IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	A. Christian Tahan	Examiner:	Sharon M. Davis
Application No:	13/665,928	Art Unit:	3646
Filing Date:	October 31, 2012	Conf. No.:	1043
Title:	System for generating particles		

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P. O. Box 1450
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DECLARATION OF A. CHRISTIAN TAHAN UNDER 37 C.F.R. § 1.132

I, A. Christian Tahan, hereby declare as follows:

1. I am the sole inventor of the subject matter in U.S. Patent Application Serial No. 13/665,928 (hereinafter "the 928 application"), which is entitled "System for Generating Particles". I make this Declaration in support of the 928 application.

2. I received Bachelor degrees in Biology, Chemistry, and History from the College of Charleston in 1996. I am currently the Chief Scientist at the organization ETHERMED in the Department of Research and Development focusing on numerous projects, e.g., energy and isotope generation. I am currently also a Fellow of the Overseas Trust/Society at the University of Cambridge. Prior to my present ETHERMED role, I served as its CEO and COO. I have also been a Fellow at the National Institutes of Health, and a Visiting Scholar and Affiliate at the Health Sciences and Technology Department at the Massachusetts Institute of Technology (MIT) and Harvard University. When working at the above organizations, I have been a researcher focusing on life and physical sciences research and have gained experience with analytical methods that include NMR, MRI, X-ray crystallography, and inductively coupled plasma mass spectrometry (ICP-MS) that are commonly used in physical science research including nuclear physics and isotope production.

3. Overall, I have over twenty-five years research experience that includes my present work at the organization ETHERMED. My life and physical sciences research includes neuroscience, chemistry that includes analytical chemistry that uses various analysis methods, biochemistry that includes cell biology and cancer research, drug delivery that includes polymer development and studies. During these physics researches, I have utilized various methods of analyses and detections (e.g., Germanium and scintillation detectors (spectrometers), and mass spectroscopy) that are used in radioisotope production. My experiences also include giving presentations on isotope production at an American Chemical Society national meeting, working with different analytical technologies (such as spectrometers and Ge detectors) and different analysis software to identify manufactured isotopes, working with software and technology distributers to examine improvements of technology for isotope analyses, working with radiation safety advisors regarding safety measures for isotope production (including isotope production by the present invention), building and managing teams to manufacture and market the present invention and related produced isotopes, working with potential investors to understand markets and research sectors for the present invention (e.g., including medical research and veterinary care such as using isotopes produced from the invention for cancer treatments), and working with business professionals (including stock market chairmen in the U.S. and South Africa) for the manufacture and sale of the present invention and isotopes produced therefrom. I am the inventor of three US patents in the field of record communications, one South African patent in the field of energy and particle and isotope productions, and have seven peer-reviewed publications involving nuclear physics. I am also working on additional papers that are presently being peer-reviewed or will be peer-reviewed because use of the invention as described in the Specification has allowed for data collection and conclusions of isotope production. All in all, I have more than twenty years experience in the research and development of generating isotopes.

4. I have been advised and understand that, in the final Office action bearing the mail date of January 16, 2020 ("Final Office Action"), the pending claims in the present application are rejected on the ground that the invention is inoperative and therefore lacks utility. I have been asked to corroborate certain disclosure made in the '928 application and provide comments on certain statements made by the Examiner in the Final Office Action.

5. In forming this report, I considered the '928 application, the Tc-99m data I obtained for the '928 application, the Final Office Action, the file history of the '928 application, and the state of the art for the synthesis of isotopes as of January 28, 2009, based on my 20 years of experience as a researcher in the field of nuclear physics and radioisotope production.

6. The pending claims in the '928 application are directed to a system for generating an isotope. The system includes (1) a holding vessel that includes a hydrogen source (e.g., sulfuric acid) and a first isotope (e.g., molybdenum (Mo)), (2) a magnet having a first magnetic pole and a second magnetic pole that define a magnetic field, the holding vessel being disposed between the first and second magnetic poles such that the hydrogen source is disposed within the magnetic field of the magnet, and (3) a frequency source that is arranged and configured to produce an electronic signal having a frequency and amplitude capable of converting the first isotope to a second isotope (e.g., technetium-99m (Tc-99m)), in which the frequency source is electrically coupled to the particle source within the holding vessel.

7. In the Final Office Action, the Examiner asserts that "[t]here is no known mechanism for a hydrogen-based nuclear reaction in the present invention to produce neutrons .... Simply put, it is categorically impossible for the present invention to operate as disclosed and as required by the claims to generate an isotope[]." *See* page 9, paragraph 26.

8. However, as mentioned in paragraph 5 above, the claimed invention is directed to generating a second isotope (e.g., Tc-99m) from a first isotope (e.g., Mo). Prior to the filing of the '928 application, I participated in the experiment described in the paragraph bridging pages 13 and 14 of the '928 application as originally filed, which demonstrates that the claimed invention successfully achieved the above objective. In particular, an example system of the claimed invention was used to generate isotope Tc-99m and was tested in a scintillation spectrometer in the cyclotron lab by Prof. John A. Correia at the Massachusetts General Hospital (MGH). Prof. Correia's biography can be found at http://gordon.mgh.harvard.edu/gc/people/faculty/jack-correia/.

9. Specifically, I tested example systems of the claimed invention with one example system using a sample containing 20 mL of 96-98% sulfuric acid and 3.5 g of stable Mo powder in a graphite tube (Crucible, Saed/Manfredi G40, 1.5"OD x 1.25"ID x 3.75"DP) in the example system. The stable Mo used in this experiment was obtained from Buffalo Tungsten Inc. (http://www.buffalotungsten.com/) and its composition is described in Exhibit C mentioned below. As shown in Exhibits A and B mentioned below, stable Mo used in this experiment did not include any radioactive Mo-99, a synthetic isotope that does not occur in nature. The sulfuric acid and the stable Mo powder were first placed into the graphite tube in the example system, which was subjected to a static magnetic field of 2000 Gs and a direct current electric field (DC electrolysis, Hewlett Packard E3631A) of 2.9 V and 5.0-5.150 A for one hour. After the DC was turned off, the mixture containing the sulfuric acid and the Mo powder was subjected to a low frequency radio wave of 2 Hz (Vp-p ≈ 4.312-4.375 V) for one hour. *See also, e.g.*, pages 5-6 and 12-14 of the '928 application. The sample (including the sulfuric acid and Mo powder) was then pipetted from the invention and collected in a VWR 20 mL tube that was closed with a screw-on top and inserted in a latex glove as a precaution against leakage by Prof. Correia in his laboratory.

10. I observed the testing of this sample by Prof. Correia, which was performed as follows. Before testing any actual sample, Prof. Correia first performed a background test using a Canberra NaI(Tl) well-type scintillation spectrometer that contained no sample for 10 minutes to determine background or environmental detections. The background test results were analyzed using Canberra Genie 2000 software and the radiation counts of the background are shown in Figure 1 below, in which the x-axis is decay energy and the y-axis is the radiation counts. Note that Figure 1 shows the radiation count over a decay energy ranging from 2.0 keV to 2048.0 keV as the top graph, and an expanded view of a decay energy region ranging from 130 to 148 keV where a characteristic Tc-99m peak is expected according to the existing literature. As shown in Figure 1, no peak for Tc-99m is found in the background graph.

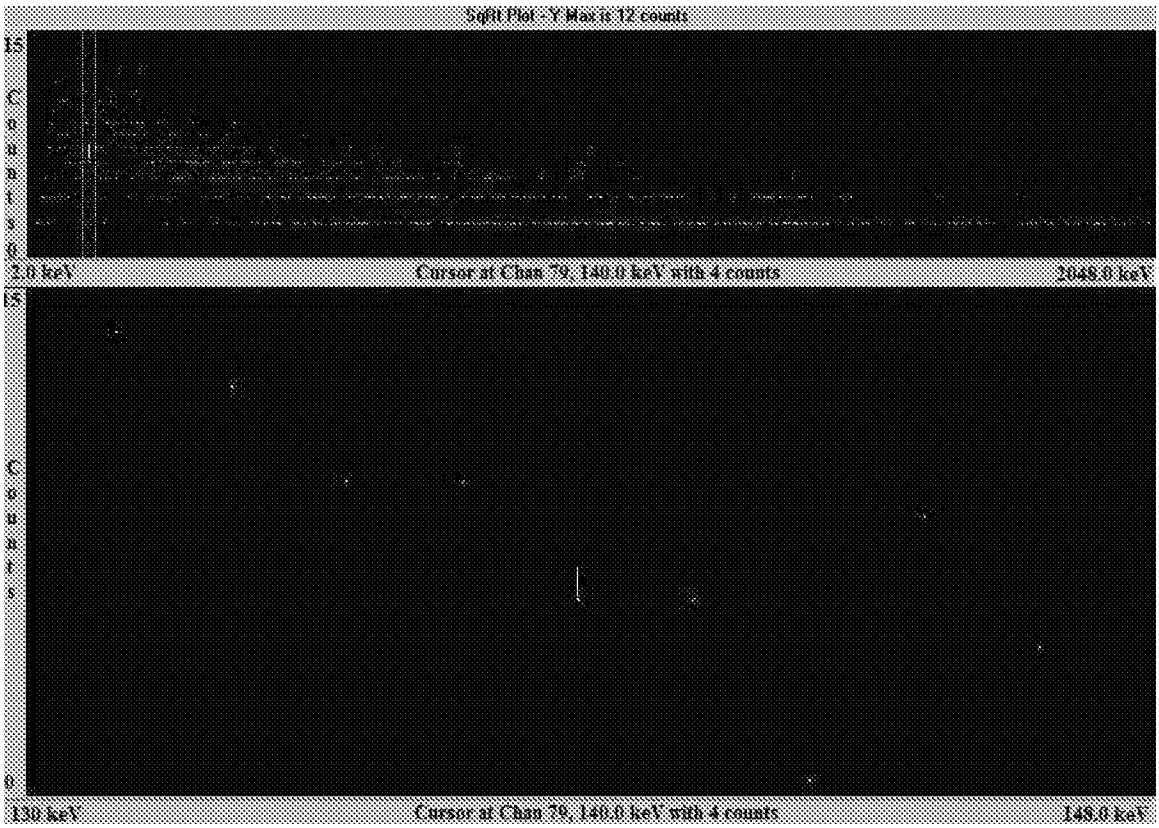

Figure 1

11. Subsequently, a standard Tc-99m run was performed in the scintillation spectrometer using a standard Tc-99m sample that was sourced from the Department of Radiology at Massachusetts General Hospital (MGH). The standard Tc-99m test was performed for 10 seconds. The test results were analyzed using Canberra Genie 2000 software and the radiation counts of the standard Tc-99m sample are shown in Figure 2 below, in which the x-axis is decay energy and the y-axis is the radiation counts. Note that Figure 2 shows the radiation count over a decay energy ranging from 2.0 keV to 2048.0 keV as the top graph, and an expanded view of a decay energy region ranging from 112 to 166keV. As shown in Figure 2, Tc-99m has a decay energy peak at about 141 keV.

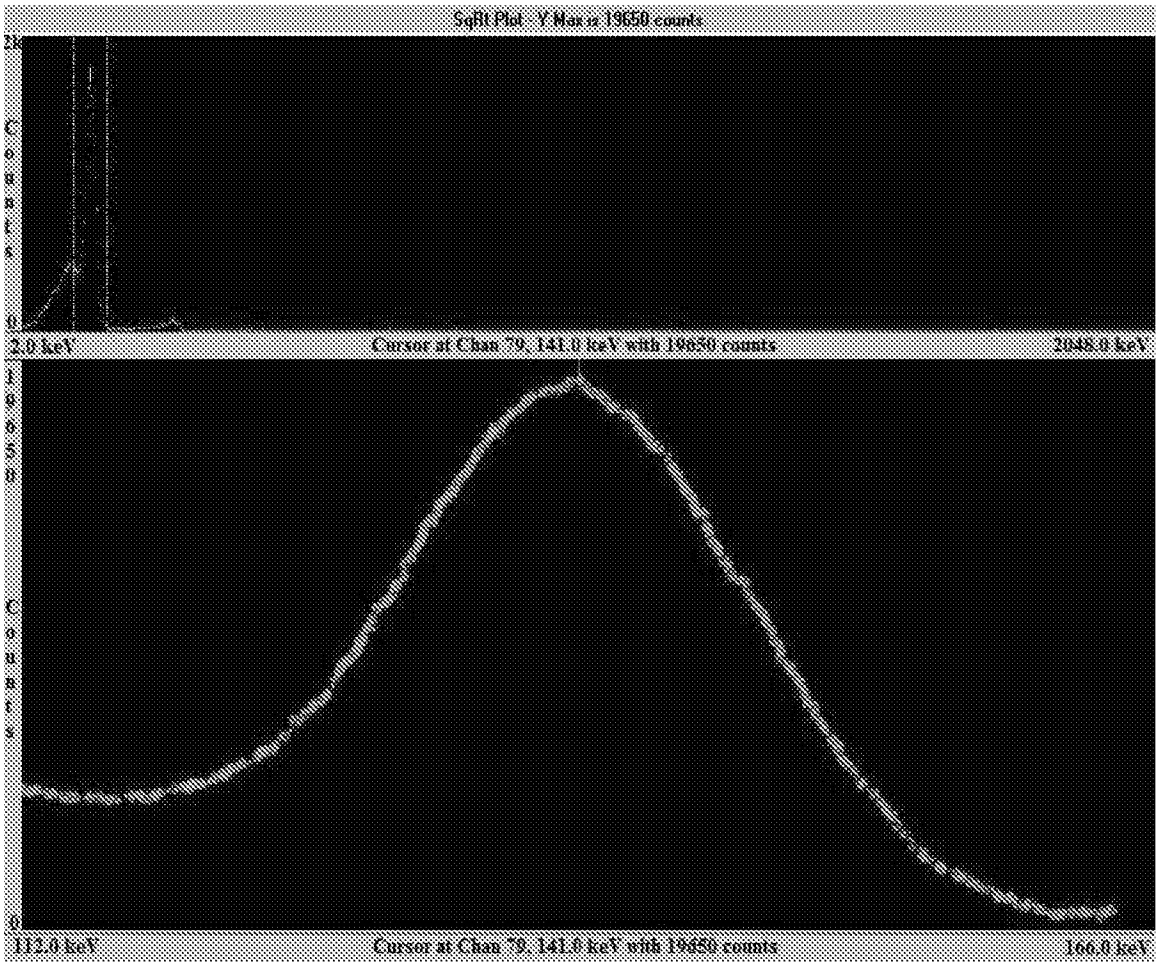

Figure 2

12. After the standard Tc-99m test was completed, Prof. Correia placed the sample obtained from the example system described above in the scintillation spectrometer. The scintillation spectrometer was then sealed and was used for isotope detection under the same conditions that were used to run the standard Tc-99m test. The results from Prof. Correia's experiment are shown in Figure 2 of the '928 application. As shown in Figure 2 of the '928 application, the sample was found to have a Curie reading of sufficient quantity to allow for the reading of approximately 141 keV, which matches the reading obtained from the standard Tc-99m test as shown in Figure 2 above. Thus, the above results demonstrate that the claimed invention successfully produced isotope Tc-99m in sufficient quantity for detection.

13. In addition, I wish to address certain statements made by the Examiner in the Final Office Action. In paragraph 6 on page 3 of the Final Office Action, the Examiner states that

> ... First of all, molybdenum is not a single isotope; it is a mixture of multiple isotopes. The specification states that "standard Mo powder" was used in experiments, but does not state the isotopic composition of this powder. In the arguments dated 08/30/17, Applicant states that the molybdenum used in the experiments is molybdenum-99. As the examiner explained in the previous office action, [molybdenum-99] spontaneously decays to Tc-99, which then also spontaneously decays to produce ionizing radiation. Accordingly, the "experimental results" purportedly illustrated in Fig. 2 are the result of measuring the spontaneous radioactive decay of Mo-99 into Tc-99 and Tc-99 into its decay products. These results would be obtained from observing *any sample of molybdenum-99*, regardless of whether the sample was subjected to the present invention. (emphasis original)

14. I would like to point out that the statements made in the reply dated August 28, 2017 that molybdenum-99 (Mo-99) was used as a starting material were incorrect and would like to clarify the records as follow. It is well known in the art that Mo-99 is a man-made isotope that does not occur in nature. I have enclosed two

documents, copies of which are attached hereto as Exhibits A and B, demonstrating that Mo-99 is a synthetic isotope. *See* the highlighted portions in each document. In other words, one skilled in the art would readily understand that Mo-99 is not present in the standard Mo powder described in the Specification, which only contains naturally-occurring Mo isotopes and was purchased off the shelf from a vendor named Buffalo Tungsten Inc. Indeed, it is known that the majority of Mo-99 is produced in five nuclear research reactors around the world using highly enriched uranium (HEU) targets and cannot be purchased off the shelf. *See* https://en.wikipedia.org/wiki/Technetium-99m.

15. Further, given that Mo-99 has a relatively short half-life (2.75 days), even if the purchased standard Mo powder includes Mo-99 when it was made (which I do not concede), it would have decayed by the time Prof. Correia's experiment above was performed because the time the Mo powder spends on the shelf and during transportation would be much longer than Mo-99's half-life. This is further supported by the Specification as filed, which states that "[t]he process, in one embodiment, can produce Technetium-99m (Tc-99m) from **stable** Molybdenum (Mo) powder." *See* page 2, 2nd paragraph; emphasis added. Mo-99 is certainly not a stable Mo isotope.

16. In addition, I have enclosed a certificate of analysis (a copy of which is attached hereto as Exhibit C) of the standard Mo powder purchased from Buffalo Tungsten Inc., which shows that it does not contain Tc. Figure 2 of the present application shows that Prof. Correia's experiment described above demonstrates that Tc-99m (an isotope that was not in the stable Mo powder used in the above experiment) was formed from a stable Mo powder that does not contain Mo-99. In other words, the Specification provides experimental results demonstrating that a claimed system was able to convert one isotope (e.g., a stable Mo powder which does not contain Mo-99) to another isotope (e.g., Tc-99m). Tc-99m is a well-known radioactive isotope used in tens of millions of medical diagnostic procedures annually. Thus, I am of the opinion that the claimed system is operative and has utility.

17. The Examiner states at paragraph 20 on page 8 of the Final Office Action that "[a] scintillation counter is incapable of providing any indication of the source of ionization radiation", that "[i]t is also impossible to determine the elemental make-up of a sample using a scintillation counter," and that "[t]he results of Figure 2 therefore indicate only that the scintillation counter of the experiment was exposed to ionization radiation." These statements are incorrect because a scintillation detector or spectrometer reports specific energy for radiation from decay that corresponds to particular isotopes. In this case, Figure 2 of the '928 application shows that decay energy of about 141 keV was detected by the scintillation detector. As mentioned above, this decay energy corresponds to the energy output of radioactive isotope Tc-99m. In other words, contrary to the Examiner's assertions, the scintillation detector was able to determine the elemental make-up of a sample and, in this case, was able to detect Tc-99m produced by the claimed invention.

18. The Examiner states in paragraph 20 on page 8 of the Final Office Action that "there is no description of experimental conditions that include a negative control experiment, so it cannot be ruled out that the 'results' of Figure 2 are due simply to the presence of background/environmental radiation." However, as mentioned above, a separate background run of the claimed system (i.e., a negative control) was made to eliminate the possibility of a background reading. In addition, one skilled in the art would readily understand that no background or environmental source would produce the specific reading (i.e., 141 keV) for Tc-99m, which is an isotope not found naturally in the environment, particularly due to its relatively short half-life (i.e., about 6 hours). Thus, even in the absence of any negative control experiment, one skilled in the art would still understand that the Tc-99m must be produced by the claimed system in view of the results shown in Figure 2 of the '928 application.

19. The Examiner states in paragraph 22 on page 8 of the Final Office Action that

> ... any sample of molybdenum-99 will exhibit ionizing radiation, regardless of whether it is placed in the present invention. Molybdenum-99 spontaneously undergoes radioactive beta decay with a half-life of 66 hours into technetium-99, which then undergoes gamma decay (i.e., releases ionizing radiation). Accordingly, a scintillation counter exposed to a sample of molybdenum-99 will always detect ionizing radiation, because natural radioactive decay processes produce this effect. No human intervention whatsoever would be required to detect ionizing radiation from a sample of molybdenum-99 using a scintillation counter.

However, as mentioned above, stable Mo powder, which did not include radioactive Mo-99, was used as the initial isotopes placed into the claimed system that resulted in Figure 2 of the '928 application. Indeed, Mo-99 is not a stable Mo isotope due to its relatively short half-life (i.e., about 2.75 days). In addition, as also discussed above, the decay energy shown in Figure 2 of the '928 application corresponds to the energy released by radioactive isotope Tc-99m. Indeed, it is well known in the art that Mo-99 has a decay energy of about 1.357 MeV (i.e., 1357 keV). In other words, based on the Specification, one skilled in the art would readily understand that the decay energy in Figure 2 of the '928 application was from Tc-99m, particularly when compared with the results obtained from the standard Tc-99m test described above. In sum, because the stable Mo introduced into the claimed system did not include Mo-99, one skilled in the art would understand that Tc-99m would not have been produced in the absence of the inventive system. Thus, the presence of Tc-99m in the claimed system as indicated by Figure 2 of the '928 application is evidence of the operability of the system, which converts one isotope (e.g., stable Mo) to another isotope (e.g., Tc-99m). Additionally, one skilled in the art would understand that Figure 2 of the Specification also provides evidence that Mo-99 was produced by the system of the invention since the decay of Mo-99 to Tc-99m is the reason for the Tc-99m detections. In other words, one would understand that Mo-

99 (an isotope not in the starting stable Mo powder) was necessarily produced by the inventive system from the stable Mo powder.

20. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

A. Christian Tahan

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