UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC.,
Petitioner,

v.

MERCK SERONO SA,
Patent Owner.

Case IPR2023-00480
Patent 7,713,947

Case IPR2023-00481
Patent 8,377,903

DECLARATION OF YOGESH DANDIKER, Ph.D.

MERCK 2055
HOPEWELL v MERCK
IPR2023-00480

I, Yogesh Dandiker, declare as follows:

I. INTRODUCTION

1. I am over eighteen years of age, and I am competent to testify as to the matters set forth herein if I am called upon to do so.

2. I have prepared this Declaration for consideration by the Patent Trial and Appeal Board in the following *Inter Partes* Review proceedings: IPR2023-00480 ("'480 IPR") and IPR2023-00481 ("'481 IPR"). I understand that the subject of the '480 IPR is U.S. Patent No. 7,713,947 ("the '947 patent") and the subject of the '481 IPR is U.S. Patent No. 8,377,903 ("the '903 patent").

3. I am a named inventor of the PCT Application, WO 2004/087101, "Oral Formulations of Cladribine" ("BODOR PCT"), which I understand has been numbered Ex. 1022 in the '480 IPR and in the '481 IPR. I have been asked to provide a declaration as an inventor of the BODOR PCT.

4. I am being compensated for my time in preparing this declaration at my usual consulting rate of $800.00/hour. My compensation is in no way contingent on the substance of my testimony or the outcome of this or any other proceeding. I have no interest in this proceeding.

5. I have personal knowledge of the facts stated herein and can testify competently to those facts.

II. BACKGROUND

6. I am the CEO of Celista Pharmaceuticals, a start-up company based in Minnesota. My professional qualifications are stated more fully in my curriculum vitae, which is attached as Appendix A. Below is a brief summary of my relevant education, work experience, and other qualifications.

7. I received my B.S., M.S., and Ph.D. all from the University of Salford in the United Kingdom. I received my B.S. and M.S. in 1979 and 1981, respectively, in biochemistry. During my M.S. studies I was involved in the development of a diagnostic radiotracer for a company in the UK; the company was later acquired by GE Healthcare. I received my Ph.D. in Physical Chemistry in 1984. My Ph.D. research focused on polymers for applications including dental fillings and drug delivery systems.

8. After graduating with my Ph.D., I joined Pfizer as a research scientist, where I researched liquid formulations of drugs including prostaglandins and cytotoxic drugs. I worked at Pfizer until 1987. Then, from 1987 to 1997, I worked at GlaxoSmithKline (GSK), where I held several positions and ultimately became a project team leader. At GSK, I was involved in the development of the Accuhaler range of respiratory devices and researched a number of new drugs, including ranitidine. In 1997, I moved to Roche to be the Head of Pharmacy Research & Development. At Roche, I worked on the first protease inhibitors and combination

therapy for HIV and many other products, including Tamiflu. I was also on a committee which selected drugs from screening to be progressed for development.

9. In 2001, I joined IVAX as Director of R&D. When I joined, IVAX was a generic manufacturer accustomed to conducting bioequivalence studies for generic drugs. IVAX did not have the capability to conduct the more onerous Phase II and Phase III clinical trials required for the approval of a drug. At IVAX, I worked on the development of an oral formulation of cladribine as a treatment for multiple sclerosis (MS), in partnership with Serono. Cladribine ultimately was approved by the FDA as an oral treatment for multiple sclerosis, which is sold under the brand name Mavenclad®.

10. I left IVAX in 2004 to join Apotex as Vice President of Product Development. In 2008, I joined Paddock Laboratories where I led research and development, leading to the successful sale of Paddock to Perrigo in 2012.

11. In 2012, I started my own pharmaceutical company, named Celista Pharmaceuticals LLC, where I am developing several orphan drugs in the areas of oncology and infectious diseases. Celista has successfully developed multiple drugs which have orphan drug designation from the FDA. We are also working on several women's health products for conditions for which there are currently no effective treatments, such as cervical cancer. I am also running clinical trials for

products to treat neurogenic orthostatic hypotension, another orphan drug indication.

III. DEVELOPMENT OF CLADRIBINE FORMULATION

12. Cladribine is a chlorinated purine analog, 2-chloro-2'-deoxyadenosine ("2-CdA"). I joined IVAX in the UK in 2001, after IVAX licensed the right to develop cladribine for treating MS from the SCRIPPS Research Institute and Johnson & Johnson. As director of R&D at IVAX, I was responsible for managing the development of formulations for cladribine. My colleagues at IVAX included Dr. Nicholas Bodor, who was IVAX's Chief Scientific Officer and my co-inventor of the BODOR PCT, WO2004/087101; Dr. Stephen Marcus; and other team members.

13. Ultimately, my team at IVAX focused on developing an oral cladribine formulation, while we partnered with Serono to design and conduct Phase III clinical trials for MS patients, as discussed below. My team at IVAX investigated many potential formulations of cladribine. We particularly investigated cyclodextrin-cladribine complexes, which resulted in our invention of an oral formulation of cladribine including a cladribine-cyclodextrin complex, as described in the BODOR PCT, WO 2004/087101.

A. IVAX PARTNERSHIP WITH SERONO

14. Because IVAX lacked the funding, clinical, regulatory, and marketing expertise to design and conduct Phase II or III clinical trials to obtain regulatory approval for cladribine to treat MS, IVAX needed to partner with another company to complete the development and seek approval for cladribine. In 2002, IVAX entered into an exclusive worldwide product development and license agreement with Ares Trading, S.A., an affiliate of Serono, S.A., (collectively, "Serono") to develop and commercialize cladribine for treating MS. Under our joint research and development agreement with Serono, IVAX was responsible for developing a suitable oral formulation of cladribine. Serono's role was to design and develop a dosing regimen for treating MS with cladribine, design and conduct Phase III clinical trials, obtain regulatory approval, and market and sell the final product.

15. Under the joint research and development agreement, the IVAX and Serono teams communicated frequently and confidentially. That included frequent meetings and emails to share information in support of IVAX's development of cladribine tablets, Serono's design and development of cladribine dosing regimen, and Serono's planning for Phase III clinical trials. I sometimes emailed directly with Dr. Munafo. These confidential communications included IVAX's progress on oral cladribine compositions and related pharmacokinetic studies as well as Serono's progress on designing a safe and effective cladribine dosing regimen for

proposed Phase III clinical trials for treating MS patients amongst other aspects of the clinical design.

16. For example, in August 2003, I and several of my colleagues attended a meeting with the Serono team in Amsterdam. I have been provided a copy of minutes from that meeting by Patent Owner's counsel. Ex. 2050.[1] It appears to me that those minutes accurately summarize the meeting, and I am not aware of any inaccuracies in those minutes.

17. At that meeting, members of both teams presented their progress. That included my colleague, Dr. Stephen Marcus, who presented on IVAX's Phase I studies of oral formulations of cladribine. Ex. 2050, 2-3. I gave a presentation on four formulations we had developed and were investigating. Ex. 2050, 3-4. Dr. Maria Lopez-Bresnahan from Serono presented a Phase III study design. Ex. 2050, 4-5. And other individuals from Serono presented on regulatory strategy. Ex. 2050, 5-6.

18. In December 2003, I recall receiving a draft regulatory Briefing Document from Serono. I was asked to review the Chemistry, Manufacturing, and Controls section of that document, and I believe I did. I have been provided a copy

[1] All citations to Patent Owner's exhibits are in reference to Patent Owner's exhibits filed contemporaneously in IPR2023-00480 and IPR2023-00481.

of a regulatory Briefing Document dated December 2003 by counsel. Ex. 2049. It appears to be the document I received in December 2003, and I am not aware of any differences between this document and what I received at that time.

B. INVENTION OF THE COMPLEX CLADRIBINE-CYCLODEXTRIN COMPLEX

19. My team at IVAX filed several patent applications related to our work on oral formulations of cladribine. I understand that IVAX filed U.S. Provisional Patent Application Nos. 60/458,922, 60/484,756, and 60/541,247 between March 24, 2003 and February 4, 2004. Ex. 2044; Ex. 2045; Ex. 2046. I understand all three were directed to aspects of Dr. Bodor's work on cladribine-cyclodextrin complexes and all three named only Dr. Bodor as an inventor.

20. I understand that on March 25, 2004, IVAX also filed two provisional patent applications entitled "Cladribine Regimen for Treating Multiple Sclerosis." '480 Ex. 1022, 23:24-29; '481 Ex. 1022, 23:24-29. I was not aware of either application. I do not believe either Dr. Bodor or I was named an inventor. I am unaware of the content of either application. I am not aware of anyone at IVAX who was working on developing or researching a cladribine dosing regimen for treating MS, nor anyone at IVAX who invented a cladribine dosing regimen for treating MS. Indeed, I understand that during the prosecution of a U.S. patent

corresponding to the BODOR PCT, the references to these two provisional applications were deleted from the patent specification, and it was stated that:

> These were provisional applications which were abandoned without the filing of non-provisional applications based thereon. Further, they were not for inventions of the present inventors and belonged to a former assignee. They were not made available to the public. In the parent case, now patented (Application No. 12/986, 310), the sentence in question was deleted during prosecution, by an amendment made October 3, 2008. Accordingly, page 23 of the specification has been amended to delete the final sentence on page 23, consistent with the parent.

Ex. 2047, 10. I have no reason to doubt the amendment is accurate.

21. On March 26, 2004, IVAX filed the BODOR PCT, later published as WO 2004/087101, which named me and my colleague Dr. Bodor as inventors. The BODOR PCT was directed to oral formulations of cladribine IVAX was developing—solid oral dosage forms containing particular amorphous mixtures of cladribine-cyclodextrin complexes. The BODOR PCT describes amorphous cladribine-cyclodextrin complexes that contain an "amorphous admixture of (a) an amorphous inclusion complex of cladribine with an amorphous cyclodextrin and (b) amorphous free cladribine associated with amorphous cyclodextrin as a non-

inclusion complex." '480 Ex. 1022 [BODOR PCT], 14-16, 33-39; '481 Ex. 1022, 14-16, 33-39. Because this formulation contains both an inclusion complex and a non-inclusion complex of cladribine, it is described as a "complex cladribine-cyclodextrin complex." '480 Ex. 1022, 16; '481 Ex. 1022, 16. This complex cladribine-cyclodextrin complex can "be saturated with cladribine." '480 Ex. 1022, 14, 16; '481 Ex. 1022, 14, 16. For example, an amorphous form of this composition can be created by freeze drying (lyophilizing) a solution of cyclodextrin that is saturated with cyclodextrin at high temperature. '480 Ex. 1022, 12-21, 26-33; '481 Ex. 1022, 12-21, 26-33.

22. I understand that certain disclosures in U.S. Provisional Application No. 60/541,247 ("the '247 Provisional") and the BODOR PCT are at issue in the *inter partes* review proceedings. Specifically, the BODOR PCT states:

> At the present time, it is envisioned that, for the treatment of multiple sclerosis, 10 mg of cladribine in the instant complex cladribine-cyclodextrin complex in the instant solid dosage form would be administered once per day for a period of five to seven days in the first month, repeated for another period of five to seven days in the second month, followed by ten months of no treatment.

'480 Ex. 1022, 23:15-20; '481 Ex. 1022, 23:15-20. The '247 Provisional contains similar language:

> At the present time, it is envisioned that, for the treatment of multiple sclerosis, 10 mg of cladribine in the instant complex cladribine-cyclodextrin complex in the instant solid dosage form would be administered once per day for one week in the first month, repeated for another week in the second month, followed by ten months of no treatment.

Ex. 2046, 20:6-10.

23. I did not invent the dosing regimen disclosed in the BODOR PCT and the ’247 Provisional. Nor, to the best of my knowledge, did anyone else on my team at IVAX, including Dr. Bodor. In fact, to the best of my knowledge, no one on my team at IVAX developed, researched, or invented any cladribine dosing regimen for treating MS. I am not aware of anyone at IVAX who was working on developing or researching a cladribine dosing regimen for treating MS. And I am not aware of any cladribine dosing regimen invented by any member of the IVAX team. We did not claim the above identified regimen in the BODOR PCT or the related U.S. patents, Nos. 7,888,328 and 8,785,415. Ex. 2069; Ex. 2029.

24. Serono was responsible for any research and development regarding proposed dosing regimens to be used in Phase III clinical trials of the oral cladribine formulation that my team and I developed. I believe Serono and IVAX followed that division of responsibilities. This division represented our respective

organizational expertise. To the best of my knowledge, Serono was the only group developing a dosing regimen for cladribine between 2002 and 2004.

25. Between 2002 and 2004, the IVAX and Serono teams met regularly to discuss the development of cladribine for treating MS, and we also communicated via e-mail. Because Serono researchers, and not IVAX, were working on developing proposed dosing regimens of cladribine for treating MS, I believe that, as part of the joint research and development agreement, Serono communicated the dosing regimen disclosed in the '247 Provisional and the BODOR PCT to me, Dr. Marcus, and other members of the IVAX team.

26. I note that the August 2003 meeting minutes and the December 2003 Briefing Document provided to me by counsel describe dosing regimens that are substantially the same as the dosing regimen described in the '247 Provisional and the BODOR PCT. Those documents include the disclosure of at least (1) a "low dose" arm with a dosing regimen of 10 mg cladribine tablets each day for 5 consecutive days each month for 2 months; (2) a yearly dosing regimen including a 6-month dosing phase with 6 dosing cycles (one each month) and a 6-month non-treatment period; and (3) a 6 monthly dosing cycle that administers the "low dose" arm through 2 months of cladribine, followed by 4 months of placebos to "fill out high dose cycles." Ex. 2050, 4; Ex. 2049, 47-51. In particular, the December 2003 Briefing Document discloses a regimen including 2-months of cladribine, 4-

months of placebos, then 6-months where no pills were administered, i.e., a 2-month cladribine dosing period followed by a 10-month cladribine-free period. Ex. 2050, 4; Ex. 2049, 47-51. I recall attending the August 2003 meeting and receiving the December 2003 Briefing Document, and both appear to be accurate.

27. I believe that the Serono team communicated additional details about their dosing regimen to me and the rest of the IVAX team in additional other meetings and emails before February 2004.

28. In signing this declaration, I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross-examination in this case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

29. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and

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.

Dated: December 21, 2023

By: _____

Yogesh Dandiker, Ph.D.

Appendix A

CURRICULUM VITAE

NAME: Yogesh Dandiker

POSITION TITLE: CEO, Celista Pharmaceuticals LLC

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Salford, UK	B.Sc.(Hons)	1979	Biochemistry
University of Salford, UK	M.Sc.	1981	Biochemistry
University of Salford, UK	Ph.D.	1984	Physical Chemistry
Open University Business School, UK	MBA	1993	Business

A. Personal Statement

I am the CEO of Celista Pharmaceuticals, a start-up company based in Minnesota. I have extensive experience in drug development. During my M.Sc., I was involved in the development of a diagnostic radiotracer for a company in UK, the company was later acquired by GE Healthcare. During my P.hD, I worked on polymers, applications for which include dental fillings and drug delivery systems. I have developed a large number of pharmaceutical products for various pharmaceutical companies, for instance I developed the range of Accuhaler respiratory devices for GSK, I worked on the first protease inhibitors and combination therapy for HIV and Tamiflu when at Roche. At Ivax, I worked on Movenclad, the first oral treatment for multiple sclerosis. At Paddock Laboratories, I led Research and Development, leading to the successful divestment of Paddock to Perrigo.

At Celista, I am developing several orphan drugs in oncology and anti-infectives areas for which I have orphan drug designations from FDA. I am also working on several women's health products for conditions for which currently, there are no effective treatments, for example, we have developed a product for cervical cancer.

More recently, we are running clinical trials for a product for neurogenic orthostatic hypotension.

Publications:

Cundall, R. B., Dandiker, Y. M., Davies, A. K., and Salim M. S., 1987, Radiation Curing of Polymers, D. R. Randell, ed., Royal Society of Chemistry, London, p. 172–183.

Geraghty, P. B., Attwood, D., Collett, J. H., Sharma, H., and Dandiker, Y. (1997). An investigation of the parameters influencing the bioadhesive properties of Myverol 18–99/water gels. Biomaterials 18, 63–67. doi: 10.1016/s0142-9612(96)00087-7

Davies AK, Cundall RB, Dandiker Y, Slifkin MA. Photo-oxidation of tetracycline absorbed on hydroxyapatite in relation to the light-induced staining of teeth. J Dent Res. 1985;64:936-939.

Bennett, F.S., Carter, P.A., Rowley, G., and Dandiker, Y. Modification of electrostatic charge on inhaled carrier lactose particles by addition of fine particles. Drug Dev Ind Pharm. 1999; 25: 99–103

Malton A, Sumby BS, Dandiker Y. A comparison of in vitro drug delivery from salbutamol Diskus and terbutaline Turbohaler inhalers. J Pharmacol Med. 1996;6:35–48.

Geraghty PB, Attwood D, Collett JH, Dandiker Y. The in vitro release of some antimuscarinic drugs from monoolein/water lyotropic liquid crystalline gels. Pharmaceutical Research. 1996;13(8):1265–1271.

Salim MS, Cundall RB, Davies AK, Dandiker YM, Slifkin MA. Application of Photoacoustic spectroscopy to UV systems. Technical Paper - Society of Manufacturing Engineers.

Cundall, R. B., Dandiker, Y. M., Davies, A. K., and Salim M. S., 1987, Radiation Curing of Polymers, D. R. Randell, ed., Royal Society of Chemistry, London, p. 172–183.

(Having worked in industry, the objective is to develop and commercialize products, hence publications are discouraged when intellectual property is involved)

Patents:

- Dandiker, Huckle PD, (1995), Controlled Release pharmaceutical compositions. US Patent 5425950
- Price PT, Davies MB, Rand PK, Dandiker Y, Heppenstall CR, Huckle PD, (1997), Depression for a tablet, US Patent D377977.
- Dandiker Y, Huckle PD, Multi-layered compositions containing histamine or serotonin antagonists, (1997), EU Patent EP0546593
- Woolfe JA, Dandiker Y, Elchidana P, (2005), Stable Gabapentin Compositions, WO 2005072736
- Bodor NS, Dandiker Y, (2011), Oral formulations of Cladribine, US Patent 7888328.
- Bodor NS, Dandiker Y, (2011), Oral formulations of Cladribine, US Patent 8785415.
- Dandiker, Y.; Panchal, M.; Yu, X. (2018), Composition of Midodrine and Methods of Using the Same. Patent Application WO 2018/064490 A1.
- Dandiker, Y, Panchal M, Yu, X. (2018) Droxidopa Compositions ad Methods. Patent Application WO 2018/119323 A1.
- Dandiker Y, Panchal M, (2019), Testosterone Transdermal spray with film, Patent Application PCT/US/2019/013047
- Dandiker Y, (2019), Testosterone and Estradiol Spray, Patent Application US 62/694,365
- Dandiker Y, Panchal M, Yu Y, (2019), Oxycodone and Methylnaltrexone Multiparticulates and suspensions containing them, Patent application PCT/US19/20010
- Dandiker Y, Panchal M, Yu X, (2019), Atomoxetine Hydrochloride Extended Release Compositions and Methods of Use, US Application 62/866,837
- Dandiker Y, (2019), Sprayable Lidocaine Solution, US Application 62/902,543
- Dandiker Y.; Panchal, M.; Yu, X. (2020) Composition of Midodrine and Methods of Using the Same. Patent Application US 2020/0022919 A1.
- Dandiker Y, Wong P, (2020), Application for Topical Composition. US Patent 10555592.
- Dandiker Y, Dandiker S, (2020), Nasal Immunotherapy for Covid-19, US Application 63/042704.
- Dandiker Y, Imiquimod Co-Crystals, (2020) US Application 63/054019.

- Dandiker Y, Topical Atomoxetine and Oxybutynin for Obstructive Sleep Apnea, (2023) US Application 63/446,083
- Dandiker Y, Topical Treatment of Arboviral Infections, USA Application (2023) 18/223,678

Positions and Employment

Celista Pharmaceuticals Jan. 2012-
CEO, Minneapolis, MN Present

Paddock Laboratories, Inc.; Minneapolis MN Aug. 2008-
Senior Vice President. Oct. 2012

Member of the Executive management team leading Paddock's R&D efforts culminating in divestment of Paddock Labs to Perrigo.

- Provided leadership of the Pharmaceutical Development and Program Management.
- Assured continued growth in resources and capabilities within R&D.
- Collaborated closely with Business Development to provide scientific guidance to development partners and key contributor to the Product Selection Process.

Apotex, Inc.; Toronto Canada
Vice President, Product Development March 2004 - July 2008

Responsible for Development for Toronto-based sites.

- Directed personnel at India and New Zealand R&D site.
- Directed development activities of groups based in Brazil,
- Member of several management committees that served the wider Apotex business.

IVAX Pharmaceuticals Ltd; **UK** July 2001-
Director, R&D, UK, Ireland & India Feb. 2004

- Managed generic product development from product selection to API selection, to formulation and analytical development, to conducting biostudies, input of submissions and launch of products both in Europe and the U.S. on patent expiry.
- Responsible for R & D groups based in UK, Ireland and India.
- Spearheaded proprietary medicine development in Europe.
- Significant input in patent and business development strategies.

Roche, UK May 1997-
July 2001

Head of Pharmacy Research & Development
Formulation/Analytical/Clinical Trials /Drug Delivery

- Responsible for pharmaceutical research and development and early clinical studies.
- Extensive interaction with personnel at all levels; particularly with staff in marketing, research, primary and secondary production sites and regulatory authorities. Developed the first combination HIV drugs and anti-virals for Roche, e.g.Tamiflu

Glaxo Ltd, UK November 1987-
May 1997

Project Team Leader (September 1995-May 1997)
Research Leader (February 1994-September 1995)
Project Leader (February 1989-February 1994)
Senior Research Scientist (November 1988-July 1989)
Research Scientist (November 1987-July 1988)

- Worked with several NCE's and line extension projects.
- Sustained and modified release oral drug delivery systems.
- Development activities related to compounds for gastric disorders, in particular Ranitidine and its successors.
- Developed several multi-dose dry powder inhalation systems for use in asthma e.g. Accuhaler and Diskhaler.
- Responsible for formulation, analytical development, scale-up and technology transfer.
- Responsible for selection and early development of pipeline compounds.
- Completed MBA while at Glaxo-Wellcome.

Pfizer, UK February 1985-
November 1987

Formulation Research Scientist
Parenteral/Controlled Release Systems

- Worked primarily with liquid formulations of NCE's, mostly prostaglandins and cytotoxic drugs.
- Conducted significant amount of work on transdermal and semi-solid (emulsions and gels) controlled release systems.

B. Contributions to Science

When at GSK, I was involved in the development of a number of dry powder multi-dose products for asthma, in particularly the Accuhaler range of products (Flixotide, Seretide, Serevent), which were launched by GSK for marketing worldwide. Amongst other projects, at Roche I was involved principally in the development of the first HIV combination therapy drugs (Invirase and AZT for example) and other anti-virals (Tamiflu).

More recently, I have filed patents for Midodrine ER Tablets for symptomatic neurogenic orthostatic hypotension (nOH). nOH is an orphan condition as it affects < 200,000 people in the US. Similarly, we have developed a once-a-day Droxidopa suspension for nOH. Droxidopa is a prodrug, which is converted to norepinephrine, increases BP, and improves symptoms of nOH. The drug is indicated largely for Parkinson's patients and therefore we have developed an extended release suspension which is easy to swallow, the suspension is housed in a novel patentable bottle which has been developed so that Parkinson's patients can

easily open the bottle. The type of packaging developed for this project may be useful for the elderly population for other products too.

- Dandiker, Y.; Panchal, M.; Yu, X. (2018), Composition of Midodrine and Methods of Using the Same. Patent Application WO 2018/064490 A1.
- Dandiker, Y, Panchal M, Yu, X. (2018) Droxidopa Compositions ad Methods. Patent Application WO 2018/119323 A1.

Other products recently developed: Around 40% of cancer patients are administered opioids for pain. However, within a week of administering the medication, patients become constipated. I have developed an opioid medicine which addresses mu receptors for both pain and constipation, is easy to swallow and has been especially developed for cancer patients.

- Dandiker Y, Panchal M, Yu Y, (2019), Oxycodone and Methylnaltrexone Multiparticulates and suspensions containing them, Patent application PCT/US19/20010

I have also developed a Testosterone / Estradiol spray product to address hypoactive sexual desire disorder (HSDD) in post-menopausal women and have obtained positive FDA feedback for the required studies. This is the the first product for HSDD for post-menopausal women, potentially, a large group of patients with an unmet medical need.

- Dandiker Y, (2019), Testosterone and Estradiol Spray, Patent Application US 62/694,365

Besides contributions to the science, I have served in senior management positions in a number of pharmaceutical companies which has enabled me to learn about the commercial aspects of getting a product to the market.

C. Additional Information: Research Support and/or Scholastic Performance

I serve as a Scientific Advisor for Nanocopoeia, a nanoparticle drug delivery company.