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Unravelling Inventorship

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UNRAVELLING INVENTORSHIP

TOSHIKO TAKENAKA*

Abstract

Inventorship, who made an invention, is one of the most important concepts under the U.S. patent system. Incorrect inventorship determinations result in patent invalidity not only because U.S. Constitution requires granting patents to true inventors, but also first-inventor-to-file novelty inherited many aspects of first-to-invent novelty which depended on inventorship whether to include prior inventions as prior art. Correcting inventorship may result in sharing patent exclusivity with competitors, which forfeits profits necessary to recover expensive development costs. However, the standard to determine inventorship has been called muddy by judges and commentators because neither the Patent Act nor case law provide any clear guidance. The standard has become overinclusive to overcome obstacles to obtaining patents when inventors work jointly on the same research project because the first-to-invent system included prior inventions as prior art even if they were kept secret (secret prior art), unless the same inventorship exception enabled inventors to remove the prior art. To address the obstacles, Congress has introduced multiple exceptions, which have resulted in an unnecessarily complex legal framework. Under the current standard, any researchers who are willing to exchange research results and ideas are subjected to the risk of a joint inventorship dispute.

This article proposes a reform to remove the obstacles which America Invents Act (AIA) was unable to address. It proposes the adoption of a simplified legal framework which would remove secret prior art and prior art during the grace period from obviousness determinations, regardless of inventorship. By eliminating any necessity for the overinclusive inventorship standard, this article proposes an improved inventorship standard to include only inventors who collectively made inventive contributions by revitalizing the collaboration requirement and inventive nature requirement for contributions.

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INTRODUCTION

Moderna is currently under fire for allegedly failing to name researchers from the National Institute of Health (NIH) in its COVID-19 vaccine patents.[1] Did Moderna intentionally fail to name the NIH researchers? To people unfamiliar with U.S. patent law, the question of who made an invention appears to be an easy one to answer. However, the more familiar you are with U.S. case law, the more confusing and difficult this question becomes. The concept used by U.S. courts and the Patent Office to determine who made an invention is known as inventorship. Both judges and patent law commentators call the inventorship standard muddy because neither the Patent Act nor the case law give any clear guidance on how to decide inventorship.[2] Not only is the statutory definition of joint inventions vague, its interpretation under the case law is also unclear because courts tend to emphasize the fact-specific nature of inventorship disputes and refuse to develop a test applicable to all cases in which researchers claim inventorship based on their contributions to various steps of a research project.

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1. Jorge L. Contreras, *Will NIH Learn from Myriad When Settling Its mRNA Inventorship Dispute with Moderna?* BILL OF HEALTH (Jan. 6, 2022), https://blog.petrieflom.law.harvard.edu/2022/01/06/nih-moderna-mrna-covid-vaccine-patent/ [https://perma.cc/9TQQ-N98E].

2. A district court commented on the theory of inventorship: "It is one of the muddiest concepts in the muddy metaphysics of the patent law." Mueller Brass Co. v. Reading Indus. Inc., 352 F. Supp. 1357, 1372, 176 USPQ 361, 372 (E.D. Pa. 1972), *aff'd*, 487 F.2d 1395 (3d Cir. 1973); 2 DONALD S. CHISUM, CHISUM ON PATENTS, § 2.02[2] (2022). *See also*, W. Fritz Fasse, *The Muddy Metaphysics of Joint Inventorship: Cleaning Up After the 1984 Amendments to 35 U.S.C. § 116*, 5 HARV. J.L. & TECH. 153, 159 (1992) [hereinafter Fasse, *Muddy Metaphysics*].

In the biopharmaceutical industry, answering the question of who made a drug or therapy is particularly challenging because many researchers from different stakeholders are involved in the development process. Often, these researchers change their employers, moving from one stakeholder to another.[3] Many researchers practice open science by sharing ideas, data, and materials while competing for obtaining patents.[4]

Dissecting such an inventive process is almost impossible because stakeholders engage in open innovation which traverses the blurred line between science and technology. Their research activities include both pre-invention contribution, such as discoveries of laws of nature which have not been applied to a therapeutic use, and post-invention contributions, including experimentation to confirm the efficacy of a therapy. A recent case from the Court of Appeals for the Federal Circuit ("Federal Circuit"), *Dana-Farber v. Ono* (2021), highlights this difficulty.[5] In *Dana-Farber*, a Harvard professor and his colleague, a former employee of the Genetics Institute, fought bitterly against Dr. Tasuku Honjo, a professor at Kyoto University, over inventorship of a cancer therapy that uses PD-1 immune checkpoint inhibitors. The therapy is based on Dr. Honjo's groundbreaking discoveries of cancer immunology, which led to an award of the 2018 Nobel Prize in Physiology or Medicine.[6] Despite no active communication between the U.S. and Japanese researchers demonstrating completion of the claimed cancer therapy prior to the conception of the invention and U.S. researchers' lack of knowledge on the completed therapy, the Federal Circuit found sufficient collaboration to award the U.S. researchers joint inventorship based on regular meetings to exchange research ideas and data. Thus, joint inventorship may unlimitedly include any researchers who made a discovery long before the completion of an invention if the discovery

3. Courtney Chandler, *Climbing The Research Ladder in Industry*, ASBMB TODAY (June 25, 2021), https://www.asbmb.org/asbmb-today/careers/062521/climbing-the-research-ladder-in-industry [https://perma.cc/3A84-QCH3].

4. The policymakers in the U.S. and EU adopted open science as a policy priority. *U.S. Open Government Initiatives*, USA.GOV, https://open.usa.gov/ [https://perma.cc/M87X-ANL4]; *Open Science: The EU's Open Science Policy*, EUROPEAN COMMISSION, https://ec.europa.eu/info/research-and-innovation/strategy/strategy-2020-2024/our-digital-future/open-science_en (last visited Apr. 13, 2022) [https://perma.cc/HG6T-25WX].

5. Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co., 964 F.3d 1365, 1367, 1371 (Fed. Cir. 2020), *cert. denied*, Ono Pharm. Co. v. Dana-Farber Cancer Inst., Inc., 141 S. Ct. 2691 (2021). The case is analyzed in Part I, B.

6. Tasuku Honjo, *The Nobel Prize in Physiology or Medicine 2018: Tasuku Honjo - Facts*, THE NOBEL PRIZE, https://www.nobelprize.org/prizes/medicine/2018/honjo/facts/ (last visited Apr. 13, 2022) [https://perma.cc/LYU4-BWJ4].

contributes to the invention because the court in *Dana-Farber* credited such a discovery to joint inventorship, even though the discovery was made before the researcher began to share his research and data with Dr. Honjo and other named inventors. The inventorship standard that the Federal Circuit applied is too easy to attain and thus *any* researcher who exchanges research ideas and data may qualify for joint inventorship if any of researchers who received the idea and data complete an invention. In short, the current inventorship standard exposes researchers in the biopharmaceutical industry to a high risk of inventorship disputes.

Correcting inventorship is not just about giving scientific credit. It is the lifeline for pharmaceutical firms to secure reasonable profits through exclusivity in order to cover the huge costs of new drug and therapy development.[7] Regarding patents on the COVID-19 vaccine, it is also matter of public interest because U.S. taxpayers have funded the vaccine developments.[8] Adding the NIH researchers on the vaccine patents would result in Moderna sharing its patent rights with the U.S. Federal Government, which can freely license the patents to Moderna's competitors. Because of patent exclusivity, the vaccine brought more than $7.3 billion in profits to Moderna in 2021.[9] Competition with NIH's licensees would significantly lower Moderna's profits and make the cost paid by taxpayers more affordable. Likewise, in *Dana-Farber*, adding the Harvard professor as an inventor on the immune checkpoint cancer therapy patents enabled his employer, Dana-Farber Cancer Institute, to license the technology to many stakeholders seeking to develop drugs and therapies for a variety of cancers. Dr. Honjo's patent assignee, Ono Pharmaceutical Co., and its exclusive licensees can no longer exclusively enjoy profits from the check point inhibitor market. For context, the check point inhibitor market—in which Ono holds the

7. A study shows that developing a new drug is estimated to cost 2.6 billion for a pharmaceutical firm. Thomas Sullivan, *A Tough Road: Cost to Develop One New Drug is $2.6 Billion; Approval Rate for Drugs Entering Clinical Development is Less Than 12%*, POL'Y & MED. https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html (Mar. 21, 2019) [https://perma.cc/F3GU-KGBP].

8. Richard G. Frank et. al., *It was the Government that Produced COVID-19 Vaccine Success*, HEALTH AFFS. FOREFRONT (May 14, 2021) https://www.healthaffairs.org/do/10.1377/forefront.20210512.191448/ [https://perma.cc/ZU3X-ZF2P].

9. Michael Hiltzik, *Raking in Profits, Moderna Denies Government Scientists Credit for the COVID Vaccine*, L.A. TIMES (Nov. 30, 2021, 11:55 AM) https://www.latimes.com/business/story/2021-11-30/moderna-denies-government-scientists-credit-for-inventing-covid-vaccine [https://perma.cc/6DB9-5JUS].

largest share—is projected to grow from $15.29 billion in 2020 to $18.04 billion in 2021 and may reach 39.81 billion in 2025.[10]

Once an inventorship error is found, the patent is invalid unless it is corrected. Because the U.S. Constitution instructs Congress to grant inventors exclusive right to their respective inventions, only original and true inventors are entitled to obtain valid patents. In addition to implications resulting from shared exclusivity, correcting inventorship may invalidate patents because inventorship is relevant to patentability.[11]

The U.S. patent system is unique in making the availability of prior art relevant to inventorship: a prior invention is removed from the prior art when the subject matter disclosed in both the prior art and the claimed invention under examination are made by the same inventor. This common inventorship exception originated from the first-to-invent system that the U.S. followed until the enactment of the American Invent Act (AIA) which took effect in 2012.[12] This exception applies to joint inventions only if the disclosed subject matter and the claimed invention were made by the same inventive entity, which requires identical joint inventors as a group.[13] Adding or deleting a joint inventor on a patent would result in different inventive entities which would introduce additional prior art and invalidate the patent. Secret prior art, which also originated from the first-to-invent system, provided an obstacle to obtaining patents when inventors work jointly on the same research project. Because prior inventions were prior art even if they are kept secret, inventors' own prior inventions and knowledge of their research teammates' prior inventions effectively prevented the patenting of inventions resulting from the same research project because they are closely related and frequently obvious in light of each other.

To remove this obstacle, courts developed today's overinclusive inventorship standard which enables removing secret prior arts

10. *Global Checkpoint Inhibitors Market (2021 to 2030) - Featuring AstraZeneca, Roche Holding and Pfizer Among Others*, GLOBAL NEWSWIRE (Dec. 07, 2021 6:58 PM) https://www.globenewswire.com/news-release/2021/12/07/2347238/28124/en/Global-Checkpoint-Inhibitors-Market-2021-to-2030-Featuring-AstraZeneca-Roche-Holding-and-Pfizer-Among-Others.html [https://perma.cc/8NPC-N8ME].

11. *See* discussion *infra* Part II. A. 1.

12. Leahy-Smith America Invents Act, Pub. L. 112-29, 125 Stat. 284 (2011). The provisions to shift from the first-to-invent system took effect on March 16, 2013. *See infra* note 265 and accompanying text.

13. The inventive entity doctrine is further discussed in context of the first-to-invent novelty. *See infra* Part II. A.

through the common inventorship exception.[14] Congress also added two more exceptions overlapping with the common inventorship exception, which resulted in a complex legal framework. Despite the AIA's adoption of the First-Inventor-To-File (FITF) novelty, the U.S. patent system retained (1) the first-to-invent feature that deems inventorship relevant to availability of prior art and (2) the complex legal framework to address the problems caused by secret prior art, which the AIA should have removed completely.

Thus, this article proposes a reform to simplify the legal framework by completely removing secret prior art from the novelty and nonobviousness determination, which will eliminate any necessity for the multiple exceptions and the overinclusive inventorship standard. Moreover, the proposed reform increases legal certainty in patent protection by making availability of prior art irrelevant to inventorship. Because the overinclusive standard would no longer be necessary, this article reinvents an inventorship standard by revitalizing the collaboration requirement and inventive nature requirement for contributions.

This article includes three parts. Part I discusses the unique features of biopharmaceutical inventions resulting from open innovation engaged in by researchers from different stakeholders, and challenges in identifying the completion of an invention and dissecting the inventive process of the invention to identify inventors. To highlight the challenges, Part I examines the inventorship dispute in *Dana Farber* as a real-life example.

Part II discusses pre-AIA legislation and case law on inventorship and examines the root of the current inclusive standard. Because the Patent Law Amendment of 1984 introduced the current definition of joint invention, Part II is divided into pre-1984 inventorship and post-1984 inventorship. The pre-1984 section reviews (1) the originality requirement which ensures correct inventorship and its close relationship with the first-to-invent novelty, (2) the restrictive inventorship standard developed by courts, and (3) the important role played by the common inventorship exception. The post-1984 section reviews (1) the statutory inventorship standard and (2) the common ownership and joint research agreement exceptions introduced in the 1984 Amendment and the 2004 CREATE Act.

14. Part II also includes an in-depth review of the current inventorship under the Federal Circuit Case. *See infra* Part II. B.

Part III examines impact of FITF novelty on inventorship and finds that some types of secret prior art remained in the U.S. patent system contrary to congressional intent. To completely remove secret prior art, the FITF novelty provision should be revised to limit availability of prior art for the purpose of novelty only if a) prior art is a) the subject matter which was publicly available on the filing date of the claimed invention or b) the subject matter which is covered by the exceptions as disclosures within one year from the filing date. With complete removal of secret prior art, the inventorship standard would be reinvented to effectively protect researchers from a risk of inventorship dispute and promote open science practices by effectively excluding those who joined a collective effort to complete the invention but failed to make an inventive contribution.

I. Cumulative Innovation: Biopharmaceutical Industry

A. Uniqueness of Biopharmaceutical Inventions

The United States Constitution gives inventors the exclusive right to their inventions for a limited time, which plays a key role in promoting the useful arts.[15] Congress developed the United States' patent system based on the utilitarian theory that presumes inventors are able to recoup investment costs and obtain profits by selling their products or services at supra-competitive prices during the temporary period of exclusivity.[16] This inventor-centric reward theory was based on the traditional innovation theory advanced by Joseph Shumpeter,[17] and presumed a closed innovation model where inventors invent, commercialize and market a new product by engaging in every stage of the value chain.[18] The traditional model was developed with a presumption to promote stand-alone innovation rather than follow-on innovation, *i.e.*, inventions through improvement and refinement.[19]

15. U.S. CONST. art. I, § 8, cl. 8.

16. *See* FRANÇOIS LÉVÊQUE & YANN MÉNIÈRE, THE ECONOMICS OF PATENTS AND COPYRIGHT 1, 5, 20, 27 (2004) (discussing the basic economics of patent protection and reward,), https://ssrn.com/abstract=642622.

17. *See generally*, JOSEPH A. SCHUMPETER, THE THEORY OF ECONOMIC DEVELOPMENT: AN INQUIRY INTO PROFITS, CAPITAL, CREDIT, INTEREST, AND THE BUSINESS CYCLE (1934).

18. David J. Teece, *Firm Organization, Industrial Structure, and Technological Innovation*, 31 J. ECON. BEHAV. & ORG. 193, 198 (1996) ("The 'Schumpeterian' view of the innovation processes appears to be one that involves full integration, from research, development, manufacturing and marketing.").

19. For the definition of "stand-alone innovation," see Peter S. Menell & Suzanne Scotchmer, *Economic Models of Innovation: Stand-Alone and Cumulative Creativity*, *in* 1 RSCH. HANDBOOK ON THE ECON. OF INTELL. PROP. L. 1, 5 (Ben DePoorter & Peter S. Menell eds., 2018) [hereinafter MENELL & SCOTCHMER, ECONOMIC MODELS]. For examples of stand-alone innovation, see RICHARD R. NELSON &

These presumptions are mainly a reflection of innovation in the mechanical field, which was the main industry when the very first Patent Act was enacted in 1790.[20] However, this stand-alone innovation model was not applicable to many inventions, even those in the mechanical field during the early era of the U.S. patent system.[21] In fact, many pioneering inventions in the early era were—independently and simultaneously—made by multiple inventors.[22] These inventions were refined and improved by follow-on innovation through cumulative innovation.[23] Just as the traditional utilitarian theory did not apply to many inventions in the early era, it seldom applies to current inventions.

Many legal and economics scholars have critiqued the current patent system for failing to take account of the changes in players, their incentives, and the innovation model.[24] This author has also criticized the system as being outdated for failing to take account of new patent uses: using patents for sharing patented inventions and guaranteeing the freedom to operate and innovate.[25] In the post-Internet era, the overwhelming majority of products and services result from cumulative innovation, sequential inventions, and improvements throughout value chains. Spurred by post-Internet technologies, firms shifted from the closed innovation model to an open model by actively seeking external resources for ideas and commercialization and collaboration with inventors from different firms and institutions.[26] This cumulative innovation leads to a thicket of interdependent and overlapping patents held by different patent owners but covering the

SIDNEY G. WINTER, AN EVOLUTIONARY THEORY OF ECONOMIC CHANGE (1985); ERIC VON HIPPEL, THE SOURCES OF INNOVATION (1988).

20. Patent Act of 1790, ch. 7, 1 Stat. 109 (April 10, 1790).

21. Mark A. Lemley, *The Myth of the Sole Inventor*, 110 MICH. L. REV. 709, 710–11, 731–33 (2012).

22. *Id.* at 716, 722. Many inventions viewed as pioneering, including the steam engine by James Watt and the lightbulb by Thomas Edison, were in fact invented simultaneously and improved incrementally.

23. *See* MENELL & SCOTCHMER, ECONOMIC MODELS, *supra* note 19, at 20–33 (discussing cumulative innovation in contrast to stand-alone innovation).

24. *E.g.*, Peter Lee, *Social Innovation*, 92 WASH. U. L. REV. 1, 26 (2014); Liza Vertinsky, *Boundary-Spanning Collaboration and the Limits of Joint Inventorship Doctrine*, 55 HOUS. L.R. 401, 434–35 (2017); Katherine J. Strandburg, *Intellectual Property at the Boundary, in* REVOLUTIONIZING INNOVATION: USERS, COMMUNITIES, AND OPEN INNOVATION 235, 241 (Dietmar Harhoff & Karim R. Lakhani, eds., 2016); Yochai Benkler, *Law, Innovation and Collaboration in Networked Economy and Society*, 13 ANN. REV. L. & SOC. SCI. 231, 232–33 (2017).

25. Toshiko Takenaka, *Patents for Sharing*, 26 MICH. TECH. L.R. 93, 93 (2019) [hereinafter Takenaka*, Sharing*]; Toshiko Takenaka*, Inclusive Patents for Open Innovation*, 29 TEX. INTELL. PROP. L.J. 187, 187 (2021) [hereinafter Takenaka, *Inclusive Patents*].

26. Takenaka, *Inclusive Patents*, *supra* note 25, at 192–93.

same product or service.[27] Therefore, the traditional theory does not apply to inventions resulting from cumulative innovation because patent owners cannot enforce their patents, thereby excluding their competitor and enjoying profits from the supra-competitive price, without a risk of counter-infringement assertion.[28] In contrast, instead of incentive through monopoly profits, economic scholars focus on the role of patent for coordinating and appropriating benefits from patented inventions among the sequential inventors.[29]

Historically, the pharmaceutical industry has predominantly engaged in closed innovation in which all R&D and commercialization activities were conducted in-house.[30] The pharmaceutical industry has been distinct from other high-tech industries because its products are covered by only one or a few patents owned by a single patent owner who can enjoy monopoly profits.[31] However, as products in the industry shifted from small molecule to biologics drugs, more and more pharmaceutical firms sought ideas from outside collaborators, especially from universities and academic research institutions ("universities"), and began to embrace an open innovation model.[32] Before the adoption of the open innovation model, the innovation process in the pharmaceutical industry was depicted as a linear model consisting of the three stages: research, development and commercialization.[33] As the biopharmaceutical industry emerged, pharmaceutical firms simply sought ideas and discoveries of laws of nature, such as DNA

27. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, *in* 1 INNOVATION POL'Y AND ECON. 119, 121 (Adam B. Jaffe et. al eds. 2001); Bronwyn H. Hall et al., *Technology Entry in The Presence of a Patent Thickets* (Inst. Fiscal Studs., Working Paper No. W16/02 2016), https://www.ifs.org.uk/uploads/publications/wps/wp201602.pdf [https://perma.cc/MMS9-3B47].

28. Takenaka, *Sharing*, *supra* note 25, at 115–16.

29. MENELL & SCOTCHMER, ECONOMIC MODELS, *supra* note 19, at 20; Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSPS. 29, 34 (1991); Edmund W. Kitch, *The Nature and Function of The Patent System*, 20 J.L. & ECON. 265, 278 (1977).

30. Alexander Schuhmacher, Oliver Gassmann, & Markus Hinder, *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 (105) J. TRANSL. MED. 1 (2016) [https://perma.cc/GRH2-X3RB].

31. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law,* 89 VA. L. REV. 1575, 1590, 1684–87 (2003).

32. Alexander Schuhmacher, Oliver Gassmann, Nigel McCracken, & Markus Hinder, *Open Innovation And External Sources Of Innovation. An Opportunity To Fuel The R&D Pipeline And Enhance Decision Making?*, 16 (119) J. TRANSL. MED. 1 (2018) [https://perma.cc/DA4K-KHY2].

33. Leonidas Aristodemou, Frank Tietze, Elizabeth O'Leary, & Matt Shaw, *A Literature Review on Technology Development Process (TDP) Models,* (Ctr. for Tech. Mgmt., Working Paper No. 2058-8887, 2019), https://doi.org/10.17863/CAM.35692 [https://perma.cc/5XZS-9DL7]; Letizia Mortara et al., *Technology Intelligence Practice in UK Technology-Based Companies*, 48 INT'L. J. TECH. MGMT. 115–135 (2009).

sequences, from universities through licensing.[34] This early stage of the open innovation model maintained the distinction of the roles played by the key stakeholders, universities and pharmaceutical firms: the former focused on creating new knowledge through basic research and science, while the latter focused on absorbing and applying that knowledge to practical uses and funding the universities' basic research.[35] Ultimately, the collaboration of different stakeholders in the linear innovation process resulted in products covered by upstream and downstream patents owned by different patent owners, which presented coordination challenges for conducting further research.[36]

One key reason the biopharmaceutical industry has become more complex and integrated after adopting the open-innovation model is the uniqueness of the industry, in which drug development relies heavily on the knowledge and experience of researchers from different stakeholders.[37] Because of this complexity and collaboration, more and more economic scholars have adopted an ecosystem model, rather than a linear model, to depict the innovation process as the transition between basic research and applied technology has become blurred, and the roles played by universities and pharmaceutical firms have become unclear.[38] Key stakeholders include not only universities and pharmaceutical firms, but also technology startups, venture capitalists and the government bodies which regulate drug marketing approvals.[39] Researchers from key stakeholders provide knowledge and experience unique to their background and contribute to discoveries and inventions in the drug innovation process. These researchers frequently move from one stakeholder to another and

34. In the U.S., the Bayh-Dole Act was enacted to promote the academic-industry collaboration. Bayh-Dole Act of 1980, 35 U.S.C. §§ 200–212 (1980).

35. Manthan D. Janodia et al., *Facets of Technology Transfer: A Perspective of Pharmaceutical Industry.* 13 J. INTELL. PROP. RTS. 28 (2008) https://www.researchgate.net/publication/237740365_Facets_of_Technology_Transfer_A_Perspective_of_Pharmaceutical_Industry [https://perma.cc/NT3N-X9JX].

36. Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813 (2001); Rochelle C. Dreyfuss, *Collaborative Research: Conflicts on Authorship, Ownership, and Accountability*, 53 *VAND. L. REV.* 1159 (2000), https://scholarship.law.vanderbilt.edu/vlr/vol53/iss4/2.

37. THE NEW FRONTIERS OF BIOPHARMACEUTICAL INNOVATION, INT'L FED'N OF PHARM. MFR. & ASS'NS, 18 (2012) https://www.ifpma.org/resource-centre/the-new-frontiers-of-biopharmaceutical-innovation [https://perma.cc/XVA3-STSK] [hereinafter IFPMA NEW FRONTIER].

38. Alberto Bettanti et al., *Biopharmaceutical Innovation Ecosystems: A Stakeholder Model and the Case of* Lombardy, J. TECH. TRANSFER (2021), *available at* https://doi.org/10.1007/s10961-021-09890-1 [https://perma.cc/URV9-2P7Q].

39. *Id.* at 12.

collaborate to share ideas and data while competing for patent rights.[40] Moreover, these researchers share their knowledge and experience with global partners as the industry's innovation model transforms.[41] Whether such researchers should be identified as inventors requires determining the date of completion of an invention and dissecting the inventive act from the cumulative innovation, both of which have become a challenging task as neither Congress nor the courts are willing to give clear guidance.

B. Real Life Example: *Dana Faber v. Ono*

The challenge that researchers face in demonstrating inventorship was highlighted in *Dana Farber v. Ono* (2021)[42] which involved a dispute among researchers from Kyoto University, Harvard University and Genetics Institute, which once collaborated and shared information of their discoveries and research results. Their collaboration led to a break-through cancer therapeutic technique and the award of the 2018 Nobel Prize to Dr. Tasuku Honjo, one of the Japanese researchers and a professor at Kyoto University's medical school.[43] The break-through technique originated from Dr. Honjo's discovery of PD-1, an inhibitory receptor on T cells, in the early 1990s.[44] T cells play a very important role in the human body's immune system by coordinating the immune response to an antigen or eliminating abnormal cells such as tumor cells.[45] PD-1 causes T cells to stop attacking the cells expressing ligands by binding to one of its ligands: PD-L1 or PD-L2. In order to disguise themselves as healthy cells, some tumor cells can express these ligands causing PD-1 to signal the T cells to stop attacking the tumor cells.[46] Dr. Honjo's treatment technique uses antibodies which bind PD-1 and block the interaction between PD-1 and its ligand, PD-L1 or PD-L2 and prevent the tumor cells disguised as healthy cells from stopping the T cell attack by preventing the transmission of an inhibitive signal.[47]

40. Hakim Djaballah, *Academic-Industry Collaboration: Intertwined for Drug Discovery*, CAS BLOG (Jan. 11, 2019) https://www.cas.org/resources/blog/academic-industry-collaboration-intertwined-drug-discovery [https://perma.cc/V6JB-GB5M].

41. IFPMA NEW FRONTIER, *supra* note 37, at 44.

42. Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co., 964 F.3d 1365 (Fed. Cir. 2020).

43. *Id.* at 1370.

44. *Id.* at 1368.

45. *Id.* at 1367.

46. *See id.*

47. *See id.*

After Dr. Honjo isolated the DNA sequence of the PD-1 receptor, he worked with his colleagues at Kyoto University, Dr. Nagahiro Minato and Dr. Yoshiko Iwai, to determine the function of PD-1 through various experiments.[48] Finding no success in this first collaboration, Dr. Honjo began to work with Dr. Wood, a researcher at Genetics Institute, to find the PD-1 ligand in September 1998.[49] After Dr. Wood agreed to collaborate and received PD-1 reagents and research results from Dr. Honjo, he became involved in a separate project with Dr. Freeman, a professor at Harvard Medical School and researcher at Dana-Farber Institute, who had independently found novel ligands in July 1998, prior to the Honjo–Wood collaboration.[50] While studying the ligands, Dr. Wood began to work with Dr. Freeman and confirmed that one of the novel ligands bound with PD-1.[51]

After Dr. Wood informed Dr. Honjo about the ligand, the three researchers named the ligand as PD-L1 and began exchanging information, reagents and other materials while meeting periodically.[52] Among those materials were anti-PD-1 antibodies developed by the Japanese researchers. Dr. Wood received these antibodies from Dr. Honjo and experimented to confirm that the antibodies inhibited the PD-1/PD-L1 interaction.[53] Dr. Wood shared the experiment results, which showed the antibodies' inhibitive effect, with Drs. Honjo and Freeman at a meeting in October 1999.[54]Around the time of the meeting, Dr. Freeman found another ligand and conducted various experiments.[55] This ligand was labeled PD-L2 because Dr. Wood tested to confirm that it is bound with PD-1, and PD-1, and PD-L2 interacts to inhibit the immune response.[56] In March 2000, Dr. Freeman emailed Dr. Honjo about PD-L2 and sent him its sequence. Their collaboration was at its peak when they worked on a journal article reporting their discoveries and research results on PD-L1. During the editing process, Dr. Freeman—for the first time—suggested the application of their discoveries to cancer treatment by the addition of a sentence suggesting the possibility that tumors use

48. *Id.* at 1368.
49. *See id.*
50. *See id.*
51. *See id.*
52. *See id.*
53. *See id.*
54. *Id.* at 1368.
55. *See id.*, Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co., 379 F. Supp. 3d 53, 72-73 (D. Mass. 2019), *aff'd*, 964 F.3d 1365 (Fed. Cir. 2020).
56. *Dana-Farber*, 964 F.3d at 1369.

PD-L1 to inhibit immune response against cancers.[57] This statement was based on his experiments which showed that PD-L1 was highly expressed on various human tumor cells.[58] At a March 27, 2000 meeting, Dr. Wood also described the therapeutic possibility of using the PD-1/PD-L1 pathway to treat cancer.[59] It is unclear when their research moved from the basic science research to drug development. However, by May 2000, all three researchers were keenly aware of the possible development of a cancer treatment technique by using anti-PD-L1 antibodies.[60] When Dr. Freeman shared strong evidence of PD-L1 expression on human tumors in September 2000, the researchers were further convinced that they are beginning to apply their discoveries to cancer treatments.[61]

In June 2000, the relationship between the U.S. and Japanese researchers began to turn sour when Dr. Honjo learned about a provisional application, filed by Dr. Wood and Dr. Freeman in November 1999, that did not name Dr. Honjo as a coinventor.[62] The provisional application was premature; it inaccurately disclosed PD-1's function in the PD-1 and PD-L1 interaction as not only inhibitive, but also stimulative.[63] Nevertheless, the application matured into three U.S. patents.[64] The accurate function of PD-1 which is only inhibitory, was confirmed in October 2000 when Dr. Iwai conducted experiments on reagents provided by Dr. Freeman.[65] This led Dr. Honjo to propose October 27, the day that Dr. Iwai reported her experiment results, as the conception date.[66] Although the parties did not dispute the conception date, it is likely that the three researchers worked simultaneously and reached a conception prior to this proposed conception date by focusing on blocking the pathway to treat cancers.[67]

After the October 2000 experiment, Japanese researchers began to focus on the development of a cancer treatment using antibodies to block the PD-1/PD-L1 pathway and stop an immune response

57. *See id.*
58. *See id.*
59. *See Dana-Farber*, 379 F. Supp. 3d at 73-74.
60. *Id.* at 75.
61. *Id.* at 93.
62. *Id.* at 71.
63. *Id*.
64. *Id.*
65. *Dana-Farber*, 964 F.3d at1369.
66. *Dana-Farber*, 379 F. Supp. 3d at 76, 88.
67. *Id.* at 94.

inhibitory signal.[68] As the inventorship dispute on the provisional application intensified, the U.S. and Japanese researchers stopped sharing information.[69] Japanese researchers continued to conduct experimentation and collect more data on the cancer treatment until they filed a Japanese patent application on July 3, 2002.[70] The Japanese claims were directed to a medication that treats cancer by blocking the PD-1/PD-L1 pathway.[71] The Japanese application disclosed results of experiments on the effect of the PD-1/PD-L1 pathway beginning in 2000.[72] A year later, the team filed an international application that matured (from 2009 to 2016) into the Honjo patents at issue.[73] The Honjo patents claim various aspects of the cancer treatment technique which administers anti PD-1 antibodies to stimulate an immune response.[74] The broadest claim of these patents recites "a method for treatment of a tumor in a patient, comprising administering to the patient a pharmaceutically effective amount of an anti-PD-1 monoclonal antibody."[75] All six patents named only Dr. Honjo, Dr. Minato, Dr. Iwai, and Mr. Shiro Shibayama, a researcher from Ono Pharmaceutical, as inventors.[76] All four named inventors assigned their interests in the Honjo patents to Ono Pharmaceutical.

In September 2015, Dana-Farber Cancer Institute, Dr. Freeman's employer, filed an inventorship suit against Dr. Honjo as well as Ono Pharmaceuticals, the assignee, and Bristol-Myer Squibb, the licensee of Honjo patents, (collectively, "Ono") in the District Court for the District of Massachusetts.[77] The District Court ordered the United States Patent and Trademark Office (USPTO) to add Dr. Wood and Dr. Freeman as inventors on all Honjo patents.[78] The court found that the two U.S. researchers are coinventors because the following contributions are significant to the conception of the claimed inventions: (a) Dr. Wood's and Dr. Freeman's discovery of

68. *Id.* at 76.

69. *Id*.

70. *Dana-Farber*, 964 F.3d at 1369–76.

71. The district court decision misstated that they were directed to "methods of treating cancer." *Dana-Farber*, 379 F. Supp. 3d at 76. The Japanese application could not claim cancer treatment methods as the district court described because a method of treating human bodies is not patentable as an industrially inapplicable invention. Patent Act, 1959 (Act. No. 121/ art. 29 Japan); Examination Guidelines for Patent and Utility Model in Japan, Pt. III, Ch. 1., 3101, https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/tukujitu_kijun/

72. *Dana-Farber*, 379 F. Supp. 3d at 76.

73. *Dana-Farber*, 379 F. Supp. 3d at 77.

74. *Id.*

75. *Dana-Farber*, 964 F.3d at 1373.

76. *Dana-Farber*, 379 F. Supp. 3d at 77.

77. *Id.* at 78.

78. *See id.* at 102.

PD-L1; (b) Dr. Wood's discovery that PD-1/PD-L1 binding inhibits the immune response; (c) Dr. Wood's and Dr. Freeman's discovery that anti-PD-1 and anti-PD-L1 antibodies can block the PD-1/PD-L1 pathway's inhibitory signal; and (d) Dr. Freeman's experiments confirming that PD-L1 is expressed in various. tumors.[79]

The Federal Circuit affirmed the decision finding joint inventorship for the U.S. researchers.[80] In denying Ono's argument that U.S. researchers' contributions were too far removed from the invention, the court emphasized that only a modicum of significance is necessary for a contribution to qualify for joint inventorship: "There is no 'explicit lower limit on the quantum or quality of inventive contribution required for a person to qualify as a joint inventor.'"[81] The court set forth three elements necessary to establish joint inventorship: (1) contribution in some significant manner to the conception or reduction to practice the invention; (2) that such contribution is not insignificant in quality when the contribution is measured against the full contribution; and (3) that such contribution more than merely explains well-known concepts and/or the current state of the art to the real inventors.[82] Moreover, failure to participate in activities that led to the conception of the invention does not necessarily forfeit inventorship because joint inventors do not need to contribute to all aspects of a conception.[83] Speculative works, functions, and unconfirmed results are sufficient for inventorship because the conception is complete even without experimentation to confirm whether the invention will work for its intended purpose.[84]

The Federal Circuit held that the novelty and nonobviousness of the invention over a particular researcher's contribution are irrelevant to determine inventorship of the invention.[85] It rejected Ono's argument that Dr. Wood's and Dr. Freeman's contributions were insignificant because the Honjo patents were patentable over the 1999 provisional application, holding that "the novelty and nonobviousness of the claimed inventions over the provisional application are not probative of whether the collaborative research efforts of Drs. Honjo, Freeman, and Wood led to the inventions claimed here or whether

79. *Dana-Farber*, 964 F.3d at 1370.
80. *Id.* at 1367.
81. *Id*. at 1371 (quoting Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1358 (Fed. Cir. 2004)).
82. *Id.* at 1371.
83. *Id.*
84. *Id.* at 1372.
85. *Id.*

each researcher's contributions were significant to their conception."[86] The Federal Circuit further refused to adopt a rigid rule to categorically exclude works in the state of art. Instead, it held that works made public before the date of conception may qualify as a significant contribution unless they were simple explanations of the state of art.[87] When inventors worked together to create a collaborative enterprise, each inventor who disclosed ideas less than the total invention to others should qualify as a coinventor.[88]

Ono's attempt to overturn the district court decision failed again when the U.S. Supreme Court rejected its request to examine the Federal Circuit's inventorship jurisprudence.[89] As a result, under the post-*Dana-Farber* inventorship standard, anyone who shared ideas and information of their research with another can qualify as a joint inventor if the person who received their ideas and information completes an invention, and the ideas and information given contribute to the conception of the invention. Even one who made a discovery of a law of nature or natural phenomenon may successfully claim to be a joint inventor without contributing to applying the discovery and converting it into an invention. Although the court focused more on collaboration than significance of contribution, the period of collaboration was stretched to include Dr. Freeman's discovery of a ligand—even though the ligand was discovered prior to his collaboration with other researchers—because Dr. Wood found the ligand bound with PD-1 after the collaboration. Moreover, the court failed to clarify the time at which the significance of the contribution should be examined. Assessing the significance at the time of contribution, instead of at conception, which would lead to a confusion that post-contribution disclosures may risk entitlement of joint inventorship. Such a confusion would discourage early disclosure of discoveries of laws of nature which are the "building blocks of human ingenuity."[90]

II. Pre-AIA Patent Act: First-To-Invent

The joint inventorship standard under the current case law is overinclusive. This standard includes both inventors who contributed

86. *Id.*

87. *Dana-Farber*, 964 F.3d at 1372.

88. *Id.*

89. Ono Pharm. Co. v. Dana-Farber Cancer Inst., Inc., 141 S. Ct. 2691 (Mem.) (2021).

90. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 85 (2012); Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 216 (2014).

to the conception of an original invention and those who contributed to the conception of improvements of the original invention—even if these inventions are separately claimed and independently patented. The standard also includes those who made related discoveries of a law of nature or natural phenomenon. This overinclusive inventorship standard resulted from courts' efforts to modernize the U.S. patent system in response to several revisions of the patent laws by Congress. These revisions were intended to address the needs of industries in new technology fields and correct the misassumption of stand-alone innovation by a single inventor. The joint inventorship standard was limited to include only inventors that contributed all claimed subject matter and satisfied a heightened collaboration requirement before the 1984 Patent Law Amendments.[91] The 1984 amendments expanded that limited inventorship standard to include all inventors who contributed to serial related inventions, overcoming a disadvantage unique to the first-to-invent system that had previously prevented joint inventors from effectively patenting the inventions resulting from the cumulative innovation and collaboration.

For example, a contribution by Dr. Wood and Dr. Freeman, *i.e.,* the inventions claimed in their 1999 provisional application, was prior art as a prior invention and a derived invention against the inventions claimed by the Honjo Patents even if the contribution was kept secret before the time that the inventions were made. Before the 1984 Amendments, had the inventions claimed in the Honjo Patents been obvious over the contribution, Drs. Wood's and Freeman's contribution should have prevented the Honjo patents from issuing unless the named joint inventors were identical.[92] Thus, omitting Dr. Honjo and named inventors in the Honjo Patents as inventors on the 1999 provisional application should have jeopardized the Honjo Patents if the inventions of the Honjo Patents been obvious over the inventions of the provisional application. Because many inventions resulting from collaboration in the same research project are closely related and likely obvious in light of each other, contributions of joint inventors' own prior work were often cited to show obviousness and therefore prevented related inventions from obtaining patents. Because joint inventors' own works were removed from the prior art for obviousness only when all joint inventors were identical between the works and the invention, the expansive inventorship standard

91. Patent Law Amendments Act of 1984, Pub. L. No. 98-622, 98 Stat. 3383 (1984).

92. For more discussion of this requirement, see *infra* notes 127–129 and accompanying text.

including all inventors in the collaboration could protect the related inventions from obviousness rejections. This common inventorship exception was the only protection for inventions from collaboration until Congress introduced another exception.

A. Pre-1984 Inventorship

1.Originality Requirement: Derivation

Determination of the true inventor (or coinventors) is essential to the constitutional goal of the U.S. Patent System, which is to give the inventor an exclusive right to the claimed invention.[93] The U.S. courts developed the jurisprudence as to the determination of a true and first inventor under the first-to-invent system until the first-inventor-to-file provision of AIA was enacted in 2013.[94] The pre-AIA requirement of granting a patent only to a true and original inventors was called "originality."[95] The pre-AIA Patent Act, § 102(f), provided lack of originality as a ground of rejection or invalidity by preventing the patenting of an invention if the invention was derived from any other source than the inventor named in the application or patent.[96] To ensure the originality of invention, the inventor had to file a patent application with an oath stating that he was the original and first inventor.[97] For joint inventions, all joint inventors had to file a patent jointly with an oath stating that the joint inventors met the originality and first-to-invent requirements with respect to the claimed invention.[98] This procedural aspect of the originality requirement stemmed from the inventor-centric policy of U.S. patent system and was in stark contrast to the patent systems of first-to-file countries which focus on ownership and allow assignees, especially employers of inventors, to file patent applications.[99]

The substantive aspect of the originality requirement prevented non-true inventors from obtaining a patent and allowed the invalidation of a patent if a patent issued to a non-inventor who

93. U.S. CONST., art. 1, § 8, cl. 8.

94. AIA was enacted in law on September 16, 2011. Most provisions became effect on September 16, 2012 but the first-to-file provision became effective on March 16, 2013. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

95. 2 CHISUM ON PATENTS, *supra* note 2, at § 2.01.

96. Pre-AIA 35 U.S.C. § 102(f), OddzOn Products Inc. v. Just Toys Inc., 122 F.3d 1396, 1401 (Fed. Cir. 1997).

97. Pre-AIA 35 U.S.C. §§ 111, 115.

98. Pre-AIA 35 U.S.C. § 116.

99. Fasse, *Muddy Metaphysics*, *supra* note 2, at 159.

derived the invention from another inventor. This substantive requirement was intertwined with first-to-invent priority as the examination of the originality requirement focused on inventorship. The inquiry aimed to determine whether the named inventor was the first and true inventor by confirming that the invention under examination was not derived from another person.[100] In addition to providing that a derived invention as prior art, pre-AIA § 102 also provided for a variety of prior art categories that were applied to determine the novelty and priority of an invention under examination.[101] One of the prior art categories was a prior invention under § 102(g).[102] Courts interpreted § 102(g) and developed a priority rule.[103] As an inventor who derived the invention from another inventor may not be a true inventor even if that inventor established the priority of the invention date under the priority rule, derivation was frequently claimed in priority disputes at the USPTO and in courts.[104] The principal rule awarded priority to the inventor who was the first to reduce the invention to practice.[105] Reduction to practice occurs either by (1) constructing a product or performing a process that is within the scope of the invention as defined by the claims and testing the product or process to demonstrate that the invention works as intended (actual reduction to practice);[106] or (2) filing a patent application with a patent office meeting the disclosure requirements under the U.S. Patent Act (constructive reduction to practice).[107]

An exception to this principal rule was an early conception.[108] Early conception allowed an inventor to establish priority over the first inventor to reduce the invention to practice by showing an earlier date of conception and continuous and reasonable diligence toward

100. *Price v. Symsek,* 988 F.2d 1187, 1190 (Fed. Cir. 1993); Applegate v. Scherer, 332 F.2d 571, 573 (C.C.P.A. 1964).

101. Pre-AIA 35 U.S.C. § 102. For more discussion, see Part II, A. 3, *infra*.

102. Pre-AIA 35 U.S.C. § 102(g).

103. 3A DONALD S. CHISUM, CHISUM ON PATENTS, § 10.03 (2022).

104. Anthony A. Hartmann, *Derivation and the PTAB*, FINNEGAN, (Jan.-Feb. 2015), https://www.finnegan.com/en/insights/articles/derivation-and-the-ptab.html [https://perma.cc/ZB9U-JJ6E].

105. *Price*, 988 F.2d at 1190 ("Priority goes to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive the invention and that it exercised reasonable diligence in later reducing that invention to practice.").

106. Scott v. Finney, 34 F.3d 1058, 1061 (Fed. Cir. 1994); 3A CHISUM ON PATENTS, *supra* note 103, at § 10.06.

107. Hyatt v. Boone, 146 F.3d 1348, 1352 (Fed. Cir. 1998); 3A CHISUM ON PATENTS, *supra* note 103, at § 10.05.

108. Griffin v. Bertina, 285 F.3d 1029, 1032 (Fed. Cir. 2002); Toshiko Takenaka, *Rethinking the United States First-to-Invent Principle from a Comparative Law Perspective: A Proposal to Restructure § 102 Novelty and Priority Provisions*, 39 HOUS. L. REV. 621, 652 (2002), *available at* https://digitalcommons.law.uw.edu/faculty-articles/349 [hereinafter Takenaka, *Rethinking*].

reduction to practice.[109] Both the first-to-reduce inventor and the early conception inventor lost their first-to-invent priority under the principal rule if they unreasonably delayed making the invention available to the public, which included abandoning, suppressing or concealing the invention ("abandonment").[110]

Alternatively, an inventor could defeat a competing inventor without showing reasonable diligence by establishing that the invention was derived from her.[111] Courts acknowledged that derivation and priority were akin to focusing on inventorship. However, the courts emphasized that these concepts were also distinct and separate from each other because an originality inquiry in a derivation involved a determination of the origin of only one invention while a priority inquiry involved a determination of the first-to-invent between the inventors of two independent inventions.[112] To show derivation, an inventor had to show (1) a conception of the invention prior to the competing inventor's conception and (2) communication of the conception to the competing inventor.[113] The communication had to be sufficient to enable one skilled in the art to make the patented invention.[114] If there was evidence of prior conception without communication, the inventions were made independently and separately and thus courts should decide the first-to-invent under the priority rule and grant a patent to one of the inventors based on the outcome of that proceeding.[115]

The case law has been unclear on whether the communication of less than the conception gives rise to joint inventorship.[116] In *Dana-Farber*, the Federal Circuit found communication of partial

[110] Pointer v. Six Wheel Corp., 177 F.2d 153, 157 (9th Cir. 1949). To defeat a patent issued, suggestions from another must include the plan of improvement and must have provide such information sufficient to enable the person to whom the communication enabled an ordinary mechanic to construct the improvement. For a general discussion of derivation, *see* 3A CHISUM ON PATENTS, *supra* note 103, at § 10:07.

110. 3A CHISUM ON PATENTS, *supra* note 103, at § 10:08. Courts typically found an abandonment when the first-to-reduce inventor was spurred into activity. *E.g.,* Woofter v. Carlson, 367 F.2d 436 (C.C.P.A. 1966).

111. Howard v. Jenkins, 202 U.S.P.Q. 774, 781 (B.P.A.I. 1977).

112. *Applegate,* 332 F.2d at 571; *Price*, 988 F.2d at 1187.

113. Creative Compounds, LLC v. Starmark Labs., 651 F.3d 1303, 1313 (Fed. Cir. 2011).

114. Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1577 (Fed. Cir. 1997); Eaton Corp. v. Rockwell Int'l. Corp., 323 F.3d 1332, 1344 (Fed. Cir. 2003).

115. Even for priority, conception had to be communicated or disclosed in some form because inventors' own oral testimony needed to be supported by written documents or testimony of non-inventor. *E.g,* Schumierer v. Newton, 397 F.2d 1010, 1368 (C.C.P.A. 1968).

116. 3A CHISUM ON PATENTS, *supra* note 103, at § 10:10[4][d][ii][A] ("It is particularly opaque on a critical point on the relationship between joint inventorship and derivation: can there be joint inventorship when two person mingle ideas in a single communication but do not otherwise collaborate or agree to coordinate work? Can two persons be unwilling joint inventors?").

conception was sufficient for joint inventorship where the inventors exchanged ideas multiple times and thus created a collaborative enterprise.[117] As in *Dana-Farber*, courts and parties frequently mix-up arguments of priority and derivation because the concepts of priority and derivation are so intertwined. Here, Dana-Farber and Ono disputed who was the first to have the complete conception, *i.e*., the connection of blocking the pathway and cancer treatment.[118] This argument was proper for priority if Dana-Farber was claiming priority of separate and independent inventions by Drs. Wood and Freeman over the inventions of the Honjo Patents. However, for joint inventorship, it does not matter who is the first to reach the conception of the invention. The U.S. and Japanese researchers should be found joint inventors only if they jointly and collectively contributed to the development of the claimed invention.

2.Restrictive Inventorship Standard

The inventorship standard that courts applied prior to the 1984 Patent Amendments was more restrictive than the current standard applied by the Federal Circuit in *Dana-Farber*. That narrow standard was highlighted by a comment by Justice Story on a jury verdict for joint inventorship by both the plaintiff and defendant:

> If the plaintiff and defendant separately and independently invented several parts of the machine, capable of a distinct use, then those parts might be considered as separate inventions, for which each inventor might, perhaps, be entitled to a separate patent. But the present patent claims the invention, as a whole; and the jury find, that in this invention they were both concerned; which I cannot understand in any other sense, than as verifying the invention to be a joint, simultaneous production of the genius and labor of both parties.[119]

Unlike *Dana-Farber*, the joint inventorship standard under the early case law depended on the patentability of the invention over a particular contribution, *i.e*., a prior work of a joint inventor. If an invention for one component and an invention for another component were separately patentable, they were considered two unique

117. Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co., 964 F.3d 1365, 1372 (Fed. Cir. 2020).

118. Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co., 379 F. Supp. 3d 53, 94 (D. Mass. 2019), *aff'd*, 964 F.3d 1365 (Fed. Cir. 2020).

119. Stearns v. Barrett*,* 22 F. Cas. 1175, 1181 (No. 13,337) (C.C.D. Mass. 1816).

inventions by two sole inventors instead of one invention by joint inventors. This was true even if the inventors sought to patent an entire machine which was the joint invention of both inventors. This same logic supported Ono's argument in *Dana-Farber* that inventors of a prior invention are not joint inventors of an improvement on the prior invention if the improvement was patentable over the prior invention.

Moreover, the collaboration requirement adopted by Justice Story was more difficult to meet than the requirement under the current case law. Justice Story's standard first required courts to dissect a machine into its respective elements, and then required that all inventors collaborate not only the entire machine, but also on all elements of the machine. Under this restrictive inventorship standard, inventors should obtain a separate patent for any distinctive element to which the other inventors failed to contribute. A feature was found to be distinct when that feature was included in a separate claim, unless the feature contributed to the operation of the machine.[120] Thus, joint inventors could not file for a patent of joint invention unless they each contributed to the subject matter covered by all of the claims ("all claims" rule.)[121] Pre-1984 Amendment case law applied this all-claims rule in examining the inventorship of mechanical inventions.[122] A patent covering a machine was invalid when issued if any of the machine elements resulted from independent contribution by respective joint inventors of the entire machine—those elements were considered sole inventions by the respective joint inventors and distinct from the entire machine.[123]

Moreover, courts historically found joint inventorship only when inventors had worked toward a common end to which they had agreed. For example, in *Pointer v. Six Wheel*, the Ninth Circuit cited the definition of joint inventorship given by Prof. Robinson's patent law treatise, holding:

120. De Laski & Thropp Circular Woven Tire Co. v. William R. Thropp & Sons Co., 218 F. 458, 464 (D.N.J. 1914), *aff'd* 226 F. 941 (3d Cir. 1915).

121. *In re* Sarett, 327 F.2d 1005, 1010 (C.C.P.A. 1964); *In re* Hamilton, 37 F.2d 758, 759 (C.C.P.A. 1930).

122. Worden v. Fisher, 11 F. 505 (1882); Butler v. Bainbridge, 29 F. 142 (1886); Consolidated Bunging Apparatus Co. v. Woerle, 29 F. 449 (1887); Belle Patent Button Fastener Co. v. Lucas, 28 F. 371 (1886); Schlicht &F. Co. v. Chicago Sewing Machine Co., 36 F. 585 (1888); Priestley v. Montague, 47 F. 650 (1888); Page Woven Wire Fence Co. v. Land, 49 F. 936 (1891); De Laval Separator Co. v. Vermont Farm Mach. Co., 135 F. 772 (2d Cir. 1904); Quincey Mining Co. v. Krause, 151 F. 1012 (6th Cir. 1907); Sieber & Trussell Mfg. Co. v. Chicago Binder & File Co., (C.C.) 177 F. 437 (N.D. Ill. 1910).

123. Rival Mfg. Co. v. Dazey Prods. Co., 358 F. Supp. 91, 101 (W.D. Mo. 1973); Stewart v. Tenk, 32 Fed. 665 (S.D. Ill. 1887).

> [J]oint invention implies, as Robinson says, that two or more inventors agree "that a result, if it could be achieved, would be desirable, neither as yet having attempted to provide a means, and from this point go forward by mutual consultations and suggestions."
>
> [T]he product of the joint endeavor is a joint invention when . . . "before the entire conception of the invention by one inventor, another meets him and by his consent unites with him in exercising inventive skill upon the development and perfecting of the conception."[124]

To meet this heightened collaboration requirement, "simultaneous conception and shared contribution" by all named inventors was necessary.[125] Under the pre-1984 case law, inventors had to work together—at least for the crucial time—towards a common end that resulted from "the contributions and united efforts" of all inventors.[126] Joint inventorship was denied when inventors did not agree to a common end such as when the alleged joint inventor rejected the named inventor's suggestion, resulting in a separately patentable improvement of the original structure that the alleged inventor was working on. Courts also focused on a common end and result, which named and alleged inventors agreed on and jointly accomplished, when determining joint inventorship.[127]

In short, many of those who qualify as joint inventors under the current case law would have been considered sole inventors under the pre-1984 case law. The requirement of the pre-1984 case law of a common end worked well with respect to inventions in the mechanical art, as the end and result of inventions in the mechanical arts are predictable to one skilled in the art of invention and the inventive process usually begins with the identification of the technical problem which the inventors are seeking to solve. However, that approach does not work as well with inventions in the unpredictable arts, such as

124. *Pointer*, 177 F.2d at 158. Courts frequently cited Robinson's treatise to support their joint inventorship determination.

125. Ethicon, Inc. v. United States Surgical Corp., 135 F.3d 1456, 1469 (Fed. Cir. 1998) (Newman dissenting).

126. McKinnon Chain Co. v. American Chain Co., 268 F. 353, 360 (3d Cir. 1920); Gorge v. Perkins, 1 F.2d 978, 979 (8th Cir. 1924).

127. *McKinnon Chain Co.*, 268 F. at 360 (Finding joint inventorship for inventors who worked at the crucial time worked together for a common end that the inventors accomplished by their contributions and united efforts of both).

chemistry and biotechnology, in which an end result becomes clear only after a sample embodying the invention is constructed and tested.

In *Dana-Farber*, for example, it was unclear when Drs. Wood, Freeman and Honjo agreed and joined their efforts to the useful end of providing cancer treatments by controlling the immune response inhibitive function of the PD-1/PD-L1 pathway. While the U.S. and Japanese researchers were keenly aware of possible drug development, they did not come up with the end result concretely before Dr. Freeman's experiments to express PD-L1 on tumor cells or Dr. Iwai's experiment to confirm the inhibitive function of the pathway.[128] In particular, it is unlikely that Drs. Wood and Freeman would have qualified for joint inventorship under the pre-1984 collaboration requirement as they failed to participate in Dr. Iwai's experiment. Therefore, they failed to collaborate at the crucial time and the invention did not result from united efforts of U.S. and Japanese researchers.[129] Because the inventions of the Honjo Patents were separately patentable, Drs. Wood and Freeman were joint inventors of the Honjo patents only if they can meet the heightened collaboration requirement.

The restrictive standard of the pre-1984 collaboration requirement introduced uncertainty in patent validity for joint inventorship because patent owners had no procedure to correct inventorship once an error was found.[130] Although the enactment of 1952 Patent Act introduced inventorship correction procedures and made procedures for preventing patent invalidity available to patent owners,[131] the restrictive inventorship standard with a heightened collaboration requirement survived the 1952 overhaul of the patent system and continued to control inventorship disputes until the 1984 Amendments adopted the current inclusive inventorship standard in § 116.[132]

128. Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co., 379 F. Supp. 3d 53, 88 (D. Mass. 2019), *aff'd*, 964 F.3d 1365 (Fed. Cir. 2020).

129. *Id.* at 89.

130. MCV, Inc. v. King-Seeley Thermos Co., 870 F.2d 1568, 1570 (Fed. Cir. 1989) ("Before the enactment of section 256, patentees and their assignees committed inventorship errors at their peril; misjoinder or nonjoinder of an inventor rendered the patent invalid."). In addition, there was no procedure to correct inventorship during the prosecution. Morris Relson, *Misjoinder of Inventors in Patent Applications*, 27 J. PAT. OFF. SOC'Y 546 (1945). *See generally* 2 DONALD S. CHISUM, CHISUM ON PATENTS, § 2.04[1] (2021).

131. Patent Act of 1952, Pub. L. No. 82-593. 66 Stat. 792, §§ 116, 256 (1952).

132. *E.g.*, S. W. Farber, Inc. v. Tex. Instruments, Inc., 211 F. Supp. 686, 690 (D. Del. 1962).

3.First-To-Invent Novelty: Common Inventorship Exception

The AIA revised the definition of the prior art and replaced the first-to-invent system with the first-inventor-to-file (FITF) system which is a hybrid of the first-to-invent and first-to-file systems.[133] The prior art definition under the FITF system applies to applications filed on and after March 16, 2013 (AIA FITF date).[134] Thus, the validity of patents resulting from applications filed before AIA FITF date, such as the Honjo patents, is still examined under the first-to-invent system.[135] Pre-AIA case law also applies when determining the inventorship of such patents.

The first-to-invent subsections concerning novelty which provide prior inventions were also intertwined with and closely related to inventorship. Under pre-AIA law, the first-to-invent was determined by whether the invention under examination was made by others than the named inventor prior to the date that the invention under examination was made. Therefore, the § 102 novelty subsections provided three types of prior inventions made by others to exclude inventors' own prior inventions ("common inventorship exception") as prior art in addition to a derived invention.[136] Among the three types of prior inventions, only the first type required public availability of the invention prior to the invention date. This requirement was based on the rationale that the named inventor was not the first-to-invent if the invention was known or used publicly or patented or described in a printed publication by others prior to the invention.[137] The remaining types of prior inventions were available as prior art with the common inventorship exception even if they were

133. For a comparison of the first-inventor-to-file system with the first-to-invent system and the first-to-file system, *see* Toshiko Takenaka, *Has the United States Adopted a First-to-File System Through America Invents Act?: A Comparative Law Analysis of Patent Priority Under First-Inventor-to-File*, GERMAN ASS'N. FOR PROT. OF INTELL. PROP. INT'L. 304 (Jan. 2012), *available at* https://ssrn.com/abstract=1986987 [https://perma.cc/NR4Q-TAQK] [hereinafter, Takenaka, *First-to-File*].

134. USPTO, Manual of Patent Examining Procedure, § 2015 (9th ed, 2019, last rev. June 2020) [hereinafter MPEP].

135. The AIA defines the filing date as the effective filing date. The effective filing date is either (1) the actual filing date with U.S.PTO, or (2) the filing date of the earliest application for which the patent or application is entitled to a right of priority or the benefit of an earlier filing date under international agreements or the U.S. Patent Act. For example, the international patent application for the Honjo patents claimed priority from the Japanese application dating July 3, 2002, which is therefore the effective filing date of the Honjo patents.

136. Pre-AIA 35 U.S.C. § 102(a), (e), (f)–(g).

137. Pre-AIA 35 U.S.C. § 102(a).

not publicly available on the invention date (secret prior art).[138] They included (1) a prior invention under § 102(e) which was disclosed in a patent application pending at the USPTO [139] and (2) a prior invention under § 102(g) where the first-to-invent inventor did not have any communication with the second-to-invent inventor of the invention under examination and did not abandon the invention.[140]

The first type of secret prior art originated from the 1926 Supreme Court *Milburn* decision allowing inventors to rely on their pending applications to establish the date of invention.[141] The *Milburn* doctrine was later codified to define the content of the patent application as prior art because an invention disclosed in a pending application showed that the invention was made on the filing date of the pending application and the named inventor was not the first-to-invent if the filing date was prior to the invention.[142] In *Hazeltine Research, Inc. v. Brenner*, the Supreme Court made clear that the first type secret prior art was available for not only lack of novelty but also obviousness.[143] In *In re Bass*, the Court of Patent Customs and Patent Appeals (CCPA) confirmed that a prior invention by others was prior art for both novelty and nonobviousness regardless of public access.[144] Accordingly, when the first-to-invent inventor communicated her invention to another inventor who made a related invention, the communicated invention was also prior art against the related invention as a derived invention even if the invention was kept secret and the communication between the two inventors was confidential.[145]

In addition, § 102 provided that disclosures of the invention by either the inventor or others were prior art under § 102(b) regardless of whether those disclosures were made prior to the date that the claimed invention was made, so long as they were patented or described in a printed publication elsewhere or in public use or on sale in the U.S. more than one year prior to the filing date.[146] This type of prior art was called a statutory bar. The first-to-invent requirement was irrelevant to policy underlying this type of prior art because the goal

138. C. Douglass Thomas, *Secret Prior Art—Get Your Priorities Straight!*, 9 HARV. J. L. & TECH. 147 (1996) [hereinafter Thomas, *Secret Prior Art*].

139. Pre-AIA 35 U.S.C. §.102(e).

140. Pre-AIA 35 U.S.C. § 102(g).

141. Alexander Milburn Co. v. Davis-Bournonville Co., 270 U.S. 390, 399(1926).

142. Pre-AIA 35 U.S.C. § 102(e).

143. Hazeltine Research, Inc. v. Brenner, 382 U.S. 252, 255 (1965).

144. In re Bass, 474 F.2d 1276, 1286 (C.C.P.A. 1973).

145. OddzOn Products Inc. v. Just Toys Inc., 122 F.3d 1396, 1401 (Fed. Cir. 1997).

146. Pre-AIA 35 U.S.C. § 102(b).

of the statutory bar was not to determine whether the inventor was the first-to-invent, but to promote early patent applications once an invention had become publicly available.[147] Given this goal, any prior disclosure of the invention was available as prior art against the current claimed invention if it became publicly available at least one year prior to the filing date of the claimed invention.[148] The statutory bar prior art included secret prior art by the inventor: using the invention commercially or offering to sell the invention confidentially by the inventor was prior art and prevented the inventor from obtaining a patent, but such confidential use and sale did not prevent others from obtaining a patent.[149]

The common inventorship exception—which excluded inventors' own prior invention from being considered as prior inventions by others under 102(a), (e), and (g) with respect to novelty and nonobviousness—resulted in the preferential treatment of inventors seeking to patent their follow-on, obvious inventions after filing an application for the original invention.[150] Because their own prior inventions were not prior art, inventions were not rejected or invalidated for lack of novelty or nonobviousness over their own work. However, inventors' own works became available as statutory bar prior art if the inventors did not file patent applications within one year from public use, sale, patenting, or publication.[151] Statutory bar prior art under § 102(b) resulted in the disadvantageous treatment of inventors seeking to improve the inventions of others. If the statutory bar did not apply to inventors' own prior works, only the double patenting doctrine prevented inventors from obtaining more than one patent on identical or obvious inventions.[152] However, inventors were able to patent obvious inventions if they filed a terminal disclaimer.[153]

For joint inventions, the theory of the inventive entity limited the exclusion or inclusion of inventors' own prior work from the novelty

147. Pennock v. Dialogue, 27 U.S. 1, 23–24 (1892). For the policy underlying the statutory bar prior art, *see* Takenaka, *Rethinking*, *supra* note 108, at 630.

148. Pre-AIA 35 U.S.C. § 102(b) reads: "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States."

149. Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co., 153 F.2d 516, 518 (2d Cir. 1946).

150. *See* discussion *supra* note 136, Amy R. Motomura, *Innovation and Own Prior Art*, 72 HASTINGS L. J. 565, 579 (2021) [hereinafter Motomura, *Innovation*].

151. Pre-AIA 35 U.S.C. § 102(b).

152. Two types of double patenting, statutory and obvious-type double patenting, prevent a patentee from receiving two patents on identical or obvious inventions. *In re* Lonardo, 119 F.3d 960, 965 (Fed. Cir. 1997). *See also* 3A CHISUM ON PATENTS, *supra* note 103, at Ch. 9.

153. 3A CHISUM ON PATENTS, *supra* note 103, at § 9.03.

prior art and statutory prior art.[154] The inventive entity theory distinguished the sole inventorship of an individual inventor from joint inventorship resulting from collaboration by an individual inventor working with other individual inventors. Unless all individual inventors are the same for a prior invention and the invention under examination, the inventive entity is different and thus the common inventorship exception does not apply to remove prior inventions from the prior art.[155] For example, if inventor A invented invention #1, filed a patent application, and then jointly made invention #2 with another individual inventor B, invention #1 would not be excluded from the prior invention prior art because invention #1 was made by an inventive entity (A) which was different from inventive entity of invention #2 (A and B).[156] Invention #2 would be rejected if it was obvious over invention #1 because the first-to-invent priority should be rewarded to the inventive entity of invention #1 (A) for not only identical but also patentably indistinct obvious variations of the invention. In contrast, both inventions would be patentable if joint inventorship was construed more broadly to include individual inventors A and B as joint inventors for both invention #1 and invention #2 so that the common inventorship exception applies to exclude invention #1 from prior art. As demonstrated by this example, pre-1984 Patent Law Amendment case law's restrictive inventorship standard resulted in many different inventive entities, including only the individual inventors who contributed to claimed subject matter. These different inventive entities prevented inventors participating in the same research project from taking advantage of the common inventorship exception for excluding prior inventions. As a result, the restrictive inventorship standard presented an obstacle to effectively obtaining patents on inventions resulting from cumulative innovation between multiple inventors because the inventions were closely related and frequently obvious in light of each other.

Because inventors' own work fell into prior inventions by others unless the common inventorship exception applies under the inventive entity theory, such works prevented them from obtaining patents on

154. 2 DONALD S. CHISUM, *supra* note 2, at § 2.03[1].

155. *In re* Land, 368 F.2d 866, 878 (C.C.P.A. 1966); *Ex parte* DesOrmeaux, 25 U.S.P.Q. 2d 2040, 2043 (B.P.A.I. 1992); MPEP, *supra* note 134, at § 2136.04.

156. 2 DONALD S. CHISUM, *supra* note 2, at § 2.03[1]. In practice, the USPTO and courts needed to make the followings step for citing a reference: Identify portions of a prior art reference that they relied on, evaluate the degree to which those portions were conceived by another, and decide whether that other person's contribution was significant. Duncan Parking Tech., Inc. v. IPS Grp., Inc., 914 F.3d 1347, 1358 (Fed. Cir. 2019).

future related inventions. This prior art problem, caused by inventors' own prior inventions, is known as "self-collision."[157] Self-collision under the U.S. Patent Act was unique to the U.S. patent system because the first-to-invent novelty requirement allowed the inclusion of secret prior art in a novelty and nonobviousness analysis. Thus, inventors could not prevent a self-collision because keeping their own prior works secret did not prevent those inventions from falling into the prior art. In contrast, under the European Patent Convention ("EPC"), which is a model for most first-to-file patent systems, only inventions and any subject matter made publicly available before the filing date of the claimed invention under examination are considered prior art.[158] The only exception to that rule is the content of European patent application which will be considered prior art even if it was not published on or before the filing date. The content of such an application is secret, as it is not publicly available on the filing date, but is considered prior art as of the filing date once the application is published.[159] However, the content only supports the first-to-file priority and thus is available only for examining novelty and is not available for rejecting or invalidating based on the inventive step, which is equivalent to obviousness under the U.S. Patent Act.[160] Moreover, the double patenting doctrine of the first-to-file system prevents only novelty type double patenting. Thus, inventors can separately patent obvious inventions over their prior inventions disclosed in a pending application as long as they file a patent application on the obvious inventions before the eighteen-month publication and the inventions are kept secret.[161] The first-to-file system effectively allows an 18-month extension of the patent term of patents on prior inventions by allowing separate patents on obvious inventions. As a result, self-collision problems in the first-to-file

157. Kate H. Murashige, *The Hilmer Doctrine, Self Collision, Novelty and the Definition of Prior Art*, 26 J. MARSHALL L. REV. 549, 556 (1993).

158. European Patent Convention, art. 54(2), Oct. 5, 1973, 1065 U.N.T.S. 255, 275-76 (Amended Nov. 29, 2000) [hereinafter EPC].

159. EPC, art. 54(3).

160. EPC, art. 56. For the comparison of patentability between EPC and pre-AIA U.S. Patent Act, *see* Toshiko Takenaka, *The Best Patent Practice or Merely Compromise?: A Review of Current Draft Patent Law Treaty and a Proposal for a First-to-Invent" Exception for Domestic Applicant,* 11 TEX. INTELL. PROP. L. J. 259 (2003).

161. EPO Case G 0004/19, Enl. Bd. App., ECLI:EP:BA:2021:G000419.20210622 at Paragraph 82 (Jun. 22, 2012), *available at* https://www.epo.org/law-practice/case-law-appeals/recent/g190004ex1.html [https://perma.cc/X4SF-3KF9] ("[T]he [double patenting] prohibition is applicable for the same invention in respect of which there are several applications with the same date of filing"). Under EPC, the invention disclosed in the pending application under EPC art. 54(3) is excluded from the prior art for inventive step. Under EPC, the double patent doctrine applies to the same invention applied by the same applicant. EPC, art. 56.

system do not present serious challenges for effectively patenting follow-up inventions resulting from the cumulative innovation.

In contrast, first-to-invent inventors could not prevent their prior inventions from being considered as prior art references in novelty and obviousness analyses by keeping them secret because their prior inventions were considered available as secret prior art if the prior inventions were made by different inventive entities.[162] Any invention later disclosed in a printed publication under § 102(a) or in a pending application under § 102(e) could be backdated as a secret prior invention under § 102(g). Therefore, any invention so disclosed became prior art as of the invention date, which was prior to the publication date or the filing date, once the invention date was established.[163] Unless the inventive entity was the same for the prior invention and the invention under examination and the common inventorship exception is applicable, the prior inventions could be cited for obviousness if the prior inventions were disclosed in the pending application with the earlier filing date[164] or if the prior inventions' actual filing dates were prior to the invention's actual invention date.[165] In other words, the scope of prior art changed drastically depending on who were included in the inventive entities as joint inventors.

Dana-Farber provides an instructive example of the potential repercussions of this change of scope. There, inventors published the discoveries concerning PD-L1 in a journal on October 2, 2000.[166] The discoveries disclosed in the journal were therefore available as prior art as the invention described in a printed publication under § 102(a) on the publication date.[167] However, under the inventive entity theory, the publication could be cited only if the inventive entities for the disclosed discovery and the invention of the Honjo patents were different.[168] Likewise, the inventions disclosed in the provisional application by the U.S. researchers became prior art under § 102(e) on the filing date, November 10, 1999, once the application was replaced

162. Pre-AIA 35 U.S.C. § 102(g).

163. In re Bass, 474 F.2d 1276, 1297 (C.C.P.A. 1973).

164. *Id*.

165. *In re* Land, 368 F.2d 866, 878 (C.C.P.A. 1966).

166. Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co., 964 F.3d 1365, 1369 (Fed. Cir. 2020).

167. Pre-AIA 35 U.S.C. § 102(a).

168. 3A CHISUM ON PATENTS, *supra* note 103, at § 9.03, 2 DONALD S. CHISUM, *supra* note 103, at § 2.03[1], *see also supra* text accompanying notes 154-56.

with the non-provisional application and subsequently published.[169] The provisional application could be cited against the Honjo Patents because Dr. Honjo was missing from the inventorship. Given these different inventive entities, the date of availability as prior art of the discoveries and inventions disclosed in the provisional application could have been pushed back even further than the filing date to actual invention dates in July 1998 through September 1999.[170]

In short, when different inventive entities were involved in research projects, different types of prior art, each with different timing to make inventors' prior inventions available as prior art, put a lot of pressure on those inventors' employers to coordinate patent prosecution in order to avoid obviousness rejections.[171] If the inventions of the Honjo Patents were obvious over the discoveries and inventions disclosed in the journal and provisional application, no patent could have issued on the pioneer cancer treatment. In contrast, the Honjo Patents would be valid regardless of obviousness if the earlier disclosed discoveries and inventions and the inventions of the Honjo Patents were all made by the same inventive entities, including all U.S. and Japanese researchers in the joint research project. Because the date the invention was made under § 102(g) was uncertain but determinable under the priority rule, effectively managing patent prosecution on related inventions was a challenging task, which ultimately led to extensive debates regarding removal of the secret prior art.[172]

As highlighted in *Dana-Farber,* many inventors did not know who qualified as joint inventors, and employers could not realistically track all the activities of their employees and their research partners' employees in order to decide the dates of the inventions resulting from the joint research. Moreover, the availability of secret prior art would incentivize research-intensive companies to move away from the U.S., since a prior invention under § 102(g) was available as prior art only

169. Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co., 379 F. Supp. 3d 53, 71 (D. Mass. 2019), *aff'd*, 964 F.3d 1365 (Fed. Cir. 2020). The invention described in a co-pending application became prior art as of the effective filing date when the application was replaced with a corresponding international application in August 2000 and published eighteen months from the November 1999 filing date. Pre-AIA 35 U.S.C. § 102(e).

170. *Dana-Farber*, 379 F. Supp. 3d at 66–69. Although discoveries are not inventions, they should become prior art when they were actually discovered under Pre-AIA 35 U.S.C. § 102(g).

171. Bernard E. Franz, *Prosecution Problems with a Plurality of Inventions From a Single Project*, 51 J. PAT. OFF. SOC'Y 559 (1969).

172. In re Bass, 474 F.2d 1276, 1297 (C.C.P.A. 1973); Harris A. Pitlick, *A Proposed Compromise to the "Prior Art" Controversy Surrounding* In Re Hellsund *and* In Re Bass, 56 J. PAT. OFF. SOC'Y 699, 710 (1974) [hereinafter Pitlick, *Proposed Compromise*].

if the invention was made in the U.S.[173] Even worse, inventors no longer had a resort if their inventions were rejected for obviousness once the USPTO overturned its practice to allow applicants to overcome an obviousness rejection with a terminal disclaimer.[174] As a result, employers who were the common assignees of applications covering inventions which were obvious in light of each other were required to elect the first invention if they wanted to avoid expensive and lengthy interference procedures.[175] In short, pre-AIA first-to-invent laws presented serious obstacles to obtaining patents for inventions resulting from cumulative innovation by limiting the common inventorship exception to joint inventions made by the same inventive entities.

Permitting secret prior art imposed the heavy administrative burden on employers of keeping track of the order of priority among the inventions claimed in all applications by different inventive entities and informing the USPTO when related inventions were rejected for obviousness.[176] This burden could be enormous as employers needed to file many applications by the different inventive entities under the "all claims" rule.[177] The best solution to avoid this burden was to expand the inventorship standard to include all individual inventors involved in a research project in the inventive entity of the inventions.

B. 1984 Amendments to the U.S. Patent Laws

1. Statutory Inventorship Standard

In response to the industry outcry, Congress enacted the 1984 Patent Law Amendments which added a joint inventorship standard for the first time.[178] The 1984 Amendments aimed to introduce flexibility into the patent application process for joint inventors which reflected the realities of modern team research and encouraged

173. Pitlick, *Proposed Compromise*, *supra* note 172, at 709; Harold S. Mayer, *Obvious Differences—What Should the Points of Reference Be?*, 55 J. PAT. OFF. SOC'Y 516 (1973). The Patent Reform Act of 2007 expanded the geographical restriction on the prior invention prior art to include inventions made in TRIPS member states. Patent Reform Act of 2007, S. 1145, H.R. 1908, 110th Cong. (*1st* Sess. 2007) (enacted).

174. Commissioner's notice of January 9, 1967, at 834 O.G. 1615, *reproduced in Bass*, 474 F.2d at 1292.

175. This requirement was called the doctrine of election and discussed in *In re* Hession*,* 296 F.2d 930, 932 (C.C.P.A. 1960).

176. Pitlick, *Proposed Compromise*, *supra* note 172, at 710.

177. *See In Re Sarett, In Re Hamilton*, *supra* note 121 and accompanying text.

178. Patent Law Amendments Act of 1984, Pub. L. No. 98-622, 98 Stat. 3383 (1984).

communication among joint inventors by removing the obstacles created by allowing secret prior art.[179] Congress viewed secret prior art as disincentivizing research members from communicating and sharing their works and intended to promote team research and thus eliminated that disincentive through the inclusive inventive standard and additional exception.[180] The amended provision for joint inventions includes negative guidance, denying the heightened collaboration requirement implemented under the early case law, stating:

> **(a) Joint Inventions.—**
>
> When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.[181]

The legislative history of the 1984 Amendments supports the proposition that Congress intended to clarify both the substantive originality requirement, by giving guidance as to how to determine joint inventors, and the procedural requirement, by clarifying instances in which joint inventors can file a single application.[182] The definition of joint inventorship remains the same under current law and is based on the inventorship guidance given by district courts in *Monsanto v. Kamp*,[183] and *Industri A B v. Bendix Corp.*[184] In *Monsanto*, in an effort to emphasize the flexibility of the inventorship standard, Judge Holtzoff held:

179. 130 CONG. REC. 28,071 (Oct. 1, 1984), *reprinted in* 1984 U.S.C.C.A.N. 5833–34. *See also* S. REP. NO. 98-663, 2d Sess., at 7–9 (1984), *available at* https://ipmall.law.unh.edu/content/legislative-ip-acts-lipa-history-archive-patents-0 [https://perma.cc/3KRM-ZA4V].

180. Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co., 973 F.2d 911, 917 (1992); *Innovation and Patent Law Reform: Hearings on H.R. 3285, H.R. 3286, and H.R. 3605 Before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice of the House Comm. on the Judiciary*, 98th Cong. 2d Sess. 26–27, 61–62, 71–72 (1984) (statements of G. Mossinghoff and H. Manbeck, Jr.,).

181. Patent Law Amendments Act of 1984, Pub. L. No. 98-622, 98 Stat. 3384 (1984)["1984 Patent Law Amendment Act"].

182. 2 CHISUM ON PATENTS, *supra* note 2, at § 2.02; Section-by-Section Analysis of H.R. 6286, Patent Law Amendments Act of 1984, CONG. REC. 10527 (1984), *reproduced in* 9 CHISUM ON PATENTS, App. 22.

183. Monsanto Co. v. Kamp, 269 F. Supp. 818 (D. D.C. 1967).

184. SAB Industri AB v. Bendix Corp., 199 U.S.P.Q. 95 (E.D. Va. 1978).

> A joint invention is the product of collaboration of the inventive endeavors of two or more persons working toward the same end and producing an invention by their aggregate efforts. To constitute a joint invention, it is necessary that each of the inventors work on the same subject matter and make some contribution to the inventive thought and to the final result. Each needs to perform but a part of the task if an invention emerges from all of the steps taken together. It is not necessary that the entire inventive concept should occur to each of the joint inventors, or that the two should physically work on the project together. One may take a step at one time, the other an approach at different times. One may do more of the experimental work while the other makes suggestions from time to time. The fact that each of the inventors plays a different role and that the contribution of one may not be as great as that of another, does not detract from the fact that the invention is joint, if each makes some original contribution, though partial, to the final solution of the problem.[185]

The current § 116 definition adopted three key aspects of negative guidance. The first two aspects of negative guidance, (1) physical collaboration and (2) degree of contributions, were adopted from *Monsanto*. However, the statute did not adopt the requirement of two or more persons working toward the same end and on the same subject matter.[186] While Judge Holtzoff required each joint inventor to contribute to the inventive thought, and thus touched upon the required quality of contribution, the updated statute did not include any guidance on quality. As a result, the § 116 joint inventorship definition has been interpreted to give no explicit lower limit on the quantum or quality of contribution in order to be qualified for joint inventorship.[187]

The third and last aspect of negative guidance provided by the amendment, expressly rejecting the "all claims" rule, is based on *SAB Industri AB*. There, Judge Bryan rejected the defendants' argument that "the joint inventors must have combined their efforts as to each claim in the patent."[188] This last aspect of guidance does not relate to

185. *Monsanto*, 269 F. Supp. at 824.

186. 35 U.S.C. § 116 (2018*), see supra* note 183 and accompanying text.

187. Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1358 (Fed. Cir. 2004); Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997).

188. *SAB Industri AB*, 199 U.S.P.Q. at 104.

the joint inventorship standard itself, but simply clarifies that inventors who contributed to any claim can file a single patent application.[189] The third aspect of guidance has no effect on the requirement of contribution to the conception of subject matter for joint inventorship. It simply allows inventors to file a single patent application unless the subject matter expressed in one claim and subject matter expressed in other claims are directed to two independent and distinct inventions and thus only one of the inventions must be elected for further prosecution.[190]

2.Expansion of Prior Art Exception

The 1984 Patent Law Amendments Act introduced another prior art exception based on the common ownership which extensively overlaps with the common inventorship exception.[191] The common ownership exception addressed the secret prior art problem highlighted in *Bass*; it removed § 102(g) prior inventions from the obviousness prior art if the prior invention and the invention claimed in the application or patent were owned by the same person or subject to an assignment obligation to the same person on the date that the invention was made.[192] In *Bass*, Judge Rich excluded § 102(f) derived prior inventions from the prior art in all obviousness inquiries.[193] Despite the broad exclusion in *Bass*, the common ownership exception under the 1984 Amendments explicitly removed derived inventions from prior art considerations for obviousness where the subject matter is commonly owned.[194]

Even if the newly introduced exception protected commonly owned inventions from an obviousness rejection over secret prior inventions and/or derived inventions, the double-patenting doctrine provides that inventors should not seek to separately patent obvious

189. Prof. Chisum commented that the guidance is simply a rejection of the "all claims" rule instead of the definition of joint inventor. 2 CHISUM ON PATENTS, *supra* note 2, at § 2.02[2][a].

190. 35 U.S.C. § 121 (2018).

191. Pre-AIA 35 USC, § 103(c)(1).

192. *See* Motomura, *Innovation*, *supra* note 150, at 583-84; Patent Law Amendments Act of 1984 § 103, 98 Stat. at 3384 ("Section 103 of title 35, United States Code is amended by adding . . . . Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.").

193. *In* re Bass, 474 F.2d 1276, 1290 (C.C.P.A. 1973). Judge Rich had the view that § 102(c) abandonment, (d) first foreign patenting, and (f) derivation were not prior art and have no relation to obviousness.

194. S. REP. NO. 98-663, 2d Sess. at 7 (1984). Pre-AIA 35 U.S.C. § 103(c). It is likely that Congress was aware of the possibility that derived inventions are viewed as prior art.

inventions to extend the term of the earliest issued patent.[195] Congress expected the USPTO to issue a double patenting rejection if the invention under examination was obvious in light of an invention claimed in an earlier patent owned by a common assignee. The USPTO would then allow the common assignee to overcome the rejection by agreeing to disclaim the term of the later patent so that both patents expire at the same time.[196] In response to this Congressional expectation, the USPTO revived the common ownership terminal disclaimer practice, allowing applicants to overcome double patent rejections for obvious inventions.[197]

Although the 1984 Patent Law Amendments did not eliminate prior inventions described in a co-pending patent application under § 102(e) from the prior art, the subsequent 1999 amendment further revised the obviousness provision and eliminated these prior inventions as prior art for obviousness under the common ownership exception.[198] Even still, neither 1984 nor 1999 Amendments protected inventions resulting from open innovation where inventors were subjected to assignment obligations to different employers, as represented by the facts in *Dana-Farber*. Contrary to Judge Rich's view in *Bass,* the Federal Circuit confirmed that a derived invention can be prior art for obviousness in *OddzOn*.[199] The industry viewed the decision as giving a serious disincentive to communication among inventors employed by different employers and providing a serious threat to public-private collaboration.[200]

In response to that critique, Congress enacted the Cooperative Research and Technology Enhancement (CREATE) Act which expanded the scope of secret prior art exceptions to works resulting from collaboration under joint research agreements.[201] In order to qualify for the exception, the invention must meet three requirements: (1) the invention was made by or on behalf of parties of a joint research

195. 3A CHISUM ON PATENTS, *supra* note 103, at § 9.01, Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc., 909 F.3d 1355, 1362 (Fed. Cir. 2018).

196. S. REP. NO. 98-663, at 8. Congress' intent to reinstitute the double patenting practice is discussed in *In re Longi*, 759 F.2d 887, 895 (Fed. Cir. 1985).

197. *In re Longi*, 759 F.2d at 895; USPTO, Initial Guidelines as to Implementation of Patent Law Amendment, *reprinted in* 29 BNA's PAT. T.M. & COPY. J. 214 (Dec. 20, 1984).

198. 35 U.S.C. § 103(c) *amended by* American Inventors Protection Act of 1999, Pub. L. No. 106-113, § 4807(a), 113 Stat. 1501A-552,1501A-591 (1999). *See also* Motomura, *Innovation*, *supra* note 150, at 586.

199. OddzOn Products Inc. v. Just Toys Inc., 122 F.3d 1396, 1401 (Fed. Cir. 1997).

200. H.R. REP. No. 108-425, at 5 (2004). Motomura, *Innovation*, *supra* note 150, at 586–87.

201. Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Pub. L. No. 108-453, 118 Stat. 3596 (2004). A terminal disclaimer requirement applies to obvious-type patents resulting from the joint research agreement exception.

agreement that was in effect on or before the invention date; (2) the invention was covered by the scope of the agreement; and (3) the application claiming the invention disclosed the names of the parties.[202] In addition, the agreement must be "a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention."[203]

In short, the CREATE amendment finally provided a solution for inventions resulting from the open innovation of the key stakeholders in the biopharmaceutical industry, such as collaborations by U.S. and Japanese inventors in *Dana-Farber*. However, this amendment did not remove all challenges associated with inventions that are the product of open innovation. For example, requiring a written contract before an invention may present a challenge because academic researchers frequently begin their collaboration and information exchange informally. Additionally, it is difficult to predict future inventions and the scope of research project at the early stage of drug and therapy development. If a formal agreement was not available, the flexible and inclusive inventorship standard sometimes came in to rescue inventions by excluding inventors' own prior inventions from the prior art for obviousness.

3.Inclusive Inventorship Standard

a. Relaxed Collaboration Requirement

In 1982, two years prior to the 1984 Patent Law Amendments, the Federal Circuit was created.[204] In response to the industry need to remove the obstacles for collaboration, the court began to develop the current overinclusive inventorship standard by taking over CCPA's case law and exercising exclusive jurisdiction over appeals from district courts on inventorship disputes.[205] In *Kimberly-Clark v. Procter Gamble,* the Federal Circuit gave its first interpretation of the

202. Pre-AIA 35 U.S.C. § 103(c)(2) (2010).

203. Pre-AIA 35 U.S.C. § 103(c)(3) (2010).

204. Federal Courts Improvements Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982).

205. The Federal Circuit was created from the merger of CCPA and the appellate division of the Court of Claims. It adopted the case law of CCPA as controlling precedents. CCPA had exclusive jurisdiction over appeals from interferences at USPTO but did not have jurisdiction over appeals from district court. Congress gave the exclusive jurisdiction over appeals from district courts when the Federal Circuit was created. Federal Court Improvement Act, Pub. L. No. 97-164, 96 Stat. 25 (1982). For more discussion, *see* Jeffrey A. Lefstin, *The Constitution of Patent Law The Court of Customs and Patent Appeals and the Shape of the Federal Circuit's Jurisprudence,* 43 LOY. L.A. L. REV. 843 (2010).

§ 116 joint invention provision.[206] The court rejected the argument that the new standard completely eliminated the collaboration requirement on basis of the legislative history. The decision cited the principles of joint inventorship in *Monsanto* to find that "[a] joint invention is the product of *collaboration* of the inventive endeavors of two or more persons *working toward the same end* and producing an invention by their *aggregate* efforts."[207] The court further explained that the requirement was not met if a person did not understand the invention but simply followed an instruction of the named inventor.[208] While preserving the collaboration requirement, the Federal Circuit relaxed the requirement for finding joint inventorship if courts find "some of elements of joint behavior, such as collaboration or working under common direction, one inventor seeing a relevant report and building upon it or hearing another's suggestion at a meeting."[209] Under this relaxed collaboration requirement, inventors no longer need to work toward the common end that they agreed upon and joined their efforts to achieve, as required by the pre-1984 case law.[210]

The Federal Circuit continued to develop the relaxed collaboration requirement through the influence of the broad joint inventorship interpretation in *General Motors v. Toyota.*[211] In *General Motors*, a few years prior to the 1984 Amendments, the Sixth Circuit upheld the district court decision finding joint inventorship for all inventors who worked in different groups to engage in serial, in-house concerted projects, despite the fact that each group did not work together at the same time. The district court distinguished collaborations within a large business entity from other types of collaborations, holding that "where numerous 'inventors' all worked under the aegis of one employer toward a common goal, it is appropriate to define the concept of joint invention broadly."[212] The court rationalized its broad interpretation because "it is not realistic to require in such circumstances that joint inventors work side-by-side, and that each step in the inventive process be taken by all the firm's

206. Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co., 973 F.2d 911, 915 (1992).

207. *Id.* at 916.

208. Stern v. Tr. of Columbia Univ., 434 F.3d 1375, 1378 (Fed. Cir. 2006), *cert. denied*, 127 S. Ct. 83 (2006).

209. *Kimberly-Clark*, 973 F.2d at 917.

210. *For the requirement to work toward the common end, see supra* notes 124-127 and text accompanying text.

211. General Motors Corp. v. Toyota Motor Co., 467 F. Supp. 1142 (S.D. Ohio 1979*), aff'd in part, rev'd in part*, 667 F.2d 504 (6th Cir. 1981), *cert. denied*, 456 U.S. 937 (1982), *on remand*, 569 F. Supp. 889 (S.D. Ohio 1983), *aff'd,* 738 F.2d 454 (Fed. Cir. 1984) (unpublished).

212. *General Motors Corp.*, 667 F.2d at 507.

collaborators."[213] The district court adopted the broad interpretation to distinguish *General Motors* from *Bass*, which did not involve in-house concerted projects, and to avoid obviousness challenges over inventors' own prior inventions by including all inventors involved in the concerted projects in the inventive entity.

Subsequently, the 1984 Amendments introduced the common ownership exception and eliminated the necessity of overcoming an obviousness rejection under the common inventorship exception when inventors worked for the same employer. Nevertheless, the Federal Circuit adopted and further expanded the *General Motors* court's broad construction in interpreting the updated § 116 joint invention statute even though the legislative history did not clearly show that Congress intended to include multiple groups of individual inventors engaging in serial in-house concerted projects as a single inventorship entity.[214] However, the court maintained that these inventors must still meet the minimum collaboration requirement. For example, if an inventor improved on a prior invention by another inventor without any communication, under any common direction, or knowledge of the prior art, the two inventors are not joint inventors [215]even if they work for the same employer and are thus under the aegis of one employer.[216] After the 1984 Amendment, the common ownership exception enables the inventor to obtain patents on the improved invention even if the invention is obvious over the prior invention.

The Federal Circuit's attempt to develop an inclusive and open-innovation-friendly inventorship standard was exemplified in *Burroughs Wellcome Co. v. Barr Labs., Inc.*[217] The inventions at dispute in *Burroughs Wellcome* included both the biopharmaceutical drug known as azidothymidine (AZT) and the preparation of AZT, and thus are considered inventions within the unpredictable arts. The validity of the patents on the drug was challenged for failing to name researchers at National Institute of Health (NIH) as inventors. Unlike in *General Motors*, the NIH researchers and the named inventors were employed by different business entities and had never worked under a common direction. The NIH researchers joined the development of the drug azidothymidine ("AZT") only when they received a sample of AZT from the patentee and tested it for the utility to treat patients

213. *Id*.
214. 2 CHISUM ON PATENTS, *supra* note 2, at § 2.02[2][a].
215. Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co., 973 F.2d 911, 917 (1992).
216. *General Motors Corp.*, 667 F.2d at 507.
217. Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1229-30 (Fed. Cir. 1994).

infected with the human immunodeficiency virus ("HIV"). The court did not examine whether named inventors and NIH researchers met the collaboration requirement, although the court cited the principle that a joint invention is the product of a collaboration to solve the problem addressed.[218] The NIH researchers did not work physically together with the named inventors and did not work on a common problem because the named inventor developed the drug independently and NIH researchers only tested whether the invention solved the problem. In determining that the NIH researchers were not joint inventors, rather than failing to find collaboration, the court relied on failure to contribute to the conception because the NIH researchers joined the development after the named inventors' conception of the invention.[219]

In *Dana-Farber*, the Federal Circuit applied the broad joint inventorship to include the U.S. and Japanese inventors who engaged in serial projects in a single inventive entity. The Federal Circuit found collaboration between the two groups based on multiple meetings, joint authorship of scientific journal articles, collaboration agreements and the sharing of experiment results and ideas.[220] Here, unlike the in-house developments in *General Motors*, U.S. and Japanese researchers worked independently and thus never worked under a common direction. Although the researchers worked toward a common goal, development of a therapy or drug, they were unaware of the problem being addressed, *i.e.*, the therapeutic applications of PD-1/PD-L1 to cancer treatments, until Dr. Freeman succeeded in expressing PD-L1 in tumor cells. With the relaxed joint inventorship standard used in *Dana-Farber*, any researchers (especially those in an academic communities where open science is the norm) who are willing to exchange research results and ideas are now subjected to a risk of a joint inventorship dispute.

b. Inclusion of Reduction to Practice in Finding Contribution

The Federal Circuit also expanded the inventorship concept by including those who contributed to reduction to practice as joint inventors. However, in doing so, the court preserved the fundamental

218. *Id.* at 1227.

219. *Id.* at 1231.

220. Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co., 379 F. Supp. 3d 53, 60 (D. Mass. 2019), *aff'd*, 964 F.3d 1365 (Fed. Cir. 2020).

principle of determining inventorship as developed by CCPA: Conception is the touchstone in determining inventorship.[221] The court adopted the CCPA's definition of conception, which is: "the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice."[222] To establish conception, showing possession of every element of an invention at the time of the alleged conception is necessary.[223] Regarding the necessary level of specificity, there must be an idea in the inventor's mind clear enough to enable an ordinary person skilled in the art to reduce the invention to practice without extensive research or experimentation.[224] If a claim is directed to a chemical substance, conception requires inventors to show possession of both the chemical structure and an operative method of making it.[225]

Completion of conception functions as a gatekeeper, excluding anyone who joined the collaboration with named inventors after the conception of the invention.[226] Contributions should qualify for inventorship only if they were communicated to named inventors before conception, as no one can contribute to the conception once the conception is complete.[227] In cases involving inventions in predictable arts, the line between conception and reduction to practice is clear. Courts reject inventorship if a putative joint inventor joined the named inventors after conception of the invention because implementing inventions in predictable arts does not require a significant skill, and joint inventorship exclude those who simply exercised ordinary skills to reduce the conception of the invention to practice.[228] However, as courts dealt more with inventorship disputes over inventions in the unpredictable arts, the line between conception and reduction to practice became blurred. This ultimately led to courts adopting a rule to find joint inventorship for those who reduced the invention to practice through experiments.

221. *Burroughs Wellcome*, 40 F.3d at 1228*;* Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997). Both cases quoted *Sewall v. Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994).

222. Coleman v. Dines, 754 F.2d 353, 359 (Fed. Cir. 1985) (quoting Gunter v. Stream, 573 F.2d 77 (C.C.P.A. 1978).) The Federal Circuit also cited Prof. Robinson's treatise to support the definition. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986).

223. *Coleman,* 754 F.2d at 359; Davis v. Reddy, 620 F.2d 885, 889 (C.C.P.A. 1980).

224. *Burroughs Wellcome*, 40 F.3d at 1228; *Sewall*, 21 F.3d at 415.

225. Oka v. Youssef*,* 849 F.2d 581, 583-84 (Fed. Cir. 1988).

226. *See supra* text accompanying notes 217-19. In *Burroughs Wellcome*, the Federal Circuit excluded NIH researchers from joint inventorship when they joined the research after the conception of the invention, *see also*, *University of Pittsburgh v. Hedrick,* 573 F.3d 1290, 1298 (Fed. Cir. 2009).

227. 2 CHISUM ON PATENTS, *supra* note 2, at § 2.02[2][a].

228. Sewall v. Walters, 21 F.3d 411, 416 (Fed. Cir. 1994); Ethicon, Inc. v. United States Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998).

This trend began in *Amgen*[229] and *Fiers v. Revel*,[230] both of which involved priority disputes over patent claims directing to DNA sequence encoding human proteins. These cases introduced the doctrine of simultaneous conception and reduction to practice by acknowledging that conception of some inventions in unpredictable arts cannot be completed until the inventions are reduced to practice.[231] For example, for DNA inventions, the Federal Circuit required isolation of genes in order to establish conception.[232] *Burroughs Wellcome*, discussed above, cited *Amgen* and *Fiers* because that case involved an invention in an unpredictable art, the biopharmaceutical drug AZT, of which the utility was not certain until NIH researchers tested a sample of it.[233] In *Burroughs Wellcome*, the Federal Circuit held that conception is complete even if inventors do not know whether their invention actually works.[234] The rationale for the holding is that inventors' actual knowledge of utility is part of reducing the invention to practice.[235] However, the Federal Circuit later clarified that inventors must have knowledge of the utility with reasonable certainty.[236] Despite a showing of reasonable certainty, conception of the invention should be retroactively negated when the following reduction to practice reveals uncertainty through experimentation and undermines "the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice."[237] Although the Federal Circuit acknowledged exceptional instances where an inventor cannot establish a conception until the invention is reduced to practice through experiments, the court clarified that in these instances the conception was in fact incomplete until reduction to practice because the only evidence of conception was experimentation leading to a reduction to practice.[238] Here, while trying to set a bright line between conception and reduction to practice, the court actually expanded the scope of inventorship in including those who only contributed to reduction to

229. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1989).

230. Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993).

231. *Amgen, Inc*., 927 F.2d at 1206. For a general discussion of the doctrine of simultaneous conception and reduction to practice, *see* 3A CHISUM ON PATENTS, *supra* note 103, at § 10.04[5]; Jackie Hutter, *A Definite and Permanent Idea—Invention in the Pharmaceutical and Chemical Sciences and the Determination of Conception in Patent Law,* 28 J. MARSHALL L. REV. 687 (1995).

232. *Fiers*, 984 F.2d at 1169.

233. Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1229 (Fed. Cir. 1994).

234. *Id.*

235. *Id.*

236. Hitzeman v. Rutter*,* 243 F.3d 1345, 1357 (Fed. Cir. 2001).

237. *Burroughs Wellcome*, 40 F.3d at 1229.

238. *Id.*

practice by emphasizing that a person whose contribution is only experimental can be a joint inventor if the person "contribute[s] to the joint arrival at a definite and permanent idea of the invention as it will be used in practice."[239]

This trend of including post-conception contributions as a contribution warranting joint inventorship was expanded to inventions within predictable arts in *Pannu v. Iolab Corp*., in which a dispute over the inventorship of an improved intraocular plastic lens was involved.[240] There, the Federal Circuit adopted a new inventorship standard that includes those who contributed only to reduction to practice of the invention as joint inventorship.[241] The court neither cited any authority nor included any discussions to support this new standard, despite a clear conflict with its precedent rejecting joint inventorship if an alleged joint inventor contributed only to reduce the invention to practice.[242] While *Pannu* is frequently cited to emphasize the low threshold for contributions to qualify for joint inventorship, the Federal Circuit has been reluctant to find joint inventorship based solely on a contribution to reducing an invention to practice, due to the conflict with the precedent in cases after the adoption of the new standard.[243] Nevertheless, the Federal Circuit's recognition in *Pannu* and *Burroughs Wellcome* of a contribution to reduction to practice as sufficient for joint inventorship introduced substantial uncertainty as to whether a person who contributed to post-conception activities is qualified for joint inventorship.

While conception at least determines the finish line of the inventive process, that line has become unclear by Federal Circuit holdings.[244] Additionally, the Federal Circuit does not set any line for the starting point of the inventive process, however collaboration can be used as objective evidence to identify that point. In other words, any pre-conception contributions can qualify for joint inventorship once inventors begin to collaborate. As highlighted in *Dana Faber,* discoveries which should be distinct from the inventive process were found sufficient for joint inventorship as long as those who made the

239. *Id.*

240. Pannu v. Iolab Corp., 155 F.3d 1344, 1345-46 (Fed. Cir. 1998).

241. *Pannu*, 155 F.3d at 1351.

242. *See* 2 CHISUM ON PATENTS, *supra* note 2, at § 2.02[2][d].

243. *See* StoneEagle Services, Inc. v. Gillman, 746 F.3d 1059, 1063 (Fed. Cir. 2014) (CAFC continues to apply the pre-*Pannu* standard that "assistance in reducing an invention to practice generally does not contribute to inventorship.").

244. *See* Fiers v. Revel, 984 F.2d 1164, 1164 (Fed. Cir. 1993), *Burroughs Wellcome*, 40 F.3d at 1223 (Fed. Cir. 1994).

discoveries began to collaborate with inventors who applied the discoveries to a therapeutic use and completed conception of an invention.[245] The court did not require a joint arrival to the conception in addition to the discoveries as required in *Burroughs Wellcome*.[246] In other words, one who made discoveries is rewarded through an inventive contribution by a joint inventor.

c. No Minimum Quantity and Quality of Contribution

In *Burroughs Wellcome,* the Federal Circuit emphasized that there is no minimum quality or quantity required for joint inventorship under the post-1984 Amendment patent statute.[247] In more recent cases, the court held that a joint invention is *simply* the product of a collaboration rather than a product of certain necessary degree of quantity or quality of inventive contribution.[248] Although the threshold is low, one must "(1) contribute in some significant manner to the conception or reduction to practice of the invention; (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention; and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art."[249]

Even though explaining well-known concepts or the state of the art is expressly excluded from sufficient contributions, the Federal Circuit has given very little guidance in drawing a line between "insignifican[t]" and "not insignifican[t]" contributions.[250] Instead, the court has refused to adopt any bright line rule, relying on the fact specific nature of inventorship determination.[251] However, the Federal Circuit has given some guidance on what constitutes an insignificant contribution by giving negative criteria. For example, one such negative criteria holds that a contribution that is "far removed from the

245. *See* Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co., 964 F.3d 1365, 1370, (Fed. Cir. 2020). Even contributions to discoveries of laws of nature qualified for joint inventorship.

246. *Burroughs Wellcome,* 40 F.3d at 1229. For more discussions about the case, see *supra* notes 217-219– and accompanying text.

247. *Burroughs Wellcome*, 40 F.3d at 1227.

248. *E.g.,* Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997); Dana-Farber Cancer Inst., Inc. v. Ono Phram. Co., 964 F.3d 1365, 1371 (Fed. Cir. 2020).

249. Pannu v. Iolab Corp., 155 F.3d 1344, 1351 (Fed. Cir. 1998); In re VerHoef, 888 F.3d 1362, 1366 (Fed. Cir. 2018); *Dana-Farber*, 964 F.3d at 1371.

250. Aaron X. Fellmeth, *Conception and Misconception in Join Inventorship*, 2 N.Y.U. J. INTELL. PROP. & ENT. L. 73, 105 (2012).

251. Vanderbilt Univ. v. ICOS Corp., 601 F.3d 1297, 1308 (Fed. Cir. 2010).

real-world realization" of an invention is insignificant.[252] The language used by the court focuses on the specificity or concreteness of the ideas contributed to the conception rather than the gap for converting contributions to the invention.[253] Accordingly, a contribution suggesting a desired result—without any means to accomplish the result—does not meet the low threshold for joint inventorship.[254] In contrast, the *Dana-Farber* court found that the U.S. researchers' discoveries were significant contributions, even though the discoveries were far removed from real world realization because the researchers did not know how to apply the discoveries to the useful end of cancer treatment.

The court frequently uses terms such as "inventive act" and "inventive contribution," which suggest the standards of patentability, novelty and nonobviousness.[255] However, the court clearly distinguishes between the degree of public availability of the information contributed for inventorship and the degree of public availability of the prior art for novelty by requiring only the former to be part of widely used products or well-known concepts.[256] Even if a prior invention by a putative joint inventor was publicly known at the time the inventor communicated the improvement of the prior invention to a named inventor of the invention, the inventor is a joint inventor because he contributed his idea to improve the prior invention and thus did more than merely provide well-known principles or explain the state of the art.[257]

It is unclear whether Congress intended to require the inventive nature in contribution after the 1984 Amendment because the original version of the Amendments included the term "inventive contribution" but the term was removed during the legislative process because

252. Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1359 (Fed. Cir. 2004).

253. Robert W. Harris, *Conceptual Specificity as a Factor in Determination of Inventorship*, 67 J. PAT. & TRADEMARK OFF. SOC'Y 315 (1985).

254. Garrett Corp. v. United States, 422 F.2d 874, 881 (Ct. Cl. 1970); Nartron Corp. v. Schukra U.S.A., Inc., 558 F.3d 1352, 1359 (Fed. Cir. 2009); Univ. of Cal. v. Synbiotics Corp., 29 U.S.P.Q.2d (BNA) 1463, 1467 (S.D. Calif. 1993).

255. Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997) ("The basic exercise of the normal skill expected of one skilled in the art, without an inventive act, also does not make one a joint inventor.").

256. *Nartron Corp.*, 558 F.3d at 1357 ("[T]he contribution of the extender is insignificant when measured against the full dimension of the invention of claim 11, not just because it was in the prior art, but because it was part of existing automobile seats, and therefore including it as part of the claimed invention was *merely the basic exercise of ordinary skill in the art.*") (emphasis added); *Caterpillar Inc. v. Sturman Indus., Inc.*, 387 F.3d 1358, 1377 (Fed. Cir. 2004) ("[A] person will not be a co-inventor if he or she does no more than explain to the real inventors concepts that are *well known* [in] the current state of the art.") (second alteration in original) (emphasis added).

257. Pannu v. Iolab Corp., 155 F.3d 1344, 1351; *Nartron Corp.*, 558 F.3d at 1357.

Congress was concerned that the term would introduce confusion rather than clarification.[258] However, there is a record in legislative history suggesting that the term was removed to relax the quantity and quality threshold developed by pre-1984 case law [259] Therefore, the Federal Circuit has been using the term "inventive concept" but is reluctant to examine the "significance" of contribution in light of novelty and nonobviousness standards.

In *Dana-Farber*, the court made clear that novelty or nonobviousness of the invention over contributions does not affect joint inventorship.[260] Moreover, the court refused to examine the significance of contribution in light of the novelty of the invention at the date of conception, holding that "collaborative enterprise is not negated by a joint inventor disclosing ideas less than the total invention to others, especially when, as here, the collaborators had worked together for around one year prior to the disclosure, and the disclosure occurred just a few weeks prior to conception."[261] The Federal Circuit also properly rejected the argument that contributions are insignificant when they were publicly available at the conception date. Although the Federal Circuit has not squarely decided the timing, the court suggested that the timing to examine significance of contribution should be at contribution[262] Unfortunately, the court introduced further confusion regarding the timing in discussing the public availability of the alleged contribution at the time of the conception in a recent case.[263] Inventors' post contribution activities should not affect the significance of their contributions. Otherwise, researchers would be reluctant to communicate with each other and this would harm collaborative research. This conflicts with the Congressional intent in passing the 1984 Amendments and other amendments which expand obviousness prior art exceptions.

258. Patent Law Improvements Act: *Hearing on S. 1535 and S. 1841 Before the Subcomm. on Patents, Copyrights and Trademarks of the S. Comm. on the Judiciary,* 98th Cong. 31 (1984) reproduced in Fasse, *Muddy Metaphysics*, *supra* note 2, at 180 n.160.

259. *Id.* The above Senate record includes a statement "even when a question exists as to whether their contribution is an "inventive contribution," which suggests that the inventive contribution was to be relaxed or ignored.

260. Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co., 964 F.3d 1365, 1372.

261. *Id.*

262. *See* Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1359 (Fed. Cir. 2004) (suggesting the timing being at contribution by stating that "[c]ontributions to realizing an invention may not amount to a contribution to conception if they merely explain what was 'then state of the art'"). For a discussion of timing, see Fellmeth, *supra* note 250, at 96 n.98.

263. Bio-Rad Labs. Inc. v. ITC, 996 F.3d 1302, 1320 (Fed Cir. 2021).

Moreover, in focusing on the public availability of a contribution on the conception date and/or the invention date, the argument confuses the first-to-invent novelty with the statutory bar. As discussed above, the public availability at the invention date is irrelevant to the first-to-invent novelty.[264] The public availability is relevant to the statutory bar, but the timing to decide the public availability is one year prior to the filing date. Instead of clarifying the impact of post-contribution disclosure and the confusion over the first-to-invent novelty, the Federal Circuit has highlighted the period of collaborative work to be "more than one year prior to the disclosure" and the timing to be "only a few weeks prior to conception." This mislead inventors that a collaboration less than one year or a disclosure of contribution more than a few weeks prior to conception may affect joint inventorship.

III. AIA: First-Inventor-To-File

A. The AIA First-Inventor-To-File Provision's Unclear Impact on Inventorship Standard

On September 16, 2012, AIA took effect following extensive congressional debates over the proposal to adopt the first-to-file system.[265] One of the most controversial aspects of the AIA was the replacement of the first-to-invent system with the first-inventor-to-file ("FITF") system. The FITF system adopted by the AIA is modeled after the first-to-file systems for determining novelty and priority in place in many other countries by the time the AIA was enacted.[266] Given the widespread use of the first-to-file system, the controversy over FITF's inclusion in the AIA may seem strange. However, some viewed FITF as unconstitutional because the Patent and Copyright Clause guarantees an exclusive right to the first-to-invent inventors.[267]

264. For multiple types of secret prior art, see *supra* notes 138-145 and accompanying text.

265. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011). The debate started as early as 1966. *See generally* George E. Frost, *The 1967 Patent Law Debate – First-to-Invent vs. First-to-File*, DUKE L. J. 923 (1967).

266. Some countries including Japan and Canada followed the first-to-invent system but abolished because of the difficulty to determine the invention date and/or for harmonization with European countries. For Japan, *see* TOSHIKO TAKENAKA ET AL., PATENT ENFORCEMENT IN THE U.S., GERMANY, AND JAPAN, 19 (2015). For Canada, *see* Shih-tse Lo and Dhanoos Sutthiphisal, *Does It Matter Who Has the Right To Patent: First-To-Invent Or First-To-File? Lessons From Canada* (Nat'l Bureau of Econ. Res., Working Paper No. 14926, 2009), https://www.nber.org/papers/w14926 [https://perma.cc/38P9-9699].

267. Alexander J. Kasner, *The Original Meaning of Constitutional Inventors: Resolving the Unanswered Question of the* Madstad *Litigation*, 68 STAN. L. REV. ONLINE 24 (2015), http://www.stanfordlawreview.org/wp-

Others argued that the first-to-file system supported by large firms would harm small firms and individual inventors who lack the resources to consistently file patent applications early.[268]

To address these concerns, Congress adopted a modified version of the first-to-file system, the FITF system. The FITF system that was adopted maintains the focus on the first-to-invent inventor but differs in how to decide who is the first-to-invent. The AIA made the filing date relevant in determining priority over independently invented patentably-indistinct inventions. In patent validity disputes, the AIA removed the uncertainty of determining the invention date, which is much more difficult to determine than the objectively determinative filing date.[269] To address the concern for inventors who cannot afford to file patent applications as soon as inventions are complete, the AIA introduced a system allowing inventors to rely on their own, earlier disclosure date to establish the priority, so long as that disclosure date was within the one year grace period.[270]

The impact of the FITF system on inventorship remains unclear as the Federal Circuit has not examined any inventorship dispute over post-AIA patents. As discussed, the pre-AIA inventorship standard was intertwined with the first-to-invent novelty rule which permitted multiple types of secret prior art. The current inclusive inventorship standard was developed to overcome obstacles provided by such secret prior art. Shifting to the FITF novelty rule, which excludes the pre-AIA § 102(g) secret prior invention, may have a significant impact on inventorship because courts developed the current inclusive standard to provide effective patent protection for obvious inventions resulting from cumulative process in light of the availability of secret prior art. However, the AIA retained pre-AIA § 102(e), allowing a prior invention described in a pending application to be used as prior art.[271] Moreover, it is unclear what role derived inventions play, if any, as prior art under the AIA. On its face, the AIA eliminated § 102(f) derived inventions from prior art because the AIA FITF novelty provision does not provide any prior art equivalent to a derived invention. Instead, the AIA introduced a derivation proceeding which

content/uploads/sites/3/2015/06/68_Stan_L_Rev_Online_24_Kasner.pdf [https://perma.cc/6D8S-X7S8].

268. Kent Hoover, *Senate Passes Patent Reform Despite Small-Business Concerns*, PHOENIX BUS. J., March 18, 2011, https://www.bizjournals.com/phoenix/news/2011/03/18/senate-passes-patent-reform.html [https://perma.cc/2VP8-8J2H].

269. H.R. Rep. No. 112-98 at 40 (2011); Takenaka, *First-To-File*, *supra* note 133, at 307.

270. 35 U.S.C. § 102(b)(1)(B) (2012).

271. 35 U.S.C. § 102(a)(2) (2012).

is used to provide remedies to the true inventor(s) of the derived invention.[272] Because the originality requirement originates from the Constitution and should have survived AIA's overhaul of the U.S. patent system, derived inventions should continue to play a role to ensure granting patents only to true inventors.

Moreover, Congress adopted new, undefined key terms to outline when pre-filing disclosures can be removed as prior art under AIA § 102(b).[273] These new terms, combined with the unclear role played by derived inventions, introduce ambiguity as to whether derivation under the AIA prevents those who received ideas of less than complete conception from claiming joint inventorship. Legislative history strongly supports the removal of derived invention from prior art and the adoption of the first-to-file policy, which would significantly impact interpretation of the FIFT novelty provision.[274] Nevertheless, courts may continue to apply the pre-AIA case law in interpreting the definitions of prior art and its exceptions despite these new terms.[275]

1.Originality Requirement: No Statutory Basis

Whether courts should retain the pre-AIA inclusive inventorship standard may depend on the necessity of removing secret prior art for obviousness rejections. However, it is unclear to what extent the AIA removed that necessity. The AIA FITF novelty rule, § 102, provides two types of prior art. The first type is a hybrid of pre-AIA §§ 102(a) and (b), requiring public availability of the invention in the defined prior art before the filing date of the claimed invention.[276] The second type is equivalent to pre-AIA § 102(e), requiring that the invention is described in a patent application filed before the filing date of the claimed invention.[277] AIA § 102 does not include any terms connected to the old first-to-invent standard (*e.g.*, conception, reduction to practice) and thus eliminates a prior, independent invention by another as a basis of rejection (pre-AIA §102(g)). In contrast, while AIA § 102 does not include any prior art equivalent to pre-AIA § 102(f), it does

272. Donald S. Chisum, 3A CHISUM ON PATENTS, *supra* note 103, at § 10.10[4][c].

273. 35 U.S.C. § 102(b) (2012).

274. *Infra* note 247 and accompanying text.

275. Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 101 (2011) ("[W]here Congress uses a common-law term in a statute, we assume the 'term . . . comes with a common law meaning, absent anything pointing another way.'").

276. 35 U.S.C. § 102(a)(1) (2012).

277. 35 U.S.C. § 102(a)(2) (2012).

include the term "obtained" which is similar to the term "derived" used in the language of pre-AIA § 102(f). This similar language is used in the AIA in outlining the conditions by which an inventor can remove disclosures from the prior art during the grace period.[278] Accordingly, the AIA eliminated from the novelty provision a ground to reject an application or invalidate a patent for failure to meet the originality requirement.[279]

Given the exclusion of this requirement from the novelty provision, the U.S. Constitution requires that the AIA provide a different basis for the originality requirement.[280] Legislative history indicates that pre-AIA § 102(f) was removed from AIA FITF prior art because it was viewed as duplicative of § 101, with both provisions embodying the originality requirement.[281] Therefore, § 101 continues to ensure that the first-to-file person is the true inventor, and provides a grounds for rejection if that is not the case. This view, that § 101 provides a basis for rejection on originality grounds, is supported by commentators.[282] However, the Federal Circuit has not yet had a chance to clarify the grounds for the originality requirement under the AIA.

In refusing to process applications naming a machine as the inventor, the USPTO cited § 101 in support of the interpretation that an inventor does not include a machine under the AIA.[283] However, in the civil action reviewing the USPTO rejection, the U.S. District Court for the Eastern District of Virginia upheld the USPTO rejection

278. 35 U.S.C. § 102(b)(1)(2) (2012).

279. Donald S. Chisum, 3A CHISUM ON PATENTS, *supra* note 103, at § 10.10[4][b].

280. *Id*. Prof. (citing the AIA revision to the definitions of inventors, joint inventors and coinventor as a basis for maintain the original requirement. 35 U.S.C. §§ 100(f) and (g). In addition, the AIA continues to require inventors to execute an oath or declaration to confirm that they believe themselves are the original inventor or joint inventors of a claimed invention. 35 U.S.C. § 100(f)).

281. Robert Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q. J. 1, 97 (2012), https://patentlyo.com/media/docs/2012/10/armitage_pdf.pdf [https://perma.cc/T3LG-F597]; Joseph D. Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. B.J. 435, 451 (2012), https://www.uspto.gov/sites/default/files/aia_implementation/guide-to-aia-p1.pdf [https://perma.cc/FJ77-ZVA3].

282. Joshua D. Sarnoff, *Derivation and Prior Art Problems With the New Patent Act*, 2011 PATENTLY-O L.J. 12 (2011), https://patentlyo.com/media/docs/2012/10/sarnoff.2011.derivation.pdf [https://perma.cc/XK9D-89VQ]. The U.S.PTO also supports the view. Dennis Crouch, *With 102(f) Eliminated, Is Inventorship Now Codified In U.S.C. 101? Maybe But Not Restrictions on Patenting Obvious Variants of Derived Information*, Patently-O (October 4, 2012), https://patentlyo.com/patent/2012/10/with-102f-eliminated-is-inventorship-now-codified-in-35-usc-101.html [https://perma.cc/FS65-H968].

283. Decision on Pet., *In re* Application No. 16/524,350 (USPTO July 29, 2019), https://www.uspto.gov/sites/default/files/documents/16524350_22apr2020.pdf [https://perma.cc/F47C-A4Z4].

without citing § 101.[284] Instead, the court's ruling focused on the definitions of "inventor" and "joint inventor"[285] as well as the procedural requirements for inventors to file or authorize to file a patent application,[286] and the requirements to execute an oath and declaration in connection with the application.[287] The court cited a pre-AIA Federal Circuit case dealing with originality as support for the ruling that an inventor must be a natural person because the mental act of conceiving an invention is necessary to be qualified as an inventor.[288]

If § 101 continues to act as the statutory basis for the constitutional originality requirement, what will be the implications of the AIA's removal of derived inventions from the prior art? One potential implication is that it will limit the scope of derived inventions to prevent others from obtaining a patent where they modified the ideas in prior art to create a complete, new invention. The legislative history of the AIA supports this outcome, given the industry's desire to remove derived inventions as prior art for obviousness rejections.[289] The Federal Circuit has interpreted any confidential communication of a work as derived invention prior art and therefore rejected any invention by inventors to whom the work was communicated if the second invention was obvious over the communicated work.[290] Accordingly, the AIA's removal of derived inventions from the prior art can be understood to result in a new originality requirement, which prevents others from obtaining a patent on grounds of derivation only if a fully conceived idea of the invention had been disclosed to a party who then subsequently sought patents on that same invention.

However, it is unclear whether this new originality requirement protects only those who communicated fully conceived ideas to others. The AIA provides new remedies to those who provide such ideas, including: (1) derivation proceedings, available where applications claiming derived inventions are *pending* at USPTO;[291] and (2) derived patent lawsuit, available where patents are *issued* to derived

284. Thaler v. Hirshfeld, 583 F. Supp. 3d 238 (E.D. Va. 2021).

285. 35 U.S.C. §§ 100(f)-(g) (2012).

286. 35 U.S.C. § 111(a)(1) (2012).

287. 35 U.S.C. § 115(b) (2012).

288. Univ. of Utah v. Max-Planck-Gesellschaft zur Forderung der Wissenschaften E.V., 734 F.3d 1315, 1323 (Fed. Cir. 2013).

289. Armitage, *supra* note 281, at 97.

290. OddzOn Prods. Inc. v. Just Toys, Inc., 122 F.3d 1396 (1997).

291. 35 U.S.C. § 135.

inventions.[292] Legislative history does provide support for pre-AIA originality which used derived invention as prior art: Derivation proceedings can be used to ensure that the originality requirement is upheld for not only those who provided fully conceived ideas, but also for those who provided less than fully conceived ideas in allowing claims for joint inventorship.[293] However, the USPTO continues to apply the pre-AIA case law and requires both an early, complete conception and communication of the conception in order to establish derivation.[294] Therefore, it is unclear whether the AIA completely removed secret derived inventions from the prior art and thus it also remains unclear whether the inclusive inventorship standard remains necessary for protecting inventions resulting from cumulative innovation.

2.FITF Novelty Rule: Unclear Underlying Policy

Another ambiguity in inventorship introduced by the AIA is an unclear policy regarding the FITF novelty rule. The first-to-file system provides a bright line novelty rule: Inventions publicly available before the filing date forfeit their patent rights and thus are in the public domain regardless of who invented the inventions.[295] This bright line rule ensures legal certainty and protects third parties who practice and improve disclosed inventions for further innovation.[296] If the AIA adopted this bright line rule, the FITF novelty provision should be read to eliminate not only pre-AIA § 102(g) prior inventions, but also derived inventions (pre-AIA § 102(f)) and prior inventions disclosed in a pending application (pre-AIA § 102(e)). However, the AIA retained the availability of § 102(e) secret prior art for use in novelty and nonobviousness rejections. As discussed, it is unclear whether the removal of derived inventions resulted in a new originality requirement under which derived invention prior art could only be used for novelty rejections.[297]

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292. 35 U.S.C. § 291; 35 U.S.C. § 135(c) (AIA authorizes the USPTO to deter a derivation proceeding until termination of a post-grant review).

293. Armitage, *supra* note 281, at 98 n.384.

294. 77 Fed. Reg. 56075 (2012), Response to Comment 24.

295. *E.g.,* EPC, art. 54.

296. Emmanuel Roucounas, *The Debate Regarding the Grace Period in International Patent Law: A Reminder,* ALLEA Biennial Yearbook 2006, New Perspectives in Academia 31 (2006), https://allea.org/wp-content/uploads/2016/02/Roucounas_Debate_Grace_Period.pdf [https://perma.cc/GHV9-4LDY]; [https://perma.cc/S425-7KPA]. Report from the Commission to the European Parliament and Council, European Commission, at 16, SEC (2002) (Jan. 14,2002), [https://perma.cc/S425-7KPA].

297. *Supra* notes 292–294 and accompanying text.

However, it is clear that the AIA's legislative history provides support for the proposition that Congress adopted the first-to-file system to define prior art under AIA § 102(a).[298] Congress listed policy justifications supporting the adoption of FITF novelty, including: (1) to bring greater certainty in patent protection by awarding the priority based on filing rather than invention dates, and (2) to harmonize the U.S. patent system with EPC, which serves as a model for many countries which adopt the first-to-file patent system.[299] AIA § 102(a)(1) is analogous to EPC Article 54(2) in that it includes every invention publicly available before the filing date as prior art.[300] Additionally, AIA § 102(a)(2) is analogous to EPC Article 54(3) in that it includes inventions disclosed in the content of patent applications filed before the filing date as prior art.[301] However, the AIA does not limit the content of patent applications which is not publicly available on the filing date of novelty applications. Therefore, just like pre-AIA § 102(e), the content of such applications constitutes secret prior art. This is a stark contrast to the EPC's novelty rule which uses the content of patent applications for novelty only—in context of the priority—instead of as prior art.[302] Therefore, Congress' adoption of the traditional first-to-file novelty rule was incomplete in retaining pre-AIA § 102(e).

Moreover, the Supreme Court ignored legislative history which clearly supports repealing the pre-AIA § 102(b) statutory bar and adopting the overarching public accessibility standard to define prior art.[303] The Court interpreted "on sale" in AIA § 102(a)(1) as a statutory bar which was unique to the policy underlying the first-to-invent system and retained secret prior art.[304] In *Helsinn Healthcare S.A. v. Teva Pharmaceuticals U.S.A, Inc.*, the Court applied pre-AIA § 102(b) case law and found an on sale bar where the patentee had a purchase agreement with a pharmaceutical company, even where the invention

298. Matal, *supra* note 281, at 452("Both § 102(a)'s adoption of the e first-to-file system and its modified definition of "prior art" were discussed extensively in the various committee reports and Senate and House floor debates leading up to enactment of the America Invents Act.").

299. H.R. Rep. No. 112-98, at S 291 (2011); 3A CHISUM ON PATENTS, *supra* note 103, at § 10.10[2][b].

300. 35 U.S.C. § 102(a)(1).

301. 35 U.S.C. § 102(a)(2).

302. For more discussion, *infra* note 308 and accompanying text.

303. Matal, *supra* note 281, at 450. *See also* Armitage, *supra* note 281, at 57 ("Hence, inventors and their legal advisors should have great confidence that § 102(a)(1) under the AIA creates a transparent definition for prior art based upon prior public disclosures made before the effective filing date of a claimed invention, and, absent a disclosure made available to the public, there is no basis for any subject matter qualifying as prior art under § 102(a)(1).").

304. For the statutory bar policy, see *supra* notes 146-149 and accompanying text.

was kept confidential.[305] The Court ignored the language "otherwise available in the public," which was carefully selected by Congress to apply the public access requirement to all means of disclosing inventions listed in the AIA novelty provision.[306] As a result, AIA § 102(a)(1) maintained the first-to-invent policy that the public accessibility of an invention is irrelevant to qualifying as prior art.[307] It is unclear which policies prevail in interpreting other parts of the AIA novelty provision, which introduces uncertainty as to the extent the Court wants to maintain secret prior art in order to promote early publication. If the first-to-file policy prevails, as Congress aimed, secret prior art should be removed completely because it is inconsistent with the first-to-file novelty rule and unnecessary due to the inherent incentive for inventors to file patent applications early.[308]

In contrast, the first-to-invent policy prevails with respect to AIA § 102(b) in providing exceptions to both types of prior art—publicly available disclosures and disclosures in a pending patent application—if such disclosures are made one year less than the filing date.[309] The period during which these exceptions apply is referred to as the "grace period" in which pre-filing disclosures of inventions do not forfeit their right to obtain a patent.[310] AIA § 102(b) was structured to resemble pre-AIA § 102(b) because circumstances for taking advantage of the grace period are unlimited in that they include any disclosures by inventors or a third party and that the removal of such disclosures is automatic.[311] The exceptions apply to both inventor-originated disclosures and independent third party disclosures.[312]

The broad scope of exceptions during the grace period under the AIA is in stark contrast to the scope of exceptions during the grace period under a first-to-file system such as the EPC. Although the AIA was intended to harmonize U.S. patent law with the first-to-file model, there remain many fundamental differences with respect to the scope

305. 139 S. Ct. 628 (2019).

306. Armitage, *supra* note 281, at 54.

307. *See* Takenaka, *Rethinking*, *supra* note 108, at 630.

308. Armitage, *supra* note 281, at 57.

309. 35 U.S.C. § 102(b).

310. Joseph Straus, *Grace Period and the European and International Patent Law: Analysis of Key Legal and Socio-Economic Aspects,* 20 IIC STUDIES: STUDIES IN INDUS. PROP. & COPYRIGHT L. 1, 3 (Gerhard Schricker ed., 2001) (Under the first-to-file system, the grace period is limited to disclosures by inventors and their successors. Prof. Straus defines grace period: "A specific period of time prior to the filing of a patent application by the inventor or his or her successor in title, during which time disclosures of an invention do not forfeit a right to patent the Invention."),

311. 35 U.S.C. § 102(b)(2); Takenaka, *Rethinking*, *supra* note 108, at 631.

312. 35 U.S.C. §§ 102(b)(1)(A)(B); 35 U.S.C. §§ 102(b)(2)(A) & (B).

of grace-period exceptions. First, the EPC's grace-period provision is titled as "non-prejudicial disclosures" to clarify that the exception does not apply to the first-to-file priority rule, and thus does not apply to the disclosure of a pending application which supports a prior right held by the first-to-file applicant.[313] Second, the EPC grace period is six months from the filing date instead of one year.[314] Third, the scope of the EPC grace period is very limited, covering only disclosures by applicants or their legal predecessors where: (1) the disclosure was at an international exhibition officially recognized to fall within the conditions under the Paris Convention;[315] and (2) the disclosure resulted from an evident abuse by applicants and their legal predecessors.[316]

The limited scope originates from the notion of "absolute novelty." In other words, there is historically a strong policy of guaranteeing legal certainty by (a) protecting inventors from inadvertently disclosing their inventions before filing a patent application as doing so would result in forfeiture of their rights for a patent, and (b) protecting third parties from infringement claims when they believed that every disclosure without a corresponding patent application was in the public domain and therefore used the disclosed subject matter for further innovation.[317] Thus, the EPO interprets the evident abuse very narrowly to exclude even errors made by governments.[318]

In most countries, no grace period is applicable to third-party disclosure if the disclosed subject matter was independently invented.[319] For inventions which were rejected due to an independent third-party pre-filing disclosure, the EPC member states provide a prior user right which allows independent inventors and their successors to continue to use their inventions under limited circumstances.[320] Lastly, the removal of pre-filing disclosure is not

313. EPC, art. 55. For more discussions of prior rights, *see infra* note 348 and accompanying text.

314. EPC, art. 55.

315. EPC, art. 55(1)(b); Paris Convention Art. 11.

316. EPC, art. 55(1)(a).

317. For the notion of absolute novelty and its underlying policy, see Straus, *supra* note 310, at 55–64.

318. EPC, art. 55 (1); Unilever v. Bayer AG, T 0585/9, Board of Appeal of the European Patent Office (1995) [https://perma.cc/FF8Y-4MJ4].

319. EUROPE ECONOMICS CHANCERY HOUSE, ECONOMIC ANALYSIS OF THE GRACE PERIOD 8, 86 (2014), https://documents.epo.org/projects/babylon/eponet.nsf/0/c4a001f6453f3d48c1257e0b0034cb2b/$FILE/europe_economics_esab_grace_period_20112014_en.pdf.

320. EPC, art. 55 (limits either applicants or their legal predecessors to make disclosures. EPC member states provide prior user rights to inventors who independently invented an invention that another

automatic and requires a notification of the disclosure with evidence at filing.[321]

In contrast, the scope of grace period exceptions under the AIA covers any disclosure after the inventor's first disclosure, even if that disclosure does not originate from the inventor.[322] Such disclosures include both those that are publicly available before the filing date and disclosures in a patent application pending at the USPTO before the filing date.[323] The broad scope of the grace period is ensured by the text of FITF § 102(b), which provides two types of grace-period exceptions being distinguished by inventorship.[324] The first type of grace-period exception covers inventor-originated disclosures which is equivalent to the common inventorship exception and include inventors' own disclosures and third-party disclosures which obtained the subject matter disclosed directly or indirectly from the inventors. [325] The second type of grace-period exception has no equivalent under the Pre-AIA patent system and covers independent third-party disclosures which were publicly disclosed after the inventors' own disclosure(s) or third-party disclosures originated from the inventors covered by the first type of grace period.[326]

As the EPC only covers disclosures by inventors and applicants to whom the inventors assigned their patent rights, the scope of the first type of AIA grace-period exception, inventor-originated disclosure, is broader than the EPC grace period. The second type of AIA grace-period exception, independent third-party disclosure, is unique to the U.S. system of FITF novelty in that it awards priority on the publication date instead of the invention date (referred to as the first-to-publish rule).[327] During the congressional debate preceding the AIA, first-to-file advocates called the second type the "first-to-publish" grace period and emphasized strong protection for inventors

inventor patented under limited circumstances); U.S.PTO: PRIOR USER RIGHTS DEFENSE (2012) https://www.uspto.gov/sites/default/files/aia_implementation/20120113-pur_report.pdf [https://perma.cc/MMJ2-UH6Z] (U.S.PTO prepared a report on prior user rights in selected European and Asian countries which adopted the first-to-file system).

321. EPC, art. 55 (2).

322. Matal, *supra* note 281, at 475.

323. 35 U.S.C. § 102(a)(A)(B).

324. 35 U.S.C. §§ 102(b)(1) & (2).

325. 35 U.S.C. §§ 102(b)(1)(A) & (b)(2)(A).

326. 35 U.S.C. §§ 102(b)(1)(B) & (b)(2)(B).

327. Matal, *supra* note 281, at 480. *E.g.*, PAUL JANICK, A COMMENTARY ON THE NEW PATENT LAW OF THE UNITED STATES 887, GRUR Int. 2011; Brad Pedersen & Christian Hansen, *Statutory Construction and Policy Arguments for a Symmetric Approach to Promulgating Guidelines for New Section 102(b) Subparagraphs (A) and (B)—the First-to-Publish Grace Period Exceptions to Prior Art*, 4 CYBARIS INTELL. PROP. L. REV., 102, 111–13 (2013).

who failed to be the first-to-file.[328] In adopting the second type of grace period, Congress made the disclosure date relevant to patentability even though the disclosure date must be determined with publicly available evidence. Further, in adopting this grace period, Congress limited the first-to-publish rule to within one year from the filing date, even though the rule is contrary to the AIA's goal of awarding priority based on a filing date which can be objectively decided based on patent office records.

In short, the public policy underlying the FITF standard of the AIA is a blend of the first-to-file policy, advancing the goal of legal certainty, and the first-to-invent policy, advancing the goal of equity between first-to-file and first-to-invent inventors. For example, the definition of prior art in § 102(a) increased the certainty of legal outcomes, although the Supreme Court retained secret prior art which introduces uncertainty in patentability. On the other hand, the grace-period exceptions in § 102(b) protect inventors who are first-to-invent but second-to-file, which introduces legal uncertainty by making inventorship relevant to patentability regarding inventor-originated disclosures and the public available date relevant to patentability regarding third-party independent disclosures. The scope of exceptions and the applicability of pre-AIA § (f) secret prior art depends on how courts interpret the AIA's prevailing policy between the first-to-invent and the first-to-file.

If the first-to-file policy of legal certainty prevails, courts should limit the scope of exceptions and prevent inventors who disclose their inventions without patent applications from claiming an exception. If inventors can claim an exception not only to the subject matter but also a variation of the subject matter, the derivation proceeding may function more like the pre-AIA interference which was expensive and was intended to be eliminated by the adoption of the FITF policy.[329] Unlike the originality requirement, which protects inventors who confidentially communicated ideas to a third party, the AIA grace period protects inventors who publicly communicated to a third party when that third party discloses the invention or files a patent application early. Courts must make a difficult decision to find the fine balance between legal certainty and equity for first-to-publish inventors. The USPTO's first proposal of the grace period examination rules gave more weight to legal certainty and required a

328. Matal, *supra* note 281, at 480.
329. *Id.* at 453.

strict match of identity between the subject matter disclosed by the inventors and the subject matter disclosed by the independent third party.[330] This rule was extensively criticized by commentators, universities, and small businesses, who were major opponents of the first-to-file system.[331]

In response to this criticism, the USPTO relaxed the identity requirement by introducing some flexibility.[332] Under the current rule, the inventor's first disclosure can, at least partially, remove any intervening third-party disclosure even if the subject matter disclosed in the third-party disclosure is a variant of the inventors' disclosed subject matter including an additional element.[333] This flexibility introduces complexity in examining genus and species disclosures: If the subject matter of the inventor-originated disclosures is a species and the subject matter of a third party intervening disclosure is a genus (*i.e.*, a description including a more generic disclosure of the species), the third-party disclosure of the genus is removed from the prior art. In contrast, if the inventor-originated disclosure of a genus, that disclosure does not remove a third-party intervening disclosure of a species and thus remains as prior art.[334] The USPTO's genus and species examples suggest the anticipation (novelty) standard to examine the subject matter disclosed by a third party and the inventor. Further, using the term "obvious" in describing a variant of the disclosed subject matter suggests the obviousness standard. Moreover, the lack of guarantee that courts adopt the USPTO's interpretation of the grace-period provision further introduces considerable uncertainty in patent protection.

330. According to the USPTO's original proposal, a third-party intervening disclosure remains prior art even if the differences between the subject matter in the inventors' own disclosures and independent third-party intervening disclosures are mere insubstantial changes, or only trivial or obvious variations. Examination Guidelines for Implementing the First Inventor To File Provisions of the Leahy-Smith America Invents Act, 77 Fed. Reg. 11,059, 43,767 (Feb. 14, 2013), https://www.federalregister.gov/documents/2013/02/14/2013-03450/examination-guidelines-for-implementing-the-first-inventor-to-file-provisions-of-the-leahy-smith [https://perma.cc/UK8L-2AQW]. This proposed rule effectively limited the grace period claims against independent third party intervening disclosures. Eric P. Racite & Arpta Bhattacharyya, *The Not-So-Amazing Grace Period Under the AIA,* CIPA J. (Sept. 2012), https://www.finnegan.com/en/insights/articles/the-not-so-amazing-grace-period-under-the-aia.html [https://perma.cc/T5L9-9WBY].

331. Jordan S. Joachim, *Is the AIA the End of Grace? Examining the Effect of the America Invents Act on the Patent Grace Period*, 90 N.Y.U. L. REV. 1293 (2015).

332. USPTO, MPEP 2153.02 Prior Art Exception under AIA 35 U.S.C. § 102(b)(2)(b) to AIA 35 U.S.C. § 102(a)(1), https://www.uspto.gov/web/offices/pac/mpep/s2153.html [https://perma.cc/3VP2-EV74].

333. *See id.* If an inventor-originated disclosure discloses elements A, B, and C, and a third-party intervening grace period disclosure discloses elements A, B, C, and D, the exception does not remove the entire subject matter, but the element D remains to be cited as prior art. *Id.*

334. *See id.*

B. Reinventing FITF Inventorship

As the AIA's FITF novelty rule no longer functions to identify first-to-invent inventors, the AIA could have adopted a simple definition of the prior art that would include everything publicly available before the filing date. Instead, the FITF rule maintained the common inventorship exception both when finding a disclosure in a pending application[335] and when determining whether exceptions apply.[336] Thus, inventorship is relevant to patentability and the muddy inventorship standard remains, introducing uncertainty in post-AIA patents. In addition, the difficulty of protecting inventions resulting from the cumulative innovation process remained due to the incomplete elimination of secret prior art. Until the Federal Circuit provides clarification, the originality standard and the scope of derived inventions as prior art will remain uncertain. With the prevalent uncertainty on secret prior art pre-AIA, the AIA expanded the scope of the common ownership exception[337] and the joint research agreement exception.[338]

As a result of these expansions, a legal commentator observed the current FITF provision as a "complex and haphazardly developed statutory framework."[339] However, with the proper implementation of the first-to-file policy, the AIA can be simplified by removing the inventorship distinction and the availability of secret prior art. With complete removal of secret prior art, the multiple and overlapping layers of exceptions to obviousness prior art currently in place would no longer be necessary. Moreover, such removal eliminates the need to keep the current inclusive inventorship standard in order to protect obvious inventions using the common inventorship exception. Therefore, the following section proposes reinventing the inventorship standard to revitalize the collaboration and inventive contribution requirements to protect inventors from the risk of inventorship and ensures the reward of those who made inventive contributions.

1.Simplified Statutory Framework

The USPTO is planning to revise its terminal disclaimer rules to permit a party to a joint research agreement to overcome obvious-type

335. *See* 35 U.S.C. § 102(a)(2).
336. *See* 35 U.S.C. § 102(b)(1)(A); 35 U.S.C. § 102(b)(2)(A).
337. *See* 35 U.S.C. § 102(b)(2)(C).
338. *See* 35 U.S.C. § 102(c).
339. Motomura, *supra* note 150, at 603.

double patenting. The current scheme to obtain patents on obvious inventions is very complex because of the multiple, overlapping exceptions. Even if one of those exceptions prevents an obviousness rejection, the USPTO rejects the claimed invention for obvious-type double patenting if the claimed invention is obvious over the prior invention. To overcome that rejection, the patent owner must file a terminal disclaimer to give up some of the term of the second patent so that the first and second patents expire at the same time. [340] The disclaimer must include a provision promising to enforce the two patents only during the period when they are commonly owned.[341] If the first and second patents issue to different parties, the disclaimer must include a provision waiving the rights to separately enforce these patents.[342] Since the USPTO's current rules only allow parties to a joint research agreement to file a terminal disclaimer and overcome an obvious-type double patenting rejection under limited circumstances, the proposed rules will relax this limitation so more parties can take advantage of terminal disclaimers.[343] In short, under the current complex statutory framework, an inventor needs to find a basis for removing a disclosure in a pending patent application cited for obviousness even if the invention described in the disclosure resulted from the research project in which the inventor participates. If the common ownership and joint research agreement exceptions do not apply, an inventor needs to rely on the common inventorship exception which is controlled by the muddy inventorship standard. In all cases where an exception applies, inventors need to file a terminal disclaimer.

What Congress aimed to accomplish through the current complex scheme can instead be accomplished by simply limiting the availability of a disclosure in a pending application to novelty grounds only. The common inventorship exception is not necessary if such disclosures are excluded from obviousness prior art regardless of disclosure's origin, as is the case under the EPC.[344] A traditional first-to-file patent system excludes such disclosures for obviousness or inventive step prior art because the disclosure of a pending patent application is not publicly available before the filing date and will be

340. *See* 35 U.S.C. § 253. For a discussion of obvious-type double patenting, *see* 3A CHISUM ON PATENTS, *supra* note 103, at § 9.03.

341. *See* 37 C.F.R. 1.321(c)

342. *See* 37 C.F.R. 1.321(d).

343. *See* USPTO, 37 C.F.R. Part 1, Disclaimer Practice in Patents and Patent Application, 85 Fed. Reg. 86518 (Dec. 30, 2020).

344. EPC, art. 54.

available only when the application matures into a patent or is published eighteen months after the filing date.[345] Thus, the AIA should have included the same limitation—allowing use of the disclosure in a pending patent application for novelty purposes only—when Congress adopted the overarching public availability requirement for prior art.[346] The adoption of a requirement removing secret prior art should have resulted in the repeal of the doctrine that the Supreme Court had developed permitting the disclosure as secret prior art as of the filing date for novelty and obviousness.[347]

The public availability requirement adopted by Congress should have converted the subject matter disclosed as filed in a pending patent application from pre-AIA prior art into a prior right, with the first-to-file priority on the filing date as the same disclosure giving the prior right.[348] The effect of prior art is to prevent the subject matter disclosed in a patent application with a later filing date from obtaining a patent under the first-to-file system[349] Because the disclosure only supports the first-to-file priority, it cannot be cited to defeat inventive step.[350] Limiting such disclosures to novelty only is supported by not only legal theory under the first-to-file system, but also by first-to-invent public policy because the limitation protects inventors who independently made obvious inventions but were unable to file early enough to be the first-to-file.[351]

More than two decades prior to the enactment of AIA, Congress addressed the question whether to limit pre-AIA § 102(e) prior art for novelty only.[352] However, the AIA's legislative history does not include any discussion about this limitation during the extensive debates over the adoption of the FITF novelty rule.[353] By failing to introduce the limitation, Congress left at least one type of secret prior

345. *E.g.,* EPC, art. 56.

346. For the overarching public access requirement, *see supra* note 303 and accompanying text.

347. *See* Alexander Milburn Co. v. Davis Bournonville Co*.,* 270 U.S. 390 (1926) (explaining the Supreme Court made the disclosure in a pending application available as prior art on the filing date); Hazeltine Research, Inc. v. Brenner, 382 U.S. 252, 256 (1965) (extending the reasoning of Milburn to make the disclosure available prior art for obviousness).

348. European Patent Guide, 3.3. 003, https://www.epo.org/applying/european/Guide-for-applicants/html/e/ga_c3_3_2.html [https://perma.cc/3K8Q-RFUP].

349. For a discussion of prior rights, *see* Reinhard Wieczoreck, *Convention Applications as Patent-Defeating Prior Rights,* 6 I.I.C. 135 (1975).

350. EPC, art. 56.

351. Thomas, *supra* note 138.

352. *See id.,* at 165. The Advisory Commission on Patent Law Reform recommended to make the disclosure of a pending application to be prior art for novelty only.

353. *See* Armitage, *supra* note 281, at 61 (explaining a drafter of industry representative expected the substantive change from pre-AIA § 102(e) minimum).

art, despite the industry's need to remove all types of secret prior art, resulting in a serious threat to the validity of post-AIA patents.[354] In short, § 102(a)(2) should be revised to limit the secret disclosure in a pending application to prior art for the purpose of novelty rejection only and remove the common inventorship exception. Section 102(b)(2) should be revised to remove the common inventorship exception for inventor-originated inventions in § 102(b)(2)(A) and the common ownership exception in § 102(b)(2)(C). In addition, the joint research agreement exception outlined by § 102(c) should be also removed.

In fact, inventors have already somewhat attained the benefit of the novelty limitation under the current complex statutory framework. If it is likely that a prior invention by another inventor of the same project who works for a different employer will be cited for obviousness and an application for the invention has already filed, the inventor or her employer can either purchase the application or execute a joint research agreement before filing an application for the likely obvious invention. If an application has already been filed for the likely obvious invention, inventors in the same research project can change inventorship of both applications to take advantage of the common inventorship exception.[355] Under the inclusive inventorship standard, inventors who engage in the same research project can readily qualify for joint inventorship. By excluding the pending application disclosure from obviousness prior art, inventors, their employers, and the USPTO can reduce the administrative burden and reduce the legal uncertainty in patentability and validity.

Even with the removal of these multiple exceptions regarding secret disclosures in pending applications, patentability still depends on the muddy inventorship standard because the common inventorship exception requiring the disclosure originating from the inventor allows the removal of publicly available disclosures otherwise permitted by § 102(a)(1) during the grace period.[356] The common inventorship exception is also relevant to the first-to-publish grace period because an inventor-originated disclosure under § 102(b)(1)(A) establishes the first-to-publish priority.[357] Moreover, as discussed above, the

354. Armitage, *supra* note 281, at 4; Matal, *supra* note 281, at 474.

355. Michael K. Henry, *How to Avoid Your Own Patents and Applications as Prior Art Under the America Invents Act (AIA)*, HENRY PATENT L. FIRM (Oct. 19, 2017), https://henry.law/blog/prior-art-under-aia [https://perma.cc/98D9-U2ZS].

356. *See* 35 U.S.C. § 102(b)(1)(A).

357. 35 U.S.C. § 102(b)(1)(B).

uncertainty of the scope of the grace-period exception (*i.e.,* whether the exception applies to obvious variants of the disclosed subject matter) introduces further uncertainty in patentability.[358]

Adoption of the same, novelty-only limitation on the publicly available disclosure exception in § 102(b)(1) can address the academic community's concerns while keeping the first-to-publish priority disputes through the derivation proceedings to a minimum. The limitation should apply to the disclosure regardless of its origin. Under the first-to-file novelty rule, if a third party disclosed an obvious variation of the subject matter of a pre-filing disclosure by a first-to-publish inventor, the first-to-publish inventor's prefiling disclosure is prior art against the second-to-publish third party inventor and the second-to-publish third-party inventor's disclosure is prior art against the first-to-publish inventor. Thus, neither party can obtain a patent regardless of the origin of the invention. Instead, the AIA should award patents to both first-to-publish inventor and second-to-publish third party inventor for obvious inventions in order to promote early disclosures during the grace period while keeping the first-to-file priority rule. While those who disclose their invention early should be awarded patents, so too should inventors who made obvious inventions based on the subject matter in pre-filing disclosures, as this would incentivize first-to-publish inventors early filing in that a pre-filing disclosure results in the risk of patent on obvious inventions by a third party.[359] The novelty-only limitation would also protect a third party who independently invented an obvious invention.[360]

In other words, the availability of the publicly available disclosures in § 102(a)(1) during the grace period should be also limited to novelty prior art only. However, excluding the disclosures in a pending application and publicly available disclosures during the grace period from obviousness prior art will often result in obvious-type double patenting. Thus, patent applicants and owners will need to file a terminal disclaimer to overcome the double patenting rejection or invalidity challenges as is the case for the common inventorship, ownership and joint research agreement exceptions under current practice.[361] Otherwise, both parties should be barred from obtaining a patent or being invalidated if patents have already issued, which gives both parties enough incentives to work on a terminal disclaimer. As a

358. *See supra* notes 329–334 and accompanying text.
359. *See* 35 U.S.C. § 102(b)(1)(A).
360. *See* 35 U.S.C. § 102(b)(1)(B).
361. *See supra* notes 340-343, and accompanying text.

result, the statutory framework will be substantially simplified, and patentability will be free from the legal uncertainty resulting from the muddy inventorship standard.

2.Collaboration Requirement

Once the simplified statutory framework removes the necessity for the current overinclusive inventorship standard, the Federal Circuit should revitalize the collaboration requirement for joint inventorship. *Dana-Farber* and many other recent Federal Circuit cases have made the collaboration requirement ineffective in protecting researchers from the risk of inventorship disputes and have also introduced uncertainty in patent protection by making derivation indistinguishable from joint invention. The court repeatedly emphasizes the requirement of collaboration or concerted effort, but the requirement is met simply if inventors have some communication during or in temporal proximity.[362] Even one meeting in which use of a material is suggested may satisfy the collaboration requirement if that material is adopted by a named inventor and appears in the claimed invention.[363]

The risk of inventorship disputes resulting from the current ineffective collaboration requirement is particularly high in the biopharmaceutical industry because researchers frequently meet at science conferences and exchange ideas and data. However, they do not work jointly to solve a problem because the problem that researchers should address is unknown until they determine the utility of their discoveries.[364] Researchers from different stakeholders work independently and competitively rather than concertedly under a single direction.

Dana-Farber represents these unique features of the innovation process in the biopharmaceutical industry. Drs. Wood, Freeman and Dr. Honjo worked independently, and thus Drs. Wood and Freeman did not know of the final claimed invention conceived by Dr. Honjo. Even without a collective effort or joint arrival at the conception due to lack of communication, the district court found there was collaboration of the three researchers.[365] This ruling is contrary to the

362. *See* Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1359 (Fed. Cir. 2004).

363. *See* Pannu v. Iolab Corp., 155 F.3d 1344, 1346.

364. This problem is highlighted in the real-life example in *Dana-Farber*. *See supra* note 128 and accompanying text.

365. *See Dana-Farber*, 379 F. Supp. 3d at 89.

precedent of *Vanderbilt Univ. v. Icos Corp*. which was cited by the district court to find collaboration despite the joint inventors' failure to recognize the completed conception. In *Vanderbilt*, the Federal Circuit required collective efforts to conception, emphasizing that each co-inventor must engage with the other co-inventors to contribute to a joint conception.[366] Such active intellectual collaboration was lacking among Drs. Honjo, Wood and Freeman. Instead, they arrived at the conception of the inventions separately and independently and thus fought over who was the first to complete the conception of the cancer treatment by blocking the pathway.[367] The inventorship dispute over the 1999 provisional application also supports their relationship as being competitive for patents instead of collaborative,[368] similar to the relationship between the two groups of researchers that the Federal Circuit denied joint inventorship in *American Bio Science.*[369] Unfortunately, *Dana-Farber* inadvertently eliminated the requirement of collective effort to the conception, instead inserting a presumption of collaboration even when every inventor did not have knowledge of the complete conception of the invention.

3.Inventive Contribution

The Federal Circuit should give a definition to "inventive contribution" that would exclude contributions that are unrelated to the inventive aspect or inventive concept of the claimed invention. With the Federal Circuit's repeated emphasis on the modicum threshold that there is no bottom-line quantum or quality requirement for contribution, any contribution is significant and sufficient for joint inventorship except for very clear cases involving no intellectual contributions (*e.g*., simply following named inventors' instructions or merely explaining a well-known concept or the current state of the art).[370] Even a contribution to a small element—which appeared in only two of the fifty-five claims included in the disputed patent—was found to be a sufficient contribution despite that contribution being measured against the dimension of the full invention.[371] As a result, this too-easy-to-pass standard cannot function to exclude contributions without any inventive nature and therefore awards joint

366. *See Vanderbilt Univ.,* 601 F.3d at 1303.

367. *See Dana-Farber*, 379 F. Supp. 3d at 94.

368. *See Dana-Farber*, 379 F. Supp. 3d at 74.

369. *See* Bd. of Educ. ex rel. Bd. of Trustees of Fla. State Univ. v. Am. BioScience Inc., 333 F.3d 1330 (Fed. Cir. 2003).

370. *E.g.*, *Dana-Farber,* 964 F.3d at 1371; *Pannu,* 155 F.3d at 1351.

371. Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456 (Fed. Cir. 1998).

inventorship to those whose collective contributions have no relevance to inventions.

Today's non-inventive contribution standard resulted from the Federal Circuit's adoption of a procedural framework to examine joint inventorship claims: First, this framework requires (1) the interpretation of claims to determine the subject matter covered by the claim and (2) comparison of the subject matter with the alleged contribution.[372] When courts find that the alleged "contribution's role appear in the claimed invention"[373] or found its way into the defined invention in a claim,[374]the inventor contributed to the conception of the claimed invention and thus a joint inventor. After *Dana-Farber*, such contributions do not need to appear explicitly in the claim in order to qualify as a significant contribution.[375] As a result, the current standard cannot function to exclude contributions without any inventive nature.

Just as a sole inventor must make an invention which has an inventive aspect to produce an advanced result over the prior art, joint inventors must collectively contribute to the inventive aspect of the invention. In *Sewall v. Walters*, one of the rare cases where contributions were found insignificant, the Federal Circuit required that the alleged contribution must be made to the *inventive aspect* of the claimed invention, not just any aspect of such invention.[376] The court identified an element in the claimed invention as the inventive aspect because adding the element in the prior art apparatus resulted in surprising and unexpected results at the time of invention.[377] Because the AIA made the filing date relevant to patentability, the inventive aspect must be determined as of the filing date.

The term "inventive aspect or feature" is used more frequently in cases applying the doctrine of patent exhaustion than inventorship. In *Quanta Computer, Inc. v. LG Elecs., Inc.*,the Supreme Court uses the term "inventive aspect" and "essential features" alternatively and ruled that a patent is exhausted if an uncompleted article embodying the inventive aspect of the patent is sold by the patent owner.[378] The

372. Trovan, Ltd. v. Sokymat SA, 299 F.3d 1292, 1302 (Fed. Cir. 2002).

373. *Ethicon, Inc*., 135 F.3d at 1462.

374. *Ethicon, Inc*., 135 F.3d at 1463.

375. *Dana-Farber*, 964 F.3d at 1373.

376. Sewall v. Walters, 21 F.3d 411, 416 (Fed. Cir. 1994).

377. *Id.* at 416–417.

378. Quanta Computer, Inc. v. LG Elecs., Inc., 553 U.S. 617, 632 (2008) (citing United States v. Univis Lens Co., 316 U.S. 241, 250–251 (U.S. 1942)).

Court also distinguished inventive and non-inventive aspects by asking whether the aspect is necessary to practice the patent or the aspect is common step or element.[379] The Federal Circuit further clarified that the inventive aspect should be uncommon and essential to produce the advantage of the invention.[380] The court also uses the term "inventive aspect" to identify novel features distinct from prior art features in examining nonobviousness of improvement inventions.[381] Applying these definitions of "inventive" to "inventive contribution" demonstrates that the non-insignificant requirement should exclude contributions to the common feature which are not essential for practicing the claimed invention's advantage over the prior art.

Moreover, inventive contributions should exclude contributions to discoveries of a law of nature and natural phenomena. Such discoveries have no inventive aspect until the inventive concept converts them into inventions "significantly more" than the ineligible discoveries.[382] Even if a contribution to a discovery is scientifically significant and provides fundamental building blocks for conception of the invention, such contribution is not inventive contribution unless the contribution is made to the inventive concept by applying such discoveries to a useful result. Therefore, contributions to discoveries by Drs. Wood and Freeman should not have been found significant to the conception of the invention. Even a discovery which Dr. Freeman made before he met Dr. Honjo was included as an inventive contribution once Dr. Wood connected the discovery to PD-1 as its ligand. Thus, the Federal Circuit's standard has no limit to the extent that an inventive contribution is found retroactively from the conception of the invention. Instead, the district court should have focused on whether the U.S. researchers collectively and jointly contributed to applying the discoveries to a useful end, which in this case was applying the discovery of the inhibitive function of PD-1/PD-L1 pathway to the treatment.

To exclude contribution without inventive nature, the procedural framework should incorporate an additional step identifying the inventive aspect of the claimed invention. For inventions in the biopharmaceutical industry, this step should exclude pre-invention

379. *Quanta*, 553 U.S. at 633–34.

380. LifeScan Scot., Ltd. v. Shasta Techs., LLC, 734 F.3d 1361 (Fed. Cir. 2013).

381. *E.g.*, Fox Factory, Inc. v. SRAM, LLC, 944 F.3d 1366, 1378 (Fed. Cir. 2019); Ethicon Endo-Surgery, Inc. v. Covidien LP, 812 F.3d 1023, 1035 (Fed. Cir. 2016).

382. *Mayo Collaborative Servs*., 566 U.S. at 72–73.

contributions which do not include inventive concept, namely discoveries of a law of nature and natural phenomena. In short, courts should find joint inventorship only if the alleged contribution appears or plays a role in the inventive aspect of the claimed invention. Even if this requirement is met, the alleged contribution is not inventive and should not be qualified for inventorship if the contribution is a discovery and does not include an inventive concept. Therefore, individuals are joint inventors only if they collectively make an inventive contribution to the conception. It is essential that all individuals must join their efforts to constitute an inventive entity independent from respective individual joint inventors. As a result, each individual does not need to make an inventive contribution for joint inventorship unless the contribution is a mere explanation of well-known principles or the current state of art. However, they must meet the revitalized collaboration requirement through a joint effort to reach the conception.

Finally, it is important that the Federal Circuit clarify that the timing to examine the significance of a respective individual's contribution is at the time of contribution.[383] If the contribution was significant at the time that it was communicated to other joint inventors, post-contribution activities such as disclosure should not affect the significance of contribution. Otherwise, joint inventors would be discouraged from disclosing their discoveries and inventions.

CONCLUSION

Ultimately, it was the notoriously muddy inventorship standard under Federal Circuit case law that led to a bitter fight between the Nobel prize winner and the top scientists at a world-renowned research institute and a leading biotech firm. All researchers who conduct research in the biopharmaceutical industry and practice open science are at risk of similar inventorship disputes if they develop drugs and therapies which will bring a big profit to their employers. Because the U.S. legacy of first-to-invent policies influenced the development of the current inventorship standard, it is likely that the inventorship standards in the rest of the world are different and may provide more efficient protection to researchers. Such a difference in standards presents challenges to international research teams and their employers who obtain and enforce patents globally. With reform

383. *Supra* notes 90 and 263 and accompanying texts.

removing secret prior art completely, the inventorship standard would no longer be muddy and overinclusive. The standard should be reinvented to reward only those who made inventive contributions, which will greatly contribute to the harmonization of patent systems in the rest of the world.