticipation) requires a showing that a single prior art reference[26] contains every element of the claimed invention, i.e. already discloses the same invention.[27] Even without a single prior art reference disclosing every element, a claimed invention might still lack novelty if, for a person skilled in the art, the missing feature necessarily – not merely possibly – results from the disclosed elements (so-called doctrine of inherent anticipation, or inherency).[28]

The requirements for the newness of nanotechnology inventions deriving from this provision are not different from those to which inventions in other fieldsof art are subject. Nevertheless, the application of § 102 to nanotech inventions deserves closer scrutiny as developments in this field often are smaller versions of products already existing on the macro- or micro-scale.[29] As described in the definition of nanotech inventions, downsizing lies at the very heart of nanotechnology. In the pharmaceutical sector, for example, there are a number of nanotech drugs which differ in size from existing products, but not with regard to

[25] For a detailed general analysis see Merges & Duffy, *supra* note 18, 357-507.

[26] Cases in which more than one prior art reference discloses the invention's elements do not raise the question of novelty but concern the obviousness standard, see *infra* III.

[27] See, e.g., *Structural Rubber Products Co. v. Park Rubber Co.*, 749 F.2d 707, 715 (Fed. Cir. 1984).

[28] See, e.g., *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 f. (Fed. Cir. 1991). See also, with a concrete example from the nanotech field, Koppikar et al., *supra* note 12, at 27.

[29] See, e.g., Sharrott & Chen, *supra* note 10, at 154; Louis M. Troilo, Patentability and Enforcement Issues Related to Nanotechnology Inventions, 2 NANOLB 36, 39 (2005); Koppikar et al., *supra* note 12, at 28; Lemley, *supra* note 5, at 621, as well as Uhlir, *supra* note 2, at 328 (referring to U.S. patent No. 6.203.768).

the basic chemical composition, field of treatment, and effects.[30] Likewise, with the number of nanotech inventions and patents rising, inventors will try to patent just a certain size or size range of a product of which a different nano size has already been disclosed. However, reducing the size of an existing object or simply changing the size of a previously know invention, does not, in principle, meet the requirement of novelty and is therefore not open to protection under U.S. patent law.[31]

The dogma that "smaller is not patentable" demands a different application in the field of nanotechnology, though.[32] First of all, the manufacturing of "nano editions" of products already existing on the macro- or micro-scale, requires new and complicated methods which in most cases are themselves patentable as processes, irrespective of "mere downsizing" concerns.[33] But even nanotech products with a "larger cousin" cannot be excluded from patent protection for lack of novelty without further ado. Two sets of cases should be distinguished. As far as a "larger cousin" of the nanotech invention exists which does not cover the nanosize range, novelty is not concerned as the state of the art does not disclose

[30] For such a (recently decided) case see William F. Prendergast & Heather N. Schafer, Nanocrystalline Pharmaceutical Patent Litigation: The First Case, 5 NANOLB 157 (2008), labelling the nanotech drug as "reformulation of the traditional breast cancer treatment".

[31] See *in re Rose*, 220 F.2d 459, 461 et seq. (C.C.P.A. 1955); *in re Rinehart*, 531 F.2d 1048, 1053 (C.C.P.A. 1976); *Thomas A. Gardner v. TEC Systems, Inc. et al.*, 725 F.2d 1338, 1345 (Fed. Cir. 1984); with numerous further references see also *Hobbs v. Wisconsin Power & Light Co.*, 250 F.2d 100, 107 f. (7th Cir. 1957). For a very early recognition of this principle see *Evans v. Eaton*, 20 U.S. 356, 431 (S. Ct. 1822), as well as § 2 of the Patent Act of 1793 (Act of Feb. 21, 1793, 1 Stat. 318, 321): "…simply changing the form or the proportions of any machine, or composition of matter, in any degree, shall not be deemed a discovery".

[32] For an analysis of the novelty of nanotech inventions and the issue of "mere downsizing" under European Patent Law see Kallinger et al., *supra* note 16, at 99, as well as Huebner, *supra* note 15, at 839 et seq.

[33] See in particular Sharrott & Chen, *supra* note 10, at 155. Simply put, the distinct character of nanotech fabrication techniques specific to nanotechnology is the use of a "bottom up" approach by starting off with constituent materials like gases or fluids and building up the nanostructure atom by atom by evoking chemical, electrical, or physical forces. In contrast to that the traditional "top down" technique departs from a larger structure and achieves smaller features by removing atoms or molecules step by step; for a description see Troilo, *supra* note 29, at 41 et seq.

the claimed size, neither expressly nor inherently.[34] It is not novelty, but nonobviousness (see infra III.) an applicant – as well as examiners and judges alike – has to worry about. The question of nonobviousness is whether in light of the prior art the downsizing into the nanosize scale would have been obvious to a person skilled in the art.[35]

More difficult to judge are those cases in which the "larger cousin" does also cover the nanosize range of the claimed product. Such a line-up is not a mere hypothetical. For example, in the field of chemistry where materials as fibers are regularly claimed by open-ended language lacking limits on the lower size boundary, an applicant might use phrasings such as "less than."[36] Likewise, an existing nanotech product might extend into the size range of the claimed nanotech invention.[37] The novelty[38] of the smaller-sized invention in relation to the "larger cousin" will in such cases largely depend on whether the patent describes the nanotech products only by its physical structure, or whether the claims also (if not exclusively) use limitations directed towards the properties of the structural elements.[39]

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[34] SeeKoppikar et al., *supra* note 12, at 28. The same holds true with respect to two nanotech patents that only differ in the size (range) claimed; see explicitly and with reference to two U.S. nanotech patents claiming silicon nanoparticles of about 1 nm and of about 10 nm respectively, Bridget A. O'Leary Smith, Everything New Is Old Again: Patentable Novelty of Nanoscale Chemical Materials Does Not Imply Newness Under the TSCA and the FDCA, 4 NANOLB 457, 462 (2007). Cf. Uhlir, *supra* note 2, at 330 (providing a sceptical view). By the same token, this reasoning can be applied to methods of producing nanotech products if the techniques refer to the making of different nano sizes of the same object; see also very convincingly O'Leary Smith, *supra* note 34, at 462.

[35] See O'Leary Smith, *supra* note 34, at 462 (footnote 45). For a discussion of the overlap between the "strict identity test" under section 102 and the "substantial identity test" for purposes of section 103 see Merges & Duffy, *supra* note 18, 367-368.

[36] See Troilo, *supra* note 29, at 42.

[37] See *ex parte Khan*, which will be discussed *infra* shortly.

[38] The significance of over-reaching size ranges for the question of nonobviousness will be discussed *infra* III.

[39] For an in-depth discussion of these claiming techniques in the field of nanotechnology, their benefits and drawbacks, see Uhlir, *supra* note 2, at 330 (referring to the exact wording of to U.S. patents in footnotes 50 and 51).

Claims drawn solely to the physical structure of a nanotech product, in spite of considerable benefits related to this claiming technique,[40] entail a greater risk of being rejected by an examiner or invalidated in infringement litigation for lack of novelty.[41] In this line of reasoning, the Board of Patent Appeals and Interferences (BPAI), in a decision on the 30th of January 2008, upheld the examiner's rejection of two patent claims whose only difference from a prior art's reference was that they were drawn to a different nanosize. Apart from that, the patent claimed the same physical structure as disclosed by the prior art reference.[42] The applicant claimed molybdenum oxid (MoO_3) in a weight range of about 33-44m²/g, meanwhile the prior art reference disclosed molybdenum nanoparticles in a range of about 1,3-32m²/g. The BPAI found that the prior art reference, by using a word of degree ("about") and decimals, overreached into the range claimed by the applicant. As for the rest, because the claims were drawn to the same physical structure, the Board concluded that the identical invention already existed by another name or rather by a different description.[43]

On the other hand, patents claiming smaller versions of already existing larger products only by its physical structure will not raise novelty concerns if the later claimed structure, irrespective of overreaching size ranges, clearly differentiates from the disputed prior art reference.[44] Also, overlapping sizes or size ranges alone do not amount to anticipation if the prior art reference does not enable a

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[40] See Uhlir, *supra* note 2, at 330.

[41] This is unequivocally assumed by Uhlir, *supra* note 2, at 330; Lemley, *supra* note 5, at 621; O'Leary Smith, *supra* note 34, at 462; Magda Carvalho, Patent Claiming Nanotech Products Only By Its Physical Structure, May 30th, 2008, http://www.nanotech-now.com/columns/?article=204; by reverse also Troilo, *supra* note 29, at 39; see also Koppikar et al., *supra* note 12, at 28. See also *ex parte Khan* discussed immediately *infra*.

[42] See e*x parte Mohamed H. Khan, James A. Cole, and Joel A. Taube*, Appeal 2007-2211, January 30, 2008, http://des.uspto.gov/Foia/ ReterivePdf?system=BPAI&flNm=fd20072211-01-30-2008-1, at 15 et seq.

[43] Id. at 15 et seq, 20.

[44] Id., at 20; see also Carvalho, *supra* note 41, at 2.

person skilled in the art to create the nano product in the claimed size[45], which the Board considered fulfilled in *Khan*.[46] If this is not the case, the nanotech invention is novel irrespective of the formally overlapping sizes.[47]

Drawing the claims to certain properties of the nanotech product, however, erodes any objection for lack of novelty because of "mere downsizing."[48] As long as equivalent macro- or micro-scale products do not exhibit such properties, the "mere" change in size does not take away an invention's novelty, but rather lies at its foundation.[49] Inherent anticipation might, if at all, become an issue in such cases if the same product already exists in a different nanosize and exhibits the same size-dependant properties without being explicitly disclosed in the prior art.[50]

In sum, the novelty requirement only poses difficulties to nanotech patent applications which claim a nanotech product exlusively by its physical structure.

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[45] See *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 555 (1870). For more details on the enablement standard for the purposes of anticipation, see Merges & Duffy, *supra* note 18, at 380-387. The differences between enablement for the purposes of anticipation and of enablement are discussed, e.g., *in re Hafner*, 410 F.2d 1403 (C.C.P.A. 1969), as well as in *Rasmussen v. Smithkline Beecham Corp*., 413 F.3d 1318, 1325 (Fed. Cir. 2005).

[46] *Ex parte Khan*, at 18. See also with special reference to nanotech inventions O'Leary Smith, *supra* note 34, at 462; Troilo, *supra* note 29, at 42 et seq. For a more general discussion, see Robert A. Matthews, Jr. & Louis M. Troilo, Schering Corp. v. Geneva Pharmaceuticals, Inc.: Just How Far Can Inherent Anticipation Extend?, 20 Santa Clara Computer & High Tech L.J. 779 (2004).

[47] Strictly speaking there is no overlap in size if the prior art reference does not enable a person skilled in the art to prepare the claimed product in the specific size. Therefore this line-up would "fall back" in the first set of cases discussed *supra*. Once more, the reasoning can be analogically applied to process patents: If prior art "formally" discloses the preparation of a size claimed by the applicant, but does not actually enable one to fabricate the nano product in this size, there is no anticipation; see very convincing O'Leary Smith, *supra* note 34, at 462.

[48] See Uhlir, *supra* note 2, at 330.

[49] See Troilo, *supra* note 29, at 39; Sharrott & Chen, *supra* note 10, at 154; O'Leary Smith, *supra* note 34, at 462 (even though, in the example given by the author, he referes to differences in the physical structure and not in the properties). For an earlier recognition of this principle, albeit with regard to nonobviousness, see *Davis v. Palmer*, 7 F. Cas. 154, 159 (C.C.D. Va. 1827): "…it is not every change of form and proportion which is declared to be no discovery, but that which is simply a change of form and proportion, and nothing more. If, by changing the form and proportion, a new effect is produced, there is not simply a change of form and proportion, but a change of principle also."

[50] See, Miller & Harris, *supra* note 21, at 448; Jeremy M. Stipkala, Overcoming obviousness when patenting nanotechnology inventions, 23 Nature Biotechnology 677, 678 (2005) with reference to *in re Dillon*, 919 F.2d 688, 693 (Fed. Cir. 1990) (*en banc*).

However, section 102 does not pose, in principle, a hurdle for the patentability of nanotechnology inventions.

III. Nonobviousness, 35 U.S.C. § 103(a)

The most essential requirement for the patentability of a nanotech (as well as any other) invention is nonobviousness. Section 103(a) stipulates that: "....[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."[51] Over decades, Supreme Court precedents have set forth a four-stepapproach for analyzing an invention's (non)obviousness. Under section 103: (i) the scope and content of the relevant prior art have to be determined,[52] (ii) differences between such prior art and the claims at issue are to be ascertained, and (iii) the level of one of ordinary skill in the relevant art has to be established[53] before, on the final and decisive stage, the (non)obviousness of the invention is determined against this background.[54] To guard against a subjective assessment of

[51] For a general, not nanotech-specific study of obviousness see Merges & Duffy, *supra* note 18, 611-780, with comparative remarks at 773-780.

[52] For a detailed analysis of this essential aspect of obviousness analysis see Merges & Duffy, *supra* note 18, 724-764.

[53] See *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983).

[54] *Graham v. John Deere Co.*, 383 U.S. 1, 17 f. (S. Ct. 1966). For additional important Supreme Court decisions on obviousness see *Cuno Engineering Corp. v. Automatic Devices Corp.*, 62 S.Ct. 37, 43 f. (1941); *Great*

(non)obviousness,[55] in ambiguous cases,[56] the law could utilize objective indicia, so-called secondary considerations, such as commercial success, long felt but unsolved needs, or failure of others, in order to shed light on the circumstances surrounding the origin of the invention sought to be patented,[57] provided that these factors are attributable to the inventive characteristics of the claimed product.[58]

Especially with regard to downsized nanotech inventions, establishing nonobviousness is likely to be much more difficult than establishing the proof of their novelty[59] as a "mere" change in size appears to be obvious at first blush.[60] This assumption is only reinforced by the fact that scientists in various disciplines have sought to reduce existing products to nanosize for quite some time, given the knowledge about the improved properties of nanostructures. However, processes for making such nanosized editions were, and still remain, unknown. If the prior art does not enable a person skilled in the art to make the claimed

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Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 71 S.Ct. 127 (1950); *Dann v. Johnston*, 96 S.Ct. 1393 (1976), as well as those referred to *infra*, note 83.

[55] See Merges & Duffy, *supra* note 18, 712-713.

[56] It is important to note that these secondary considerations, true to their denomination, become important only on a secondary level. If the four-step test reveals an invention's obviousness, secondary considerations can, in principle, not alter this finding; see, e.g., Merges & Duffy, *supra* note 18, at 684 (discussing the recent Supreme Court ruling in *KSR v. Teleflex*, where the court found the invention to be obvious inspite of its significant commercial success). See also *B.F. Goodrich Co. v. Aircraft Braking Systems Corp*., 72 F.3d 1577, 1583 (Fed. Cir. 1996); but compare *Arkie Lures, Inc. v. Gene Larew Tackle, Inc*., 119 F.3d 953 (Fed. Cir. 1997). However, a finding of obviousness in spite of an invention meeting long felt but unsolved needs, or, even more, previous failure of other inventors, seems less likely as these two secondary considerations appear to be much more closely intertwined with the primary obviousness analysis.

[57] *Graham v. John Deere Co.*, 383 U.S. 1, 17 f. (S. Ct. 1966); *Hybritech, Inc. v. Monoclonal Antibodies*, Inc., 802 F.2d 1367 (Fed. Cir. 1986). For a critique of the commercial success factor, and in favour of the failure of others consideration see, with further referenes, Robert P. Merges, Commercial Success and Patent Standards: Economic Perspectives on Innovation, 76 Cal. L. Rev. 805 (1988).

[58] For a more detailed analysis of this important nexus requirement see, e.g., *in re GPAC*, 57 F.3d 1573, 1580 (Fed. Cir. 1995), as well as, with further references, Merges & Duffy, *supra* note 18, 714-717.

[59] In line with this assumption, most authors discuss the issue of mere downsizing in the framework of the nonobviousness requirement; see the numerous references *infra* under this section; from Europe see, e.g., EPO Boards of Appeal, Decision of 23 January 2003, T 0070/99 - 3.3.5, *Trustees of the University of Pennsylvania gegen Affymetrix, Inc.*, http://legal.european-patent-office.org/dg3/pdf/t990070eu1.pdf. For a general statement of the nonobviousness requirement's decisiveness compared to those of novelty and utility see Merges & Duffy, *supra* note 18, 611-612.

[60] See *supra* note 31.

invention, section 103(a) does not bar the patentability of a "nano cousin" of an existing product.[61] The Court of Customs and Patent Appeals (CCPA) explicitly acknowledged this basic principle already about 40 years ago for the field of chemistry.[62] Only recently the CAFC has extended this rule to nanotech inventions. *In re Kumar*[63] the court reversed a decision of the BPAI by which the Board had rejected an application claiming aluminium oxide particles for purposes of polishing ultra-smooth surfaces. The BPAI found the invention to be obvious under § 103 as the prior art disclosed identical micro-sized aluminium particles for the same use.[64] On appeal the judges critized the BPAI for not allowing the applicant to submit evidence in form of expert testimony stating that prior art, in spite of the formally overlapping size ranges, did not disclose the claimed nanosize as it did not enable a person skilled in the art to achieve sub-micron aluminium oxide particles. Even though the case was adjudicated on procedural grounds, the court affirmed that the "enablement-obviousness nexus" applies equally to nanotechnology as to other disciplines. The downsizing of an existing larger product to the nano-scale is not obvious unless the prior art is enabling. If the claims are not exclusively drawn to its physical structure, but also to a nano products' properties, prima facie obviousness can be rebutted by referring to the invention's new or improved properties as compared to the prior art,[65] and by

[61] See Koppikar et al., *supra* note 12, at 28 et seq.; Stipkala, *supra* note 50, at 678; Andrew S. Baluch et al., In re Kumar: The First Nanotech Patent Case in the Federal Circuit, 2 NANOLB 342, 345 (2005); Miller & Harris, *supra* note 21, at 448, as well as Dowd et al., *supra* note 1, at 305.

[62] See *in re Hoeksema*, 399 F.2d 269 ff. (C.C.P.A. 1968), as well as *in re Irani*, 427 F.2d 806 ff. (C.C.P.A. 1970).

[63] 418 F.3d 1361 (Fed. Cir. 2005); for a detailed discussion see Baluch et al., *supra* note 61, at 342 et seq., as well as Dowd et al., *supra* note 1, at 305.

[64] In accordance with what was said *infra*, the examiner (as well as the BPAI) had allowed the process claims directed to making the aluminium nano particles.

[65] It is not sufficient to show that the newly discovered property is not disclosed in the prior art. Rather, the decisive question is whether the propertiey the claims are drawn cannot be found in the prior art compound or material; see persuasive Stipkala, *supra* note 50, at 678, referring to *in re Dillon*, 919 F.2d 688, 693 (Fed. Cir. 1988).

showing how they attain unexpected results or solve problems specific to nanotechnology.[66] Even if the properties of the nanotech invention are close to those of the "larger cousin," the allegation that similar structures and uses would necessarily suggest similar properties can be overcome by recalling the difficulty of assessing the structure-property relationships for nanoscale materials, which makes their properties anything but foreseeable.[67]

The more the state of the art in nanotechnology will grow with every new development in the field, so will the burden for applicants in order to establish their invention's nonobviousness vis-à-vis other nano inventions rather than existing macro or micro products.[68] In principal, the above conclusion applies one-to-one to cases of "horizontal" nonobviousness. As long as the applicant shows that either the prior art does not enable a person skilled in the art to achieve the claimed size, or the claimed product possesses unexpectedly new or improved properties, the respective claims will not be subject to a section 103(a) rejection. Still, difficulties might result from the interdisciplinary nature of nanotechnology.[69] Besides the macro- or micro-sized version of the claimed product, a process of making similar materials in nanosize might be well known in a field of technology other than the one to which the claimed invention pertains. The combination of the two (or more) references from different disciplines could cause the examiner to reject the claim for obviousness.[70] The question of whether and to what extent

[66] Stipkala, *supra* note 50, at 678; Troilo, *supra* note 29, at 39 et seq., as well as Miller & Harris, *supra* note 21, at 448 et seq., providing examples from the field of pharmaceuticals. For earlier decisions outside the field of nanotechnology where the courts considered a mere change of size not to bar patentability if the claimed product taught the solution of new problems or showed unexpected results, see *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 43 S. Ct. 322, 329 (1923), as well as *Hobbs v. Wisconsin Power & Light Co.*, 250 F.2d 100, 107 f. (7th Cir. 1957).

[67] For an in-depth description of this specificity of nanotechnology see Troilo, *supra* note 29, at 39 et seq.

[68] As was the case, e.g., in re *Kumar*, discussed *supra*.

[69] See Miller& Harris, *supra* note 21, at 448.

[70] For a specific example see Stipkala, *supra* note 50, at 678.

a combination of prior art references can lead to a rejection for lack of obviousness – a key question in the framework of § 103(a)[71] – has only recently been the subject of a widely observed and significant[72] Supreme Court case. In the decision *KSR v. Teleflex*[73] the Justices decided that a rigid application of so-called Teaching-Suggestion-Motivation (TSM) test is inconsistent with section 103(a).[74] Under this test, developed and previously almost religiously[75] relied upon by the CAFC, teachings of prior art references could not be combined to prove an invention's obviousness unless there was some teaching, suggestion, or motivation to do so in the prior art.[76] It is indeed still not sufficient that each of the claimed invention's elements are independently known in the prior art. The "reason"[77] for combining the existing elements, however, does not have to emanate from published articles or the exact content of existing patents. Rather, design incentives and market forces can lead an inventor to arrange known elements in a certain way. Besides, in assessing the obviousness of a

[71] The decisiveness of § 103(a) for this question follows from the fact that in order to destroy novelty a *single* prior art reference needs to contain all elements of the claimed invention (see already *supra* under II.). As a consequence, cases in which the elements of a claim are contained in more than one reference fall exclusively under § 103(a). The CAFC had shown great reluctancy to recognize such "combination cases" as a separate category under § 103(a), as the Supreme Court had done in a number of decisions and now reaffirmed in *KSR*; see Merges & Duffy, *supra* note 18, 680.

[72] There is, however, still uncertainty among scholars about the exact effect of the decision on the standard of obviousness. In any case, after the ruling, the USPTO amended its guidelines for the examination of an invention's obviousness. For a helpful overview of post-*KSR* decisions of the USPTO, district courts, and the CAFC see Dowd et al., *supra* note 1, at 298 et seq.

[73] *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007); for earlier Supreme Court decisions regarding combination patents see *United States v. Adams*, 86 S.Ct. 708 (1966); *Anderson's-Black Rock v. Pavement Salvage Co.*, 90 S.Ct. 305 (1969), as well as *Sakraida v. Ag Pro*, 96 S.Ct. 1532 (1976). The decision's importance for the nanotech industry is analyzed in more detail by Dowd et al., *supra* note 1, at 293 et seq.

[74] Due to the Supreme Court's general statements about (non)obviousness, it is safe to assume that the *KSR*-ruling is likewise of importance for single-reference obviousness rejections, which are said to rise as a result of the decision; see Dowd et al., *supra* note 1, at 305.

[75] According to Merges & Duffy, *supra* note 18, 664 "the rule had achieved nearly canonical form".

[76] For a recent application of the TSM-test see *in re Kahn*, 441 F.3d 977, 986 ff. (Fed. Cir. 2006); before that see, e.g., *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d, 1572, 1577 (Fed. Cir. 1984); *Ashland Oil v. Delta Resins & Refractories*, 776 F.2d 281, 297 (Fed. Cir. 1985); for a recognition even before the CAFC's birth see *in re Bergel*, 292 F.2d 955, 956 f. (C.C.P.A. 1961). For a detailed analysis see Alan P. Klein, Understanding the Doctrines of "Reason, Suggestion, or Motivation to Combine" and "Reason, Suggestion, or Motivation to Modify", 45 IDEA 293 (2005).

[77] Even though the Supreme Court uses the term "reason", it does not seem to refer to something substantially different from what the CAFC described as "teaching, suggestion, or motivation." See Dowd et al., *supra* note 1, at 299.

combination of prior art elements, examiners and courts alike must assume that a person of ordinary skill and creativity would (i) take into account more than those elements of prior art designed to solve the same problem, and (ii) look to any demand or problem known in the field of the endeavour instead of considering that his motivation could only be triggered by the problem the patentee was trying to solve. The standard for assessing obviousness is the knowledge and creativity of a person of ordinary skill in the art, and not the patentee him or herself.[78] If such inquiry leads to the finding that the invention "does no more than unite old elements with no change in their respective functions,"[79] or results from the testing of "a finite number of identified…solutions"[80] with predictable results, the application must be rejected for obviousness.[81]

So far, only three decisions of the BPAI seem to deal with the obviousness of nanotechnology inventions post-*KSR*.[82] *In re Kamins*[83] the Board confirmed the rejection of an application claiming a method for making nanosized pores for molding purposes by use of a nanoparticle size etch mask. The prior art contained two references, one of which disclosed a technique of fabricating micropores using microspheres as etching masks. This reference also taught the

[78] *KSR*, 127 S.Ct. at 1727 et seq.

[79] *KSR*, 127 S.Ct. at 1736 (citing *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp*., 340 U.S. 147, 152 (1950)).

[80] *Id.* at 1740.

[81] *Id.* at 1727 et seq. The present paper can and shall not deal with this important decision in general terms, but only as its rationale applies to the specific field of nanotechnology. There is, however, some indication in the Supreme Court's ruling that the fourth prong of the *Graham*-approach will consist of a combination of a more flexible TSM test and those obviousness standards reaffirmed and further developed in *KSR*. With good reason many authors underline the necessity to clearly define the relationship between the TSM test and the *KSR* ruling. According to Judge Randall R. Rader of the CAFC post-KSR obviousness determinations will circle around secondary considerations (unpublished talk given at BerkeleyLaw on Nov. 3, 2008, attended by author). This assumption however tends to clash with the truly secondary nature of these considerations as discussed with references *infra*, note 57.

[82] For a more detailed analysis see Magda Carvalho, Obviousness: KSR Rationale Applied to Nanotechnology, June 27, 2008, http://www.nanotech-now.com/columns/?article=208; as well as Magda Carvalho., Obviousness: On Carbon Nanotubes, November 1, 2008, http://www.nanotech-now.com/columns/?article=251.

[83] *Ex parte Kamins et al.*, Appeal No. 2007-2983, August 3, 2007, http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&flNm=fd20072983-08-03-2007-1.

desirability of making smaller sized pores but did not reveal a nanoparticle-sized mask as claimed by the applicant. The availability of such masks, though, was taught by a second reference. The BPAI agreed that an artisan would necessarily have combined these references, thus substituting nanoparticles for microspheres in order to achieve nanosized pores for the known use. In consequence, the claimed invention was no more than a combination of familiar elements yielding predictable results and therefore obvious under section 103(a).

In contrast, in the case of *In re Yoshizawa,*[84] the Board did not affirm the examiner's obviousness rejection. In this case, the application was directed to a material made of pore free nanoparticles of a compound containing, inter alia, litium iron phosphate ($LiFePO_4$). The use of $LiFePO_4$ in batteries, as claimed by the applicant, was well-known in the art, but the reference cited by the examiner in this regard did not reveal a method of making pore-free nanoparticles. A second reference, however, taught a method of producing pore-free nano-sized lithium metal oxide particles. All elements thus being present in the prior art, the examiner considered it obvious for an artisan to fabricate pore free material using the process disclosed in the second reference. The Board disagreed arguing that, as the prior art patent taught only a method of making metal material, an obviousness rejection under *KSR* required an additional showing that an artisan would have had a reason to apply the process to non-metals like phosphorous. The examiner had not provided such evidence indicating that a reasonable person skilled in the art could have reasonably expected to succeed in making pore free nanoparticles of a compound containing $LiFePO_4$ by combining the cited

[84] *Ex parte Yoshizawa et al.*, Appeal No. 2007-3414, October 4, 2007, http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&flNm=fd20073414-10-04-2007-1.

references.[85] Eventually, in *In re Colbert*[86] the Board considered an invention claiming a method of making single-walled carbon nanotubes with derivatized ends to be obvious under section 103(a). Prior art references revealed not only the fabrication of single-walled carbon nanotubes but also a process of end derivatization. The inventors argued that only end-derivatized multi-walled carbon nanotubes were part of the prior art. The BPAI, however, considered the combination of the teaching of both references by an artisan seeking to make end-derivatized single-walled carbon nanotubes to be obvious. The pertinent reference, rather than teaching away from applying the derivatization method to single-walled nanotubes, actually suggested such an application. The applicant had failed to bring forward evidence showing the unlikelihood of such an approach's success, the likelihood of unpredictable results, or any improved properties of the claimed method regarding the known process.[87]

In conclusion, even nonobviousness as the strictest patentability requirement does not pose unsurmountable hurdles to the protection of nanotechnology inventions under U.S. patent law. If the prior art does not enable an artisan to make the claimed product in (a specific) nanosize, or if the invention compared to existing macro-, micro- or even nano-scale products reveal non-obvious new or improved properties, the patentability requirement of section 103(a) is met. Given the interdisciplinary nature of nanotechnology, the question of how prior art references can be combined for obviousness rejection emerges as a key issue.

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[85] See in great detail Carvalho, *supra* note 82, at 2.

[86] *Ex parte Colbert et al.*, Appeal No. 2008-3765, September 30, 2008, http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&flNm=fd20083765-09-30-2008-1.

[87] For an in-depth analysis see Carvalho, *supra* note 82, at 2. The applicant had, in addition, tried (but failed) to show that the prior art process did not actually disclose a method of end-derivatization of single-walled carbon nanotubes, because an application of the known technique to such nanotubes would necessarily lead to their destruction. If proved right, the prior art's lack of enabling the claimed invention would indeed have destroyed the nonobviousness rejection; compare *supra*.

Once the application of the *KSR* rationale to nanotech inventions gets tested in court, it will be interesting to see whether prior art references from diverse nanotech-related fields can be combined to reject nanotech patent applications.[88] Under the current standard, can one assume that a person skilled in the field of nanotechnology has knowledge cross the multiple disciplines involved? And if so, to what extent? Whatever the CAFC's stance on this issue will be, the fact remains that inventions based on the combination of prior art elements will also pass the obviousness test, if such prior art does not enable the achievement of the claimed product, if the invention possesses unexpected novel properties, or if the prior art was actually teaching away from the invention in question.[89]

IV. Utility, 35 U.S.C. § 101/112

Alongside an invention's novelty and nonobviousness, utility completes the three prongs of substantive patentability requirements. Section 101 reads: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." This section establishes the utility requirement in express terms. In addition, section 112 indirectly refers to it by obliging the applicant to disclose "the manner and process of….using" his invention.[90] Moreover, the requirement of an invention's utility can be traced back to Art. 1 Sec. 8 Cl. 8 of the Constitution, the foundation

[88] Identifying this question as a key issue is Miller & Harris, *supra* note 21, at 448, as well as Carvalho, *supra* note 82, at 2.
[89] For an assessment of the importance of this aspect ("teaching away from the invention") post-*KSR* see Merges & Duffy, *supra* note 18, 692 with numerous case law references.
[90] For a detailed analysis of the disclosure obligations applied to nanotechnology see *infra* V. to VII.

of Title 35 of the U.S.C., pursuant to which "Congress shall promote the Progress of Science and useful Arts."[91] The utility requirement is met if an invention, at the time it was made, has some substantial enough utility (so-called 'practical' or 'specific' utility), which is not socially harmful (beneficial utility), and can actually be achieved through the operation of the invention (operability).[92] An invention is considered to have a well-established utility "(1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful…, and (2) the utility is specific, substantial, and credible."[93] At first glance, this requirement might appear to be unnecessary, because a useless invention would neither create market demand nor hamper real innovation. Most likely, one could assume, no reasonable person would even try to obtain patent protection for such an invention. However, often scientists vaguely discern that their invention will have some utility and therefore attempt to obtain an exclusive right at a very early stage of development when the specific utility or useful result is still unpredictable.[94] Even though an invention's use is rarely ever an issue in USPTO or court proceedings,[95] some authors predict that nanotechnology inventions might encounter difficulties in meeting the utility requirement.[96] In very general terms, this prediction is based on the observation that a great number of nanotechnological inventions pertain to chemistry and biotechnology, disciplines

[91] For a detailed, general analysis of the utility requirement see Merges & Duffy, *supra* note 18, 207 et seq.

[92] This last prong of the utility test bars the patenting of inventions which either violate the laws of science (see, e.g., *Newman v. Quigg*, 877 F.2d 1575, 1581 f. [Fed. Cir. 1989] for a perpetual motion machine, as well as more recently *EMI Group North America, Inc. v. Cypress Semiconductor Corp.*, 268, F.3d 1342, 1349 [Fed. Cir. 2001] speaking of "incorrect science"), or contain mistakes.

[93] USPTO Utility Examination Guidelines of 2001. For more details see David S. Almeling, Patenting Nanotechnology: Problems with the Utility Requirement, 2004 Stan. Tech. L. Rev. N1, 15 (2004).

[94] See Merges & Duffy, *supra* note 18, 207-208 (noting that the utility requirement is an influental patent policy instrument as it has an important influence on the time inventions can or rather should get patented). Apart from that, it can prevent abuses of the patent system through very early patenting.

[95] For an account of the requirement's relative insignificance see Merges & Duffy, *supra* note 18, 207: "The vast majority of patent applications are processed without the PTO raising any question as to utility, and the utility doctrine is also rarely litigated as a defense in infringement actions."

[96] For an in-depth analysis see Almeling, *supra* note 93.

where the utility requirement, has always been subject to closer scrutiny than other fields.[97] More precisely, the assumption is that processes in the nanotechnological field might be prevented from receiving patents on grounds of lack of utility where the corresponding nano product does not (yet) possess a known specific use.[98] Also, the use relied on by the patentees might be considered implausible given the difficulty of predicting the consequences of size reductions to the nanometer scale on a physical structure's properties.[99] The same would have to be assumed with regards to nanotech patent claims which are solely drawn to a product's physical structure without disclosing a specific use. Only nanotech patent applications exhibiting a product's size-dependent properties and its credible, substantial use could, under such assumptions, be considered passing the 'utility test' without many hurdles.

However, a closer look does not only unmask these assumptions as highly hypothetical but also shows that they are not backed by existing case law.[100] The utility requirement of section 101 does not pose greater obstacles to the patenting of nano developments than to other inventions. First of all, even with regard to the allegedly stricter utility standard for chemical and biotechnological inventions, the CAFC acknowledged that "usefulnes…necessarily includes the expectation of

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[97] For a deeper look into the utility of inventions in these fields see Merges & Duffy, *supra* note 18, 222 et seq., as well as Almeling, *supra* note 93, at 16. The latter assumes that in the vast majority of cases USPTO and CAFC will apply the "chemistry/biotech utility standard" to nanotechnology inventions.

[98] Almeling, *supra* note 93, at 19 et seq. For such a case in the chemical field see, e.g., *in re Ziegler*, 992 F.2d 1197, 1203 (Fed. Cir. 1993), as well as the Supreme Court's landmark decision *Brenner v. Manson*, 383 U.S. 519, 520 ff. (S. Ct. 1966).

[99] For an account of this specificity of nanotechnology see already *supra* p. 12 with reference to Troilo, *supra* note 29, at 39 et seq. This argument is brought forward by Almeling, *supra* note 93, at 16 et seq. The author also discusses that nanotechnology inventions might be excluded from patenting for lack of utility as nanotech applications mostly cite other patents but no scientific literature, and also because and an existing scepticism against nanotechnology as "science fiction." Both assumptions are considered here to be far too vague and hypothetical; see also the general assessment of the problems nanotech invention might face (or rather not) with the utility requirement, *infra*.

[100] Based on an analysis of the CAFC's utility jurisprudence, Almeling, *supra* note 93, at 32 et seq., confesses himself the hypothetical character of his assumptions.

further research and development."[101] Therefore, even inventions in the very early stage of the development of a new technological field do not automatically or necessarily lack utility. Apart from that, experience so far suggests that most nanotechnological inventions indeed have practical utility.[102] Accordingly, there is no known court or even USPTO decision that even discusses the utility of a nanotech patent application. Ultimately, as in other fields of technology the decisive issue is whether the applicant is willing and able to disclose at least one specific and sufficiently substantial utility, instead of relying on a speculative, overly broad use of the invention, which will not only cause problems under section 101 but will also certainly raise doubts as to the enabling character of the specification.[103]

V. Disclosure Requirements, 35 U.S.C. § 112(1)

Title 35 of the U.S. Code adds substantial disclosure requirements to the three prongs of substantive patentability requirements discussed, supra. These additional requirements are detailed in section 112(1) which states that:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

[101] *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995).
[102] See Almeling, *supra* note 93, at 34.
[103] See, e.g., Sharrott & Chen, *supra* note 10, at 155. For a discussion of the enablement standard see *infra* V. 2.

Although there is some dispute, generally section 112(1) is considered to contain three different disclosure requirements: (1) written description , (2) enablement, and (3) best mode.

1. Written Description

Experts in the field of patent law still disagree on whether the obligation to describe the invention involves anything beyond what is required under the enablement standard.[104] In case law, to the contrary, the CAFC has been settled on this issue for quite a while. In a number of decisions,[105] the court ascertained that enablement and written description are separate and distinct requirements for patentability. The obligation to describe the claimed invention in sufficient detail is meant to ensure that the inventor actually had possession of the claimed invention at the time the application was filed. In other words, the applicant has to show that he really invented what he claims. Consequently, the written description limits the width of the patent claims if they claim more than what was disclosed in the patent application.[106]

Whether the written description requirement has been satisfied is a question of fact that depends on the nature of the subject matter claimed and must be

[104] For disagreement within the CAFC itself see *Univ. of Rochester v. G.D. Searle & Co*., 358 F.3d 1303, 1307 (Fed. Cir. 2004) (Rader, J., Gajarsa, J., and Linn, J. dissenting). For a scholarly contribution see Margaret Sampson, The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology, 15 Berkeley Tech. L.J. 1233 (2000). But compare Jeffrey A. Lefstin, The Formal Structure of Patent Law and the Limits of Enablement, arguing that the role of written description doctrine in defining patent law scope is by far more essential than enablement.

[105] *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); *Regents of the Univ. of California v. Eli Lilly & Co*., 119 F.3d 1559, 1562 (Fed. Cir. 1997); *Union Oil Co. of Cal. V. Atlantic Richfield Co*., 208 F.3d 989 (Fed. Cir. 2000); *Univ. of Rochester v. G.D. Searle & Co*., 358 F.3d 916, 920 ff. (Fed. Cir. 2004).

[106] See *Univ. of Rochester v. G.D. Searle & Co*., 358 F.3d 916, 920 (Fed. Cir. 2004); Magda Carvalho, Written Description Requirement in Applications Involving Nanotechnology, July 29th, 2008, http://www.nanotech-now.com/columns/?column=34. For a general study of the written description requirement see Merges & Duffy, *supra* note 18, at 299 et seq.

reviewed on a case-by-case basis.[107] Therefore, particularities in applying this standard to nanotech inventions are in principal conceivable. Once more, experiences in the fields of chemistry and biotechnology can be fructified as the written description doctrine can be expected to pose similar problems with regard to many nanotech patent applications as in these disciplines. Thus, it can be assumed that a genus of nano materials can only be claimed if the applicant describes at least a few species of the materials as well as their common characteristics and relation to each other.[108] Apart from that, an analysis of the first decisions of the BPAI concerning the written description doctrine in applications involving nanotechnology shows that the BPAI does not raise specific questions as to such inventions' compliance with this requirement.[109] Rather, as in other fields of technology, the BPAI circles around well-known section 112(1) problems, for example, the consequences of claim expansion after filing and the examiner's exact burden of proof to support a written description rejection.

2. Enablement

Without a doubt, the enablement requirement as part of an applicant's disclosure obligation presents far more interesting questions with respect to nanotechnology.[110] The underlying purpose of this requirement is to enable a person of ordinary skill in the art to make and use the claimed invention without

[107] See *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); *Noelle v. Ledermann*, 355 F.3d 1343, 1349 (Fed. Cir. 2004), as well as *Enzo Biochem, Inc. v. Gen-Probe, Inc*., 63 U.S.P.Q.2d 1609, 1612 (Fed. Cir. 2002) ("fact-based enquiry that will necessarily vary depending on the nature of the invention claimed"). See also Carvalho, *supra* note 106, at 1, and Leonard P. Diana et al., Untangling the Nanothreads Between the Enablement and Written Description Requirements, 4 NANOLB 41, 44 (2007).

[108] See Diana et al., *supra* note 107, at 47.

[109] For a detailed analysis of three recent decisions see Carvalho, *supra* note 106.

[110] See Miller & Harris, *supra* note 21, at 448: "Applying this enablement requirement to nanotechnology inventions raises several new questions for courts to address." For a general study of enablement see Merges & Duffy, *supra* note 18, 261-299.

undue experimentation.[111] Problems with the enabling nature of applications in the field of nanotech are likely to arise through the use of very broad claim language. Such broad claiming can routinely be observed at the early stages of a new discipline's development, as applicants seek to obtain vast proprietary rights in order to control a large part of the technological field.[112] Nanotechnology is no exception in this respect. In fact, some authors even estimate there will be a greater number of broad patents in nanotechnology than in biotech or computer science, because patenting of nanotechnology started from the very outset of the field's evolution.[113] Broad nanotech patents are characterized, for instance, by claims which incorporate size ranges or, more specifically, use the term "nanotube" without distinguishing between multi- and single-walled carbon tubes.[114] It has already been mentioned several times throughout this article that the achievement of a certain nano size constitutes one of the main difficulties of this technology and entails great unpredictability with regard to the properties of nano structures. Therefore, if the claims are too broad in relation to the examples provided in the application's specification, the unpredictability of achieving other nano sizes formally covered by the claims (or differently walled nanotubes, etc.)

[111] For a detailed analysis of the undue experimentation criterion see, e.g., *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). The factors to consider when determining whether unde experimentation is required are: breadth of the claims; nature of the invention; state of the prior art; relative skill of a person skilled in the art; (un)predictability of the art; amount of direction or guidance by the inventor; existence of working examples; quantity of experimentation necessary; see *in re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); Diana et al., *supra* note 107, at 43 et seq.; see also the USPTO Examination Guidelines, discussed by Melissa D. Schwaller & Gaurav Goel, Getting Smaller: What Will Enablement of Nanotechnology Require?, 3 NANOLB 145, 147 et seq. (2006).

[112] For a short allusion to the problem of so-called "patent thickets" and "anti-commons" which might evolve from such overly broad patents see *infra* C.

[113] See Sean O'Neill et al., Broad Claiming in Nanotechnology Patents: Is Litigation Inevitable?, 4 NANOLB 29 (2007); Lemley, *supra* note 5.

[114] See Miller & Harris, *supra* note 21, at 449. For a real life example of such a patent see Schwaller & Goel, *supra* note 111, at 146 et seq.

will trigger a rejection on grounds of a lack of enablement.[115] However, a review of the first wave of nanotechnology patents indicates that the USPTO does not (yet) subject these applications to the particularly stringent enablement standard that biotechnological inventions face.[116] Rather, claims of considerable breadth have been granted with neither objection nor even doubt about the specifications' enabling character.[117] No court decisions dealing with this issue have been found yet at the time of writing this paper. Still, as nanotechnology prior art will steadily grow as time passes, experts predict the patent office will more carefully scrutinize the enabling character of nanotechnology claims.[118] Even with closer scrutiny, applicants can prevent enablement rejections by including at least one claim whose width is supported by the written description, or by arguing "that the specification does provide a 'representative' group of examples in relation to the scope of the claim based on the relative predictability of the area in question."[119] The parties should also provide as many working examples and test data as possible in support of their arguments.[120]

Beyond concerns of the enablement of broad claims, nanotech patent applications also call for a reassessment of the applicant's duty to provide information that is, allegedly, generally known in the art. Even though the specification does not, in principle, need to provide such information to be considered enabling,[121] determining the body of knowledge an artisan can be

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[115] See Koppikar et al., *supra* note 12, at 29; Dowd et al., *supra* note 1, at 248, note 64; Miller & Harris, *supra* note 21, at 449; Troilo, *supra* note 29, at 43.
[116] See Miller & Harris, *supra* note 21, at 449; Koppikar et al., *supra* note 12, at 29 et seq., as well as Schwaller & Goel, *supra* note 111, at 149 et seq.
[117] See Koppikar et al., *supra* note 12, at 29.
[118] *Id*. at 30.
[119] *Id.* , at 30.
[120] See Sharrott & Chen, *supra* note 10, at 155.
[121] See *Hybritech, Inc. v. Monoclonal Antibodies, Inc*., 802 F.2d 1367, 1384 (Fed. Cir. 1986) : "[A] patent need not teach, and preferably omits, what is well known in the art."

presumed to possess is a difficult process.[122] For instance, a nanotech invention pertaining to the realm of biotechnology might incorporate a nanotech-related aspect from another disclipine which might be a common expertise in the latter, but not necessarily be known by the average person in the former field.[123] Once more, the decisive question is how to define the "person of ordinary skill in the art" for purposes of nanotechnology inventions. More precisely, can one assume this fictive artisan to have interdisciplinary skills?[124] For practical considerations, applicants are well advised to include a full disclosure of the knowledge relevant to the invention in the specification.[125]

Lastly, it should be noted that section 112(1) also requires an applicant to disclose how the invention's specific and substantial use[126] can be realized.[127] Providing an enabling specification may not be feasible in situations where the nanotech product's use cannot be achieved due to technological issues that are outside the patent's scope yet are an essential part of the invention's effectiveness. Reliance on a more immediate use, if any exists, would be the recommended alternative.[128]

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[122] See Diana et al., *supra* note 107, at 47.

[123] See Diana et al., *supra* note 107, at 47 : "Despite the extraordinary levels of technical and scientific knowledge and expertise displayed by many who are active in nanotechnology, the body of knowledge that can be presumed to be in the possession of "a person of ordinary skill in the art" is, paradoxically, relatively low, because of the highly interdisciplinary nature of so much of the work in this field. Even if it is assumed that any typical person in the field knows a tremendous amount, only a little of that knowledge may be in the possession of more than a few other people in the field."

[124] Schwaller & Goel, *supra* note 111, at 157, regard this problem as key issue of the patentability of nanotech inventions.

[125] Diana et al., *supra* note 107, at 47.

[126] For a discussion of the utility requirement as applied to nanotech inventions see *supra* IV.

[127] See Diana et al., *supra* note 107, at 47 et seq., referring to examples from the realm of biotechnology where the specification did not enable an artisan to achieve the invention's use.

[128] See Diana et al., *supra* note 107, at 48, creating, inter alia, a hypothetical example involving nanocars. However, the authors do not seem to consider sufficiently whether such an application would not already violate the utility requirement itself for lack of operability; see *supra* IV.

3. Best Mode

The last disclosure obligation contained in section 112(1) is the requirement to set forth the best mode the inventor knows for practicing the claimed invention.[129] The requirements of written description and enablement, discussed supra, already serve one of the key functions of every patent system—to increase the amount of technical information in the public domain.[130] Disclosure requirements are meant to strike a fair balance between rewarding the inventor and enlarging the technological know-how in the public domain. However, under U.S. Patent Law, the *quid pro quo* of the patent grant is not satisfied if the inventor just sets forth any mode of making or using what he claims, even though such a description might enable a person of ordinary skill in the art to carry out the invention.[131] Rather, in contrast to the enablement requirement,[132] the inventor must disclose the best mode of practicing the invention, if this is known to him at the time of filing.[133] Under its first prong, best mode is analyzed on a subjective basis. The subjective view of the inventor alone is relevant.[134] Therefore, a rejection of a patent application, or rather an invalidation of a patent, cannot be based on an alleged violation of the best mode requirement if the inventor did not contemplate

[129] For a detailed analysis Merges & Duffy, *supra* note 18, 340-356. For a nanotech-specific study see Dowd et al., *supra* note 1.

[130] For a brief historical outline of the emergence of this "new" role of patents, see Merges & Duffy, *supra* note 18, 340-342.

[131] See *Amgen, Inc. v. Chugai Pharm Co.*, 927 F.2d 1200, 1209 f. (Fed. Cir. 1991): "[The purpose of the best mode requirement is] to ensure that a patent applicant plays "fair and square" with the patent system. It is a requirement that the *quid pro quo* of the patent grant be satisfied."

[132] Regarding the distinction between enablement and best mode, see *Bayer AG v. Schein Pharmaceuticals, Inc.*, 301 F.3d 1306, 1314 (Fed. Cir. 2002); *Randomex, Inc. v. Scopus Corp*., 849 F.2d 585, 590 (Fed. Cir. 1988) (Mayer J., dissenting); *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 928 (Fed. Cir. 1990), as well as *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1532 (Fed. Cir. 1987).

[133] A duty to update does not exist under U.S. Patent Law. See Art. 29 of the TRIPs Agreement.

[134] The knowledge of others involved in the business, research, or patenting process is irrelevant; see *Glaxo, Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1050 (Fed. Cir. 1995); see also Dowd et al., *supra* note 1, at 244 et seq.

a preferred mode of carrying out his invention at the time of filing.[135] Likewise, because the optimal means of practicing the invention is what the inventor subjectively believes it to be, it is immaterial whether an objectively better mode of putting the invention into practice exists. The inquiry focuses solely on the subjective, not the absolute best mode.[136] Only under the second prong does the analysis shift to an objective inquiry into whether the specification adequately describes the best mode so as to enable an artisan to practice the invention in such a way.[137] Although there is some confusion, unclaimed subject matter does not seem to be subject to the best mode requirement.[138] In principle, a violation of the best mode requirement only invalidates the respective claim covering the best mode. However, egregiously concealing the best mode might render the entire patent unenforceable.[139]

Special concerns with regard to nanotechnology inventions arise from the fact that section 112(1) requires disclosure of the best mode of making or using the claimed invention if that preferred aspect materially affects the invention's properties.[140] By now it should be evident that this applies to the vast majority of nano structures. Claims incorporating size scales of a certain nanotech product must therefore – if contemplated by the inventor – disclose the size structure

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[135] See, e.g., *Bruning v. Hirose*, 161 F. 3d 681, 687 (Fed. Cir. 1998); also Dowd et al., *supra* note 1, at 244: "Furthermore, there is no requirement that the inventor have a best mode."

[136] See with great detail and clarity Dowd et al., *supra* note 1, at 244.

[137] See *Chemcast*, 913 F.2d at 927-928.

[138] See *Bayer AG v. Schein Pharmaceuticals, Inc.*, 301 F.3d 1306, 1315 (Fed. Cir. 2002), deciding that the non-disclosure of the preferred method of making an antibiotic did not amount to a best mode violation because the claims were drawn to the compound and did not cover the method. Compare however *Nobelpharma AB v. Implant Innovations*, 141 F.3d 1059, 1065 (Fed. Cir. 1998). For a detailed discussion with numerous case law references see Dowd et al., *supra* note 1, at 245 et seq. Compare also the discussion in the following paragraph.

[139] See, with further references, Dowd et al., *supra* note 1, at 244. Some case law suggests that voluntary concealment is a compulsory requirement under section 112(1), so that mere neglect or oblivion would not amount to a best mode violation. The difficulties in proving such intent, however, clearly militate against this interpretation. On equitable conduct in general see Merges & Duffy, *supra* note 18, 1102-1140.

[140] *Bayer*, 301 F.3d at 1319-20.

which, in the inventor's view, allows achieving the invention's properties in an optimal manner. Also, despite the CAFC's acknowledgment of the limiting character of the claims in a best mode analysis,[141] there is still some uncertainty as to whether an unclaimed feature could under certain circumstances still be considered within the scope of the best mode requirement, specifically if the unclaimed aspect is critical to the functioning of the invention or materially affects its properties.[142] However, there seem to be practices available to ensure compliance with the best mode requirement when filing nanotech patent applications.[143] Any hope or expectation that the problem might become the subject of patent history beyond just nanotechnology inventions, have recently been shattered, though, as the Patent Reform Act of 2008 no longer provides for the abolishment of the best mode requirement.[144]

C. Conclusion

Nanotechnology presents new challenges for the patent system. Amidst these, the patentability of nanotechnology inventions must be a major concern for all stakeholders in the field of patents. Under U.S. Patent Law, novelty and nonobviousness, as well as, to a lesser degree, utility and disclosure obligations raise certain original questions when applied to nanotech inventions. The special

[141] See *supra* with reference to *Bayer*, 301 F.3d 1306.

[142] See in this regard *Nobelpharma*, 141 F.3d at 1065, as well as *Bayer*, 301 F.3d 1306, 1327 (Rader, J., concurring). For an in-depth discussion with regard to nanotechnology it shall be once more referred to Dowd et al., *supra* note 1, at 247 et seq.

[143] For a discussion of available procedures see Dowd et al., *supra* note 1, 249 et seq.

[144] This is in direct contrast to earlier versions, see, e.g., the Patent Reform Act of 2005; see also Dowd et al., *supra* note 1, at 238.

need for clarification is primarily caused by the interdisciplinary nature of nanotechnology. Apart from organizational adjustments, such as creating a new patent class and providing examiners with specialized training,[145] the accommodation of the cross-industry character of nanotechnology into the existing metes and bounds of the patent system has a major impact on determining the skills of a fictitious artisan for purposes of nonobviousness and enablement analysis. Still, Title 35 of the U.S. Code neither poses insurmountable hurdles to the patentability of nanotech inventions nor stricter protection requirements as compared to other fields of technology.

In addition to the issues raised by prosecuting nanotech patents, nanotechnology raises other thrilling questions at the stage of patent enforcement. Evidently, the above remarks regarding the patentability of nanotech inventions have the same relevance and apply *mutatis mutandis* on the enforcement level[146] – often becoming an issue only there[147] – whenever a defendant attacks the validity of the patent in an infringement proceeding. Scholars, though, are much more concerned about the blocking effect of patenting activity in the field of nanotechnology. Fears of growing "patent thickets" which will hamper innovation and impede commercialization dominate numerous contributions.[148] If these

[145] See Diana et al., *supra* note 107, at 42.

[146] However, there are some slight differences. For instance, to invalidate a patent for inherency a litigant must provide clear evidence of the contentious element's presence in the prior art, and cannot rely on probabilities or possibilites. An examiner, in contrast, must "only" reasonably support his finding that the missing characteristic necessarily flows from existing teachings. See in more detail Uhlir, *supra* note 2, at 333 et seq.

[147] Generally the best mode rarely becomes an issue in USPTO proceedings because of the difficulty of determining whether a patent application discloses the preferred way of practicing the invention at this stage. See Dowd et al., *supra* note 1, at 249.

[148] See, with further references, Lemley, *supra* note 5, at 601 et seq. For a short discussion of the same issue in the field of biotechnology see, with numerous references, Wolrad Prinz zu Waldeck und Pyrmont, Research Tool Patents After Integra v. Merck – Have They Reached a Safe Harbor?, 14 Mich. Telecomm. Tech. L. Rev. 367, 384 et seq.

predictions are to be believed at all,[149] USPTO and CAFC are well equipped to countervail such a development through a strict application of the patentability requirements as discussed above.[150] The moment of political interference through formulation of a nanotechnology policy aimed at preventing the privatization of basic research and development in the field has certainly passed.[151] Patent owners on their part, should be sensitive about the language they apply in wording their claims to avoid doubts about validity and scope of their rights. Also, they have to ensure, through license agreement or the "pooling" of patents (as the case may be), that the exercise of their patents does not conflict with the rights of third parties.[152] Finally, with regard to nanotech inventions in the field of pharmaceuticals, a major concern is the extent to which the use of a patented nanotech research tool is permitted under the "safe harbor" exemption of section 271(e)(1).[153] However, in the framework of this general article it cannot be done more than to allude to the need for further research into these and other specific questions of nanotechnology patent law and to emphasize the topic's great appeal.

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[149] Robert P. Merges, 85 Tex. L. Rev. 1627, 1632 et seq. (2007) argues with respect to the software industry and based on an analysis of industry revenues, product innovation, and firm entries, that the early predictions about the hampering effects of patenting were wrong.

[150] See the remarks *supra* regarding utility (B. IV.) and enablement (B. V. 2.); see also Almeling, *supra* note 93, at 19 et seq., as well as *Brenner*, 383 U.S. at 520 et seq. and 534 et seq. On claim construction in nanotechnology cases see O'Neill et al., *supra* note 113, at 29 et seq., as well as Magda Carvalho, Nanotechnology and Claim Construction: DuPont v. Cabot, August 25th, 2008, http://www.nanotech-now.com/columns/?article=229.

[151] For a discussion of the role of IP policy see Ted Sabety, Nanotech Innovation and the Patent Thicket: Which IP Policies Promote Growth?, 1 NANOLB 262 (2004).

[152] See Alexander Lee, Examining the Viability of Patent Pools for the Growing Nanotechnology Patent Thicket, 3 NANOLB 317 (2006); Albert P. Halluin, Incorporation of Parts Into the Whole: Avoiding Liability When Incorporating Nanotechnology Improvements, 3 NANOLB 25 (2006); Drew Harris et al., Strategies for Resolving Patent Disputes Over Nanoparticle Drug Delivery Systems, 1 NANOLB 372, 383 et seq. (2004).

[153] With special reference to nanotechnology patents see Stephen B. Maebius & Harold C. Wegner, Merck v. Integra: The Impact of a Broader "Safe Harbor" Exemption on Nano-Biotechnology, 2 NANOLB 254 (2005); for a very recent general analysis see Prinz zu Waldeck und Pyrmont, *supra* note 148, at 367 et seq.