

United States Court of Appeals  
for the Federal Circuit

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RESTEM, LLC,  
*Appellant*

v.

JADI CELL, LLC,  
*Appellee*

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2023-2054

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Appeal from the United States Patent and Trademark  
Office, Patent Trial and Appeal Board in No. IPR2021-01535.

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**CORRECTED AMICUS CURIAE BRIEF OF TIMOTHY G. DIXON  
THE UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT  
IN SUPPORT OF APPELLEE AND AFFIRMANCE OF  
THE FINAL WRITTEN DECISION**

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FEDERAL CIRCUIT

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8 **UNITED STATES COURT OF APPEALS**  
9 **FOR THE FEDERAL CIRCUIT**

<p>10 Restem LLC,</p> <p>11 <i>Plaintiff-Appellant</i></p> <p>12 v.</p> <p>13 Jadi Cell LLC,</p> <p>14 <i>Defendants-Appellees</i></p>	<p>2023-2054</p> <p>Before,</p> <p>CUNNINGHAM, Circuit Judge.</p>
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17 **CORRECTED AMICUS CURIAE BRIEF OF TIMOTHY G. DIXON**  
18 **THE UNITED STATES COURT OF APPEALS**  
19 **FOR THE FEDERAL CIRCUIT**

20 1. I, **Timothy G. Dixon** aver as follows: I am over 18 years of age, CEO, Chairman of the Board  
21 of Therapeutic Solutions International, Inc. ("TSOI"), and its majority shareholder, as well as being a  
22 co-author of twenty-three patent applications stemming from the patent, U.S. Patent No. 9,803,176 B2  
23 ("the '176 patent") at the heart the underlying *Inter Partes Review* ("IPR") (IPR2021-01535) and  
24 subject matter of the appeal before this Court.

25 2. I am the author of this corrected Amicus Curiae brief, corrected, and have personal knowledge  
26 of each fact stated herein except as to those matters stated as knowledge based on information and  
27 belief, and as to those matters I am informed and believe them to be true and correct. Costs associated  
28 with the filing of the Motion for Leave and the Amicus Curiae Brief have been paid by TSOI.

1 3. Therapeutic Solutions International, Inc. (“TSOI”) is a Nevada Corporation that is publicly  
2 traded on OTC Markets, and is the exclusive worldwide license holder of use of the ‘176 patent for all  
3 lung indications and CTE (“Chronic Traumatic Encephalopathy”) and TBI (“Traumatic Brain Injury”)  
4 indications for the brain, and unfettered use, the drug master file, and master cell bank one for  
5 JadiCells, the mesenchymal stem cells at issue and subject matter of this appeal.

6 4. Amici Timothy G. Dixon (“Dixon”) submits this corrected Amicus Curiae brief (“Amicus  
7 Brief”) in support of upholding the Final Written Decision of the Patent Trial and Appeal Board  
8 (“PTAB”). Amici submits that the Amicus Brief collects and describes background and factual  
9 references, particularly as to motive and truthfulness of the parties in this appeal that merit judicial  
10 notice and will provide a perspective that may benefit the Court and warrants their participation as  
11 amici and presentment of this Amicus Brief.

12 5. Moreover, the Amicus Brief does not purport to respond directly to arguments in the Parties’  
13 briefs, but rather provides insight into testimony given in the IPR, as evidenced in the transcripts,  
14 including inconsistent statements and factual inaccuracies, as well as potential undisclosed conflicts of  
15 interest of key witnesses and the Parties. As a result, it is not a “responsive briefing” so much as it is  
16 background and factual information that may benefit the Court in its appellate review.

17 6. To wit, on or about October 24, 2022, amici caused to be filed on behalf of TSOI a Form 8-K  
18 with exhibits on the SEC’s EDGAR site publicly disclosing the genesis of issues that arose involving  
19 the Parties and witnesses to this appeal, specifically the Principal Investigator in a Phase 1/2b Clinical  
20 Trial at the University Miami, Dr. Camillo Ricordi, M.D. (“Ricordi”) and key witness, Dr. Amit N.  
21 Patel (“Patel”), inventor and patent holder of the ’176 Patent at issue, key witness, and sole member of  
22 Jadi Cell LLC (“Jadi”), Appellees, as well as Restem LLC (“Restem”), Party and Appellant. [Please  
23 see link below:

24 <https://www.sec.gov/ix?doc=/Archives/edgar/data/1419051/000149315222029460/form8-k.htm>]

25 7. The Form 8-K includes references to the depositions of Ricordi and Patel taken by counsel for  
26 the Appellant and Appellee, and amici believes that certain facts testified to or materially relevant to  
27 the IPR were either factually misstated, intentionally misleading, or material information withheld in  
28 order to hide relationships and important information. Although amici believes that the PTAB reached

1 the correct decision, Appellants attempt to overturn the Final Written Decision are disingenuous and  
2 made with motives that are not in the interest of justice or based on sound scientific reasoning.

3 8. In late November of 2021 amici became aware of the Inter Parties Review (“IPR”) in *Restem*  
4 *LLC v. Jadi Cell, LLC* through a social media post. Jadi Cell LLC, by virtue of the exclusive,  
5 worldwide, Patent License Agreement (“EPLA”) effective since February 9, 2021, had an obligation to  
6 inform amici and TSOI of any challenges to the patent underlying EPLA, yet failed to do so until  
7 nearly 6 months after the filing of the IPR by Appellant Restem.

8 9. On September 27, 2022, Patel was deposed in the matter of *Restem LLC vs. Jadi Cell LLC*. On  
9 Pg. 77 of his transcript, Patel states he was offered \$15 million dollars for JadiCells approximately 2  
10 years ago, which would have been the August/September of 2020 timeframe. On pages 78 and 79 of  
11 the transcripts, Patel’ sworn testimony states that the offer that preceded TSOI’s was “left up in the air  
12 due to the IPR. That’s what was stated by the lawyers.”

13 10. This is practical impossibility as the IPR was not filed by Restem until September 29, 2021,  
14 two weeks to the day after Jadi entered into the lung EPLA clarifying agreement of the 2/9/2021  
15 convertible promissory note and license. In other words, a \$15 Million license agreement was entered  
16 into with TSOI and not “left in the air” as stated by Patel due to the filing of the IPR.

17 11. Dr. Patel is asked (on page 80 of his transcript) how much TSOI paid Jadi Cells [for its  
18 exclusive license for lung indications], and Dr. Patel responded, “hundreds of thousands.” Again, this  
19 is incorrect and a gross misstatement as the Convertible Promissory Note, EPLA, and later the  
20 Settlement Agreement, clearly states Jadi received \$15,000,000 worth of TSOI stock at a fixed price of  
21 \$0.1004. This is of extreme importance that Dr. Patel was in the process of clearing their \$15,000,000  
22 worth of TSOI stock and depositing with a broker at the very time his deposition was being taken.

23 12. On August 26, 2022, Ricordi, was deposed. On page 13 of his transcript, he is asked if he has  
24 had any communication with Jadi Cell LLC (i.e., Dr. Patel as the LLC is a single-member LLC alter  
25 ego) about his deposition and under oath states the following:

26 “No, I didn’t. I didn’t communicate about this procedure or the deposition. I’ve been  
27 communicating in the past because this trial has been halted and we had all kind of  
28 difficulties moving forward to identify standing sources because when everyone —

1 we had a Phase III trial approval FDA like a year ago or around a year ago and still we  
2 have been unable to move forward because when people come close and they see that  
3 there is a legal proceeding, they run in the opposite direction. I guess they don't want to  
4 get involved. So practically we had very good results from the — spectacular results  
5 from the Phase I/IIA trial and then we obtained permission to move for a Phase III trial  
6 multisite and we were stuck and unable to save life and just witness the — COVID-19  
7 to continue to unfold, but we were unable to help patients.”

8 13. This is factually inaccurate and Ricordi knew it was inaccurate when he provided the sworn  
9 testimony. On March 24, 2022, University of Miami (“UM”), and TSOI, entered into an Asset  
10 Transfer and License Agreement which stated “Within ten (10) days of the Effective Date, 1) TSOI  
11 shall make an initial payment of two hundred thousand dollars (\$200,000) to UM; 2) Within six (6)  
12 months of the Effective Date, TSOI shall make a second payment of one million eight hundred  
13 thousand dollars (\$1,800,000) (at the completion of the primary endpoint of the phase 2b/3 clinical  
14 trial specified in the IND or (ii) one (1) year from the Effective Date), and 3) TSOI shall make a final  
15 payment of two million dollars (\$2,000,000). In turn, upon FDA approval of TSOI as Sponsor, TSOI  
16 will replace UM as Sponsor, receive all trial doses, and intends to appoint James Veltmeyer, MD,  
17 Chief Medical Officer as Principal Investigator.”.

18 14. On March 28, 2022, Ricordi sent a letter to the FDA on behalf of UM stating that the IND has  
19 been transferred to TSOI and that TSOI is the new owner of IND 19757. On March 28, 2022, Dr.  
20 Thomas Ichim also sent a letter notifying the FDA of the IND transfer on behalf of TSOI, and on April  
21 1, 2022, TSOI received notice from the FDA that the IND had officially been transferred.

22 15. Knowing all the above, Ricordi states that right up to August 2022, “we have been unable to  
23 move forward because when people come close and they see that there is a legal proceeding, they run  
24 in the opposite direction.” It cannot reasonably be argued that the IPR has ever interfered with the  
25 IND moving forward. Furthermore, when Ricordi provided his sworn statement in his deposition he  
26 knew these statement were untrue.

27 16. Amici believes the following to be one possible explanation for the blatant untruths and  
28 motivations behind them.

1 17. Jadi not only failed to notify TSOI in a timely manner of the filing of the IPR as was their  
2 obligation under the EPLA, but consistently failed to communicate or provide progress reports of the  
3 litigation. Most egregious, Jadi failed to inform amici or TSOI of the prior (current) relationship  
4 between Ricordi and Restem. Amici had to learn of it through its own research.

5 18. On page 15 of Ricordi's transcript he is asked about affiliations, advisory boards, institutions  
6 etc., that he is involved in, and he provides a list of people and entities. Notably, Ricordi failed to  
7 disclose his own relationship with Restem, which includes using Restem's mesenchymal stem cell in at  
8 least 3 patients, as well as an article published on Restem's website, and at least three (3) scientific  
9 papers Ricordi has co-authored with scientists from Restem. Oddly, the lawyer representing Restem  
10 doesn't seem to know that his client has a long-standing working relationship with Ricordi and UM.  
11 Amici wonders at the likelihood of that. Even more odd is the fact that this failure to disclose a  
12 relationship that likely rises to a conflict of interest has not been corrected in the records, even though  
13 Ricordi amended his deposition at the bequest of some unknown attorney to say the "aliquots" in  
14 question came from the 176' patent.

15 19. On or about August 18, 2021, a long-time requested meeting occurred involving Ricordi, Patel,  
16 Dixon, and others via a Zoom conference call wherein Ricordi expressed surprise and "claimed" this  
17 was the first time he was hearing about TSOI and their exclusive world-wide patent license agreement  
18 ("EPLA") with Jadi Cell LLC ("Jadi"). Unsurprisingly, Ricordi's reactions to TSOI's presence was  
19 unnerving for Dixon given how long the EPLA was in existence and the parties' established  
20 relationships, let alone the many updates provided by Patel of the FDA review of the Phase III IND  
21 application. Why Patel and Jadi kept TSOI's existence Ricordi, if true, is a mystery that continues  
22 today. TSOI later discovered that on August 12, 2021, just days before this meeting, Ricordi, on UM  
23 Letterhead sent to the FDA a "Letter of Authorization" (LOA) for Arugula Sciences LLC to utilize  
24 data that TSOI owns the exclusive rights to. Neither Patel the Licensor, nor Ricordi the letter writer  
25 has ever informed TSOI of this infringement.


26 20. On Pg. 30 of the Ricordi transcript the lawyer for Restem asks "Q. Okay. But you're saying that  
27 you don't have any financial connection to any company that uses cells claimed by the '176 Patent?" to  
28 which Ricordi responds:

1 "No. As a matter of fact, I was invited by Neil Re-all-tin (phonetic) in Dallas that has a  
2 facility with MSC that I thought had intention to work with Jadi Cells for some  
3 application. But then he told me that when they found out that there are this legal things  
4 or issues unresolved, they prefer to keep their respectful (INAUDIBLE). So I think  
5 they're keeping their own sourced cells. So I'm not aware where Jadi Cell may be using  
6 cells for other trials."

7 21. We know that the person he is referencing is actually Neil Riordan ("Riordan"), who is in  
8 reality an alter ego of Arugula Sciences LLC. Of note, Ricordi, Neil Riordan, and Keith March of  
9 Restem have all published scientific papers together, conducted clinical research together, and all have  
10 ongoing working relationships that were never disclosed to the IPR Panel of Judges by either Party.

11 22. While none of this goes to the essence of whether or not the PTAB reached the correct decision  
12 as to patentability claims, amici Dixon believes pointing out the above factual inaccuracies and failure  
13 to disclose important relationships may shed light on the true motivation for filing the IPR and this  
14 appeal; namely, because TSOI already obtained an EPLA for the '176 patent that includes the lung, a  
15 crucial organ for any intravenous use of JadiCells, and because prior attempts at wresting the license  
16 away from TSOI failed, invalidation of the patent, particularly Claim 1, was the only avenue remaining  
17 to the parties involved.

18 Respectfully Submitted,

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20 \_\_\_\_\_  
21 Timothy G. Dixon, Amici

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**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

**CERTIFICATE OF SERVICE**

Case Number 23-2054

Short Case Caption Restem LLC v. Jadi Cell LLC

NOTE: Proof of service is only required when the rules specify that service must be accomplished outside the court's electronic filing system. See Fed. R. App. P. 25(d); Fed. Cir. R. 25(e). Attach additional pages as needed.

I certify that I served a copy of the foregoing filing on 08/25/2023

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on the below individuals at the following locations.

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Additional pages attached.

Date: 08/25/2023

Signature: \_\_\_\_\_



Name: \_\_\_\_\_

Lynda Dixon

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