UNITED STATES OF AMERICA
BEFORE THE
SECURITIES AND EXCHANGE COMMISSION

ADMINISTRATIVE PROCEEDING
File No. 3-19788

In the Matter of

DECISION DIAGNOSTICS CORP.

PETITIONER'S OPENING BRIEF IN SUPPORT OF PETITION TO TERMINATE TRADING SUSPENSION

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Petitioner Decision Diagnostics Corp. respectfully submits this opening brief in support of its petition to terminate the April 23, 2020 Order of the United States Securities and Exchange Commission suspending the trading in Decision Diagnostic's securities pursuant to Section 12(k) of the Securities Exchange Act of 1934 for ten (10) business days starting on April 24, 2020 (the "Trading Suspension Order"). Decision Diagnostics' ("DECN") petition to terminate the trading suspension was filed on May 7, 2020 at 5:54 P.M., prior to the expiration of the trading suspension at 11:59 P.M. that day. The petition is therefore timely, even though the suspension has now expired by its terms, and trading in DECN's securities resumed the following business day, May 8, 2020. *See, e.g., Accelerated Bus. Consolidation Corp.,* Securities Exchange Act Release No. 73420, 2014 SEC LEXIS 4594, at *4 (Oct. 23, 2014). Petitioner DECN is "adversely affected" by the trading suspension within the meaning of Rule 550 of the Rules of the Securities and Exchange Commission.

PRELIMINARY STATEMENT

DECN acknowledges the broad discretion afforded the Commission under Section 12(k) of the Exchange Act. DECN further acknowledges that certain unscrupulous issuers, promoters and others have undoubtedly sought to capitalize on the COVID pandemic and resulting desperation and fear that has swept the country. However, an examination of the facts of this investigation compels the conclusion that the trading suspension was imprudently and improperly issued against a company that is at the very forefront of the efforts to develop an efficient and reliable test kit to assist in the detection of the highly contagious and deadly Coronavirus. Even if all the information which the Division of Enforcement asserts was before the Commission as of April 23, 2020 was in fact available to the Commission on that date, which has been demonstrated could not have been the case, the Trading Suspension Order was improper. Section 12(k) is simply

not a cure-all for virtually any perceived problem in the marketplace. *SEC v. Sloan*, 436 U.S. 103, 117 (1978). For the reasons set forth herein, and in the accompanying Affidavit of Keith M. Berman and Affirmation of Ronald S. Herzog, the Trading Suspension Order should be terminated.

THE TRADING SUSPENSION SHOULD BE TERMINATED

A review of the largely indisputable facts quickly reveals that DECN stands in marked contrast to the situations which presumptively justified the Commission's imposition of and refusal to terminate temporary trading suspensions under Section 12(k) of the Exchange Act. DECN recognizes the torrent of information, much of it undoubtedly dubious at best, prompted by the COVID-19 pandemic, and the SEC's need to respond appropriately and expeditiously in these situations. However, the potential validity of the Trading Suspension Order is not to be determined against the general backdrop of individuals or their companies who may be improperly attempting to profit from a worldwide pandemic, but rather from the extensive information DECN placed in the market, none of which has been refuted. Separating the wheat from the chaff warrants granting petitioner the relief now requested.

(i) The Factors Upholding a Trading Suspension are Not Present

As a general matter, one of the primary issues normally to be considered by the Commission in determining whether or not a 10-day trading suspension should be instituted is whether or not there is sufficient public information upon which informed investment decisions can be made. Adopting Release, Rules of Practice, 60 Fed. Reg. 32738 at 32787 (June 23, 1995). DECN consistently updated investors about its proposed COVID test kits, thereby allowing them to make knowledgeable investment decisions. From the time DECN publically announced that its existing glucose technology used by diabetics had the potential to be utilized to test for the COVID-19 Virus the date of the Trading Suspension Order, the company issued no less than twelve (12)

detailed releases concerning its proposed COVID-19 GenViro! test kits and the Emergency Use Applications being sought from the Food and Drug Administration. The Trading Suspension Order cannot be justified on the ground that investors needed even more information concerning the proposed GenViro! test kits. Rather, reliable public information was regularly provided by DECN, which has extensive experience in the blood analysis area on which the technology for the proposed GenViro! test kits is predicated. Berman Affidavit, ¶ 5-6. Compare *Bravo Enterprises Ltd.,* Securities Exchange Act Release No. 75775, 2015 SEC LEXIS 3597, at *33 (August 27, 2015) (issuer had changed name eight times and pursued a variety of unrelated business interests during its existence). No corrective disclosures were required (or made) after the Trading Suspension Order.

There has also been no showing of any demonstrable falsity, a virtual staple of the Commission's denial of petitions seeking the termination of 12(k) trading suspensions, in any of DECN's detailed press releases. *See, e.g., Bravo Enterprises, supra,* 2015 SEC LEXIS 3597 at *38 (press release that company had received "official recognition" from FEMA admittedly false as were statements concerning nonexistent product); *EFuel EFN Corp*, Securities Exchange Act Release No. 86307, 2019 SEC LEXIS 1663 at *9, 14-15, 20 (July 5, 2019) (letter from FINRA intentionally altered, resulting in deliberate dissemination of materially false information concerning the company); *Immunotech Laboratories, Inc.,* Securities Exchange Act Release No. 75790, 2015 SEC LEXIS 3598, at *16 (August 28, 2015) (misrepresentation of scope of licensing agreement to treat Ebola pandemic; independent investigation revealed purported contra-party to be a dormant shell with no operations).

The information available to the Commission on April 23, 2020 completely lacks any of the misconduct or blatant misrepresentations which have resulted in the imposition of temporary

trading suspensions. For example, there is no evidence that DECN may have been the subject of a pump and dump scheme in March and April of this year or any nefarious conduct by market makers. Compare *Bravo Enterprises, supra,* 2015 SEC LEXIS at *45. Nor is there any evidence of the touting of DECN's stock by any promoter, investor relations from or broker-dealer, or any coordination between any of the foregoing and DECN. *Id.* (press release admittedly coincided with paid stock tout; company subject of 48 penny-stock touts); *Amogear, Inc.,* Securities Exchange Act Release No. 71514, 2014 SEC LEXIS 478 at * 1 (February 10, 2014) ("spam emails touting the company's shares"). In fact, DECN made all its FDA filings concerning GenViro! exactly when and how reported. Mr. Berman, who has no adverse regulatory history in over twenty-five years of significant executive positions at reporting companies, has never directly or indirectly purchased, sold or been issued any DECN stock since the company started working on its COVID-19 test kits. (Berman Aff. ¶ 41).

Stripped of its excess verbiage, the Trading Suspension Order was based on nothing more than a fundamental lack of understanding of the technology on which the proposed GenViro! test kits are based, coupled with inherently unreliable information from disgruntled outsiders that appears to have been provided to and simply accepted without investigation by the Division of Enforcement. In addition, as the Berman Affidavit makes clear, the SEC could not have had all the information it now claims it possessed on April 23, 2020. Having not visited DECN's subsidiary Pharma Tech Solutions' website (Petitioner's sole Establishment registered with the FDA) until May 11, 2020, how could the SEC have known the site's content several weeks earlier, as now represented by Mr. Perkins? Yet this is what Mr. Perkins has now certified to under oath. As the Commission recognized in *Efuel Efn Corp., supra*, a determination of a deliberate misstatement "'certainly gives the [fact finder] sufficient reason to invoke the hoary doctrine of

falsus in uno, falsus in omnibus' – false in one thing, false in everything." 2019 SEC LEXIS 1663 at *21 (quoting *United States v. Connolly*, 504 F.3d 206, 216 (1st Cir.)). Application of this doctrine is particularly warranted given the significant weight Enforcement now seeks to attach to the comments Mr. Berman is alleged to have made or "suggested" during his voluntary interviews with the Division.

According to the Staff, during one of his interviews, Mr. Berman purportedly said or suggested various comments that the Staff now maintains supported the Trading Suspension Order. Not surprisingly, the Staff conveniently fails to identify what Mr. Berman is alleged to have stated as opposed to merely "suggested", or even during which of his two lengthy interviews the comments are claimed to have been made.[1]

Regardless, these comments, whenever made and however they were construed by the Staff, simply do not support a trading suspension. The claim that DECN did not have any convertible test kits (or prototypes) is hardly remarkable given the undisputed fact that the GenViro! test kits were proposed products awaiting FDA approval. For the same reason it defies reason (and prudent business practices) for a small company such as DECN to have pre-ordered the additional components the GenViro! kit meters required in advance of regulatory clearance. Mr. Berman's comments, whether stated or suggested, merely communicated the obvious. Logic and common sense compel the conclusion that nothing Mr. Berman is now alleged to have said to the Staff warranted the Trading Suspension Order.

CONCLUSION

For the foregoing reasons, the Petition of Decision Diagnostics Corp. should be granted and the April 23, 2020 Order suspending the trading of Petitioner's stock should be terminated.

[1] This is yet another reason why Petitioner is entitled to a hearing and the right to cross-examine the Staff.

Dated: White Plains, New York
June 17, 2020

Respectfully submitted,

GOLDBERG SEGALLA LLP

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CERTIFICATE OF SERVICE

Pursuant to Commission Rule of Practice 151, I hereby certify that true copies of the *Petitioner's Opening Brief in Support of Petition to Terminate Trading Suspension* were served on the following on this 17th day of June, 2020, in the manner indicated below:

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UNITED STATES OF AMERICA
BEFORE THE
SECURITIES AND EXCHANGE COMMISSION

ADMINISTRATIVE PROCEEDING
File No. 3-19788

In the Matter of DECISION DIAGNOSTICS CORP.	AFFIDAVIT OF KEITH M. BERMAN IN SUPPORT OF PETITION TO TERMINATE TRADING SUSPENSION

STATE OF CALIFORNIA)
) ss.:
COUNTY OF VENTURA)

I, **KEITH M. BERMAN**, being duly sworn states:

1. I am the Chief Executive Officer of Petitioner Decision Diagnostics Corp., a position I have held since September 2017.[1] From August 2006 through September 2017 I was the Principal Executive Officer of Petitioner. I submit this affidavit pursuant to the May 13, 2020 Order of the United States Securities and Exchange Commission (the "SEC" or the "Commission") to address the information that was purportedly before the Commission as of April 23, 2020 when the SEC issued Release No. 88735 ordering the temporary suspension of trading of the securities of

[1] Although totally irrelevant to the current proceeding, I am compelled to respond to the Commission's reference to an unsworn allegation against me made approximately twenty-five (25) years ago, and months after my separation as President of Access Health Net. The reason only a passing reference to me from a 1996 class action complaint is made is that, as the Division of Enforcement undoubtedly knows, I was dismissed as a defendant some two years before that suit settled in 1999, without any payment or other form of consideration. If anything, resorting to this tactic demonstrates the lack of any relevant basis for the suspension order which is the subject of this Petition. Additionally, during my first interview with SEC Staff on March 25, 2020, I was asked questions specifically about this suit, which I answered forthrightly.

Decision Diagnostics Corp. ("DECN") for ten (10) business days commencing April 24, 2020, and in support of DECN's petition to terminate the trading suspension.

2. As will be demonstrated, it is not possible that all the information identified in the May 20, 2020 Declaration of Carlise E. Perkins, Esq. (the "Perkins Declaration") as having been before the Commission as of April 23, 2020, was in fact available to the Commission at the time the trading suspension was ordered. Rather, the whole of this episode depicts an "investigation" filled with inaccuracies and untruths, pushed and twisted by a group of outsiders with no connection to the company who on the one hand committed sophisticated cybercrimes and on the other presented stolen documents and volumes of untruths, innuendo and concocted stories to SEC personnel, who exhibited a general lack of understanding of even the most basic functions of the Petitioner's business or its technology as well as elementary FDA policies and procedures for Establishment companies and applicants. As a result, the Perkins Declaration reads more like a series of internet message board posts, which we have seen and read all too often, rather than the basis for a trading suspension. What transpired here was largely concocted because these outsiders were looking to damage both the Petitioner and me directly and personally. This effort continues even today. For this and other reasons, including the Division of Enforcement's misrepresentation of certain filings DECN made with the Food and Drug Administration, the April 23, 2020 trading suspension order be terminated.

3. The sole substantive paragraph contained in the Commission's April 23, 2020 Order suspending the trading in DECN stock (the "Trading Suspension Order") reads as follows:

> The Commission temporarily suspended trading in the securities of DECN because of questions regarding the accuracy and adequacy of information in the marketplace since at least March 3, 2020. Those questions relate to, among other things, (i) DECN's statements claiming to have "technology perfected" to allow it to manufacture and sell a COVID-19 test kit that would provide results "in 15 seconds, based on a small finger prick blood sample," and (ii) DECN's sales forecasts for the COVID-19 test kit that up to 525 million test kits would be sold in the first year of production.

It has become very clear that these points were completely misunderstood by the Staff of the Enforcement Division ("Staff"). In addition, ample evidence exists which demonstrates that the Perkins Declaration contains information that could not have been known at the time the Trading Suspension Order was issued, which calls into serious question the veracity of statements made under oath by Mr. Perkins. Given the incontrovertible inaccuracies in the Perkins Declaration, Petitioner's counsel must, at a minimum, be afforded an opportunity to cross-examine both Mr. Perkins and other staff members (the recipients of the calls from non-shareholding message board posters) about the basis and sources of the information in the Perkins Declaration, as well as the Staff's efforts to determine the credibility and reliability of the information it was provided, which it appears was simply taken as gospel. Put simply and directly, Enforcement staff was misled by a group of outsiders, and the Staff has continued to direct its misguided efforts against Petitioner[2].

[2] On March 25, 2020 the Staff sent Petitioner a letter asking for among other things information about trading in DECN stock conducted by several individuals or entities. Petitioners responded that it lacked any such knowledge. Having identified particular individuals indicates the Commission must have suspected them of wrongdoing, but there is no indication this is being pursued. In addition, a FOIA letter to the Commission seeking this information has been ignored.

4. At the onset, it should be noted that the Trading Suspension Order was issued more than seven (7) weeks after alleged "questions regarding the accuracy and adequacy" of certain information concerning DECN appeared in the marketplace. No explanation of this inordinate delay has ever been provided. When it was finally issued, the Trading Suspension Order referred to only isolated statements from the detailed information contained in DECN's press releases regarding its proposed GenViro! test kits designed to assist in the detection of the Coronavirus that has for several months paralyzed the United States (and a number of countries worldwide), creating untold human and financial hardship. None of these statements, or any other information that may in fact have been in the Commission's possession prior to the issuance of the Trading Suspension Order, warranted the issuance of the trading suspension.

BACKGROUND FACTS

5. DECN is the leading manufacturer and worldwide distributor of diabetic test strips engineered to operate on legacy glucose meters. DECN has been manufacturing, distributing and selling its own brand of diabetic glucose test strips since early 2013, after having distributed diabetic test strips manufactured by legacy companies for approximately nine years. Petitioner has been an Establishment registered with the U.S. FDA for the totality of that time.

6. Legacy glucose meters are currently used by millions of diabetics worldwide. During my first interview with the Staff, conducted on March 25, 2020, I was asked numerous questions concerning Petitioner's business, and I explained what is described above in much greater detail. When I politely questioned the Staff about their knowledge of diabetic glucose testing directly, which is Petitioner's current business, Staff claimed that they had no idea what a diabetic glucose test strip was. After my follow up inquiry I explained that glucose test strips and devices are

used daily by between 20-25 million Americans, are sold primarily by four of the largest worldwide pharmaceutical companies and make up a multi-billion-dollar (some estimates are $20+ billion) medical device niche worldwide. The Staff's purported ignorance regarding these devices made further discussion of Petitioner's business difficult. Despite this claimed lack of knowledge concerning the fundamentals of Petitioner's business, the Staff nonetheless attempted to usurp the FDA's authority at a time Petitioner had multiple applications under FDA review in an attempt to obtain expedited clearance for its unique COVID testing products and an innovative diabetic test strip.

7. My involvement with this horrific virus begins in mid-February 2020, when I learned from a CNN news report of the outbreak of COVID-19 in Daegu, Korea (a/k/a Ground Zero), the location of DECN's diabetic test strip factory and research and development arm. Discussions with the company's technical advisors in Korea as well as Dr. Matthew Musho, an inventor and/or collaborator of approximately 32 patents in the United States and internationally, all of which relate to the family of technologies in use by the Petitioner, confirmed that DECN's impedance measurement technology, that had been used for red blood cell detection and blood glucose mathematical adjustment in blood glucose testing would require only certain modifications to be able to detect the presence of the COVID-19 virus. A preliminary analysis determined that the Company's DECN glucose detection and hematocrit correction technology could be used on a commercially viable basis to identify the presence of the Coronavirus. The fact that Petitioner had both the understanding and commercial use for this technology would (and did) cut months from the development time required for our Coronavirus detection products. Time obviously is of the essence in this deadly struggle.

8. Based on these determinations DECN filed Emergency Use Applications ("EUA") with the Food and Drug Administration, first on April 3, 2020 and then on May 1, 2020, for our proposed commercial professional and home use GenViro! test kits, respectively. Pre-EUA acknowledgments and, for want of a better term, device serial numbers were promptly received from the FDA and the GenViro! test kits are currently under FDA review. In addition, Petitioner has a new glucose test strip, itself an innovative technology under 510(k) review by the FDA.

THE MISREPRESENTATION OF INFORMATION
BEFORE THE SEC AS OF APRIL 23, 2020

9. According to the Division of Enforcement, a significant piece of information before the SEC as of April 23, 2020 was the picture of DECN's purported COVID-19 test kit, which, as stated in paragraph 16 of the Perkins Declaration, "looks identical to the Company's diabetes glucose test kit – marketed '4 Pets' listed on its website". However, the sworn assertion that this information was before the Commission as of April 23, 2020 is simply not accurate. The statement itself also lacks accuracy. Instead it reads like countless message board postings on the toxic environment of the Investors Hub internet message board, a place where I am maligned, libeled, and a place where outlandish stories (big lies) are conjured up daily.

10. DECN monitors who and when its website and the website of its wholly owned subsidiary Pharma Tech Solutions are accessed. DECN's records reflect that the SEC first visited Pharma Tech's website on May 11, 2020. This visit occurred approximately 2-1/2 weeks *after* the issuance of the Trading Suspension Order. See Exhibit A. There is no record of the Commission ever visiting Pharma Tech's website prior to May 11, 2020. The sworn statement that information contained on Pharma Tech's website was known to the SEC not later than April 23, 2020 is

demonstrably false, since no one from the SEC including from the Division of Enforcement had visited the Pharma Tech website by that date[3]. This raises the obvious question of what other false information is contained in the Perkins Declaration, since Enforcement's statement that the now challenged press releases "were also published on [Petitioner's] website" suggests at least repeated visits to Pharma Tech's website prior to April 23rd, which based on Exhibits A and B simply did not occur.

THE DECN PRESS RELEASES DID NOT CONTAIN ANY FALSE OR MISLEADING STATEMENTS

11. On March 3, 2020, DECN issued a lengthy press release which contained one of the allegedly false statements identified in the Trading Suspension Order. Specifically, the March 3rd press release stated that DECN had the "technology perfected" that would allow it to produce a COVID-19 test kit that would provide results "in 15 seconds, based on a small finger prick sample."

12. This statement, as well as the other snippets of the press releases now identified by the Division of Enforcement but which were not referred to in the Trading Suspension Order, was true when made, and the Division has totally failed to demonstrate that it had any information or reason to dispute these statements in any way. DECN's COVID-19 "technology" consisted of an evolution of the basic electrical impedance (EIS) technology that had by that time been used for

[3] It is also significant that on June 3, 2020, shortly after DECN brought this false assertion to the Staff's attention in a letter accompanying DECN's document production, the Staff suddenly undertook a second visit to the Pharma Tech website, this time for a total of approximately 13 seconds. The Pharma Tech website contains two web pages and a link to a product display. In neither of the two visits by the SEC staff did the visitor progress past Page 2. Page 1 bears the statement "Not for Sale in the USA or Puerto Rico. Emergency Waivers in Process" and page 2 bears the statement "**This product is currently still in development and not available for sale" in bold typeface and in red.** See Exhibit B.

over one year by the Petitioner to precisely count red blood cells that "leak" into a plasma glucose measurement. Petitioner's EIS technology was in fact "perfected," as attested to by thousands of tests completed which show unparalleled precision and accuracy in a diabetic test strip. This technology is also used in two different but important ways in Petitioner's GenViro! product. One way is nearly identical to Petitioner's blood glucose products. The second way EIS is used comprises the "secret sauce" in Petitioner's GenViro! product. What DECN has formulated is in fact a "new screening methodology" to detect COVID-19 that had not, and to this day has not, been offered by any other proponent of the virtually identical test kits that flooded the market once the scope of the COVID-19 pandemic became as widespread as I feared back in February. Moreover, as accurately stated in this press release, DECN's proposed test kit would in fact be "simple to use" (requiring only a simple finger prick, remember 20-25 million people, primarily diabetics, use this similar technology daily), as well as cost effective, since its results would be available almost immediately without the associated cost and delay (and potential errors and sample contamination) of remote laboratory or hospital involvement. None of these factual assertions have ever been challenged and, I submit did not factually or legally warrant the harsh remedy of a temporary trading suspension. To avoid any potential doubt in either the scientific or investment communities about DECN's proposed testing kit, the March 3, 2020 press release prominently stated, "We [DECN] have developed a Coronavirus screening method, not a cure or vaccine for this virus." If the Staff had legitimate questions about this press release they could have been addressed in my interviews. They were not.

13. Although not mentioned in the Trading Suspension Order, the Division of Enforcement suddenly claims to have taken exception, albeit ***sub silentio***, to the content of the press releases which DECN issued on March 11, 2020 and March 16, 2020 concerning its proposed GenViro! test kit.

14. The Commission now asserts that DECN's "apparently baseless" March 11, 2020 sales projection of 420 Million COVID-19 test kits in the first year of production was before the Commission when the Trading Suspension Order was issued. While this press release predates the Trading Suspension Order by over a month, the lack of any reference to it in the order calls into serious question Enforcement's current assertion that this release factored into the decision to issue the Trading Suspension Order.

15. There is no suggestion or indication that this forecast was anything other than DECN's good-faith projection of the significant demand the unique COVID-19 test kit would be expected to command upon FDA emergency use authorization being secured. This projection was in fact based on the analysis of the anticipated need for an accurate test kit that would provide immediate and reliable results, both of which are essential to enable commercial institutions to resume anything that would approach normal operations.

16. The Division of Enforcement further disputes for lack of supporting evidence the statement that DECN's COVID-19 test kits "should allow 80% of the suspected carriers of Coronavirus to exit the quarantine system in places where Coronavirus is rampant." However, this statement is fully supported by facts, data and information in anecdotal literature, interviews with public health officials (Federal, State and local) and in the media, that at that time specifically stated that only a small number of persons tested would expected to be confirmed positive for the Coronavirus, while the remaining non-positive persons would be able to leave the testing

environment and resume relatively normal lives. Once again, the Division of Enforcement has failed to provide any basis for questioning this factual statement. If the Division of Enforcement had a legitimate concern about this statement, it would have been a simple task to ask me for the basis for it. Their failure to do so suggests to me they did not want to receive this information or for that matter anything exculpatory.

17. Enforcement now makes the remarkable assertion that the pictured kit for the proposed COVID-19 test kit included in the March 11, 2020 release appeared identical to DECN's well-established glucose testing product line. How packaging for a prototype that contains the prominent disclaimer "Not yet available for sale in U.S.A. or Puerto Rico" can be deemed to endanger the public interest and require the protection of investors simply because it bears a visual similarity to one of DECN's existing commercial products is impossible to comprehend. More significantly, it is the task of the FDA to monitor and enforce these types of issues, (the FDA to date has not), not the SEC. In fact, this whole series of events seems fabricated in order to justify the Staff's handling this investigation. Regardless, this certainly does not support or warrant a trading suspension. Rather it appears that the false and inflammatory topics on the toxic-like discourse on the Investor's Hub message board have unfortunately "bled" into the Perkins Declaration, which is devoid of reality. The full extent to which the Staff allowed this to occur can only be determined by the cross-examination of the Staff at a hearing.

18. While the Division of Enforcement and the Commission also admittedly had access to DECN's March 16, 2020 press release prior to the Trading Suspension Order, the portions of this press release that are now quoted by Enforcement in its May 20th submission also cannot be deemed to support the grounds for a suspension. The statements that the proposed COVID-19 test kit could produce results "through a finger-stick" in "less than one minute" are completely accurate

and have never been challenged by the Staff. The statement announcing DECN's anticipated filing of an Emergency Use Authorization ("EUA") with the FDA upon the completion of testing was also accurate; in fact, such an application was filed on April 3, 2020, shortly after the issuance of this press release. See Exhibit C (EUA Acknowledgement Letters for GenViro! COVID-19 Screening Kit and GenViro! Swift Home COVID-19 Kit). The expectation of 200,000 kits being available in the United States and Canadian markets by May 2020 was based on the expected expedited approval by the FDA of DECN's EUA, which despite DECN's efforts, has not yet been received.

19. The second (and final) item identified in the Trading Suspension Order is the statement contained in DECN's March 17, 2020 release in which the Company increased its sales forecast to up to 525 million test kits during its first full year of production. As acknowledged by Enforcement Staff, all DECN's forward-looking projections were derived from an analysis of various institutional market segments that would be expected to purchase the test kits once they could be sold in various countries worldwide. Major markets segments in the USA for the Petitioner's GenViro! kit include pharmacies, clinics, hospitals, physician group practices, dental practices, houses of worship, reopening businesses and sports facilities among others. It defies belief that a good faith review of this projection would have created legitimate questions, particularly in view of any known competitive point of care swift testing kit.

HACKING AND OTHER ILLEGALITIES BY NON-SHAREHOLDING INDIVIDUALS WHO CONTACTED SEC STAFF AND SOLD THEM ON LIES, INNUENDO AND FALSEHOODS THAT RESULTED IN THE TRADING SUSPENSION ORDER AND EVENTUALLY THE PERKINS DECLARATION

20. Petitioner strongly believes that the Staff, including Mr. Perkins, have been in regular contact with non-shareholding individuals who have provided false information with the intent to damage DECN and me personally. These individuals, for unknown reasons, have continuously threatened the company, many for at least 2 years, several for over 10 years. None of these individuals, who try to hide behind various user names are currently shareholders in the Company. Whatever their actual motives may be, they certainly are not legitimate. Unfortunately, their misguided efforts have to date met with success.

21. In early May 2020, a screengrab of what appeared to be the Petitioner's coronavirus GenViro! product page from the Phama Tech Solutions website appeared on an Amazon Web Services (AWS) account. This 'slide' identified GenViro! as 'FDA Approved'.

https://s3.amazonaws.com/bbemail/PROD/ulib/3d0u1e/img/gVFDA_approved.png

It was immediately clear that the slide did not come from the Pharma Tech website (for, among other reasons, the company never has had an AWS account) but appeared to have been removed, e.g. 'hacked' (stolen) from the Pharma Tech private file structure, where it was maintained in 'read only' format. Around the same time, numerous posts appeared from the same non-shareholders, purporting that the screengrab was authentic, and that the Company was misrepresenting the FDA status of GenViro! The slide was actually an unfinished work product, which was removed illegally (stolen) from the company's internal, non-public database, traded among this group and then (according to the individuals themselves) provided to the SEC.

22. Admissions of this cybercrime as well as repeated lies concerning the documents' authenticity can be found in the links below to Investors Hub message board posts from the user 'Johnny_C':

A https://investorshub.advfn.com/boards/read_msg.aspx?message_id=155536304

B https://investorshub.advfn.com/boards/read_msg.aspx?message_id=155533755

C https://investorshub.advfn.com/boards/read_msg.aspx?message_id=155542978

D https://investorshub.advfn.com/boards/read_msg.aspx?message_id=155533324

23. The company also strongly believes one or more of these non-shareholders contacted the Staff and misrepresented that this artwork was obtained directly from the Pharma Tech website. However, since this was housed in a non-public facing file folder, this was not possible. An example of this contact can be found in the link below to an Investors Hub message board post from the user 'rawman', who claims to have provided this "information" to the SEC.

https://investorshub.advfn.com/boards/read_msg.aspx?message_id=155533585

24. The Company finds this criminal behavior both abhorrent, and unfortunately, predictable from these individuals. What is extremely troubling however, is it appears that that the Staff took this illegally obtained information, as well as additional information (lies and smears) provided to them and used it without even the most basic verification, to support the Trading Suspension Order as well as additional document demands to coincide with the expiration of the 10-day suspension. As stated previously, information that was or purported to be on Pharma Tech's website could not have been known to Enforcement Staff or Mr. Perkins as of April 23,

2020 through any legitimate means, but the Perkins Declaration states, under penalty of perjury, the contrary.

STATEMENTS CONCERNING DECN'S FDA FILINGS

25. In an effort to uphold the Trading Suspension Order, the Division of Enforcement has now misrepresented both the timing and substance of DECN's press releases concerning its EUA applications for its proposed COVID-19 test kits. Moreover, as with DECN's other releases, the information concerning the EUA applications was completely accurate.

26. According to the Staff, in press releases issued in late March and early April, DECN claimed to have filed an EUA with the FDA. However, DECN did not file for an EUA until Friday, April 3, 2020, which filing was announced on Tuesday, April 7, 2020. DECN never claimed to have filed an EUA in March as Enforcement now states, as is made clear by the Company's March 23, 2020 announcement stating: "Company's Emergency Use (EUA) application to be updated in the next week as manufacturing specifications are finalized..." (emphasis added).

27. While the March 23rd press release expressed DECN's gratitude that its pre-EUA application had been acknowledged in less than twenty-four (24) hours, nothing in the release can even subjectively be construed as "touting" this as a "huge development akin to FDA approval of the test kits" as Enforcement now asserts. No credible interpretation of a pre-Emergency Use Application can in any way be deemed "akin to FDA approval," and nothing DECN said in any way even remotely supports this interpretation. In fact, EUA applications, if successful, are not "approved" (drugs are approved) they are "authorized." Given the clear and unambiguous

language of this release, no reasonable investor could be deemed to have come to the unsupported assertion now advanced by the Division of Enforcement.

BERMAN'S INTERVIEWS WITH THE SEC

28. I was interviewed by Staff for approximately three hours. The first interview occurred on or about March 25, 2020 during which I, unaccompanied, spoke to the Enforcement Staff for slightly less than one hour and answered all of their questions.

29. On April 13, 2020, following the retention of counsel, I spoke to the Staff for approximately two hours, during which I again answered all of their questions. The second interview was cut short by the Staff due to their prior commitment. At the Enforcement Staff's request, I agreed to make myself available for a third interview, but the Enforcement Staff never scheduled this interview. Instead the Commission initiated the Trading Suspension Order.

30. The Staff now maintains that I "stated or suggested" various information that contradicted certain information in Petitioner's press releases. I believe this was done in significant part to cover Enforcement's tracks, based on false information Enforcement received approximately one month after my second interview, which information the Staff appears to simply have accepted as gospel. I strongly dispute the majority of the adverse inferences Enforcement has now suggested from what I am alleged to have "stated or suggested. Lacking any documentary basis for the Trading Suspension Order, Enforcement has been forced to resort to either fabricating or taking completely out of context my comments.

31. I inferred nothing in either the first or second interview. Inferring is not how I communicate. I am direct, forthright, knowledgeable and honest.

32. I am responsible for Petitioner's Covid-19 products. I am also the products Program Manager. I was responsible for communicating its design and function as well as managing its upcoming commerce. The scientists in Pennsylvania, Dr. Musho and his wife Leslie, the engineers and clinical chemists in Korea, all take their direction from me. Business associates (although obviously not persons who infest the Investors Hub message board) and colleagues often tell me I am too forthright. The Staff, to satisfy its own agenda, has been quite the opposite.

33. During my second interview with the Staff the vast majority of questions were asked by Enforcement counsel Lesley Atkins. Ms. Atkins asked her questions based on the various press releases starting on March 3, 2020, tracking her questioning on the SEC document request letter of March 25, 2020. Ms. Atkins questions generally were in chronological order. During the scheduling of the second interview Mr. Perkins stated that the interview itself would replace the document requests made in their March 25, 2020 letter.

34. In a final effort to justify the Trading Suspension Order the Staff now identifies several remarks I am alleged to have "stated or suggested" during the two lengthy telephonic interviews I voluntarily agreed to. Conveniently, the Staff fails to distinguish what I am alleged to have stated as opposed to merely "suggested", or even the particular interview during which these comments were purportedly made.

35. Disregarding these significant omissions, in Mr. Perkins' May 20, 2020 sworn Declaration, nothing I am now alleged to have communicated during these interviews supports the Temporary Suspension Order. Both the commercial and home versions of the proposed GenViro! test kits are developmental products that require regulatory approval before they can be sold in various countries, including the United States. Although the technology currently

being utilized for glucose testing was determined after a slight modification to be applicable for the GenViro! test kits, a small company with limited resources like DECN could not simply rush into production in the hope that regulatory approval would be forthcoming. This risky strategy might be an option for a Johnson & Johnson or a Merck, but not for DECN.

36. The fact that DECN did not have any test kits (or prototypes) available at the time I was interviewed by the Staff is hardly remarkable; in fact, any assertion to the contrary would correctly be deemed to lack credibility. For the same reason the pre-approval absence of a purchase order for the modified component parts that will be required once regulatory approval is secured can only be viewed as prudent business practices for a company such as DECN. In addition, neither of these two issues were ever discussed, inferred, stated or suggested in either of my two interviews. They were, however, discussed at great length, repeatedly, during the months of April and May on the Investors Hub message board.

37. The examples in the above sections clearly illustrate the situations where the Enforcement Staff has resorted to arguments based on nothing more than repeated message board posts by non-shareholders. The fact that there were repeated posts containing these statements do not make them true, accurate or for that matter important. However, the Staff has chosen yet again to treat them as gospel without first making an effort to verify their veracity.

38. In short, there is nothing I said or "suggested" about a proposed product that is awaiting FDA approval that could in any way be deemed to have afforded the Staff a reasonable basis for concluding that a Trading Suspension Order was warranted.

39. If the Commission is prepared to afford any credence to what I am alleged to have "stated or suggested", the Perkins Declaration provides no such basis, just statements and many untrue words, such as 'infer'. Ad previously noted, Mr. Perkins does not even attempt to identify during which interview these suggestive comments were made.

SUMMARY

40. In conclusion, the Company has outlined and explained in detail the following points which warrant not only further investigation into the origins of various information contained in the Perkins Declaration, but the issuance of an order terminating the Trading Suspension Order:

A. Various examples of information that could not have been known at the time of the Trading Suspension Order but have somehow found their way into the Perkins Declaration, and the apparent attempt by the Staff to bolster their case for the suspension after the fact. This, and this alone, should be grounds for an immediate order vacating the Trading Suspension Order, as well as further investigation by the SEC into the origins and motivations of such behavior.

B. A complete lack of understanding by Mr. Perkins and the Staff with respect to the Petitioner's basic business processes and products, and by extension, the technology behind GenViro!. A dialogue with the FDA would quickly have demonstrated the bona fides of GenViro!; instead the SEC appears intent on usurping the FDA's authority. Additionally, the Staff had even less of an understanding of the basic FDA concepts with respect to the current and dire COVID-19 pandemic, specifically the difference between submission of and EUA,

and FDA authorization. However, they identified these 'issues' in the Perkins Declaration as deficiencies by the Company.

C. The apparent concerted activity between the Staff and non-shareholder message board posters who provided the SEC with false information specifically intended to damage the Company and me. Rather than contact the Company or investigate for themselves, or simply access the Pharma Tech website to ascertain what it actually contained, the Staff chose to accept this information as true and use it to further damage the Company.

D. The assertion by Mr. Perkins and Staff that during multiple interviews, Mr. Berman made statements 'asserting' or 'inferring' things that simply were not stated and did not happen.

41. Although this does not appear to be an issue that the Staff is exploring, for the record I want to make it clear that I have not directly or indirectly purchased, sold or been issued any DECN stock at any time during 2020.

Keith M. Berman

Sworn to before me this
17 Day of June 2020

Notary Public

DANIKKA MORRISON
COMM. #2245978
Notary Public - California
Los Angeles County
My Comm. Expires June 14, 2022

EXHIBIT A

(Extract from StatCounter Tool)

Pharma Tech website

Page Views: 1	Total Visits: 1
Exit Time: May 11 2020 08:43:02 AM	Location: Arlington, Virginia, United States
Resolution: 1920x1080	IP Address: U.S. Securities & Exchange Commission (162.138.200.3)
System: Chrome 81.0 Win10	Referring URL: (No referring link) Visit Page: www.pharmatechsolutions.co/genviro.html

EXHIBIT B

(Extracts from StatCounter Tool)

Pharma Tech website

Jun 3	10:24:18 AM	Chrome 83.0 Win10 1536x864	Arlington, Virginia, United States/ en-us	U.s. Securities & Exchange Commission (162.138.200.3) www.pharmatechsolutions.co/genviro.html https://www.google.com/

Decision Diagnostics website

Page Views:
3 (2 this visit)
Exit Time:
Jun 3 2020 10:26:24 AM
Visit Length:
26 seconds
Resolution:
1536x864
System:
Chrome 83.0
Win10

Total Visits:
2
Location:
Arlington, Virginia, United States
IP Address:
U.S. Securities & Exchange Commission (162.138.200.3)
Referring URL:
(No referring link)
Entry Page:
www.decisiondiagnostics.co/extra.html
Exit Page:
www.decisiondiagnostics.co/extra.html

EXHIBIT C

Acknowledgment Letter

4/4/2020

Lisa Pritchard, Regulatory, Quality & Compliance Consultant
DUVAL & ASSOCIATES, P.A.
825 NICOLLET MALL, SUITE 1820
MINNEAPOLIS, MN 55402
UNITED STATES

Dear Lisa Pritchard:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: PEUA200323
Received: 4/3/2020
Applicant: Pharma Tech Solutions, Inc.
Device: GenViro!(TM) COVID-19 Screening Kit

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Acknowledgment Letter

5/2/2020

Lisa Pritchard
DuVal & Associates, P.A.
825 Nicollet Mall, Suite 1820
Minneapolis, MN 55402
UNITED STATES

Dear Lisa Pritchard:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: PEUA200947
Received: 5/1/2020
Applicant: Pharma Tech Solutions, Inc.
Device: GenViro! Swift Home COVID-19 Test

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

CERTIFICATE OF SERVICE

Pursuant to Commission Rule of Practice 151, I hereby certify that true copies of the *Affidavit of Keith M. Berman in Support of Petition to Eliminate Trading Suspension*, were served on the following on this 17th day of June, 2020, in the manner indicated below:

By Email:

Office of the Secretary
Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549-2557
apfilings@sec.gov

David Misler, Trial Counsel
Carlisle Perkins, Senior Counsel
Lesley Atkins, Senior Counsel
Securities and Exchange Commission
Division of Enforcement
100 F Street, N.E.
Washington, D.C. 20549-5041
Mislerd@sec.gov
PerkinsC@sec.gov
AtkinsL@SEC.gov

/s/ Ronald S. Herzog

UNITED STATES OF AMERICA
BEFORE THE
SECURITIES AND EXCHANGE COMMISSION

ADMINISTRATIVE PROCEEDING
File No. 3-19788

In the Matter of .

DECISION DIAGNOSTICS CORP. **AFFIRMATION**

RONALD S. HERZOG, an attorney duly admitted to practice in the State of New York, hereby affirms under penalty of perjury:

1. I have been counsel to Decision Diagnostics and Keith M. Berman since on or about April 6, 2020 in connection with this informal investigation being conducted by the United States Securities and Exchange Commission. I submit this affirmation to address the statement contained in Paragraph 26 of the May 20, 2020 Declaration of Carlise E. Perkins, Esq. that "DECN did not produce documents substantiating its press releases and the FDA EUA application, although the Staff requested them."

2. On April 7, 2020, I discussed with Mr. Perkins the information the Commission had requested from Decision Diagnostics in its letter to the company of March 25, 2020. During that conversation, Mr. Perkins advised me that the company did not have to respond to this request as the Staff had instead elected to conduct a follow-up telephone interview of Mr. Berman. That interview was promptly scheduled and conduct on April 13, 2020, lasting nearly two hours during which Mr. Berman answered all the Staff's questions. Following this interview, the Staff served

a new request for documents, which Decision Diagnostics has been complying with on a rolling basis.

3. In view of the agreement I reached with Mr. Perkins, there is no basis for the suggestion in his declaration that Decision Diagnostics has in any way failed to cooperate with the Commission's investigation. Cf. *Bravo Enterprises, Ltd.*, Securities Exchange Act Release No. 75775, 2015 SEC LEXIS 3597, at *49 Fn. 66 (Aug. 27, 2015).

Dated: White Plains, New York
June 17, 2020

/s/ *Ronald S. Herzog*
Ronald S. Herzog

CERTIFICATE OF SERVICE

Pursuant to Commission Rule of Practice 151, I hereby certify that true copies of the *Affirmation of Ronald S. Herzog, Esq.*, were served on the following on this 17th day of June, 2020, in the manner indicated below:

By Email:

Office of the Secretary
Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549-2557
apfilings@sec.gov

David Misler, Trial Counsel
Carlisle Perkins, Senior Counsel
Lesley Atkins, Senior Counsel
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Mislerd@sec.gov
PerkinsC@sec.gov
AtkinsL@SEC.gov

/s/ Ronald S. Herzog