A Broad Win for CRISPR: Federal Circuit Affirms No Interference-in-Fact Between the University of California and the Broad Institute

I. OVERVIEW OF THE CASE

Researchers represented by the Regents of the University of California (UC) and the Broad Institute, Inc. (Broad) developed and sought patent protection for similar gene-editing techniques using nascent clustered regularly interspaced short palindromic repeats (CRISPR) technology.[1] In May 2012, UC filed provisional patent application 13/842,859 ('859), seeking protection for methods of cleaving DNA using CRISPR without reference to a specific cell type or environment.[2] Broad filed a patent application in December 2012 and, unlike UC, confined their use of CRISPR to eukaryotic cells.[3] The United States Patent and Trademark Office (USPTO) approved Broad's application in 2014 and issued patent 8,697,359, while UC's application was still under review.[4] The USPTO subsequently awarded Broad eleven additional CRISPR-related patents.[5]

UC requested an interference proceeding before the USPTO Patent Trial and Appeal Board (PTAB) to establish whether UC and Broad's inventions overlapped, and if so, which party was the first-to-invent the CRISPR gene-editing tool.[6] The proceeding involved an analysis of UC's '859 application and Broad's twelve issued CRISPR patents and one pending application.[7]

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1. Regents of the Univ. of Cal. v. Broad Inst., Inc., 903 F.3d 1286, 1289 (Fed. Cir. 2018).
2. *Id.*
3. *Id.*
4. *Id.* at 1290.
5. *Id.* at 1289.
6. *Id.* at 1290.
7. *Id.* at 1289; U.S. Patent No. 8,697,359 (filed on Oct. 15, 2013); U.S. Patent No. 8,771,945 (filed on Feb. 18, 2014); U.S. Patent No. 8,795,965 (filed on Feb. 18, 2014); U.S. Patent No. 8,865,406 (filed on Mar. 24, 2014); U.S. Patent No. 8,871,445 (filed on Apr. 23, 2014); U.S. Patent No. 8,889,356 (filed on Feb. 18, 2014); U.S. Patent No. 8,895,308 (filed on

In patent interference proceeding no. 106,048, PTAB determined there was no interference-in-fact.[8] UC timely appealed PTAB's ruling, arguing that (1) PTAB improperly adopted a rigid test for obviousness, and (2) PTAB erred in dismissing evidence of simultaneous invention as irrelevant.[9] The Court of Appeals for the Federal Circuit rejected UC's arguments on appeal and *held* there to be no interference-in-fact between UC's claims and Broad's claims because substantial evidence supported PTAB's finding that Broad's claims were not obvious over UC's claims.[10] *Regents of the University of California v. Broad Institute, Inc.,* 903 F.3d 1286 (Fed. Cir. 2018).

II. BACKGROUND

CRISPR is considered this decade's biggest biotech invention and has produced a revolutionary and transformative impact on the life sciences in the seven years since its first demonstration.[11] Laboratories around the world employ CRISPR gene-editing techniques through hosts of innovative and experimental model systems.[12] Over 2000 CRISPR research articles were published in 2018 alone, while four countries approved human embryo experiments involving the technology.[13] Further, CRISPR is approved for use in several human clinical trials to treat cancer.[14]

Gene editing enables scientific researchers to modify an organism's genetic material (genome), or DNA.[15] CRISPR is composed of DNA sequences naturally found in prokaryotic cells, such as bacteria, but it is not found naturally in eukaryotic cells (i.e., cells of humans, plants, and

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Jun. 2, 2014); U.S. Patent No. 8,906,616 (filed on May 29, 2014); U.S. Patent No. 8,932,814 (filed on Apr. 22, 2014); U.S. Patent No. 8,945,839 (filed on Apr. 18, 2014); U.S. Patent No. 8,993,233 (filed on Dec. 12, 2013); U.S. Patent No. 8,999,641 (filed on Mar. 26, 2014) (Broad's CRISPR Patents).

8. *Regents*, 903 F.3d at 1290.

9. *See id.* at 1290-95.

10. *Id.* at 1296.

11. *See* Alexis C. Komor et al., *CRISPR-Based Technologies for the Manipulation of Eukaryotic Genomes*, 168 CELL 20, 20-21 (2017).

12. *See* Patrick D. Hsu et al., *Development and Applications of CRISPR-Cas9 for Genome Engineering*, 157 CELL 1267, 1267 (2014).

13. April Pawluk, *CRISPR: No Signs of Slowing Down*, 174 CELL 1039, 1039 (Aug. 23, 2018); Elizabeth Lopatto, *Gene Editing Will Transform Cancer Treatment*, VERGE (Nov. 22, 2016), http://www.theverge.com/a/verge-2021/jennifer-doudna-crispr-gene-editing-healthcare.

14. Lopatto, *supra* note 13.

15. *See What Are Genome Editing and CRISPR-Cas9?*, U.S. NAT'L LIBR. MED., http://ghr.nlm.nih.gov/primer/genomicresearch/genomeediting (last visited Oct. 8, 2018).

animals).[16] Microbes harness CRISPR and CRISPR associated proteins (CAS) to record and target foreign DNA sequences as part of an adaptive immune system response to protect host cells.[17] Researchers repurpose this natural process into a simple and efficient technique for editing the genomes of living cells.[18] CRISPR may be used for cell and animal models of human diseases, systematic interrogation of gene function, gene therapy, genetic modification of agricultural products, and disease eradication.[19]

The CRISPR system and the potential licensing revenue associated with the technology is estimated to be worth billions of dollars.[20] According to legal scholars, the litigation between UC and Broad "[h]as been one of the single most heated disputes between two educational institutions over inventorship."[21] Each party has spent millions of dollars litigating CRISPR ownership domestically and in Europe.[22] The full scope of CRISPR applications and benefits remain unknown; however, it is clear CRISPR will maintain its status as an indispensable research tool and a highly coveted, lucrative commercial product.[23]

CRISPR first garnered international recognition when UC and Broad researchers published separate reports on CRISPR-mediated genome engineering within months of each other.[24] In UC's report, researchers described how CRISPR could be used as a powerful tool to modify genes and specifically demonstrated its use *in vitro*, in a test tube.[25] In contrast, Broad's publication demonstrated CRISPR's use in mammalian cells.[26] UC and Broad filed individual CRISPR-related

16. Regents of the Univ. of Cal. v. Broad Inst., Inc., 903 F.3d 1286, 1289 (Fed. Cir. 2018).

17. Eric Lander, *The Heroes of CRISPR*, 164 CELL 18, 18 (2016).

18. *Id.*

19. Pawluk, *supra* note 13; *see* Victor Tangermann, *A CRISPR Future: Five Ways Gene Editing Will Transform Our World*, FUTURISM (Jan. 30, 2018), http://futurism.com/crispr-genetic-engineering-change-world.

20. *See* Jacob S. Sherkow, *How Much Is a CRISPR Patent License Worth?*, FORBES (Feb. 21, 2017), http://www.forbes.com/sites/jacobsherkow/2017/02/21/how-much-is-a-crispr-patent-license-worth/#7b495b7b6b77.

21. Heidi Ledford, *Pivotal CRISPR Patent Battle Won By Broad Institute*, NATURE (Sept. 10, 2018), http://www.nature.com/articles/d41586-018-06656-y.

22. *See* Sharon Begley, *CRISPR Patent Fight: The Legal Bills Are Soaring*, STAT NEWS (Aug. 16, 2016), http://www.statnews.com/2016/08/16/crispr-patent-fight-legal-bills-soaring/.

23. *See* Hsu et al., *supra* note 12, at 1262.

24. Catherine Jewell & Vijay Shankar Balakrishnan, *The Battle to Own the CRISPR-Cas9 Gene-Editing Tool*, WIPO MAG. (Apr. 2017), http://www.wipo.int/wipo_magazine/en/2017/02/article_0005.html.

25. *Id.*

26. *Id.*

patent applications in May 2012 and December 2012, respectively.[27] The claims of each party's patent application essentially mirrored the findings of their respective scientific publications.[28]

The USPTO reviewed Broad's application first because Broad paid additional fees for accelerated examination under the USPTO fast-track review process.[29] As a result, the USPTO granted the first CRISPR patent to Broad in April 2014 and subsequently ignited a legal firestorm between Broad and UC.[30] UC immediately pursued litigation and requested a patent interference proceeding against Broad's issued patent.[31] The USPTO granted the interference proceeding request and PTAB hearings began in January 2016.[32]

Patent interference proceedings, colloquially referred to as "priority contests," are *inter partes* adjudicatory contests between two parties who claim to be the first inventor of the same invention.[33] The purpose of an interference proceeding is to establish which party was the first-to-invent and hence is entitled to patent protection on the disputed invention.[34] "Typically a USPTO patent interference proceeding comes into being when different patent applications filed before the USPTO by different inventors may potentially overlap as the same invention."[35] Interferences involve disputes between a pending patent application and another application or a granted patent.[36] PTAB is responsible for granting interference requests and adjudicating all interference proceedings.[37] The procedure is considered a remnant of the United States's first-to-invent patent system.[38] This system was replaced with a first-to-file system through Congress's enactment of the Leahy-Smith America Invents Act

27. *Id.*

28. *See* Ted Mathias et al., *The CRISPR Tug of War*, IP WATCHDOG (Aug. 17, 2018), http://www.ipwatchdog.com/2018/08/17/crispr-tug-of-war/id=100378/.

29. Jewell & Balakrishnan, *supra* note 24; *USPTO's Prioritized Patent Examination Program*, USPTO (Sep. 25, 2017, 12:02 PM), http://www.uspto.gov/patent/initiatives/usptos-prioritized-patent-examination-program.

30. Jewell & Balakrishnan, *supra* note 24.

31. Mathias et al., *supra* note 28.

32. Jewell & Balakrishnan, *supra* note 24.

33. JANICE M. MUELLER, PATENT LAW 293 (5th ed. 2016).

34. *Id.*

35. Jewell & Balakrishnan, *supra* note 24.

36. MANUAL OF PATENT EXAMINING PROCEDURE § 2301 (9th ed. 2018) [hereinafter MPEP].

37. *Id.*

38. MUELLER, *supra* note 33, at 294 n.246.

(AIA), which came into effect on March 16, 2013.[39] Under today's AIA regime, a patent is awarded to the party who filed the patent application first.[40] Because the disputed CRISPR patent applications were filed prior to March 16, 2013, both UC and Broad qualified for a patent interference proceeding under pre-AIA law.[41]

Under pre-AIA 35 U.S.C. § 102(g), the USPTO issues a patent to the first inventor.[42] Pre-AIA 35 U.S.C. § 102(g) states that "[a] person shall be entitled to a patent unless . . . another inventor involved therein establishes . . . that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed."[43] Thus, when two parties claim inventorship over the same invention, an interference proceeding is requested to determine priority of inventorship and to establish which inventive entity is entitled to patent protection.[44]

Patent interference proceedings are governed under pre-AIA 35 U.S.C. § 135.[45] In an interference, "[t]he party who is the last to file her patent application (the "junior party") bears the burden of overcoming a presumption that the first to file (the "senior party") was also the first to invent."[46] Under the pre-AIA system, the senior party is presumptively entitled to the patent, unless the junior party can overcome this *prima facie* presumption.[47]

During the proceeding, PTAB judges compare each party's claims by looking at each party's filing date, relevant prior art, and background information of the inventions.[48] Before PTAB can rule on priority of inventorship, it must first confirm there is overlapping or "interfering" subject matter between both parties.[49] PTAB uses a "two-way" test to determine whether subject matter is interfering.[50] Specifically, PTAB asks whether "the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of

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39. *See* Leahy-Smith America Invents Act, Pub. L. 112-29, § 3(n)(2), 125 Stat. 284, 293 (2011).
40. *Id.*
41. MPEP, *supra* note 36, § 2159.
42. 35 U.S.C. § 102(g) (2012).
43. *Id.*
44. *See* MPEP, *supra* note 36, § 2301.
45. *Id.*
46. MUELLER, *supra* note 33, at 294.
47. *Id.*
48. Noelle v. Lederman, 355 F.3d 1343, 1352 (Fed. Cir. 2004).
49. *See* MPEP, *supra* note 36, § 2301.
50. 37 C.F.R. § 41.203(a) (2012).

the opposing party and vice versa."[51] Thus, an interference-in-fact exists when invention *A* anticipates or makes obvious invention *B*, and invention *B* anticipates or makes obvious invention *A*, thereby satisfying both prongs of the two-way test.[52] If the two-way test is met, an interference-in-fact exists and PTAB must determine which party has priority as the rightful owner of the patent.[53] Conversely, a finding of no interference-in-fact suggests the recited subject matter is separately patentable and priority of inventorship between parties does not need to be resolved.[54]

An interference-in-fact can be based on a finding of anticipation or obviousness; however, "[w]hen an interference-in-fact turns on whether one set of claims renders obvious the subject matter of another set of claims, the standard of review mirrors that in an obviousness review."[55] Obviousness, as applied under the two-way test, is a question of law.[56] In *Graham v. John Deere Co.*, the Supreme Court set forth four factors to determine obviousness: (1) the scope and content of the prior art, (2) the differences between the prior art and the claims, (3) the level of ordinary skill in the art, and (4) objective considerations of nonobviousness.[57] The criteria for assessing obviousness is whether "a skilled artisan would have been motivated to combine the teachings of the prior art" and whether the skilled artisan would have had a reasonable likelihood of success in doing so.[58] The standard of review for whether an artisan would have successfully combined prior art references is a question of fact.[59]

UC argued an interference-in-fact existed and claimed the rights to the subject matter recited in Broad's '839 patent pursuant to UC's earlier-filed provisional application.[60] However, in a one-sentence *per curiam* decision, a PTAB three-judge panel entered a judgment of no interference-in-fact between UC and Broad in patent interference

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51. *Id.*
52. *Id.*
53. *See* MPEP, *supra* note 36, § 2301.
54. MPEP, *supra* note 36, § 2308.
55. Regents of the Univ. of Cal. v. Broad Inst., Inc., 903 F.3d 1286, 1291 (Fed. Cir. 2018).
56. *Id.*
57. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966).
58. *In re* Stepan Co., 868 F.3d 1342, 1345-46 (Fed. Cir. 2017) (quoting Intelligent BioSys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359, 1367-68 (Fed. Cir. 2016)).
59. *Regents*, 903 F.3d at 1291.
60. Mathias et al., *supra* note 28.

proceeding no. 106,048.[61] Both parties claimed the CRISPR technology and its associated methods for application, yet, PTAB found significant differences between each party's claims.[62] PTAB concluded Broad's claims were specifically limited to a method or system in eukaryotic cells whereas UC's claims described the use of CRISPR gene-editing technology more generally.[63] Using the two-way obviousness test, PTAB found that if UC's claims were considered prior art, they would not have rendered Broad's claims obvious because a person of ordinary skill in the art (POSITA) would not have had a reasonable likelihood of success applying CRISPR to eukaryotic cells.[64] As the later filing party, or junior party in the proceeding, Broad had the burden of proving no interference-in-fact.[65] "[T]o prevail on its argument of no interference-in-fact, Broad need only provide persuasive argument supported by a preponderance of the evidence that UC's claims would not render Broad's claims obvious if UC's claims are considered to be prior art to Broad's claims."[66]

First, UC alleged Broad's use of CRISPR in eukaryotic cells was an obvious extrapolation of its 2012 published technology.[67] In response, Broad argued its use of CRISPR to modify complex genomes (e.g., human cells) was a huge inventive leap and not obvious.[68] Moreover, Broad argued a POSITA would not have reasonably expected CRISPR to work successfully in eukaryotic cells.[69] Broad's experts testified that following UC's successful use of CRISPR *in vitro*, ordinary skilled artisans would not reasonably expect the system to work in eukaryotic cells because of the technical hurdles inherent to eukaryotic genetic modification.[70] Broad also cited to statements by UC researchers that expressed doubt over whether CRISPR could work in human cells due to the general difficulties of genetic modification techniques in

61. Broad Inst., Inc., v. Regents of the Univ. of Cal., No. 106,048, Document 864, at 2 (P.T.A.B. Feb. 15, 2017).
62. *Id.* at 2-3.
63. *Id.* at 2.
64. *Id.*
65. *Id.* at 6; *see* 37 C.F.R. § 1.657(b) (2002).
66. *Broad*, No. 106,048, at 12.
67. Regents of the Univ. of Cal. v. Broad Inst., Inc., 903 F.3d 1286, 1290 (Fed. Cir. 2018).
68. *Id.*
69. *Broad*, No. 106,048, at 13.
70. *Id.* at 13-18.

eukaryotes.[71] In response to these claims, UC argued that their expert testimony was discussed out of context.[72] UC pointed to commentary in its 2012 published research article in *Science* in which it predicted CRISPR would be an important tool for treating genetic disorders.[73] However, PTAB was unpersuaded that "positive, forward-looking" statements by UC researchers would have provided others in the art with a reasonable expectation of success applying CRISPR in eukaryotic cells.[74] Ultimately, PTAB relied on the contemporaneous statements by both parties and concluded "[o]ne of ordinary skill in the art would not have reasonably expected success before experiments in eukaryotic cells were done."[75]

Second, UC alleged simultaneous invention demonstrated a reasonable expectation of success.[76] UC argued the six research groups that successfully applied CRISPR in eukaryotes would not have tried doing so unless there was sufficient motivation and expectation of success.[77] However, PTAB was "[n]ot persuaded that such success indicated there was an *expectation* of success before the results of the experiment were known."[78] Moreover, PTAB disagreed with UC's argument that "[a] scientist's 'belief' in the success of his or her own experiments is necessarily a reasonable expectation of success that indicates obviousness."[79]

Third, PTAB looked to the context of the art to determine if there was an expectation of success using CRISPR in eukaryotic cells.[80] PTAB looked at precedential case law and determined "[w]hether or not one of ordinary skill in the art would have had a reasonable expectation of success for purposes of determining obviousness depends on the specific nature of what was known from the prior art about closely related subject matter."[81] For example, "[s]pecific instructions that are

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71. *Id.* at 8. The inventor stated she experienced "many frustrations" getting CRISPR to work in human cells and that if she succeeded, CRISPR would be a "profound discovery." *Id.*

72. *Id.* at 18.

73. *Id.* at 20.

74. *Id.* at 11-12.

75 *Id.* at 17.

76. *Id.*

77. *Id.* at 24.

78. *Id.* at 12.

79. *Id.* at 13.

80. *Id.* at 25; *see* Abbott Labs v. Sandoz Inc., 544 F.3d 1341, 1352 (Fed. Cir. 2008) ("Each case must be decided in its particular context, including the characteristics of the science or technology, its state of advance, the nature of the known choice, the specificity or generality of the prior art, and the predictability of results in the area of interest.").

81. *Broad*, No. 106,048, at 15-16.

relevant to the claimed subject matter or success in similar methods or products have directed findings of a reasonable expectation of success."[82] Broad argued ordinarily skilled artisans knew of differences between prokaryotic and eukaryotic systems that rendered CRISPR application in eukaryotic systems unpredictable.[83] It cited to three systems that work in *in vitro* and prokaryotic systems but have limited efficiency and transferability in eukaryotic systems.[84] UC argued that a reasonable expectation of success using CRISPR in eukaryotes actually existed because each of Broad's cited prokaryotic systems eventually worked in eukaryotes.[85] However, PTAB rejected UC's arguments, finding that because each prokaryotic system required a unique set of conditions to function in eukaryotes, "one skilled in the art would have expected that the CRISPR-Cas9 system would have also required its own set of unique conditions."[86] PTAB found "[t]he preponderance of the evidence cited by Broad persuades us that there would not have been specific instructions relevant to CRISPR-Cas9 to give one of ordinary skill in the art a reasonable expectation of success it would work in eukaryotic cells successfully."[87]

III. COURT'S DECISION

In the noted case, the Court of Appeals for the Federal Circuit affirmed PTAB's decision that no interference-in-fact existed between UC's '859 application and Broad's twelve issued patents and one pending patent application.[88] The court held, "The Board's underlying factual findings are supported by substantial evidence and the Board did not err in concluding that Broad's claims would not have been obvious over UC's claim."[89] The court agreed with PTAB's decision that a POSITA would not have had a reasonable expectation of success in

82. *Id.* at 15.

83. *Id.* at 16 ("[D]ifferences in gene expression, protein folding, cellular compartmentalization, chromatin structure, cellular nucleases, intracellular temperature, intracellular ion concentrations, intracellular pH, and the types of molecules in prokaryotic versus eukaryotic cells, would contribute to this unpredictability.").

84. *Id.* at 19. Researchers have used ribozymes, riboswitches, and group II introns to transfer prokaryotic, RNA-based systems into eukaryotic environments. *Id.*

85. *Id.* at 20.

86. *Id.*

87. *Id.* at 24.

88. Regents of the Univ. of Cal. v. Broad Inst., Inc., 903 F.3d 1286, 1296 (Fed. Cir. 2018).

89. *Id.* at 1289.

applying the CRISPR system to eukaryotic cells.[90] Moreover, the court found UC's remaining arguments unpersuasive.[91]

The court based its decision on the substantial evidence standard.[92] It found that PTAB performed a thorough and exhaustive analysis of all the factual evidence to support its determination that a POSITA would not have had a reasonable likelihood of success in applying CRISPR to eukaryotic cells.[93] PTAB considered expert testimony describing the differences between prokaryotic and eukaryotic systems that would render CRISPR application in eukaryotic cells unpredictable and would have given skilled artisans little reasonable expectation of success.[94] Similarly, PTAB evaluated statements made by UC researchers expressing doubts over CRISPR functionality in eukaryotic cells.[95] In addition, PTAB considered three other prokaryotic gene-editing systems and the inherent difficulties in adapting those systems for use in eukaryotic cells.[96] In sum, the court stated, "In light of the record evidence, which includes expert testimony, contemporaneous statements made by skilled artisans, statements by the UC inventors themselves, and prior art failures, we conclude that [PTAB]'s factfinding as to a lack of reasonable expectation of success is supported by substantial evidence."[97]

The Federal Circuit also rejected UC's argument that PTAB erred in adopting a rigid test that required specific instructions in the prior art to establish a reasonable expectation of success.[98] In its analysis, PTAB stated a reasonable likelihood of success "depends on the specific nature of what was known from the prior art about closely related subject matter."[99] PTAB noted the combination of generalized instructions and evidence of failures with similar subject matter typically indicates the lack of a reasonable expectation of success.[100] The court found PTAB

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90. *Id.* at 1293.

91. *Id.*

92. *Regents*, 903 F.3d at 1291; *see* Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229-30 (1938) ("Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.").

93. *Regents*, 903 F.3d at 1296.

94. *Id.* at 1292-94.

95. *Id.* at 1293.

96. *Id.* at 1292-94.

97. *Id.* at 1294.

98. *Id.* ("[PTAB] adopted a rigid test for obviousness that formalistically looked for specific instructions in the prior art while ignoring 'the inferences and creative steps that a person of ordinary skill in the art would employ' without the need for specific guidance." (quoting UC)).

99. *Id.* at 1295.

100. *Id.* at 1294.

"performed a factual analysis based on the correct legal standard" and found no error in PTAB's statement of the law.[101] The court further asserted, "At no point did [PTAB] suggest it found there would not have been a reasonable expectation of success solely because there were not specific instructions in the art describing how to apply CRISPR-Cas9 in eukaryotes."[102] Accordingly, the court found no error in PTAB's analysis because PTAB established that the art lacked specific instructions for using CRISPR in eukaryotes and in addition, many prior art failures existed trying to adapt prokaryotic systems to eukaryotic environments based on general instructions.[103]

The Federal Circuit further rejected UC's argument that PTAB erred in dismissing evidence of simultaneous invention as irrelevant.[104] UC claimed, "Simultaneous invention is strong objective evidence of what constitutes the level of ordinary skill in the art and is relevant as a secondary consideration under the fourth *Graham* factor."[105] Specifically, UC argued the fact that six independent research groups successfully applied CRISPR to eukaryotic cells within months of its 2012 publication serves as evidence of a reasonable expectation of success.[106] However, PTAB was unpersuaded, finding that the evidence of simultaneous invention did not establish an expectation of success based on the specific context of the art at the time.[107] The court found no error in PTAB's analysis because PTAB did not treat the evidence of simultaneous invention as irrelevant but "recognized the relevance of simultaneous invention to the question of obviousness."[108] The court explained, "We consider Broad's evidence of simultaneous invention, along with evidence regarding the state of the art, the statements of the inventors, failures involving similar technologies, and the remainder of the record evidence, and conclude [PTAB]'s finding is supported by substantial evidence."[109]

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101. *Id.*
102. *Id.* at 1295.
103. *Id.*
104. *Id.* at 1295-96.
105. *Id.* at 1295.
106. *Id.* at 1296.
107. Broad Inst., Inc., v. Regents of the Univ. of Cal., No. 106,048, Document 864, at 23-25 (P.T.A.B. Feb. 15, 2017).
108. *Regents*, 903 F.3d at 1296.
109. *Id.*

IV. ANALYSIS

The Court of Appeals for the Federal Circuit's holding is correct because PTAB, as fact finder, based its decision on substantial evidence.[110] As an appellate body, the court was tasked with determining whether PTAB's findings were supported by substantial evidence.[111] PTAB performed a thorough analysis of the factual evidence that included expert testimony from both parties, past failures in the field, evidence of simultaneous invention, and instructions in the art that would indicate success.[112] Considered as a whole, the court correctly found this evidence substantial enough to support PTAB's conclusion that UC and Broad's claims cover different subject matter and therefore do not interfere with one another.[113]

The court did acknowledge that some evidence could support the position that a POSITA would have had a reasonable expectation of success in applying CRISPR in eukaryotes.[114] However, the court was not tasked with reweighing the evidence.[115] For these reasons, the court solidified PTAB'S decision of no interference-in-fact between UC and Broad.[116]

While the legal field will be relatively unaffected by this decision, science has already been impacted.[117] Many scientific researchers disagree with both the court and PTAB's decisions finding that they fail to comport with how molecular biology is practiced.[118] Moreover, others believe the patent system fails to give sufficient credit to those who make contributions in the scientific field.[119] To further illustrate the dichotomy between scientific research realities and the legal landscape of patent law, the original UC CRISPR researchers have won almost every major award for their discoveries of the CRISPR-Cas9 genome-editing tool.[120]

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110. *Id.* at 1291.
111. *Id.* at 1294.
112. *Id.* at 1296.
113. *Id.*
114. *Id.* at 1294.
115. *Id.*
116. *Id.* at 1291.
117. Jacob Sherkow, *CRISPR Patent Decision Didn't Get the Science Right*, STAT NEWS (Sept. 11, 2018), http://www.statnews.com/2018/09/11/crispr-patent-decision-science/.
118. *See* Jacob Sherkow, *Inventive Steps: The CRISPR Patent Dispute and Scientific Progress*, 18 EMBO REPORTS, 1047, 1047-51 (2017).
119. *Id.* at 1050.
120. Sharon Begley, *Three CRISPR Scientists Win Prestigious Award, Fanning Controvery over Credit*, STAT NEWS (May 31, 2018), https://www.statnews.com/2018/09/11/crispr-patent-decision-science/.

In fact, some consider the UC researchers, Jennifer Doudna and Emmanuelle Charpentier, favorites to win the Nobel Prize in Chemistry.[121] Broad may hold the most patents, but the recognition and credit in the scientific community is mostly going to UC.[122]

Following the court's decision, Broad stated, "It is time for all institutions to move beyond litigation. We should work together to ensure wide, open access to the transformative technology."[123] UC responded to the court's decision by stating that it was "evaluating further litigation options."[124] While UC can appeal the decision to the Supreme Court, it is unclear whether the Court would agree to hear the case because it does not present a novel legal issue.[125] Unless the Court grants judicial review, this Federal Circuit decision marks the end of a fierce legal battle over CRISPR patent ownership in the United States.[126]

Jacqueline T. Moran*

121. Steve Connor, *Scientists' Hopes to Win Nobel Prize for Gene-Editing Technique at Risk Over Patent Dispute,* INDEPENDENT (Oct. 2, 2015), http://www.independent.co.uk/news/science/crispr-scientists-hopes-to-win-nobel-prize-for-gene-editing-technique-at-risk-over-patent-dispute-a6677436.html.

122. *Id.*

123. Alexis Phillippidis, *CAFC Upholds Broad Institute CRISPR Patents*, GEN (Sept. 10, 2018), http://www.genengnews.com/gen-news-highlights/cafc-upholds-broad-institute-crispr-patents/81256219.

124. *Id.*

125. *Id.*

126. *Id.*

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