


In the  
Supreme Court of the United States



FLEUR T. TEHRANI,

*Petitioner,*

v.

HAMILTON TECHNOLOGIES LLC,

*Respondent.*

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On Petition for a Writ of Certiorari to the  
United States Court of Appeals for the Federal Circuit

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REPLY BRIEF OF PETITIONER

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Mark Kendrick

*Counsel of Record*

KENDRICK INTELLECTUAL PROPERTY LAW

4127 Woodcliff Road

Sherman Oaks, CA 91403

(818) 941-8604

mkendrick852001@gmail.com

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## INTRODUCTION

The Petition (“Pet.”) presented five questions to the Court. The Petitioner explained in the Petition for Writ of Certiorari, that the ruling of the Federal Circuit was based on serious errors and misquoting of US7,802,571 (the Patent). She explained that the ruling would strip her of her patent rights in clear violation of the established patent laws and was in clear conflict with this Court’s established guidelines and previous decisions. She further explained that the ruling would disrupt the settled expectations of the inventing public against the guidelines established by this Court (Pet.26-33).

The Respondent’s (Hamilton’s) Brief in Opposition (“Bio.”), claims that the rulings of the Patent Trial and Appeal Board (the Board) and the Federal Circuit in this case align with the findings of the United Kingdom Intellectual Property Enterprise Court (IPEC) that ordered the revocation of 79 claims of GB2423721, the UK counterpart of the Patent (Bio.1-2). This is a misleading claim by Hamilton.

Hamilton has been marketing an advanced automatic ventilation and oxygenation system called the Intelli-Vent ASV in the UK for more than a decade. To the knowledge of the Petitioner, that system has not yet received FDA approval. IPEC found the Intelli-Vent ASV infringing on GB2423721.

In paragraph 74 of its “Judgment” on the case (IP-2019-000196), IPEC stated as follows<sup>1</sup>:

Therefore when Intellivent-ASV is being used to increase treatment, claim 1 is infringed on a normal construction of the claim.

The main prior art used by Hamilton in the UK case included Anderson, Taube, and Waisel<sup>2</sup>. Waisel which was also used by Hamilton against the Patent before the Board, described a look-up table (Waisel; Figure 1) for intermittent adjustment of PEEP and FIO<sub>2</sub> by trial-and-error to single discrete pairs in 15 minutes to 2 hours intervals. Taube was dropped in the UK court after its fatal nature was discussed. Anderson was rejected by that court against the validity of the UK patent claims. The IPEC Judgment stated in its paragraphs 89 and 90 as follows:

89: “Neither claim 1 nor claim 45 lacks novelty over Anderson.”

90: “. . . neither claim 1 nor claim 45 lacks inventive step over Anderson.”

Therefore, despite Hamilton’s claim, there was no alignment between the rulings of the Board that was affirmed by the Federal Circuit and the UK ruling.

On Pet.6, Petitioner quoted the decision of the UK patent office showing the reason that IPEC ordered the revocation of GB2423721. Central to that decision was the use of “a” v. “the” in a claim term “a

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<sup>1</sup> *Tehrani v Hamilton Bonaduz AG & Ors* [2021] EWHC 3457 (IPEC) (22 December 2021) (bailii.org)

<sup>2</sup> D.B. Waisel et al., *PEFIOS: An Expert Closed Loop Oxygenation Algorithm by Waisel et al.*, MEDINFO 1995, pp.1132-1136.

next breath” despite that the claim language was in accordance with MPEP 2173.05(e). The UK ruling shows that even a court that was prepared to revoke a major patent with 79 claims that had been found as infringed, based on nothing but the use of “a” versus “the” in one claim term, could not find any relevance between the main prior art documents used in this case and the validity of the claims of GB2423721. IPEC resorted to the difference between “a” versus “the” in a claim term to strip the patentee of her patent rights in the UK. This comparison should indicate how irrelevant the main prior art documents used by Hamilton in this case are in relation to the validity of the claims at issue<sup>3</sup>.

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<sup>3</sup> Hamilton states that IPEC ordered the Petitioner to pay £ 50,000.00 damages to Hamilton and the Petitioner has not paid those damages. This matter is not relevant to the Petition and Hamilton has raised it to prejudice the Court against the Petitioner. At IPEC, fines are capped at £ 50,000.00 and this maximum fine is hardly ever granted to a party. IPEC found GB2423721 infringed by Hamilton’s product in the UK. IPEC decided that the patent term “a next breath” would mean a breath “some time in the future” and would not mean the same as “the next breath” to refer to a patient’s next breathing cycle. By this definition, the entire purpose, and the specification of GB2423721 that was designed for breath-by-breath oxygenation and ventilation became meaningless. By this definition, IPEC could compare any intermittent table for adjustment of PEEP and FIO2 (*i.e.*, the Waisel’s table) to the claims of GB2423721. However, another limitation of the patent claims was that the ratio of PEEP/FIO2 had to be maintained in a prescribed range. Therefore, IPEC still could not attack the validity of the claims of GB2423721 by using Waisel. The IPEC Judgment claimed that Hamilton had presented an annotated figure that showed that in Waisel the ratio of PEEP/FIO2 was kept within a prescribed range (paragraphs 98-99 of IPEC Judgment). That Judgment presented the alleged annotated figure in its paragraph 98. The





## ARGUMENT

### **I. THE FEDERAL CIRCUIT ERRED AND DEPARTED FROM THE ACCEPTED AND USUAL COURSE OF JUDICIAL PROCEEDINGS BY DECLARING A NON-EXPERT AS A POSITA AND BY RELYING ON HIS UNSUPPORTED TESTIMONY VERSUS CREDIBLE PUBLISHED EVIDENCE.**

Hamilton's expert, Dr. Imbruce, provided expert testimony as a "clinician" claiming to be a respiratory therapist. (Pet.8-9). As it turned out, Dr. Imbruce was a respiratory therapist (RT) more than forty years ago and had never renewed his certificate. Respiratory technology is an evolving technology and respiratory therapists need to renew their certificates every two years to be allowed to practice. The Patent describes a fully automatic breath-by-breath system for determination and control of oxygenation and ventilation parameters of ICU patients. These technologies did not exist forty years ago and Dr. Imbruce has no experience with such ventilators. Dr. Imbruce claimed

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annotated figure that the Judgment claimed was presented by Hamilton had never been presented and did not exist in the record. The Petitioner requested IPEC to either point to where the documents referred to in paragraphs 98-99 of its Judgment could be found in the record or to revoke its invalidity ruling. IPEC never explained where its claimed documents could be found in the record and did not provide the patentee with any meaningful response. Petitioner is not aware of any convention that would automatically enforce the ruling of IPEC in the U.S. The Petitioner is a U.S. citizen, and she is aware that foreign rulings that are based on non-existing documents cannot be enforced against U.S. citizens.

during his deposition that he had designed some modalities for ventilators, but that claim could not be substantiated and was not even found in his CV. *Id.*

The Board relied entirely on Dr. Imbruce's testimonies that were never supported by a shred of evidence but did not declare him a POSITA. The Federal Circuit declared Dr. Imbruce a POSITA, claimed he was still a "clinician" forty years after the expiration of his RT certificate, relied entirely on his unsubstantiated testimony (rather than the Petitioner's extensive knowledge in the field of the Patent that is reflected in her CV), and completely ignored a refereed published review article that clearly showed the falsehood of Dr. Imbruce's testimonies (Pet.App.91a-111a). According to 37 C.F.R. § 42.65(a), "Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight." Therefore, the Federal Circuit erred and departed from the accepted and usual course of judicial proceedings against Fed. R. Evid. 702(c),(d) and 37 C.F.R. § 42.65(a).

## **II. THE FEDERAL CIRCUIT ERRED AND DEPARTED FROM THE ACCEPTED AND USUAL COURSE OF JUDICIAL PROCEEDINGS BY USING A PAPER PRESENTING UNTRUE DATA (ANDERSON) AND A PATENT DESCRIBING A FATAL DEVICE (TAUBE) AGAINST THE PATENT CLAIMS.**

The Petitioner described to the Court why Anderson does not present true data and why Taube presents a fatal device (Pet.11-13, Pet.24-25).

The Federal Circuit erred by using an untrue paper and a fatal device against the challenged claims

of the Patent and by doing so, the Federal Circuit departed from accepted course of judicial proceedings.

**III. FIGURE 7 OF CARMICHAEL HAS NO RELATION TO THE PATENT'S CONTINUOUS ALGORITHM FOR A NEXT BREATH.**

Carmichael is a refereed article presenting true survey results on how PEEP and FIO<sub>2</sub> were adjusted manually by physicians several hours apart. Such manual adjustments are always done by trial and error. Figure 7 of Carmichael shows that responding physicians kept on increasing PEEP to some maximum levels before they changed FIO<sub>2</sub> to the next higher level. This is not what the Patent claim algorithm does. In the continuous algorithm of the Patent, FIO<sub>2</sub> and PEEP are both determined to go higher or lower or remain unchanged for the next breath while the ratio of PEEP/FIO<sub>2</sub> is kept within a prescribed range. There is no such ratio mentioned in Carmichael. Hamilton argues that for each column shown in Figure 7 of Carmichael, one can divide various PEEP values by the fixed FIO<sub>2</sub> level to come up with some ratios. That may be true but has nothing to do with the Patent algorithm. The Patent does not and cannot use multiple prescribed ratios for PEEP/FIO<sub>2</sub> for different FIO<sub>2</sub> values and in a system where FIO<sub>2</sub> is subject to continuous control, such practice requires infinite prescribed ranges for the ratio and becomes meaningless. (Pet.21-24).

#### **IV. “A NEXT BREATH” IN THE PATENT CLAIMS MEANS THE NEXT BREATHING CYCLE.**

The claim term “a next breath” means the next breathing cycle. (Pet.16-19).

Both Grounds require combining Figure 7 of Carmichael which shows a manual chart for adjusting FIO<sub>2</sub> and PEEP several hours apart, with other references. Combining a manual chart with anything does not result in a system for a next breath operation. (Pet.16-19). Neither of the Grounds operates for a next breath as required by the Patent claims as emphasized during the Oral Hearing by the Petitioner’s counsel (Bio.27a).

#### **V. PID CONTROL OF PEEP IS NOT USED IN THE PATENT AND IS AGAINST THE METHOD OF THE PATENT CLAIMS. THIS IS A SERIOUS ERROR BY THE FEDERAL CIRCUIT.**

Even if none of the serious flaws in the two Grounds existed, if all the impossible combinations were possible, if Anderson was true and Taube was not a fatal device, still both Grounds require PID control of PEEP which is against the method of the Patent claims and neither Ground could render any claim of the Patent obvious. One of the requirements of the Patent claims is to keep the ratio of PEEP/FIO<sub>2</sub> within a prescribed range in a continuous operation. In a system where FIO<sub>2</sub> is subject to continuous determination and control, this condition cannot be satisfied with PID control of PEEP. These conditions are mutually exclusive. This matter was brought to the attention of the Board and the Federal Circuit numerous times. The Federal Circuit misquoted the Patent specification and stated that PEEP is adjusted

by PID control in the Patent (Pet.App.2a). This is a profoundly serious error by the Federal Circuit as was brought to the attention of the Court (Pet.25-26). “Whether a prior art reference teaches away from the claimed invention is a question of fact.” *Para-Ordnance Mfg., Inc. v. SGS Imps. Int’l, Inc.*, 73 F.3d 1085, 1088 (Fed. Cir. 1995) and in “*Santarus, Inc. v. ParPharm., Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012), which is also reviewed for substantial evidence. *Gen. Elec. Co. v. Raytheon Techs. Corp.*, 983 F.3d 1334, 1354 (Fed. Cir. 2020). Substantial evidence is “such evidence as a reasonable mind might accept as adequate to support a conclusion.” *Consol. Edison Co. v. Nat’l Labor Relations Bd.*, 305 U.S. 197, 229 (1938).

**VI. NONE OF THE REQUIREMENTS OF THE PATENT CLAIMS AND NONE OF THE REQUIREMENTS FOR OBVIOUSNESS ARE MET BY THE COMBINATIONS IN TWO GROUNDS. THE RULING OF THE FEDERAL CIRCUIT CONFLICTS WITH PREVIOUS DECISIONS OF THIS COURT.**

Well-established patent law holds that an obviousness rejection cannot be sustained unless the cited reference(s): (a) provide a suggestion or motivation to combine reference teachings in the manner claimed; (b) provide a reasonable expectation of success; and (c) teach all of the claim limitations, except for those limitations already within the knowledge or common sense of a person of ordinary skill in the art. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991); *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).

The main references against the Patent claims in one Ground are Carmichael and Anderson, and in the other Ground, Carmichael, and Taube. The Petition described the differences between these references

and the Patent and described that neither Ground could meet any of the limitations of the Patent claims and any of the obviousness requirements under 35 U.S.C. § 103(a). (Pet.7-13, Pet.26-30)

**VII. THE COURT’S REVIEW IS WARRANTED UNDER SUPREME COURT RULE 10.**

Review on a writ of certiorari is a matter of judicial discretion. Sup. Ct. R. 10 (“Rule 10”). Rule 10 provides several examples of “compelling reasons” that may justify review. Among those are the following that apply to this case:

- (a) a United States court of appeals has . . . departed from the accepted and usual course of judicial proceedings,
- (c) a state court or a United States court of appeals . . . has decided an important federal question in a way that conflicts with relevant decisions of this Court.

The Opposition Brief states that the matters brought to the attention of this Court by the Petitioner are factual findings of the courts that cited substantial evidence in support of those findings and applied established legal principles to those findings, and the Petition should be denied (Bio.1-2).

In fact, the “substantial evidence” that Hamilton talks about is nothing but the totally unsupported testimony of Dr. Imbruce, in combination with the rulings issued by the Board and the Federal Circuit. Hamilton has repeatedly made statements in this case that show complete lack of understanding of the Patent and the prior art. For example, Hamilton stated at the Oral Hearing that Carmichael involved

“automated ventilators” (Bio.14a-15a) while Carmichael presents a chart for manually adjusting PEEP and FIO<sub>2</sub> several hours apart in its Fig. 7. Hamilton further stated that in Carmichael “PEEP is restricted to something like 0.6 millimeters of hemoglobin” (Bio. 17a), while PEEP is a pressure and the unit stated by Hamilton does not exist. Hamilton further stated:

--I think what my friend's definition of automatic is, is something like a fully automatic and what--what Carmichael was--was de— was using were automated ventilators that had computers in them to perform this assist control.

(Bio.17a)

Therefore, Hamilton was not aware that the Patent describes a “fully automatic” system for oxygenation and ventilation, that every basic ventilator nowadays has a computer inside and that does not constitute an “automated ventilator” in the context of this case.

Hamilton repeatedly uses intermittent tables and charts against the Patent claims and suggests combining such documents with continuous systems. Hamilton asserts that using a manual table in Anderson is the same as using loop indicators in the continuous algorithm of the Patent without realizing that loop indicators are used in a fraction of a second and such indicators that are commonly used in continuous algorithms when there are loops within other loops have nothing to do with using intermittent tables. The record in this case is riddled with similar statements by Hamilton that have been reflected in the Board’s decision and the Opinion of the Federal Circuit. These are monumental errors and are direct

results of relying on the testimony of Dr. Imbruce who did not know anything about the technology of the Patent.

Any POSITA on this case would know that tables and charts have no application in continuous systems, that they cannot be combined, that scientific publications must provide the types of methods that they use and two different methods cannot produce identical results, that a positive feedback system is inherently unstable, and that PID control of PEEP is against the method of the Patent claims.

In essence, any POSITA would find the findings of the Federal Circuit on this case clearly erroneous. This Petition is about the manner that the case has been dealt with by the Board and the Federal Circuit which has resulted in rulings with numerous serious and obvious errors. That has led to completely overlooking the U.S. patent laws and the obviousness requirements as set out and emphasized by this Court.

In summary, the requirements of obviousness are well-established by patent law and are emphasized to be upheld by this Court. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991); *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007). None of those requirements are met by the decision of the Federal Circuit in this case. This Court has repeatedly advised that “courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community.” *Festo Corp. v. Shoketsu Kinzoku Kogyokabushiki Co.*, 535 U.S. 722, 724 (2002); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997).

The decision of the Federal Circuit in this case is based on relying on Hamilton expert’s testimonies



against Fed. R. Evid. 702(c),(d) and 37 C.F.R. § 42.65(a) as explained above. The decision of the Federal Circuit clearly conflicts with the previous decisions of the Supreme Court and disrupts the settled expectations of the inventing public. Stripping someone of her patent rights against all the provisions of the law and the guidelines set by this Court sends a chilling message to the inventing public in the U.S. Inventors need to be assured that their patent rights are protected by the law and cannot be taken away based on irrelevant documents and unsupported testimonies. Without that trust in the system, the inventors will not have the incentive to develop cutting edge technologies and the Patent system cannot foster innovation under the constitutional mandate. The decision on this case has a broader impact than this case alone and the Petition should to be granted.



## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

Mark Kendrick

*Counsel of Record*

KENDRICK INTELLECTUAL PROPERTY LAW

4127 Woodcliff Road

Sherman Oaks, CA 91403

(818) 941-8604

mkendrick852001@gmail.com

*Counsel for Petitioner*

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