NO. 2019-2050

United States Court of Appeals for the Federal Circuit

DANA-FARBER CANCER INSTITUTE, INC.,

Plaintiff-Appellee,

v.

ONO PHARMACEUTICAL CO., LTD., TASUKU HONJO, E. R. SQUIBB & SONS, L.L.C., BRISTOL-MYERS SQUIBB COMPANY,

Defendants-Appellants.

On Appeal from the United States District Court for the District of Massachusetts, No. 1:15-cv-13443-PBS, Judge Patti B. Saris

PLAINTIFF-APPELLEE DANA-FARBER CANCER INSTITUTE, INC.'s BRIEF IN RESPONSE TO DEFENDANTS-APPELLANTS' COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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September 14, 2020

CERTIFICATE OF INTEREST

Counsel for Plaintiff-Appellee Dana-Farber Cancer Institute, Inc. hereby certifies the following:

1. The full name of every party represented by me is:

Dana-Farber Cancer Institute, Inc.

2. The name of the real party in interest represented by me is:

Not applicable.

3. All parent corporations and any publicly held companies that own 10% or more of the stock of any party represented by me are:

None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

FOLEY HOAG LLP: Michael B. Hoven, Brendan T. Jones, Daniel L. McFadden, Emma S. Winer

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal:

Dana-Farber Cancer Institute, Inc. v. Bristol-Myers Squibb Co. et al., No. 1:19-cv-11380-PBS (D. Mass.)

Dated: September 14, 2020

/s/ Donald R. Ware

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INTRODUCTION

BMS presents no grounds warranting panel rehearing, let alone en banc review. Determination of inventorship is case-specific and fact-intensive. The district court (Saris, J.) weighed the evidence, assessed witness credibility, and made extensive factual determinations in a 111-page decision. On appeal, the panel carefully reviewed the record and agreed that Drs. Freeman and Wood made significant contributions to each of the six patents' conception. Op. 13-15. BMS's Petition identifies no conflict with this Court's precedents, nor does it raise issues of "exceptional importance" justifying rehearing en banc and further delaying final resolution.

Recognizing the high hurdle to overturn the district court's factual determinations, BMS attempts to recast them as issues of law. Nearly all of BMS's arguments go to the weight of the evidence. To the extent BMS claims that certain inventive contributions must be disqualified as a matter of law, it would have this Court overrule decades of caselaw and adopt an "unnecessarily heightened inventorship standard." Op. 10.

BMS's Petition also should be denied because its arguments, even if successful, would not change the outcome of this appeal. BMS vaguely asserts that "most" or the "majority" of Dr. Freeman and Dr. Wood's contributions were published before conception or were contained in a November 1999 provisional

patent application that ripened into § 102(e) art in 2004. They thus concede that their theories do not apply to all the contributions the district court found to be significant. In 2000, for example, Dr. Freeman shared unpublished data with Dr. Honjo establishing that PD-L1 is highly expressed on many different human tumors. BMS did not challenge the district court's finding that this discovery represented a significant contribution, and the panel agreed it represented a "significant building block" underlying the claimed inventions. Appx40; Op. 15.

Under this Court's precedents, a not insignificant contribution to even one aspect of a claim establishes joint inventorship. *Vapor Point LLC v. Moorhead,* 832 F.3d 1343, 1348-49 (Fed. Cir. 2016). Through his collaboration with Dr. Freeman and Dr. Wood, Dr. Honjo obtained confidential access to their unpublished discoveries a year before BMS's asserted conception date. These discoveries contributed significantly—indeed, the district court found them essential—to conception of the claims. Even if BMS could persuade the en banc Court to accept its arguments, the result would be the same: each of the six patents-in-suit ("Patents") would be corrected to add Drs. Freeman and Wood as inventors.

BACKGROUND

BMS's Petition is built on a factual premise the district court rejected: that the discoveries Drs. Freeman and Wood shared with Dr. Honjo were "too far removed from conception to have yielded significant contributions" because the

two scientists did not participate in Dr. Iwai's October 2000 mouse studies. Pet. 13, 16; Op. 9, 11-12. Treating Dr. Iwai's experiments as the only ones that mattered, the Petition dismisses Dr. Freeman and Dr. Wood's research as "separate work," part of a "previous" collaboration with Dr. Honjo. *Id.* 3, 16.

But whether their contributions were separate and "too far removed from conception" is a question of fact, and the district court's findings emphatically rejected BMS's contention. It found that the three collaborators worked together over a lengthy period "to develop therapeutic applications for treatment of cancer," and that the three of them "collectively conceived of harnessing the [PD-1/PD-L1] pathway as a method of treating cancer." Appx70-75, 90. As the panel explained in affirming these findings, the fact that "Drs. Freeman and Wood were not present for or participants in all the experiments that led to the conception of the claimed invention does not negate their overall contributions throughout their collaboration with Dr. Honjo." Op. 11.

At trial BMS sought to buttress its "too-far-removed" contention with testimony of Dr. Honjo in which he denied collaborating with Dr. Freeman on cancer immunotherapy. Appx1630. But this testimony was flatly contradicted by his Nobel lecture, given shortly before trial, in which he identified Dr. Freeman as a "major outside collaborator" on "cancer immunotherapy by PD-1 blockade." Appx50, 72; Op. 7. The district court was free to discredit Dr. Honjo's self-serving

denial at trial, and there was ample evidence to conclude that "the collaborative research efforts" of all three scientists led to the claimed inventions. Op. 12.

BMS asserts that research Dr. Freeman and Dr. Wood shared with Dr. Honjo in 1999 should be disregarded on the ground that the Patents "issued over" their November 1999 provisional patent application (U.S. Patent Application No. 60/164,897, Appx3487-3640). As an initial matter, the '897 application was not even before the examiner; it is not identified in any of the Patents. BMS presumably means a different reference, U.S. Patent No. 6,808,710 (Appx3042-3132), which claims priority to the provisional. The '710 patent did not issue until 2004, when it became § 102(e) prior art. Although it is listed on the face of the Patents, it was cited by the examiner[1] in the prosecution of only the '048. Appx114.[2] BMS did not offer the Patents' prosecution histories into evidence at trial, so the record contains no evidence as to the grounds for any rejection or the reasons for allowance of any of the claims.

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[1] MPEP § 1302.12 provides that references cited by the examiner are indicated with an asterisk.

[2] The '048 claims are directed to cancers in which "PD-L1 or PD-L2 is over-expressed." The existence of such cancers was discovered by Dr. Freeman in 2000, too late to include in the November 1999 provisional. Issuance of the '048 patent over the provisional thus could have no bearing on the district court's finding that Dr. Freeman made significant contributions to conception of the '048 claims. Appx99-100.

BMS's Petition mostly ignores the district court's findings that many of Drs. Freeman and Wood's significant contributions were made ***after*** their filing of the provisional. *See* Op. 12 (noting that provisional's disclosures may not be co-extensive with their contributions). Although the provisional briefly mentions the idea of using antibodies to block the PD-1/PD-L1 interaction, it provides no supporting data; their proof that antibodies could block the interaction came later. The provisional does not disclose the existence of a second PD-1 ligand, PD-L2, which they had not yet discovered. And it contains no disclosure that PD-L1 (then called "B7-4") is expressed on any tumor cell. Appx3487-3640.

The co-authored journal article referred to in BMS's Petition ("Freeman 2000) was published October 2, 2000. Appx5796. As the panel noted, the publication occurred "just a few weeks prior to conception," after the collaborators had been working together and sharing their research for a year. Op. 13. As with the provisional, Freeman 2000 disclosed "less than the total invention." *Id.* It made no mention of PD-L2, did not report that antibodies can block the PD-1/PD-L1 interaction, and did not disclose that a wide variety of human tumors highly express PD-L1, all of which the district court found to be significant individual and joint contributions of Drs. Freeman and Wood. Appx78-89.

The panel highlighted the significance of Dr. Freeman's contribution to conception through his "important immunohistochemistry experiments revealing

that several types of tumors express PD-L1." Op. 15. This was supported by detailed (and unchallenged) findings below that conception was "inextricably linked to the expression of PD-L1 on human tumors" and that "Dr. Iwai's tumor model experiments only triggered conception because Dr. Honjo knew from Dr. Freeman's work that, like the transfected tumors in Dr. Iwai's experiments, human tumors express PD-L1. Appx94-95; *see* Appx2017-19, 2167-78. In affirming these findings, the panel agreed that "Dr. Freeman's discovery of PD-L1 expression by human tumors" was a "significant building block" underlying conception. Op. 15.

In July and August 2000, Dr. Iwai conducted a mouse model experiment. It tested, *in vivo*, Dr. Freeman's earlier hypothesis that tumors use the PD-1/PD-L1 pathway to escape the antitumor immune response. Appx6226-6230. Consistent with the collaborators' earlier *in vitro* data, the experiment showed that PD-L1-expressing tumors grew larger than non-PD-L1-expressing tumors. Appx40, 6226-6230.

BMS's attempt to suggest that Dr. Iwai conducted her mouse experiments without the benefit of Dr. Freeman and Dr. Wood's contributions (Pet. 7) relies on a false chronology. In fact, by the time Dr. Iwai conducted her experiments in late summer 2000, she had the benefit of critical information provided by Drs. Freeman and Wood suggesting the potential cancer treatment. At a collaboration meeting on March 27, Dr. Wood had proposed to Dr. Honjo the therapeutic use of PD-1

and PD-L1 antibodies to treat cancer. Appx37. In early April, Dr. Freeman had shared with Dr. Honjo his hypothesis that tumors use PD-L1 to inhibit an antitumor immune response. Appx33. And in May, at another collaboration meeting, Dr. Freeman had disclosed to Dr. Honjo the top line results of his PD-L1 tumor expression studies. Appx39.[3]

Dr. Honjo himself did not treat Dr. Iwai's mouse experiments as "separate from" the ongoing collaboration. At a key collaboration meeting on September 8, 2000, the three scientists continued to share and discuss their latest data. Dr. Honjo reported on Dr. Iwai's mouse study, and Dr. Freeman shared his slides showing that many different human tumors highly express PD-L1. Appx42. Dr. Wood and colleagues at Genetics Institute ("GI") shared new T cell inhibition data and described their development of blocking antibodies. Dr. Wood also reported the results of an *in vivo* mouse study at GI showing that blocking the PD-L1/PD-1 interaction causes the proliferation of T cells. Appx41-42. GI's mouse data

[3] The district court's statement that Dr. Iwai "began" her experiments by March 16, 2000, Appx38, refers to when she constructed an expression vector to insert PD-L1 into host cells for use in various future studies, many of them unrelated to cancer. Appx6178. She first outlined a plan to study antitumor immunity on March 31. Appx38, 4445. Her laboratory notebook confirms that she did not begin the tumor immunity experiments until July. Appx6226.

provided evidence that administering PD-1 or PD-L1 blocking antibodies would enhance the immune response and could treat cancer.

The district court properly rejected BMS's attempt to divorce the important discoveries shared on September 8 from BMS's asserted conception date in October. Appx88; Appx102-103. The collaborative research discussed that day established both that PD-L1 is highly expressed in human tumors, and that the PD-1/PD-L1 interaction in mice enhances tumor growth. Appx1164. It was a short leap, if any, from there to conception.

ARGUMENT

I. REHEARING EN BANC IS UNWARRANTED.

A. The Panel Correctly Rejected BMS's Argument that Certain of Dr. Freeman and Dr. Wood's Contributions Were Insignificant Because the Patents Issued Over their Disclosure in a Provisional Patent Application.

On appeal, BMS argued that contributions appearing in Dr. Freeman and Dr. Wood's November 1999 provisional "should not have qualified as significant." BMS Reply 9. BMS thus challenged the district court's significance findings ***as a matter of law***, urging a categorical rule that if a patent "issues over" a reference disclosing an alleged contribution, the contribution is disqualified. *Id.*

BMS's Petition tries a new theory. Contradicting its argument to the panel, it now tells the Court it does ***not*** seek a bright-line rule. Pet. 11. BMS cannot use a

petition for rehearing to make new arguments. *Rumsfeld v. Freedom NY, Inc.*, 346 F.3d 1359, 1361 (Fed. Cir. 2003) (finding waiver).

BMS asserts that the panel's decision would preclude a court's consideration of the Patent Office's allowance of claims over prior art when evaluating the significance of an inventor's contributions to conception. Not so. The panel was responding to and rejecting BMS's argument that where a prior art reference discloses an alleged contribution, that contribution can never be significant. Op. 12. Application of BMS's categorical rule made no sense here, where the discoveries were shared with Dr. Honjo in October 1999, before the provisional was filed, and its disclosures only became available as prior art five years later due to the application of § 102(e). In these circumstances, the asserted "novelty and non-obviousness of the claimed inventions over the provisional application" was not probative of whose efforts "led to the inventions claimed here or whether each researcher's contributions were significant to their conception. *Id.*

BMS's argument also fails because it conflates the test for inventorship with the test for patentability. The two concepts involve different legal standards and are assessed at different points in time. The significance of a contribution to conception is measured at the time of the contribution. A court asks whether, when the putative inventor contributed her ideas, she did more than merely explain "***well-known*** concepts and/or the ***current*** state of the art," *Pannu v. Iolab Corp.*,

155 F.3d 1344, 1351 (Fed. Cir. 1998); Op. 12. These terms have temporal import; they do not refer to the state of the art as of a patent's priority date, which is relevant only to patentability. And patentability is entirely different from inventorship. As the panel explained, "inventorship of a complex invention may depend on partial contributions to conception over time." Op. 23. Those contributions may be significant steps in the path to conception, yet not suffice to defeat patentability if they appear in later prior art.

The cases cited by BMS do not hold otherwise. In each, the court found that at the time of the communication, the putative inventor had merely explained well-known concepts or the current state of the art. *See O'Reilly v. Morse*, 56 U.S. 62, 111 (1854) (information Morse obtained from "men skilled in the science" was no different from the information available to Morse in books); *Garrett Corp. v. United States*, 422 F.2d 874, 879-81 (Ct. Cl. 1970) (idea of a water ballast pocket feature was disclosed in nine-year-old prior art); *Levin v. Septodont, Inc.*, 34 F. App'x 65, 73-74 (4th Cir. 2002) (unpublished) (mouthwash ingredients suggested by putative inventor were well-known in the literature; he "did no more than explain the existing state of the art"); *Bd. of Educ. ex rel. Bd. of Trs. of Fla. State Univ. v. Am. Bioscience, Inc.*, 333 F.3d 1330, 1340-42 (Fed. Cir. 2003) (putative inventors did not conceive the claimed compounds, nor did they contribute to their

conception by prior disclosures of the properties of similar compounds and other "well-known principles").[4]

BMS's reliance on *American Bioscience* is also misplaced because unlike this case, the record contained extensive evidence of the patent's prosecution history, including testimony of the prosecuting attorney. That evidence showed that American Bioscience's original claims encompassed chemical compounds made at FSU, but those claims were withdrawn following their rejection over FSU prior art. 333 F.3d at 1335. The issued patent claimed only three specific compounds, conceived entirely at American Bioscience. This history thus provided added support for the court's determination, on all the evidence, that the patented compounds were "not the invention of the FSU scientists." *Id.* at 1340.

In this case, as noted above, BMS did not offer any prosecution histories into evidence. Its argument that the Patents "issued over" disclosures in the provisional is based on nothing more than the fact that the '710 patent was listed on the face of the Patents. As a result, the record is devoid of evidence that the patentability of the claims is probative of the significance of contributions disclosed in the

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[4] In *Vanderbilt Univ. v. ICOS Corp.*, 601 F.3d 1297, 1307 (Fed. Cir. 2010), the Court further illuminated its reasoning in *American Bioscience*, explaining that after the patent owner's claims were narrowed in prosecution, the dispute became a priority contest—the scientists were "competing for the patent rights in the compounds at issue" rather than collaborating in their conception.

provisional. The panel's opinion does not conflict with the decision in *American Bioscience* or any other case, and en banc rehearing is not warranted.

B. The Panel Correctly Rejected BMS's Proposed Rule that Research Made Public Before Conception Cannot Qualify as a Significant Contribution.

BMS also urges the en banc court to create a categorical rule that "research made public before the date of conception of a total invention cannot qualify as a significant contribution to the conception of the total invention." Op. 12. As the panel observed, such a rule would ignore the realities of research collaborations, which generally span a period of time and involve multiple contributions. *Id.* It would also defeat Congress' intent. Congress amended Section 116 of the patent statute in 1984 specifically to encourage team research, inserting the provision that joint inventors need not work physically together or "at the same time." *See* Dana-Farber Br. 56.

In this case, the three scientists shared their "confidential, unpublished experimental results," Appx84, long before publication of Freeman 2000. BMS argues that as of October 2, 2000 the information in Freeman 2000 was "free for all to use." Pet. 15. But by then Dr. Honjo, unlike other members of the public, had had confidential access to that same information for a year, making possible his laboratory's extensive testing of the PD-1/PD-L1 interaction throughout 2000 and enabling conception of the total invention within three weeks after publication.

As the panel correctly held, "there is no principled reason to discount genuine contributions by collaborators" just because they publish portions of their work prior to conception. Op. 13. In petitioning for en banc review, BMS fails to address the Court's leading precedent on this subject, *Pannu v. Iolab* (cited at Op. 10-11). There, Iolab argued that Dr. Pannu could not be a joint inventor "because [he] placed his contribution in the prior art more than one year before" he shared his ideas for a prototype embodiment of the invention. 155 F.3d at 1351. Despite this, the Court held that Dr. Pannu was an inventor because he did more than merely provide well-known principles: he contributed his ideas to a "total inventive concept" in a "collaborative enterprise." *Id.* To adopt BMS's proposed rule, the Court would have to overrule *Pannu.* If publication of an idea more than a year before the parties collaborate does not preclude inventorship, then without overruling *Pannu*, there can be no bright-line rule precluding inventorship where the idea is not published until a year ***after*** the parties begin collaborating.

Instead of confronting *Pannu*, BMS's requests rehearing en banc on the ground that the panel "disregarded" an unpublished decision, *Maatuk v. Emerson Elec., Inc.*, 781 F. App'x 1002 (Fed. Cir. 2019) (nonprecedential). The pro se plaintiff there did not bring *Pannu* to the Court's attention, and the per curiam panel did not overrule it. In any event, *Maatuk* is readily distinguishable. The district court there determined that Maatuk never collaborated with the inventors

on what it found to be the patented invention. *Maatuk v. Emerson Elec., Inc.*, 2019 U.S. Dist. LEXIS 17403 at *26 (N.D. Ohio Feb. 4, 2019). It further found that the inventors conceived the invention ***four years after*** their last communication with Maatuk, and that the only information Maatuk provided them was known in prior art. *Id.* *26-30. This Court affirmed, holding that that Maatuk failed to make a showing of "how [his] ideas were significant" to conception. 781 F. App'x at 1006.

More to the point is *CardiAQ Valve Techs., Inc. v. Neovasc Inc.*, 708 F. App'x 654, 660 (Fed. Cir. 2017) (nonprecedential), quoted by the district court but ignored by BMS. Appx84-85. This Court there stated it has never "barred co-inventorship, as a matter of law, just because the contribution later appeared in the public domain, where the ideas contributed were not contemporaneously available to an ordinary skilled artisan and were otherwise significant in producing the inventive conception at the time it was completed." The Court added, "[w]e have been presented no sound reason for adopting such a legal bar now." *Id.* at 660.

It should not. Adopting BMS's bright-line rule would eviscerate incentives for collaborative scientific research, discourage publication of joint work, and upend Congress' intent. Appx81. A collaborator's public disclosure of another's contribution prior to conception of the complete invention—even inadvertently—would eliminate her claim to inventorship. The leak of a collaborator's

groundbreaking discovery to a science reporter could end up barring co-inventorship by the one who contributed the most. It would be hard to imagine an outcome more fundamentally unfair, more likely to discourage collaborative research, and more destructive of scientific progress.

II. PANEL REHEARING IS UNWARRANTED.

BMS's claim that the panel refused to accept its conception date, Pet. 17, is baffling. The panel recited the October 2000 date in recounting the invention story, later referenced the mouse experiments that "led to the conception," and observed that Freeman 2000 published "just a few weeks prior to conception." Op. 7, 11, 13.

In truth, BMS is not asserting that the panel adopted a different conception date. Instead, it uses this argument to reinforce its contention that Dr. Freeman and Dr. Wood's contributions were "too far removed" from conception to have been significant. Pet. 16. In BMS's telling, Dr. Iwai's experiments "played the key role" in achieving conception, representing a "giant leap" over prior work on the PD-1/PD-L1 pathway, as compared to the "relative insignificance" of Dr. Freeman and Dr. Wood's research. *Id.* at 16-7. But these are factual contentions, and the district court had ample evidence to reject them. Moreover, as the panel noted, "joint inventors need not contribute to all aspects of a conception." Op. 11.

BMS seizes on the panel's observation that *in vivo* verification is not required to establish conception. Pet. 16; Op. 11-12. But the panel was not rejecting BMS's conception date, it was responding to BMS's assertion that Dr. Freeman and Dr. Wood's "previous work was at most speculative because it was not *in vivo*." Op. 9-10. The panel rightly corrected BMS's misstatement of the law. While *in vivo* data can be valuable, they are not essential to inventorship and do not make all other contributions insignificant.

Next, BMS argues that the panel erred in referring to Dr. Freeman as having "connected the 292 sequence to PD-1" when it briefly summarized some of his contributions. Pet. 17; Op. 15. Its shorthand phrase is scarcely grounds for rehearing. In its more detailed Background section, the panel explained how Dr. Freeman identified the "292" molecule through a targeted BLAST search for B7 homologs and then collaborated with Dr. Wood to investigate 292's binding partner. Op. 4-5. As the district court found, both scientists contributed to the discovery of PD-L1 as PD-1's ligand. Dr. Freeman identified 292, generated its full length sequence, investigated its immunologic properties, shared genetic materials with GI, told GI that 292 was a B7 protein, and discussed with GI the likelihood that its receptor would be similar to CD28 and CTLA-4. Appx21-23. Dr. Freeman's research played a key role in connecting the 292 sequence to PD-1.

BMS closes by arguing that that panel erred because Dr. Freeman's independent discovery of the 292 sequence was not "original." Pet. 17. This attempt to denigrate his contributions was thoroughly debunked at trial, and the court rejected it. Dana-Farber Br. 13-14, 61-62; Appx 30, 79. The panel found BMS's "remaining arguments" unpersuasive, Op. 16, and this is one of them.

CONCLUSION

Just twelve months after Drs. Freeman and Wood began sharing their discoveries with Dr. Honjo, the three had collectively conceived a new treatment for cancer that has dramatically improved the lives of cancer patients everywhere. Dr. Freeman and Dr. Wood's contributions should be celebrated, not belittled. This Court should deny BMS's Petition and allow Dana-Farber to carry out its mission to ensure broad patient access to PD-1/PD-L1 cancer immunotherapies.

Dated: September 14, 2020

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CERTIFICATE OF SERVICE

I hereby certify that on September 14, 2020, the foregoing Brief in Response to Defendants-Appellants' Combined Petition for Panel Rehearing and Rehearing En Banc was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), I hereby certify that this brief complies with the page limitations of Fed. Cir. R. 32(a). This brief contains 3,876 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b), as counted by Microsoft® Word 2016, the word processing software used to prepare this brief.

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6). This brief has been prepared in a proportionally spaced typeface using Microsoft® Word 2016, Times New Roman, 14 point font.

Dated: September 14, 2020

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