

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARIOSIA DIAGNOSTICS, INC.,
Petitioner,

v.

ILLUMINA, INC.,
Patent Owner.

Case IPR2014-01093
Patent 7,955,794 B2

Before LORA M. GREEN, ZHENYU YANG, and TINA E. HULSE,
Administrative Patent Judges.

GREEN, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. *Background*

Petitioner, Ariosa Diagnostics, Inc. (“Ariosa” or “Petitioner”), filed a Petition requesting *inter partes* review of claims 1–22 (“the challenged claims”) of U.S. Patent No. 7,955,794 B2 (“the ’794 patent”). Paper 1 (“Pet.”). Patent Owner, Illumina, Inc. (“Illumina” or “Patent Owner”), filed a Patent Owner Preliminary Response. Paper 12 (“Prelim. Resp.”). We determined that the information presented in the Petition and the Preliminary Response demonstrated that there was a reasonable likelihood that Petitioner would prevail in challenging claims 1–22 as unpatentable under 35 U.S.C. § 102. Pursuant to 35 U.S.C. § 314, the Board instituted trial on January 8, 2015, as to the challenged claims of the ’794 patent. Paper 14 (“Institution Decision” or “Dec. Inst.”).

Patent Owner filed a Response (Paper 31, “PO Resp.”), but did not file a motion to amend. Petitioner subsequently filed a Reply. Paper 44 (“Reply”). An oral hearing was held on August 24, 2015. The transcript of the hearing has been entered into the record. Paper 65. Patent Owner filed a Motion for Observation on certain cross-examination testimony of Petitioner’s declarant, Dr. Charles Cantor. Paper 51. Petitioner filed a Response to Patent Owner’s Motions for Observation. Paper 59. Patent Owner also filed a Motion to Exclude (Paper 52), to which Patent Owner filed an Opposition (Paper 61), and Patent Owner filed a Reply (Paper 62).

We have jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Based on the record before us, we conclude that Petitioner has not

demonstrated by a preponderance of the evidence that claims 1–22 of the '794 patent are unpatentable.

B. Related Proceedings

The parties state that the '794 patent is the subject of the copending district court case, *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, Case No. 3:14-cv-01921 (N. D. Cal.). Pet. 2; Paper 7.

In addition, this IPR is related to IPR2015-01091, in which we declined to institute trial. IPR2015-01091, Paper 18.

C. The '794 Patent (Ex. 1001)

The '794 patent issued on June 7, 2011, with Min-Jui Richard Shen, Arnold Oliphant, Scott L. Butler, John E. Stuelpnagel, Mark S. Chee, Kenneth M. Kuhn, and Jian-Bing Fan as listed co-inventors. Ex. 1001. The '794 patent was filed on June 20, 2002, and claims priority as set forth below:

The present application claims the benefit of U.S. Application Ser. Nos. 60/234,143, filed on Sep. 21, 2000, 60/234,732, filed on Sep. 22, 2000, 60/297,609, filed on Jun. 11, 2001, 60/311,271, filed on Aug. 9, 2001, 60/336,958, filed on Dec. 3, 2001, 60/305,118, filed on Jul. 12, 2001, and 60/341,827, filed on Dec. 17, 2001 and claims priority to Ser. No. 09/779,376, now abandoned, filed on Feb. 7, 2001, Ser. No. 09/915,231, now U.S. Pat. No. 6,890,741, filed on Jul. 24, 2001 and Ser. No. 09/931,285, now U.S. Pat. No. 6,931,884, filed on Aug. 16, 2001, all of which are expressly incorporated herein by reference.

Id. at 1:3–14; *see also* Certificate of Correction (correcting statement of priority). Thus, the earliest possible effective filing date of the '794 patent is September 2000.

The '794 patent provides “a number of methods directed to the multiplexing amplification and/or genotyping reactions of target sequences

to create amplicons that can subsequently be detected on an array.” *Id.* at 1:54–57. Specifically, the ’794 patent discloses “a variety of compositions and methods directed to multiplexed analysis of nucleic acids.” *Id.* at 5:32–34. The ’794 patent states “[a]s used herein, the phrase ‘multiplex’ or grammatical equivalents refers to the detection, analysis or amplification of more than one target sequence of interest.” *Id.* at 5:61–64. As taught by the ’794 patent, the methods generally include steps of complexity reduction, specificity, and amplification. *Id.* at 5:47–49. The nucleic acid to be detected, that is, the target sequence, may be DNA or RNA. *Id.* at 8:9–17.

D. Illustrative Claim

Petitioner challenges claims 1–22 of the ’794 patent. Claim 1, the only independent claim, is illustrative, and is reproduced below:

1. A multiplex method for determining whether a sample contains at least 100 different target sequences, comprising:
 - a) providing a sample which may contain at least 100 different single-stranded target sequences attached to a first solid support;
 - b) contacting said target sequences with a probe set comprising more than 100 different single-stranded probes, wherein each of said more than 100 different probes comprises:
 - i) a first universal priming site, wherein each of said more than 100 different probes has identical universal priming sites, and
 - ii) a target specific domain, such that different double stranded hybridization complexes are formed, each of the different hybridization complexes comprising one of said more than 100 different single-stranded probes and one of the different single-stranded target sequences from the sample;

- c) removing unhybridized probes;
- d) contacting said probes of the hybridization complexes with a first enzyme and forming different modified probes;
- e) contacting said modified probes with:
 - i) at least a first primer that hybridizes to said universal priming site;
 - ii) NTPs; and
 - iii) an extension enzyme;wherein said different modified probes are amplified and forming different amplicons;
- f) immobilizing said different amplicons to a second solid support, and
- g) detecting said different amplicons immobilized to said second solid support, thereby determining whether the sample contains at least 100 different target sequences.

Ex. 1001, 68:44–69:12.

E. Instituted Challenge

Claims	Basis	Reference
1–22	§ 102	Fan

II. ANALYSIS

A. *Overview of Fan (Ex. 1004)*

Fan, a published U.S. application, was filed on February 7, 2001, and was published on November 21, 2002. Ex. 1004. Fan claims priority to provisional application No. 60/180,810, filed on February 7, 2000 (“the ’810 provisional,” Ex. 1012), as well as provisional application No. 60/234,731,

filed on September 22, 2000, both of which were incorporated by reference.

Id. ¶ 1. The listed co-inventors are Jian-Bing Fan and Xiang-Dong Fu. *Id.*

Fan “is directed to providing sensitive and accurate assays for gene detection, genome-wide gene expression profiling and alternative splice monitoring, with a minimum or absence of target-specific amplification.”

Id. ¶ 2. Specifically, Fan teaches “a method of detecting a first target sequence comprising a poly(A) sequence in a sample.” *Id.* ¶ 15.

For example, Fan teaches

a method of detecting a first target sequence comprising a first target domain, a second adjacent target domain and a poly(A) sequence. The method includes hybridizing a first probe comprising an upstream universal priming site (UUP) and a first target-specific sequence substantially complementary to the first target domain . . . , and hybridizing a second probe comprising a second target-specific sequence substantially complementary to the second target domain and a downstream universal priming site (DUP), wherein at least one of the first and second probes comprises at least a first adapter sequence. The poly(A) sequence remains single-stranded, and the target sequence and the first and second probes form a ligation complex. The method further includes contacting the ligation complex with a ligase to form a ligated complex, contacting the ligated complex with a support comprising a poly(T) sequence, such that the poly(A) sequence hybridizes with the poly(T) sequence, removing unhybridized first and second probe sequences, denaturing the ligation complex, amplifying the ligated first and second probes to generate a plurality of amplicons, contacting the amplicons with an array of capture probes to form assay complexes, and detecting the assay complexes.

Id. ¶ 16.

B. Whether Fan Is Available as Prior Art

Patent Owner contends that Fan is not prior art as its filing date is after the effective filing date of the '794 patent. PO Resp. 7–9. Patent Owner contends further that Fan is not entitled to priority back to its listed provisional applications. *Id.* at 10–18. Petitioner responds that the disclosure of the '810 provisional was incorporated by reference into Fan, and, thus, Fan is prior art as of the filing date of the '810 provisional. Reply 4–5.

In particular, Petitioner asserts that claims 1–22 are anticipated by Fan, which Petitioner asserts is “prior art to the '794 patent under 35 U.S.C. § 102 (a), (b), and/or (e).” Pet. 4. In the claim charts, Petitioner referred to where certain limitations could be found in the '810 provisional. *Id.* at 15–26. Petitioner specifically noted that the '810 provisional was expressly incorporated by reference into the Fan published patent application. *Id.* at 14. Notably, Petitioner did not argue that the '794 patent was not entitled to its earliest possible effective filing date of September 2000.

Patent Owner did not challenge the availability of Fan as prior art in its Preliminary Response, but contends in its full Response that Fan is not prior art as its filing date was after the filing date of three priority applications to which the '794 patent claims priority. PO Resp. 7–8. Patent Owner argues that it was Petitioner’s burden to establish that Fan was prior art to the challenged claims, and that Petitioner did not meet that burden. *Id.* at 7. In particular, Patent Owner argues that Petitioner acknowledged that the '794 patent claims priority as early as September of 2000, but did not attempt to demonstrate that the '794 patent was not entitled to that filing date. *Id.* at 8.

Patent Owner argues further that “[w]hile the Petition makes a passing reference to the ’810 application as the earliest priority document for the Fan Pub (Paper 1 at 8), Ariosa failed to prove that the subject matter cited from the Fan Pub is supported by the ’810 application.” *Id.* at 11. According to Patent Owner, “[c]onclusory assertions that the ’810 application discloses certain claim elements is not the same as showing that the disclosures made in the Fan Pub are supported by the ’810 application.” *Id.* at 12.

Petitioner responds that Fan “is clearly prior art because it incorporates the ’810 application by reference and is entitled to the priority date of that application for the disclosures therein.” Reply 3 (citing *In re Giacomini*, 612 F.3d 1380, 1383–85 (Fed. Cir. 2010)). Petitioner further asserts that Patent Owner “does not and cannot establish that the ’794 patent has priority” before the filing date of Fan, i.e., February 7, 2001, arguing that “the earliest disclosure of an element of claim 1 is in a subsequent provisional application.” Reply 3. Specifically, Petitioner argues that U.S. Provisional Application 60/311,271, filed on August 9, 2001 (provided as Exhibit 1050), contained the first disclosure of more than 100 probes, as recited in section (b) of claim 1. *Id.* at 23 (citing Ex. 1050, 17). Thus, according to Petitioner, Fan, as well as the ’810 provisional, which was incorporated by reference into Fan, anticipate the challenged claims of the ’794 patent. *Id.* at 3–4.

After the oral hearing held on August 24, 2015, our reviewing court issued the decision *Dynamic Drinkware, LLC. v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015). We authorized additional briefing from the parties addressing the impact of *Dynamic Drinkware* on the instant

proceeding. Petitioner filed an Opening Brief (Paper 63), to which Illumina filed a Response (Paper 66), and Petitioner filed a Reply (Paper 67).

Dynamic Drinkware involved an appeal of a Board decision in an *inter partes* review. *Dynamic Drinkware*, 800 F.3d at 1377. In that case, the petitioner argued that certain of the challenged claims were anticipated by Patent No. 7,153,555 (“the ’555 patent”), which claimed benefit to U.S. Provisional Application 60/182,490 (“the ’490 provisional”). *Id.* The Board concluded that the petitioner had failed to demonstrate that the ’555 patent was entitled to the filing date of the ’490 provisional. *Id.* In particular, the Board noted that although the petitioner had shown where the subject matter of one of the challenged claims could be found in the ’490 provisional, it had failed to compare the portions of the ’555 patent it was relying upon to the ’490 provisional. *Id.*

The Court of Appeals for the Federal Circuit affirmed the Board’s determination that the petitioner had failed to demonstrate that the ’555 patent was entitled to the filing date of the ’490 provisional. *Id.* at 1382. In doing so, the court noted that the Board properly placed the burden on the petitioner “to prove that the prior art [’555] patent was entitled to the filing date of its provisional application.” *Id.* at 1379. In coming to that determination, the court distinguished two distinct burdens of proof, the burden of persuasion and the burden of production. *Id.* The “burden of persuasion ‘is the ultimate burden assigned to a party who must prove something to a specified degree of certainty;’” and in an *inter partes* review, the burden is on a petitioner to show unpatentability by a preponderance of the evidence. *Id.* (quoting *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326–27 (Fed. Cir. 2008)).

In addition, according to the court, the petitioner also had the burden of production to demonstrate that the '555 patent was prior art, which it satisfied by arguing that the '555 patent anticipated the challenged claims under 35 U.S.C. § 102(e)(2). *Dynamic Drinkware*, 800 F.3d at 1379. The burden of production then shifted to patent owner “to argue or provide evidence” that the '555 patent was not prior art to the challenged claims. *Id.* at 1380. The burden of production then returned to the petitioner to prove that the '555 patent was entitled to the filing date of its provisional application. *Id.*

The court noted that in order for a patent to be entitled to the effective filing date of a provisional application, it must satisfy the requirements of 35 U.S.C. § 119(e)(1) (2006). *Id.* at 1378.

In other words, the specification of the *provisional* must ‘contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms,’ 35 U.S.C. § 112 ¶ 1, to enable an ordinarily skilled artisan to practice the invention *claimed* in the *non-provisional* application.

Id. (quoting *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002)).

In *Dynamic Drinkware*, the court found that the petitioner failed to compare the claims of the '555 patent to the disclosure of the '490 provisional, noting that “[a] reference patent is only entitled to claim the benefit of the filing date of its provisional application if the disclosure of the provisional application provides support for the claims in the reference patent in compliance with § 112, ¶ 1.” *Id.* at 1381 (citing *In re Wertheim*, 646 F.2d 527, 537 (CCPA 1981)). That is, “[a] provisional application’s

effectiveness as prior art depends on its written description support for the claims of the issued patent of which it is a provisional.” *Id.* at 1382.

Thus, as *Dynamic Drinkware* makes clear, the claims of the patent document must be supported by the earlier filed application to which priority is being sought, in compliance with 35 U.S.C. § 112, first paragraph. In addition, as held by the Court of Appeals for the Federal Circuit in *In re Giacomini*, 612 F.3d 1380, 1383 (Fed. Cir. 2010), “an applicant is not entitled to a patent if another’s patent discloses the same invention, which was carried forward from an earlier U.S. provisional application or U.S. non-provisional application.” Thus, the material being relied upon as teaching the subject matter of the challenged claims must be carried through from that earlier filed application to the patent document being used against the claim.

In the instant case, the incorporation by reference of the ’810 provisional into the Fan published patent application may arguably meet the requirement that the subject matter being relied upon as teaching the subject matter of the claims against which it is being applied as prior art must be carried through from that earlier filed application through the patent document being used against the claim. That incorporation by reference, by itself, however, does not meet the requirement that the claims of the Fan application are supported by the ’810 provisional in compliance with 35 U.S.C. § 112, first paragraph.

In its opening brief addressing the *Dynamic Drinkware* decision, Petitioner contends that *Dynamic Drinkware* discusses a shifting of burdens, such that:

- (1) the initial burden was on Petitioner Ariosa to make a *prima facie* showing that [Fan] (Ex. 1004) is Section 102(e) prior art;
- (2) the burden of production then shifted to Illumina to

establish that the '794 patent is entitled to a priority date before [Fan]; and (3) if Illumina had satisfied that burden, the burden would have shifted to Ariosa to establish that [Fan] antedates the earliest priority date of the '794 patent.

Paper 63, 3. Petitioner argues that it made a *prima facie* showing that Fan is prior art to the '794 patent, as it notes the filing date of the application that led to the '794 patent, and repeatedly argues that Fan is anticipatory prior art. *Id.* at 3–4. Petitioner contends that the burden of production then shifted to Patent Owner to demonstrate that the '794 patent application was entitled to a filing date of an earlier provisional application, which Patent Owner failed to do. *Id.* at 4–5. Thus, Petitioner argues that the burden of production never shifted back to it to demonstrate that Fan has an effective filing date that is earlier than the filing date of the '794 patent. *Id.* at 5.

Thus, Petitioner asserts, it has “established that the earliest priority date of the '794 patent is August 9, 2001, which is after the filing date” of Fan. *Id.* Petitioner argues also that the Petition repeatedly references the '810 provisional, which has a filing date earlier than any possible priority date of the '794 patent, noting also that it was incorporated by reference in its entirety into Fan. *Id.* at 5–6. Petitioner argues further that Patent Owner never argued that the claims of Fan are not supported by the '810 provisional and, thus, waived that argument. *Id.* at 8. According to Petitioner, if Patent Owner had done so, it would have demonstrated that the '810 provisional provides written description support for the claims of Fan. *Id.* at 8 n.3.

Patent Owner responds that in *Dynamic Drinkware*, the petitioner’s initial burden of production was met by identifying the '555 patent as prior art under 35 U.S.C. § 102(e), identifying the effective filing date of the '555 patent, and showing that effective filing date was before the earliest priority

date of the patent at issue. Paper 66, 1. Patent Owner contends that in this case, however, the Petition only “averred vaguely that [Fan] is ‘prior art to the ’794 patent under 35 U.S.C. § 102 (a), (b), and/or (e),’” without explaining how Fan was prior art under any of those sections. *Id.* at 2. In particular, Patent Owner asserts, the Petition only mentioned the filing date of the ’810 provisional. *Id.* Thus, Patent Owner argues, Petitioner did not put Patent Owner on notice as to Petitioner’s prior art theory, and did not meet its initial burden of production as required by *Dynamic Drinkware*. *Id.*

Patent Owner responds further that the burden of demonstrating that Fan is entitled to an effective filing date of the ’810 provisional is Petitioner’s to meet. *Id.* at 7. In addition, Patent Owner asserts, it did argue in its Response that the ’810 provisional failed to provide support for Fan. *Id.* Moreover, Patent Owner contends, *Dynamic Drinkware* makes clear that the ultimate burden of persuasion to demonstrate that Fan is prior art to the ’794 patent never shifted from Petitioner, which burden Petitioner failed to meet. *Id.* at 8.

We conclude that Patent Owner has the better position. As we have already noted, there was no argument in the Petition that the ’794 patent was not entitled to its earliest possible effective filing date of September 2000. In addition, unlike the petitioner in *Dynamic Drinkware*, Petitioner did not even specify which subsection of § 102 under which Fan was being applied: Petitioner stated only generally that Fan qualified as prior art under 35 U.S.C. § 102 (a), (b), and/or (e). Pet. 4. Petitioner then pointed to where certain limitations of the challenged claims were disclosed by the ’810 provisional. Thus, we find that a fair reading of the Petition would have put Patent Owner on notice, at best, that Petitioner was relying on the Fan

application with an effective filing date of the '810 provisional; but not as putting Patent Owner on notice that Petitioner was contending that the '794 patent was not entitled to priority back to September 2000. Specifically, as Petitioner never explicitly stated that Fan was prior art under 35 U.S.C. § 102(e), and never argued that the '794 patent was not entitled to its earliest effective filing date, it did not shift the burden of production to Patent Owner to demonstrate that the '794 patent was entitled to its earliest effective filing date. .

In addition, in its full Response, Patent Owner argued that Fan was not entitled to the effective filing date of the '810 provisional. Thus, even though Patent Owner may not have specifically argued in its Response that the claims of Fan were not supported by the '810 application, we do not find that Patent Owner waived the argument that Fan was not entitled to the filing date of the '810 provisional. That is, even though Patent Owner may not have specifically argued in its Response that the claims of Fan were not supported by the '810 application, we determine that Patent Owner met its burden of production sufficiently by arguing that Fan was not entitled to the filing date of the '810 provisional. We disagree, therefore, with Petitioner that it did not have the burden of demonstrating that Fan has an effective filing date that is earlier than the earliest effective filing date of the '794 patent.

Moreover, Petitioner did not meet that burden as it did not demonstrate that Fan was entitled to the effective filing date of the '810 provisional, as it failed to demonstrate that the claims of Fan were supported by the disclosure of the '810 provisional in compliance with 35 U.S.C. § 112, first paragraph. Thus, Petitioner did not meet its burden of persuasion

of demonstrating that Fan is prior art to the '794 patent, and, thus, could not demonstrate by a preponderance of the evidence that Fan anticipates the challenged claims.

According to Petitioner, the holdings in *Dynamic Drinkware* and its predecessor, *In re Wertheim*, do not apply to the facts of the instant case as both of those cases dealt with issued patents, which are prior art under 35 U.S.C. § 102(e)(2), and not a published patent application, such as Fan, which is prior art under 35 U.S.C. § 102(e)(1). Paper 63, 6. Petitioner relies on *Ex parte Jo Anne Robbins*, No. 2009-001866, 2009 WL 3490271, *4 (BPAI Oct. 27, 2009), as well as *Ex parte Yamaguchi*, 88 U.S.P.Q.2d 1606 (BPAI Aug. 29, 2008), for the proposition that a published patent application constitutes prior art for all that it discloses as of its earliest filing date. Paper 63, 7. Petitioner also cites also the legislative history of the America Invents Act, which notes that “*Wertheim* . . . was almost completely overruled by the American Inventors Act of 1999 . . . which, by making any published application prior art [under § 102(e)(1)], effectively displaced *Wertheim*’s requirement that the application have been capable of becoming a patent on the day it was filed.” *Id.* (quoting 157 Cong. Rec. S1360-01 (Mar. 8, 2011)). According to Petitioner, therefore, “*Wertheim* and *Dynamic Drinkware* have no application to published applications under Section 102(e)(1).” *Id.*

Patent Owner responds that there is nothing in *Dynamic Drinkware* that suggests that the rationale applies only to issued patents. Paper 66, 7–8. In particular, Patent Owner argues that the court focused on 35 U.S.C. § 119(e)(1), which applies equally to 35 U.S.C. §§ 102(e)(1) and 102(e)(2). *Id.*

We cannot agree with Petitioner that the holding of *Dynamic Drinkware* applies only to issued patents, and not to published patent applications. As noted by Patent Owner, *Dynamic Drinkware* relied upon 35 U.S.C. § 119(e)(1), in holding that the disclosure of the provisional application must describe and enable the ordinary artisan to practice the claims of the non-provisional application, in compliance with 35 U.S.C. § 112, first paragraph. *Dynamic Drinkware*, 800 F.3d at 1378. Petitioner has provided no persuasive authority demonstrating that 35 U.S.C. § 119(e)(1) applies only to issued patents, and not published patent applications. We have considered the cases and legislative history cited by Petitioner, but they do not convince us otherwise.

C. Conclusion

After considering Petitioner's and Patent Owner's positions, we conclude that Petitioner has failed to meet its burden of demonstrating that Fan is prior art to the '794 patent. Thus, Petitioner has failed to demonstrate by a preponderance of the evidence that claims 1–22 of the '794 patent are anticipated by Fan.

D. Patent Owner's Motion to Exclude (Paper 52)

In its Motion to Exclude, Patent Owner seeks to exclude Exhibits 1035–1037, 1039–1044, and 1047–1052. As we do not rely on those Exhibits in this Decision, Patent Owner's Motion to Exclude is dismissed as moot.

E. Motion for Observations (Paper 51)

Patent Owner's observations are directed to the cross-examination testimony of Petitioner's Reply witness, Dr. Charles Cantor, who was cross-examined after Petitioner filed its Reply. Paper 51. We do not rely on the

Declaration of Dr. Cantor filed with Petitioner's Reply in this Decision; therefore, we have not considered Patent Owner's observations directed to the cross-examination testimony of Dr. Cantor.

III. ORDER

Accordingly, it is hereby:

ORDERED that Petitioner has not shown by a preponderance of the evidence that claims 1–22 of the '794 are unpatentable under 35 U.S.C. § 102;

FURTHER ORDERED that Petitioner's Motion to Exclude is *dismissed* as moot; and

FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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