

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Sreenivas S. Bhat	Confirmation No.:	3403
Application No.	15/697,199	Art Unit:	1612
Filed:	September 6, 2017	Examiner:	YU, HONG
For:	TABLET COMPOSITIONS	Attorney Docket No.:	14247-200-999
		CAM:	206986-999201

DECLARATION OF DARSHAN PARIKH UNDER 37 C.F.R. § 1.132

Mail Stop RCE
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

I, Darshan Parikh declare that:

1. I am a citizen of United States of America, residing at 862 Garfield Ave, Bridgewater, NJ.
2. I have 18 years of experience in developing pharmaceutical compositions. My *curriculum vitae* is attached as **Exhibit 1**.
3. I am presently employed as Director at Celgene Corporation ("Celgene"). Celgene is the co-assignee with Agios Pharmaceuticals, Inc., of the above referenced application.
4. I have read and am familiar with the present application (US Application No. 15/697,199, "the '199 application"). I have reviewed the final Office Action mailed May 17, 2019 (the "Office Action"), the references cited in the Office Action: WO 2015/018060 (Gu et al.) and US 7,132,114 (Daggy et al.), and pending claims 1-5, 7-13, 15-17, 19-23 and 25-26. I understand that this Declaration will be presented in response to the Office Action.
5. The '199 application describes in Example 4, the compositions of exemplary tablets within the scope of the instant claims.

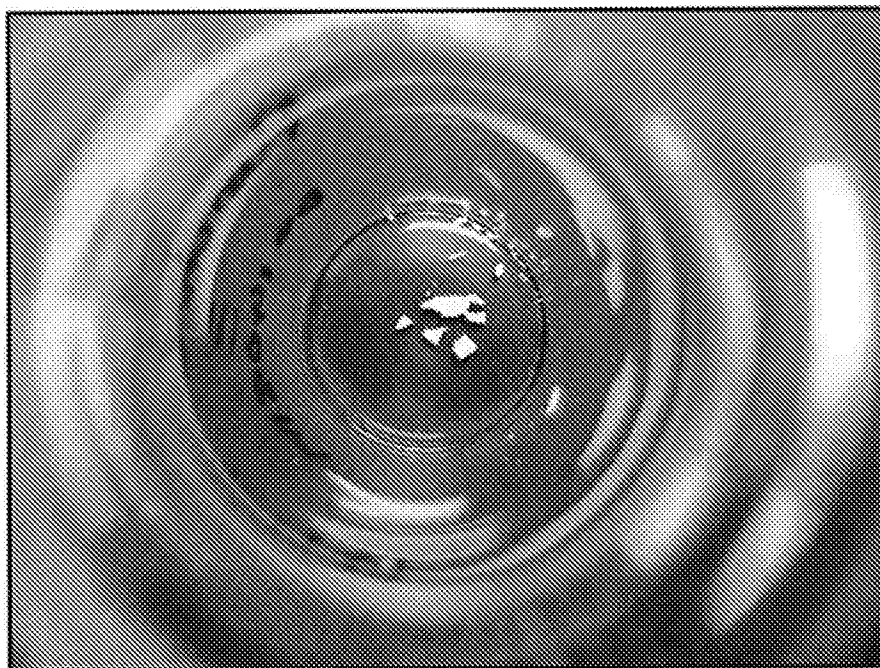
6. International publication no. WO 2015/017821 ("the '821 publication") describes exemplary compositions of the tablets comprising Compound 1, *see* the '821 publication, pages nos. 107-110. During the manufacture of the tablets having the composition provided below in Table 1, disclosed in the '821 publication (*see* page 109, Table C), it was observed that tablet residue was lost due to sticking and punch filming.

Table 1

Component	Weight Composition	100 mg tablet* Amount per tablet (mg)	150 mg tablet* Amount per tablet (mg)
Compound 1	30%	120.0	180.0
Microcrystalline Cellulose	45%	180.0	270.0
Hydroxypropyl Cellulose	2%	8.0	12.0
Sodium Starch Glycolate	6%	24.0	36.0
Sodium Lauryl Sulfate	1%	4.0	6.0
Hypromellose Acetate Succinate	1%	4.0	6.0
Colloidal Silicon Dioxide	1.50%	6.0	9.0
Magnesium Stearate	0.75%	3.0	4.5
Microcrystalline Cellulose	9.50%	38.0	57.0
Sodium Starch Glycolate	2%	8.0	12.0
Colloidal Silicon Dioxide	0.50%	2.0	3.0
Magnesium Stearate	0.75%	3.0	4.5
TOTAL	100%	400.0	600.0

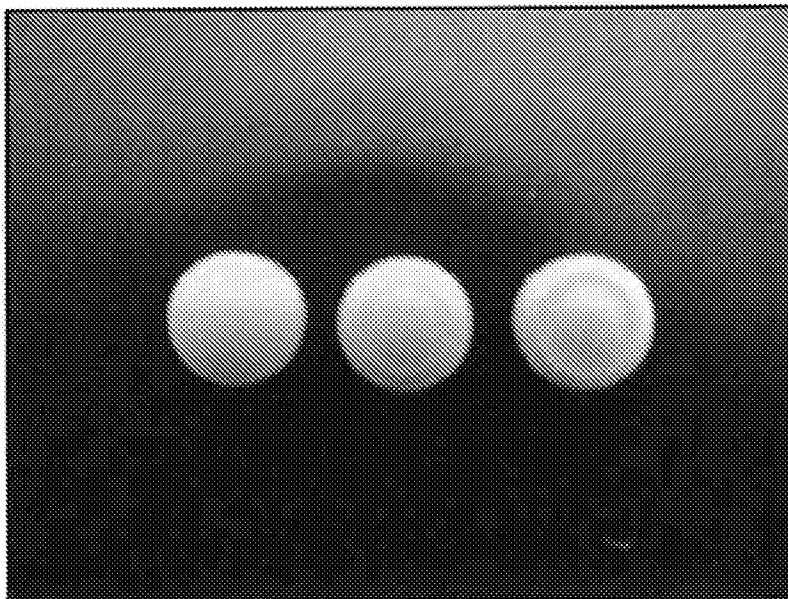
7. Figure 7 in the '199 application, reproduced below, illustrates a loss of tablet residue due to sticking and punch filming for the tablet composition described in Table 1.

Figure 7



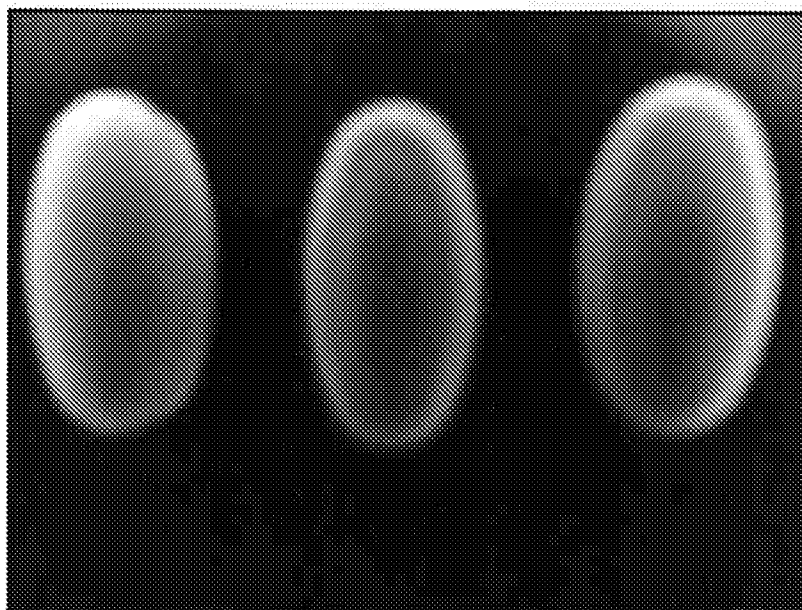
8. Figure 8 in the '199 application, reproduced below, illustrates a loss of crown during the manufacture of round tablets having the composition described in Table 1.

Figure 8



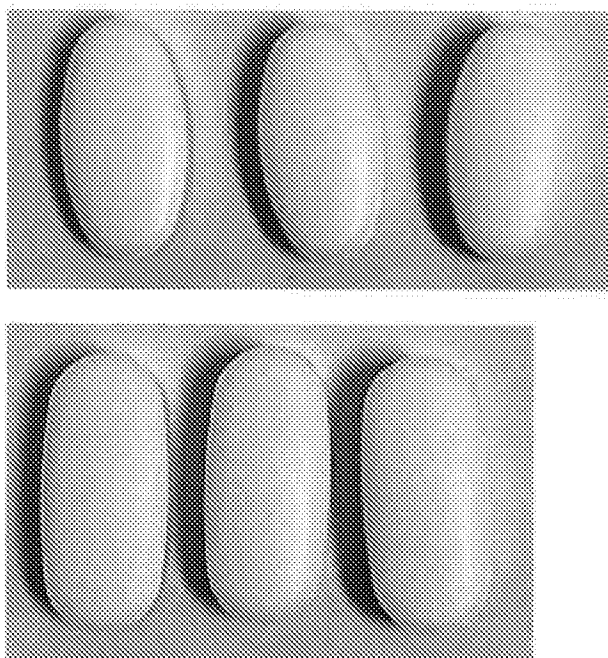
9. Figure 9 in the '199 application, reproduced below, illustrates a loss of crown during manufacture of oval tablets having the composition described in Table 1.

Figure 9

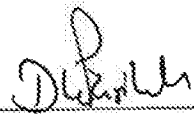


10. The tablet compositions claimed in the '199 application reduce or eliminate the loss of material from the tablet surface due to sticking and/or punch filming observed during the manufacture of the tablets reported in the '821 publication as shown in Figure A below.

Figure A



11. I, Darshan Parikh, further declare that all statements made herein are of my own knowledge to be 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 this application or any patent that may issue there from.



Darshan Parikh

18 Sep 2019

Date

Exhibit A: *Curriculum Vitae* of Darshan Parikh

Darshan K. Parikh, R.Ph., Ph.D.

862 Garfield Avenue, Bridgewater, NJ 08807 • Phone: 734-417-9756 • Email: parikhdk@hotmail.com

Pharmaceutical Professional with 20 years of experience in product and process development, technology transfer, and commercial launch. Filed four New Drug Applications (NDA). Experienced working with the alliance companies to develop commercial drug product leading to a successful NDA. Led drug product teams to successfully develop products and execution of commercial manufacturing launches using internal capabilities and contract manufacturing organizations.

SKILLS

- Leading technical teams
- Management of product development
- Technology identification and execution
- Skilled communicator
- Problem solver
- Management of vendor partnerships

PROFESSIONAL EXPERIENCE

2018 – Present Director, Group Lead, Drug Product Development, Celgene, Summit, NJ

Led drug product development team. Provided technical and strategic guidance to successfully develop, commercialize and author global regulatory filings while effectively controlling project finances, timelines, and resources for multiple projects.

- Provided technical and strategic guidance to the development teams for successful development of oral solids and parenteral drug product
- Managed finances, timelines, and resources for multiple projects.
- Led strategic initiatives for establishing best practices for drug product development and technology transfer
- Represented the company in meetings with FDA and global regulatory agency.
- Identified and escalated the risk of manufacturing amorphous and crystalline drug product at the same site, enabling manufacturing site to timely stop the construction plans and save Celgene ~20MM dollar.

2014 – 2018 Associate Director, Technical Operations/Drug Product Development, Celgene, Summit, NJ

Led product development through commercial launch of immediate release and modified release small molecules following concepts of Quality Risk Management. Identified technologies and CMOs for successful execution of development and commercialization. Led CMC due diligence.

- Collaborated with the external partner on an alliance project to develop commercial drug product, leading to a successful regulatory submission
- Provided tactical guidance to the alliance partners for product development and scale-up to commercial scale.
- Led cross functional teams for successful development of complex products including oligonucleotide and modified release dosage form.
- Led technology transfer at internal and external commercial sites and build a framework for continuous process verification.

- Led process development and commercialization across sites, vendors, and functions and managed outsourcing budget.
- Negotiated service agreements, capex and commercial agreements with the CMO's.

2011 – 2014 Senior Manager, Technical Operations, Celgene, Summit, NJ

- Led development and commercialization of dosage forms containing amorphous API.
- Designed modified release dosage form using multiparticulate, matrix, and osmotic technologies.
- Designed and commercialized modified release dosage form using osmotic technologies.
- Developed clinical formulations and processes using experimental designs and statistical process controls.
- Authored development and manufacturing sections of IND/NDA filing.
- Developed pediatric liquid oral dosage form and manufactured clinical supplies.

2007 – 2011 Senior Research Investigator, Sanofi-Aventis, Bridgewater, NJ
2005 – 2006 Research Investigator, Sanofi-Aventis, Bridgewater, NJ

- Developed robust formulations and optimized processes using statistical tools.
- Contributed to CMC section of pediatric investigation plans and pediatric dossier submissions.
- Performed due-diligence and provided recommendation for in-licensing.
- Worked cross-functionally to design dosage form based on biopharmaceutical properties.

2002 – 2005 Senior Scientist, Pfizer Inc., Ann Arbor, MI

- Developed formulations and processes for liquid (solution, suspension and microemulsion) and semi-solid dosage forms for enhancing topical delivery of new drug molecules.
- Collaborated with external vendors to design new equipment and techniques for novel applications.
- Led the material sparing formulation approach to reduce API consumption.

PATENTS

Ciotti, S. and Parikh, D. 2006. Formulations for Stimulating Hair Growth. WO 2006/011046 A1, filed Jul 11 2005, and issued Feb 2, 2006.

Menon, A., Parikh, D., Visky, D., Kreilein, M., Boersen, N., Lee, T., Li, Y., Xu, J., Liang, X., Leong, W., Cohen, B. 2014. Pharmaceutical formulations, processes, solid forms and methods of use relating to 1-ethyl-7-(2-methyl-6-(1h-1,2,4-triazol-3-yl) pyridin-3-yl) -3,4-dihydropyrazino[2,3-b]pyrazin-2(1h)-one. WO 2014/172423 A1, filed Apr 16 2014, and issued Oct 23 2014.

Parikh, D., Menon, A., Tutino, A. 2014. Tablet formulations of (+)-2-{1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonyl-ethyl}-4-acetylaminoisindoline-1,3-dione. WO 2014/204825 A1, filed Jun 16, 2014, and issued Dec 24, 2014.

Parikh, D., Burnside, S., Bhat, S., Liu, J. 2017. Pharmaceutical Tablet. US D787042 S, filed April 28 2015, and issued May 16 2017.

Parikh, D., Menon, A. 2015. Formulations of (s)-3-{4-[(4-(morpholinomethyl)benzyloxy)-1-oxoisindolin-2-yl]piperidine-2,6-dione. WO 2015/054199 A1, filed Oct 7 2014, and issued Apr 16 2015.

Parikh, D. and Raju, P. 2014. Tablet formulation of a phosphatidylinositol 3-kinase inhibitor. WO 2014/041142 A1, filed Sep 13 2013, and issued Mar 20 2014.

Eckert, J., Menon, A., Parikh, D., Boersen, N., Lee, T. 2015. solid forms of 1-ethyl-7-(2-methyl-6-(1h-1,2,4-triazol-3-yl)pyridin-3-yl)-3,4-dihydropyrazino[2,3-b]pyrazin-2(1h)-one, compositions thereof and methods of their use. WO 2015/160875 A1, filed Apr 15 2015, and issued Oct 22 2015.

Bhat, S., Burnside, S., Parikh, D., Gu, C., Altaf, S. 2018. Tablet compositions. WO 2018/048847 A1, filed Sep 6 2017, and issued Mar 15 2018.

EDUCATION

Ph.D. in Industrial Pharmacy/Pharmaceutics- 2002

Massachusetts College of Pharmacy and Health Sciences, Boston, MA.

Bachelor of Pharmacy- 1995

Lalubhai Motilal College of Pharmacy, Gujarat University, India.