

PUBLIC SUBMISSION

As of: 12/7/20 6:39 PM Received: December 03, 2020 Status: Posted Posted: December 07, 2020 Tracking No. 1k4-9kg3-gwpm Comments Due: December 03, 2020 Submission Type: API
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Docket: PTO-C-2020-0055

Request for Comments on Discretion to Institute Trials Before the Patent Trial and Appeal Board

Comment On: PTO-C-2020-0055-0001

Discretion to Institute Trials Before the Patent Trial and Appeal Board

Document: PTO-C-2020-0055-0828

Comment from Tracey Kennedy

Submitter Information

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General Comment

As a disruptive nurse inventor from the State of Ohio. I am the creator of a design patent for a redesigned patient gown (#D781 528) and the author of the summary and paper of The Reverse-Engineered Patient Gown; Magnetic Connections for Viable Solutions in the Delivery of Safe Care. I am contacting you to consider stricter regulations to support inventors to further regulate well-known nursing innovation competitions and large corporations when a competition paper falls outside the boundaries of the competition and is shared with other industry leaders and what I feel violates inventor rights. It is unacceptable when peer reviewers do not follow rules and have no regard for business conduct, ethics, and fairness and this should be considered patent infringement; 2) a copyright violation which should be an infringement when the same paper is submitted from an academic institution and is respun from the "trolling" industry and industry executives take credit by quoting phrases from the inventor's competition paper and blog without permission from the inventor; 3) identity theft which should be considered an infringement when the design is copied, tested, and sold in the marketplace as the design concept and blueprint was never intended to go outside the limits of the competition(s).c These

nursing competitions exploit the weaknesses of the inventor during discovery to have a competitive advantage without the peer reviewers or the company they represent being disclosed to the inventor.

I urge the adoption of regulations to govern the discretion to institute PTAB trials consistent with the following principles.

I: PREDICTABILITY

Regulations must provide predictability. Stakeholders must be able to know in advance whether a petition is to be permitted or denied for policy reasons. To this end regulations should favor objective analysis and eschew subjectivity, balancing, weighing holistic viewing, and individual discretion. The decision-making should be procedural based on clear rules. Presence or absence of discrete factors should be determinative, at least in ordinary circumstances. If compounded or weighted factors are absolutely necessary, the number of possible combinations must be minimized and the rubric must be published in the Code of Federal Regulations.

II: MULTIPLE PETITIONS

- a) A petitioner, real party in interest, and privy of the petitioner should be jointly limited to one petition per patent.
- b) Each patent should be subject to no more than one instituted AIA trial.
- c) A petitioner seeking to challenge a patent under the AIA should be required to file their petition within 90 days of an earlier petition against that patent (i.e., prior to a preliminary response). Petitions filed more than 90 days after an earlier petition should be denied.
- d) Petitioners filing within 90 days of a first petition against the same patent should be permitted to join an instituted trial.
- e) These provisions should govern all petitions absent a showing of extraordinary circumstances approved by the Director, Commissioner, and Chief Judge.

III: PROCEEDINGS IN OTHER TRIBUNALS

- a) The PTAB should not institute duplicative proceedings.
- b) A petition should be denied when the challenged patent is concurrently asserted in a district court against the petitioner, real party in interest or privy of the petitioner, and the court has neither stayed the case nor issued any order that is contingent on the institution of review.
- c) A petition should be denied when the challenged patent is concurrently asserted in a district court against the petitioner, real party in interest or privy of the petitioner with a trial is scheduled to occur within 18 months of the filing date of the petition.
- d) A petition should be denied when the challenged patent has been held not invalid in a final determination of the ITC involving the petitioner, real party in interest, or privy of the petitioner.

IV: PRIVY

- a) An entity who benefits from invalidation of a patent and pays money to a petitioner challenging that patent should be considered a privy subject to the estoppel provisions of the AIA.
- b) Privy should be interpreted to include a party to an agreement with the petitioner or real party of interest related to the validity or infringement of the patent where at least one of the parties to the agreement would benefit from a finding of unpatentability.

V: ECONOMIC IMPACT

Regulations should account for the proportionally greater harm to independent inventors and small businesses posed by the institution of an AIA trial, to the extent it harms the economy and integrity of the patent system, including their financial resources and access to effective legal representation.

Attachments

TK cover letter ANA 1-13-2020

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January 15, 2020

American Nurses Association/BD, USA

Subject: Nurse Innovation Competition 2019

Reference: Article Spinning

Dear ANA/BD/Siemens Nurse Pitch Administration:

I am contacting you to inform you of major concern after entering the 2019 ANA Nursing Innovation competition. Before I begin, I would like to state after being a nurse for thirty years, I have great respect for the ANA for being a premier organization and leader to improve the quality of healthcare. I entered the ANA's innovation competition to make patients' lives better in times of extreme conditions with the opportunity to challenge the ideas of mainstream thinking. I wanted to make meaningful and measurable change in the patient experience by redesigning the patient gown (The Old is New Again) as a nursing leader with a vision and a strategy to blaze a new trail of nursing innovation.

I submitted my entry timely which was entitled, The Reverse-Engineered Patient Gown; Magnetic Connections for Viable Solutions in the Delivery of Safe Care. My paper offered solutions to the most challenging problems with the current traditional patient gown and generated trail-blazing new ideas for the development of an alternative and improved patient gown which has not been realized. I consider myself to be the mother of a new generation of patient gowns redesigned in mutual cooperation with the ecosystem to transform original ideas into a modern-day framework. The framework consisted of the impact of the sustainability of the environment (Oeko-Tex Standard 100), the principle of reverse-engineering, my love for art (design thinking), and the development of scientific fact of patient-centric vertical integrations, such as wearables and other items to mitigate risk to create a paradigm shift. The disruptive care design and combined elements are extraordinary. My redesigned patient gown has the potential to affect the lives of many in unexpected ways and to complement life-saving strategies but has reached corporate healthcare textile companies within the United States without my knowledge.

As I was preparing for the 2020 competition, I discovered an article titled: The Evolution of the Patient Gown, Part 1 and 2 which was published in March 2019. I feel strongly the language was likely received and spun from my competition paper/nurse pitch entry. Some of the information was probably used from articles from my blog (www.patientgownredesign-cii.com). I assume I have an unidentified "follower(s)." My competition paper had not been released to my blog as it entailed the details of my redesign for the competitions. More specifically, the design, material used, and a new process of certified laundry was cleverly described in the articles. They highlighted the

importance of the evolution of the patient gown in simple textile language and mentioned the healthcare textile industry's adoption to enact change after all this time. There was a discussion of the conclusions from the cost-benefit analysis conducted but no mention of the current way in which business was currently conducted. The articles supported how they suddenly stumbled upon "new discoveries." Why the sudden change? I had mixed feelings. Could someone have finally realized the relevance of my work? The possibility to realize the shift of American manufacturing capabilities to boost the economy? To meet patient goals of healthy, progressive alternatives to improve and maintain health while achieving superior patient care and outcomes? I realized change can be difficult, but sometimes you have to dream the unimaginable if you want something different to occur. I found opportunities where no one else seemed to be looking....

Therefore, it is not clear how my confidential competition paper with its bold and authentic approach to drive change arrived in so many other hands outside of the boundaries of the competition. I question the timing, a similar framework, and the launching of the article with no credible source as these items seemed highly improbable.

I am respectfully requesting at this time an investigation into the processing of IP and CBI as I did not grant authorization as the submitter of the work cited above to be used without my permission. I did request the strong support of an ally/mentor to be able to finish a project dear to my heart in the conclusion of my paper. I do not find it satisfactory for a writer to respin my article when an authentic work and God-given talent could be used for the right purposes.

A new care redesign is a chance to transform the future of healthcare; time, technology, and a different theory can achieve clinical needs and financial success simultaneously in the types of gowns that can be manufactured given the willingness to adapt. Consumers have the right to choose wisely as we are in a time of rising expectations in which economic forces are very powerful and the marketplace has been desperate for change. I did reach for an opportunity to shatter rudimentary thinking to make it a priority to build a better patient gown alongside a strong ally with a common goal to create high-performance garment(s) for patients in various settings. Unfortunately, I was not privileged to have received an invitation to complete a dream, be recognized, or given the chance to provide a better life for patients, for my contribution to the environment, or my family.

In my humble opinion, American Healthcare textile has spent an exorbitant amount of resources having professionals in design and textiles attempting to redesign a medical device (mainly focusing on design only) when an opportunity existed within the scope of the NURSING profession. A collaboration with nursing may have resulted in the development of unique, trendy, and much needed redesigned products. I have dedicated my life to caring for, honing my skills, using quality management principles, and advocating for patients to arrive at this end-point. Leonardo da Vinci stated, "to develop a complete mind: study the science of art; study the art of science; learn how to see." The FDA should consider changing the category of the patient gown as science emerges. Patients want nurses to care for them, to meet their needs in time of illness or injury, and to be treated with compassion.

Certainly, I should not be overlooked as a woman in science and deserve to take my rightful place in society and will advocate for my rights. I have struggled to reinvent myself through-out my career, I obtained my BSN after beating stage III breast cancer, and the best should be yet to come. I have been advocating as the VOICE of patients on my blog by blazing a new trail of innovation through wisdom, operational efficiencies, and evidenced-based research which was reflected in my research paper. Besides, science and life cannot be separated as all things are connected

Regrettably, I do not find it acceptable to not be treated as a leader in healthcare innovation or as an independent health care professional in the industry news impacting patient outcomes and innovation. My breakthrough ingenuity crosses several industries. Compassion, independent thinking, passion, and autonomy is not a chance for others to benefit from a decade-plus of hard work and research of another, it is simply unethical. I am not invisible and this imbalance as a woman of science is disturbing. In addition, copycat designs being tested on the market is harsh and damaging. I refuse this injustice and not to be represented in the decision making of such a large project in which I am the author and creator is unacceptable. Everything considered nurse(s) should not be undervalued when considering this project. It is also destructive to the image of the professional nurse having others outside our profession create a product that should make a difference in the lives of patients every day! The individuals closest to the patient and the care delivery process.

In conclusion, I have expressed my frustration through-out this letter. I will continue as a nurse entrepreneur to advocate for the Inventor's Rights Act (H.R. 5478) which creates protection for inventor owned ideas and inventor rights. Disappointingly, you will not receive a submission for your 2020 Innovation competition but are clear on my position. I would ask for a response to my letter as this has caused a great deal of heartbreak and remorse for me. I wish for ANA to also consider a category for innovation for emerging technology/innovation for current and future submissions, a list of peer reviewers to be declared for those entering the competition, and rigid review and protection/security of IP to prevent reoccurrence. Finally, I wish you to consider the image of nurses as they contribute to the global economy and the cruel impact on the nursing profession when these types of actions occur.

#BuildABetterPatientGown #NurseLeader#CreativeThinker#ChangeMaker
#NurseImage2020 #OhioNurseInventor

Regards,

Tracey L. Kennedy

Tracey L. Kennedy, BSN RN