

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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INTAS PHARMACEUTICALS LTD.,  
Petitioner

v.

ATOSSA THERAPEUTICS, INC.,  
Patent Owner

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Case PGR2023-00043

Patent No. 11,572,334

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**REPLY EXPERT DECLARATION OF JASON McCONVILLE, Ph.D.**

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## Reply Declaration of Jason McConville, Ph.D.

I Jason McConville, Ph.D., do hereby declare:

### **I. Introduction**

1. I have been retained to provide my expert opinions on behalf of Intas Pharmaceuticals, Limited., in support of a petition for post grant review of claims 1-22 of U.S. Patent No. 11,572,334 (“the 334 patent”; Ex. 1001), which challenges the validity of the 334 patent.

2. The opinions set out by this declaration are based on my education, knowledge and experience. I have considered the materials and items identified by this declaration.

### **II. Education and Professional Background**

3. My qualifications and credentials to testify as an expert in this case are set forth in my curriculum vitae (attached as Appendix A).

### **III. Liu and Fauq teach (Z)-endoxifen API that can be used in oral formulations**

4. I understand that Patent Owner argued “Liu does not describe a synthetic method to produce an oral pharmaceutical formulation.” I am not an organic chemist, so I cannot speak to the synthetic method, but nothing in Liu suggests to me that the API could not have been used in an oral formulation. Reviewing Liu, it is clear that is Liu’s purpose. *See, e.g.*, Ex. 1004 at [0002]-[0004] (teaching that the product can be used to treat breast cancer). There is no indication in Liu that anything in the method would render it unsuitable for use in oral

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formulations. For example, Ali (Ex. 2011) uses benzene as a solvent. I agree with Dr. Davies that this would render it unsuitable for use in an oral formulation. Ex. 2020 ¶ 93. But Dr. Davies identifies no such issue with Liu, and I do not see any. Similarly, I see no reason the API made by Fauq (Ex. 1022) could not have been used for oral formulations. For example, Fauq teaches that the endoxifen can be used “for animal and tissue studies.” Ex. 1022 at 3038. A POSA would have understood that this is because at the time of publication, (Z)-endoxifen was in pre-clinical stages, but that the method could also have been used in oral formulations for human use, once the pre-clinical testing demonstrated likely safety and efficacy.

#### **IV. A POSA Would Have Been Motivated to Combine Ahmad with Cole**

5. As I explained in my prior declaration (Ex. 1020), it would have been routine for a POSA to have taken (Z)-endoxifen made using methods known in the prior art and enclosed it in a capsule and then applied an enteric coating to the capsule. *See* Ex. 1020 ¶ 71; *see also* ¶ 55. Indeed, Ahmad teaches that “[i]n some embodiments, the composition comprises a tablet or a filled capsule, wherein said tablet or filled capsule optionally comprises an enteric coating material.” Ex. 1003 at 4:41-44; *see also* 18:19-21 (“[w]hen desired, composition containing endoxifen or endoxifen-lipid complex can be encapsulated in enteric-coated capsules to protect it from acids in the stomach.”).

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6. As I discuss in my earlier declaration, a POSA would have been motivated to employ an enteric coating because “enteric coatings prevent release of medication before it reaches the small intestine.” *Id.* at 18:22-24. Additionally, in the case of endoxifen, a POSA would have been further motivated to use an enteric capsule as taught by Ahmad because it was known that endoxifen could be susceptible to degradation in the acidic conditions of the stomach. *See, e.g.,* Ex. 1019 at 1353 (“Our finding suggested that Z-endoxifen is unstable to the acidic conditions of the silica gel column chromatography but, in our hands, stable to the basic cleavage and mildly acidic work-up conditions.”) A POSA would have thus been motivated to use an enteric capsule to avoid acidic degradation and improve bioavailability.

7. Cole teaches the effective use of an enteric coating to form capsules that will bypass the stomach and release drug in the intestine. *See, e.g.,* Ex. 1008 at 83. Cole demonstrates the routine and predictable nature of applying an enteric coating to a capsule. *See, e.g., id.* at 93 (“The investigations described demonstrate that the enteric coating of HPMC capsules is an industrially viable process.”) Therefore, in addition to Ahmad’s teachings, a POSA would have been further motivated to enterically coat a capsule loaded with (Z)-endoxifen as taught by Cole. In Paragraph 164, Dr. Davies criticizes Cole as being “silent to the use of these formulation with endoxifen compositions and instead investigates the enteric

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properties of these compositions with a different pharmaceutical, Paracetamol.”

Paracetamol (*i.e.*, acetaminophen) is a commonly used model drug. In the case of an enteric coated capsule, it is the degradation of the enteric coating and capsule that will control the release of the drug, not the nature of the drug itself. *See, e.g.*, Ex. 1008 at 84 (“As previously mentioned, site specific delivery into the upper intestine has been achieved for many years by the use of pH-sensitive coatings (Healey, 1989). By applying a thicker coating and/or raising the threshold pH at which dissolution of the coating begins, colon specific delivery using enteric polymers has been achieved (Hardy et al., 1987a).”) While Cole utilized paracetamol as an example drug, a POSA would have understood that the capsule would have the same benefits for use with other drugs, such as endoxifen.

8. In Paragraph 166, Dr. Davies characterizes my analysis as an “oversimplification of what a POSA would readily understand to be a highly technical and unpredictable endeavor.” However, the only complications Dr. Davies points to are “potential interactions between enteric coatings and pharmaceutical compositions” and “variations in release profiles for salts versus corresponding free acids or bases of a given oral formulation.” Dr. Davies does not cite to any actual evidence of these theoretical concerns. To the contrary, it would have been routine for a POSA to incorporate (Z)-endoxifen into an enteric formulation and would not have been “highly technical” or “unpredictable.”

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Encapsulating formulation is quite routine – and while there are of course complexities that can arise, I have seen no evidence of any such complexities with endoxifen. Dr. Davies cites only to Gupta at page 10. But Gupta says nothing about endoxifen or any potential interaction between an enteric coating and a pharmaceutical composition. Gupta generally addresses certain considerations with respect to salts of therapeutic agents, but does not mention endoxifen and certainly does not support Dr. Davies’ assertion that a POSA would not have been motivated to combine Ahmad with Cole.

9. First, with respect to any “potential interactions between enteric coatings and pharmaceutical compositions,” Dr. Davies ignores the fact that it is standard practice that enteric coatings are applied to the exterior of a capsule after the drug is loaded into the capsule. As a result, the enteric coating and the drug do not come into contact with one another at any point during the manufacturing process or use. The reason for this is practical in nature. In short, if a coating were applied prior to capsule filling, this could lead to issues with the capsule properly fitting together. Additionally, applying the coating prior to capsule filling would lead to a very uneven application of the coating on the inside of the capsule, which would adversely affect uniform drug delivery. Furthermore, it would be most cost effective to coat as a final step in a streamlined manufacturing scheme. At least for these reasons, coatings are applied to capsules after filling. Thus, even if there

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were any risk associated with the interaction between endoxifen and the enteric coating material (of which there is no evidence), it would have been of no concern in the context of an enterically coated capsule.

10. Further, I note that the 334 patent does not say anything about interactions between the enteric coating and endoxifen. If there were any issues related to interactions between the enteric coating and endoxifen, the 334 patent fails to disclose any solutions to such a problem. The 334 patent simply states that “[t]he capsules are coated with an enteric coating designed to achieve intestinal targeting (upper GI and colon), by the method of Cole et al.” Ex. 1001 at 86:55-58. It would have been routine and predictable for a POSA to incorporate (Z)-endoxifen into an enteric coated capsule formulation as was well known in the art.

11. Dr. Davies also argues that the HPMC capsules taught by Cole would be unsuitable for use with endoxifen. Dr. Davies again points only to “potential” issues and cites to no actual evidence that HPMC would be incompatible with endoxifen. HPMC is the abbreviation for hydroxypropyl methylcellulose. HPMC has long been used in a variety of pharmaceutical formulations due to its desirable properties and general compatibility with many active pharmaceutical ingredients. Dr. Davies merely states, without citing any evidence, that “the HPMC of Cole carries a positive charge” and “that charged formulation components can have

unpredictable effects on other formulation elements, including pharmaceutical compositions.” Ex. 2020 at ¶ 164.

12. Dr. Davies’ assertions are flawed for several reasons. First, Dr. Davies merely states, without citing any evidence, that “the HPMC of Cole carries a positive charge” and “that charged formulation components can have unpredictable effects on other formulation elements, including pharmaceutical compositions.” Ex. 2020 at ¶ 164. Dr. Davies does not cite any evidence that charge would have been a concern in the context of endoxifen. Further, the only evidence Dr. Davies cites that HPMC would actually carry a positive charge is my deposition transcript. Dr. Davies asserts in Paragraph 164 that, at deposition, I “acknowledged” that “HPMC of Cole carries a positive charge.” In truth, I testified that HPMC “can” carry a positive charge. Ex. 2021 at 108:14-17. I did not testify that HPMC carries a positive charge under all conditions. Under certain conditions, such as during capsule filling, it is possible that HPMC could carry a positive triboelectric (*i.e.*, electrostatic) charge. Whether HPMC would actually carry a positive charge is dependent on what surface it is placed on in the dry state. However, this does not seem relevant, since the issue I refer to is concerned with the capsule filling of powders, as powders can sometimes adhere to the sides of a capsule during the filling process, particularly in a low humidity environment. These concerns are well characterized, and capsule filling with powders is well understood in the field.

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A POSA would understand that capsule filling with powders does not pose a significant problem in the industry, as capsule filling is used routinely for thousands of medications on a daily basis. . In any case, Dr. Davies does not cite to any evidence, I have not seen any evidence, and I am not aware of any reason, that a positive electrostatic charge on HPMC would have been a concern in relation to the stability of endoxifen.

13. Further, in contrast to Dr. Davies' conclusory remarks that HPMC would "potentially" be incompatible with endoxifen, HPMC is widely used in connection with pharmaceutical formulations because of its general compatibility with a wide range of active pharmaceutical ingredients. *See, e.g.,* Majee, S.B., et al, Int. J. Pharm. Pharm. Sci., Vol. 9, Issue 10, 1-6 ("Majee") (Ex. 1026) at 6 ("Studies conducted by various manufacturing companies and research laboratories have reported HPMC capsules to be superior to hard gelatin capsules in terms of mechanical strength and compatibility with a wide range of drugs and excipients possessing reactive functional groups and varying degrees of hygroscopicity."); Marzorati, M., et al., LWT – Food Science and Technology 60 (2015) 544-551 ("Marzorati") (Ex. 1027) at 549 ("the naturally low moisture content of HPMC and the lack of chemically reactive groups make it suitable for protecting water-unstable drugs."); Al-Tabakha, M.M., J. Pharm. Pharmaceut. Sci., 13(3) 428-442 (2010) ("Al-Tabakha") (Ex. 1028) at 439 ("The cross-linking of gelatin that affects

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product dissolution and disintegration has not been observed for HPMC capsules under similar conditions. This makes HPMC capsules compatible with wider range of products except for some oxidizing agent.”); Honkanen, O. (2004), Biopharmaceutical Evaluation of Orally and Rectally Administered Hard Hydroxypropyl Methylcellulose Capsules, Academic Dissertation, University of Helsinki (“Honkanen”) (Ex. 1029) at 4 (“Another notable difference between HPMC and gelatine capsule shells is that HPMC capsule shells are compatible with most filling materials, since the only incompatibility known for HPMC is the interaction between some oxidizing agents.”) A POSA would have expected HPMC to be compatible with endoxifen due to its general compatibility with most drugs, including moisture sensitive drugs. Rather than being deterred by the “potential” compatibility concerns discussed by Dr. Davies, in reality a POSA would have been motivated to use an HPMC capsule as taught by Cole *because* of its general compatibility.

14. Further, the 334 patent does not include any disclosure related to issues with compatibility between HPMC and endoxifen. Thus, to the extent that there were any issues with compatibility associated with endoxifen loaded into an HPMC capsule, the 334 patent does not disclose any solutions. The 334 patent simply states that commercial HPMC capsules can be used. *See, e.g.*, Ex. 1001 at 40:21-23 (“Commercial sources for delayed-release oral dosage forms are

available, for example DRCaps made of Hypromellose (HPMC) from Capsugel, USA.”). Further, the 334 patent explicitly states that HPMC (also referred to as hypromellose) is compatible with (Z)-endoxifen. *See* Ex. 1001 at 86:51-55 (“The VCaps® Plus enteric capsules (Capsugel) are made with gluten free, non-animal self-gelling product hypromellose (methyl and hydroxypropyl mixed ether of cellulose), with low-moisture content that is suitable for moisture sensitive ingredients such as (Z)-endoxifen.”). This would not have been surprising to a POSA, as HPMC was known for its compatibility and low-moisture content. *See, e.g.,* Majee at 6; Marzorati at 549; Al-Tabakha at 439; Honkanen at 4.

15. As discussed above, in Paragraph 166 Dr. Davies also characterizes my analysis as an “oversimplification” because “a POSA must consider...variations in release profiles for salts versus corresponding free acids or bases of a given oral formulation.” It is entirely unclear what Dr. Davies even means. Of course, a POSA considers these factors when finalizing a formulation to achieve the exact desired pharmacokinetic profile, but that is not an element of the claims and does not relate to the *release* profile. Dr. Davies cites only to Gupta (Ex. 2017) in support of this assertion. But Gupta says nothing about endoxifen, let alone any supposed issues that would come from incorporating endoxifen or endoxifen salts into an enteric coated capsule as taught by Cole. Gupta simply discloses examples of drugs (not endoxifen), where salts can be employed to

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control certain properties of the drug. Notably, Gupta does not say anything about “variations in release profiles for salts versus corresponding free acids or bases” as Dr. Davies alleges. In truth, the degradation of the enteric coating is what would control the release profile of the drug from the capsule, not whether the endoxifen is a salt or a free base. *See, e.g.*, Ex. 1008 at 84 (“As previously mentioned, site specific delivery into the upper intestine has been achieved for many years by the use of pH-sensitive coatings (Healey, 1989). By applying a thicker coating and/or raising the threshold pH at which dissolution of the coating begins, colon specific delivery using enteric polymers has been achieved (Hardy et al., 1987a).”). Thus, the salt form would not have impacted the release rate of the drug from the capsule (though it could potentially affect its absorption *after* release).

16. In sum, a POSA would not have been led away from using HPMC capsules and enteric coatings, and it would have been routine to fill an HPMC capsule with (Z)-endoxifen and coat it, as taught in Cole. In other words, a POSA would have been motivated to use HPMC capsules and would have had far more than a reasonable expectation of success in doing so. This is the type of routine work a formulator does every day.

#### **V. A POSA Would Have Been Motivated to Combine Ahmad with Benameur**

17. As I discuss in my prior declaration (Ex. 1020), Benameur teaches that “[e]nteric capsule drug delivery technology (ECDDT) was developed to

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provide oral delivery with full enteric protection and rapid release in the upper gastrointestinal (GI) tract without the use of coatings.” Ex. 1010 at 34. Further, “ECDDT’s intrinsically enteric properties are attained by incorporating pharmaceutically approved enteric polymers in the capsule shell using conventional pin-dipping capsule manufacturing processes.” *Id.* I understand that such capsules were commercially available by October 7, 2016, according to Capsugel’s website.<sup>1</sup>

18. In Paragraph 170, Dr. Davies states that “Benameur, like Cole (EX1008), does not describe oral formulations comprising endoxifen or provide a motivation to combine the enteric formulations with an endoxifen composition comprising at least 90% (Z)-endoxifen.” The fact that Benameur does not teach a formulation with (Z)-endoxifen does not render its teachings regarding enteric capsules irrelevant with respect to the preparation of endoxifen formulations. To the contrary, a POSA would understand that Benameur can be applied to a wide range of drugs, just as with Cole’s teachings.

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<sup>1</sup> Such capsules are sold as Vcaps Enteric. <https://www.capsugel.com/biopharmaceutical-products/vcaps-enteric-capsules>. These capsules were released October 7, 2016. <https://www.capsugel.com/news/capsugel-launches-vcaps-enteric-capsules-forenteric-protection-and-delayed>

19. Benameur teaches that “[t]he enteric properties and rapid release of specialized ECDDT capsule shells have been demonstrated to meet pharmacopeia standards for both in vitro and in vivo performance using esomeprazole magnesium trihydrate (EMT) *as a model compound*.” Ex. 1010 at 34. Thus, a POSA would understand that Benameur used EMT as a model drug, and that the technology taught by Benameur would be applicable to other drugs, such as endoxifen. Further, Benameur teaches that “EMT was chosen as a model compound due to both market relevancy of Nexium® and the high gastric sensitivity. EMT is known to rapidly degrade in acidic media.” *Id.* at 35. Therefore, a POSA would have been motivated to incorporate (Z)-endoxifen, another acid labile drug, into a formulation using the enteric technology taught by Benameur. Dr. Davies does not cite to any evidence that would demonstrate a lack of such a motivation, and simply repeats the same conclusory arguments made with respect to Cole.

20. First, Dr. Davies states in Paragraph 172 that “oral formulations are known to have different controlled-release characteristics (*e.g.*, enteric properties) dependent on the oral formulation used (*e.g.*, a salt oral formulation or a free base oral formulation).” The dissolution of the enteric capsule will control the timed-release characteristic of the formulation, not the nature of the active ingredient (*e.g.*, salt compared to free base). As such, a POSA would expect that the timed

release of Benameur's formulations with model drug EMT would be comparable to any other active ingredient, including (Z)-endoxifen.

21. In Paragraph 173, Dr. Davies concludes, without citing any evidence, that "a POSA would not know how to achieve the desired characteristics of a delayed release oral formulation (*e.g.*, enteric formulation) without undue experimentation." This is nonsensical. As I explain above, Benameur teaches an enteric formulation and demonstrates the utility of such a formulation using a model drug. It would be routine for a POSA to incorporate a different active ingredient, such as (Z)-endoxifen, into Benameur's enteric formulation. Further, a POSA would have been motivated to do so based on Benameur's disclosure of the value of its enteric capsule drug delivery technology (ECDDT) for the delivery of sensitive active ingredients. *See, e.g.*, Ex. 1010 at 37 ("ECDDT represents a new, faster, and easier means for oral delivery of labile entities"). That Benameur does not disclose the incorporation of (Z)-endoxifen is of no consequence. A POSA would have been motivated to combine Ahmad and Benameur and it would have been routine for a POSA to incorporate (Z)-Endoxifen into Benameur's formulation.

22. Nothing in Benameur would have indicated to a POSA that its formulation would only be suitable for use with the model compound EMT. To the contrary, Benameur teaches that its formulations are suitable for use in a broad

range of active ingredients. For example, Benameur teaches that “ECDDT represents a new, faster, and easier means for oral delivery of labile entities, such as peptides, nucleotides, live biopharmaceutical products, and vaccines.” *Id.* at 37. Further, “[i]ntegrated enteric functionality in a capsule dosage form enables new possibilities for rapid prototype development and formulation screening, allows rapid testing of in vivo performance and minimizes the risk of out-of-specification events during enteric performance challenges on manufacturing scale-up and stability trials.” *Id.* “Avoiding the high temperatures associated with enteric coating application can also enable oral delivery of actives that require enteric protection but are sensitive to thermal degradation.” *Id.*

23. Of course, only simple and routine tests would have been needed to determine the exact pharmacokinetics for each drug, but a POSA would have expected the delayed release of the drug afforded by the ECDDT to be similar. Thus, a POSA would have been motivated to use the intrinsically enteric tablets of Benameur with the (Z)-endoxifen taught in Ahmad.

24. Further, the 334 patent does not disclose anything regarding any of the potential issues with enteric capsules that Dr. Davies states. The 334 patent simply states that the endoxifen could be loaded neat into enteric capsules. *See, e.g.*, Ex. 1001 at 86:47-49 (“endoxifen which was at least 90% (Z)-endoxifen was filled neat in a VCaps® Plus enteric capsule using Xcellodose technology (Capsugel).”)

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Thus, to the extent any issues existed with incorporating endoxifen into Benameur's enteric capsules, the 334 patent does not disclose any solutions. I am not aware of any issues that would have needed to be overcome, and a formulation scientist would have understood that Benameur's capsules could be used with Ahmad's (Z)-endoxifen with a very high likelihood of success.

**VI. A POSA Would Have Been Motivated to Combine Ahmad with Standard Excipients as Taught in e.g., the HPE and Stegemann**

25. As I discussed in my prior declaration, Claims 9-13 of the 334 patent recite various common excipients for use in capsules. Each of these excipients was well-known as disclosed for example in Stegemann and the HPE.

26. In Paragraph 176, Dr. Davies criticizes Stegemann and the HPE for not describing formulations comprising endoxifen. Dr. Davies once again relies only on conclusory assertions to support his conclusion in Paragraph 175 "that there is no articulable motivation to combine Ahmad with Stegemann (EX1011) and/or The Handbook of Pharmaceutical Excipients (HPE, EX1012) and expect a reasonable expectation of success from said combination to reach the claimed invention of the '334 patent."

27. First, in Paragraph 176, Dr. Davies states that neither the HPE nor Stegemann "describe[] oral formulations comprising endoxifen." As I discuss above with respect to both Cole and Benameur, that a reference does not specifically discuss an endoxifen formulation does not negate its relevance. Claims

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9-13 of the 334 patent recite the incorporation of common excipients into an endoxifen formulation. As I explained in my prior declaration (Ex. 1020), these excipients were all well-known in the prior art, as taught for example by Stegemann and the HPE. Further, these references are general teachings of common excipients for all classes of drugs. A POSA would have been motivated by these references to use these standard excipients for their well-known purposes. Further, the 334 patent does not disclose any challenges associated with incorporating these common excipients into an endoxifen formulation.

28. In Paragraph 178, Dr. Davies states that “[o]ral formulations are known to have variable compatibilities (*e.g.*, chemical stabilities and chemical interactions) with pharmaceutical excipients, and those interactions depend on the oral formulation used (*e.g.*, a salt oral formulation or a free base oral formulation).” Dr. Davies cites to Gupta at 9 in support of this assertion. Gupta states that “[t]here are numerous examples in the literature regarding the selection of suitable salt forms to minimize the interaction of APIs with various excipients, thereby making the drug product chemically feasible to develop.” Ex. 2017 at 8. In other words, Gupta simply says that salt forms of a compound can be compatible with “various excipients.” Gupta does not say anything about the claimed excipients, let alone anything that would indicate to a POSA any alleged incompatibility of endoxifen with the claimed excipients.

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29. In Paragraph 178, Dr. Davies also cites to my deposition transcript, where I stated that “for any drug you would consider if there was any potential interaction” with any of the excipients. Ex. 2021 at 120:16-20. First, the HPE generally lists known incompatibilities. *See* Ex. 1032 at 348 (Section 12 Incompatibilities noting Hypromellose [HPMC] has incompatibilities with “some oxidizing agents”), 768 (Section 12 Incompatibilities noting talc is incompatible “with quaternary ammonium compounds”). Thus, a POSA would have quickly identified known issues. Even ignoring that knowledge, it would have been standard practice for a POSA to run tests to ensure that there were not any negative interactions between the drug and the excipients. My statements at deposition that a POSA would run standard experiments to ensure the quality of the formulation certainly do not support, as Dr. Davies concludes, “that a POSA would not have been motivated to combine the teachings of Stegemann or the HPE with the endoxifen compositions of Ahmad.” Ex. 2020 at ¶ 179.

30. A POSA would have understood that incompatibilities between an API and certain excipients are possible. This basic fact does not somehow negate the motivation a POSA would have to combine Ahmad with Stegemann and the HPE incorporated the claimed well-known excipients into endoxifen formulations. To the contrary, a POSA would have looked to the HPE as a general guide on pharmaceutical excipients, including assessing the likelihood of issues related to

incompatibilities between certain excipients and an API. Thus, a POSA would have been able to predictably select excipients that would not have any undesirable interactions between the excipients and endoxifen. From there, it would have been routine practice for a POSA to run conventional experiments to ensure that there were in fact no interactions between the excipients and endoxifen.

31. I understand that Petitioners argued that formulation sciences were unpredictable. I disagree that such a broad statement can be made. At the relevant time period of 2017, formulating enteric capsules with standard excipients was routine and highly predictable. Most excipients had been used for decades, and any potential issues were well-known. In particular, selecting fillers and lubricants was quite routine. I also note that the claims recite a broad group of well-known fillers and lubricants—there is no indication for example that the inventors had to discover a particular species of excipient that was compatible with (Z)-endoxifen. Rather, they simply disclosed that such standard excipients could be used—which would have been highly predictable and standard to a POSA.

## **VII. A POSA Would Have Been Motivated to Select the Claimed Endoxifen Dosage**

32. As I discuss in my prior declaration (Ex. 1020), a POSA would have understood that the formulations should contain from 0.01 to 200 mg of (Z)-endoxifen. For example, Ahmad teaches in its examples that “oral doses of endoxifen (1 mg-10 mg/day) with bicultamide [sic] are expected to prevent

development of bicalutamide-induced [sic] gynecomastia and breast pain.” Ex. 1003 at 29:20-31.

33. Further, Ahmad 2010 and Ahmad 2012 provide safety data suggesting the appropriate dosage of endoxifen. For example, Ahmad 2010 teaches that “a dose of 4 mg of endoxifen should be appropriate for breast cancer prevention and therapy.” Ex. 1006 at 816. Similarly, Ahmad 2012 confirmed that 4 mg doses “were safe, well tolerated and bioavailable” and that “Multiple daily endoxifen doses of 4.0-8.0 mg resulted in endoxifen exposures that would be sufficient for effective therapy.” Ex. 1007 at 1-2. While Ahmad 2010 and 2012 do not disclose whether the endoxifen is (E), (Z), or a mix, a POSA would understand that the (Z) form is more active, and thus preferred, and would understand to use a highly pure (Z) form. From the teachings of Ahmad 2010 and 2012, a POSA certainly would have expected the appropriate dosage to fall within the range of 0.01-200 mg. From there, it would have been routine practice for a POSA to run experiments to determine the proper dosage that is most safe and efficacious. Indeed, a POSA simply would have executed similar testing to the dosage testing described in Ahmad 2010 and 2012. Ex. 1006 at 814 (“A study involving single escalating oral doses was conducted in humans to evaluate the safety, tolerability, and pharmacokinetics (PK) of endoxifen.”); Ex. 1007 at 1 (“A multiple-dose escalating study was conducted in 3 cohorts and each cohort had 6 patients (18 metastatic

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breast cancer patients). Endoxifen at 3 dose levels (2, 4, or 8 mg) was given once daily for 28 days. Routine laboratory tests, vital signs and electrocardiograms were measured throughout the study. Blood samples for PK analysis were collected after 28 days post dose.”). As such, a POSA would have had a reasonable expectation of success in selecting a (Z)-endoxifen dosage between 0.01 and 200 mg.

34. A POSA would have understood that highly pure (Z)-endoxifen would likely be more active than (E)-endoxifen, but that would not have led a POSA to expect that the dosage amount would be dramatically different from other endoxifen formulations. A POSA would have done pharmacokinetic testing (like that done in Ahmad 2010 and 2012) to determine the ideal dosing range, but it would have been readily apparent to a POSA to test dosages similar to Ahmad 2010 and 2012 (perhaps slightly broader), and in any event well within the range of 0.01 to 200 mg.

35. Indeed, it would have been shocking if the efficacious and safe dosage amount was outside of this incredibly broad range. I also note that the 334 patent does not show the full claimed range is efficacious and safe. Thus, the 334 patent appears to do no more than claim a broad range that a POSA would have understood to experiment within to determine the ideal dosing regimen.

**VIII. The pharmacokinetic limitations are the natural result of dosing a patient with (Z)-endoxifen capsules**

36. I want to clarify that I did not opine (and do not opine) that a 90% (Z)-endoxifen capsule would have the exact same pharmacokinetic results as a (E)/(Z)-endoxifen citrate tablet. A POSA would expect these two formulations to have *different* pharmacokinetics, mainly because of the difference in dosage form (tablet v. capsule). Rather, I opined that the pharmacokinetic limitations in the 334 patent are the inherent and natural result of dosing a patient with a 90% (Z)-endoxifen capsule as taught in Ahmad. In other words, the 334 patent simply claims the results of dosing a patient with 90% (Z)-endoxifen capsules, which was known in the art.

37. Indeed, there is nothing unique that the 334 patent teaches in order to obtain such pharmacokinetics (*e.g.*, use of particular excipients to modify the release rate). Rather, the 334 patent teaches the use of “neat” (Z)-endoxifen (*i.e.*, with no excipients). Ex. 1001 at 88:15-18 (“DRCaps capsules manually filled with 1, 2, or 4 mg of (Z)-endoxifen neat in compliance with GMP requirements were used.”). Then routine pharmacokinetic tests were performed. *Id.* at 89:26-27 (“AUC(inf) was measured on Day 1 blood draw samples”); 90:25-27 (“Area under the concentration-time curve from time 0 to infinity ( $AUC_{0-inf}$ ) was also determined for the first dose, on Day 1”); 90:61-63 (same). And the results were disclosed. Ex. 1001 at 92:10-25 (Table 17 displaying results for 4 mg from 736 to 4624

hr\*ng/mL); *see also* 11:46-50 (“Subjects were dosed on day 1 and plasma endoxifen levels were measured as shown in Table 17.”).

38. This is simply the natural result of dosing a patient with 90% (Z)-endoxifen in an enteric coated capsule—and a POSA would have expected the same or very similar results dosing a patient with the 90% pure (Z)-endoxifen enteric capsules taught in Ahmad. While there could be minor variances due to things such as impurities, a POSA would understand that the results would be quite similar, and well within the recited ranges (which are quite broad). Indeed, even the different formulation taught in Ahmad 2010 resulted in pharmacokinetics within the claimed ranges.

39. Further, as I explained in my opening declaration, it was understood what pharmacokinetic profile was expected to be safe and efficacious, as tamoxifen was a well-known drug, known to metabolize into endoxifen (as explained in Ahmad 2010 and Ahmad 2012). Thus, a POSA would have known the target pharmacokinetics. To the extent any modification of a formulation was needed (*e.g.*, increasing or decreasing the release rate) to achieve such pharmacokinetics, it would have been routine for a POSA to do so with a high expectation of success.

**IX. The objective indicia do not affect my opinions**

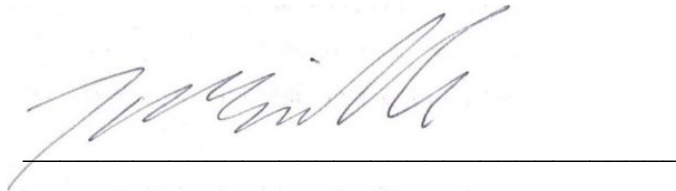
40. I understand that Patent Owner claims the formulations described in the 334 patent exhibit improved bioavailability over prior art formulations. But the claims recite a broad range of pharmacokinetics, including those exhibited in the prior art such as Ahmad 2010. In other words, the claims are not limited to any particular formulation that achieves improved pharmacokinetics. To the extent Patent Owner is arguing that the synthetic method taught in the 334 patent leads to improved pharmacokinetics over other synthetic methods, the claims are similarly not limited to that method.

41. Putting aside that the claims do not appear to be limited to a free base, let alone a free base made by any particular synthetic method, I do not see any evidence that the free base made by the 334 patent's synthetic method has improved stability. Patent Owner has presented no evidence comparing the stability of the free base made according to its method to prior art free bases (such as those taught in Ahmad and Liu).

42. Finally, I have seen no evidence of a long-felt need for a free base. There is no apparent reason that prior (Z)-endoxifen formulations were insufficient to meet a need for an alternative to tamoxifen. Nor have I seen any evidence that such a need was not met by prior methods such as taught in Ahmad and Liu.

**X. Conclusion**

43. I hereby 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.

A handwritten signature in dark ink, appearing to read 'J. McConville', is written over a horizontal line.

Jason McConville, Ph.D.

CURRICULUM VITAE  
Jason T. McConville, Ph.D.  
Associate Professor of Pharmaceutics

Mailing Address:

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College of Pharmacy, 2705 Frontier Avenue NE, Albuquerque, NM 87131.

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I. Personal

Born July 13, 1971 in Coventry, United Kingdom.  
Married.

Citizen of The United Kingdom of Great Britain and Northern Ireland.  
Citizen of The United States of America.

II. Education

Oct 91 – Jun 94	Bachelor of Science with Honors, Applied Chemistry Coventry University, Coventry, United Kingdom
Jul 99 – Sep 02	University of Strathclyde, Glasgow, United Kingdom. Doctor of Philosophy, Pharmaceutics
Dissertation:	“Pulsed-Release Drug Delivery and Development of the Time-Delayed Capsule”

III. Positions Held

September 1994 to July 1999 –Research Technician in Pharmaceutics,  
Centre for Drug Formulation Studies, University of Bath, Bath, United Kingdom.

July 1999 to September 2002 – Ph.D. Student/Candidate,  
Department of Pharmacy, University of Strathclyde, Glasgow, United Kingdom.

October, 2002 to August 2006 – Post Doctoral Fellow/ Research Associate,  
College of Pharmacy, University of Texas at Austin, Austin, TX.

August, 2006 to May 2012 – Assistant Professor of Pharmaceutics,  
College of Pharmacy, University of Texas at Austin, Austin, TX.

July, 2012 to Present – Associate Professor of Pharmaceutics,  
College of Pharmacy, University of New Mexico, Albuquerque, NM.

August, 2012 to Present – Adjunct Professor  
Department of Pharmaceutical Technology and Biopharmacy,  
University of Bonn, Germany.

July, 2021 to Present – Vice Chair of Education in Pharmaceutical Sciences,  
College of Pharmacy, University of New Mexico, Albuquerque, NM.

#### IV. Professional Memberships

American Association of Pharmaceutical Scientists <i>Sections: Formulation Design &amp; Development</i> <i>Physical Pharmacy &amp; Biopharmaceutics</i>	1997 - present
Aerosol Society	1997 - present
Controlled Release Society	2002 – present
Canadian Society for Pharmaceutical Sciences	2004 – present
American Association of Colleges of Pharmacy	2006 – present
American Association of Pharmaceutical Scientists <i>Inhalation and Nasal Community Leadership Member</i>	2020 - present

#### V. Professional Training

Short course: *Particle Characterization using Low Angle Laser Light Scattering*,  
Malvern Instruments, Limited, Malvern, Worcestershire, UK, June, 1996.

The Royal Institute of Biology, *Accredited Training for Personnel Working under the*  
*Animals (Scientific Procedures) Act 1987* (Modules 1, 2, 3, and 4),  
Guy's, King's and St Thomas' Medical School, London, UK, April, 1997.

Short course: *Advances in Controlled Release and Drug Delivery Technologies*.  
The Center for Microencapsulation and Drug Delivery, Texas A&M University,  
College Station, TX, October, 2004.

Short course: *Particle Engineering Technologies: Theory and Practice*,  
American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.

Short course: *Basic Pharmacokinetic Concepts for the Pharmaceutical Scientist*,  
University of Minnesota, College of Pharmacy, Minnesota, MN, July, 2005.

Workshop: *Tablet Coating Technologies, International Pharmaceutical Excipients Council*  
*(IPEC Americas 2008)*, San Juan, Puerto Rico, April, 2008.

The Royal Institute of Biology, *Accredited Training for Personnel Working under the Animals (Scientific Procedures) Act 1987* (Modules 1, 2, 3, 4, and 5), Vesalius, London, UK, June, 2009.

Joint American Association of Pharmaceutical Scientists/Controlled Release Society Workshop: *Developing Pharmaceutical Products for Controlled Pulmonary Delivery*, Annual Meeting of the American Association of Pharmaceutical Scientists, Washington, DC, October, 2011.

Workshop: *Setting Release Specifications for in vitro Testing of Controlled Release Dosage Forms*, 39th International Symposium on Controlled Release of Bioactive Materials, Quebec City, Canada, July, 2012.

Short Course: *Macromolecule Drug Delivery: Challenges and Triumphs*, AAPS National Biotechnology Conference, San Diego, CA, May, 2014.

National Association for Biomedical Research (NABR), Reducing Burden: Options and Opportunities, November, 2017.

Collaborative Institutional Training Initiative, Planning Research and Completing the Protocol Form, December, 2018.

Office of Laboratory Animal Welfare (OLAW), 21st Century Cures Act, December, 2019.

## VI. Current Research Interests

New technologies to improve patient compliance and health outcomes with inhalation, oral, thin film, and 3D printed drug delivery technologies.

## VII. Honors and Awards

1. Annual Research Day Award for “Design and Evaluation of Pulsatile Drug Delivery Capsule”, *University of Strathclyde*, Glasgow, May, 2001.
2. Outstanding Presentation Award: “Microwave Dielectric Analysis of Wet Granulations for Erodible HPMC Tablets”, *138th British Pharmaceutical Conference*, Glasgow, United Kingdom, September, 2001.
3. Editor’s Choice Award: “Design and Evaluation of a Restraint-Free Small Animal Inhalation Dosing Chamber”. *LeadDiscovery*, February, 2005.

4. Innovative Aspects of Oral Drug Delivery and Absorption Graduate/Post-Doc Award: “Improved Dissolution Rate and Bioavailability through the Formation of a Highly Miscible Binary Mixture”, *32nd International Symposium on Controlled Release of Bioactive Materials*, Miami, FL, June, 2005.
5. Best Resident and Research Presentation Award: “Aerosolized Itraconazole (ITZ) as Prophylaxis against Invasive Pulmonary Aspergillosis (IPA) due to *Aspergillus fumigatus*”, *27th American College of Clinical Pharmacy Annual Meeting*, St. Louis, MS, October, 2006.
6. Invited article: J.T. McConville, N.P. Wiederhold, Antifungal Prophylaxis to the Lung Using Itraconazole, *Inhalation*, 1(2007) 6-9.
7. Invited article: J.T. McConville, Targeted Lung Delivery of Antifungals: Preclinical Studies Using Itraconazole Nanoparticles, *RDD Europe 2007*, 1(2007) 43-50.
8. Invited article: D.A. Miller, J.T. McConville, W. Yang, R.O. Williams III, J.W. McGinity, Hot-Melt Extrusion for Enhanced Delivery of Drug Particles, *Journal of Pharmaceutical Sciences*, 96(2007) 361-76. Invited Article.
9. Featured News Article: “University of Texas at Austin Pharmacy Researcher Works to Lower Carbon Footprint of Pharmaceuticals”, *www.BiobasedNews.com*, August, 2008.
10. Featured News Article in Carbon Market News: “Research Reveals Pharmaceuticals Can Cut Carbon Footprint with Organic Solvent”, *www.carbonoffsetsdaily.com*, August, 2008.
11. Guest Editor: Innovative Inhalation Technologies: Special Edition: *Drug Development and Industrial Pharmacy*, 34(2008).
12. Invited article: Y-J. Son, J.T. McConville, Advancements in Dry Powder Delivery to the Lung, Special Edition: Innovative Inhalation Technologies, *Drug Development and Industrial Pharmacy*, 34(2008) 948-959.
13. Invited article: A.B. Watts, J.T. McConville, R.O. Williams III, Current Therapies and Technological Advances in Aqueous Aerosol Drug Delivery, Special Edition: Innovative Inhalation Technologies, *Drug Development and Industrial Pharmacy*, 34(2008) 913-922.
14. Invited article: W. Yang, J. Tam, D.A. Miller, J. Zhou, J.T. McConville, K.P. Johnston, R.O. Williams III, High Bioavailability from Nebulized Itraconazole Nanoparticle Dispersions with Biocompatible Stabilizers, Special Edition: Pharmaceutical Nanotechnology, *International Journal of Pharmaceutics*, 361(2008) 177–188.

15. Session Judge: Poster on the Podiums, *Respiratory Drug Delivery (RDD2008)*, Scottsdale, Arizona, 2008.
16. Research Presentation Award: "Manufacture and Characterization of Natural Polymer Based Films as Buccal Delivery Systems", *International Pharmaceutical Excipients Council (IPEC Americas 2009)*, San Juan, Puerto Rico, April, 2009.
17. Invited article: S. Thitinan, J.T. McConville, Interferon Alpha Delivery Systems for the Treatment of Hepatitis C, *International Journal of Pharmaceutics*. 369(2009) 121-135.
18. Invited article: J.T. McConville, S.A. Kucera, T.C. Carvalho, E.M. Hurley, Ethyl Lactate as a Pharmaceutical-Grade Excipient and Development of a Sensitive Peroxide Assay, *Pharmaceutical Technology*, 33(2009) 74-84.
19. Invited article: Y-J Son, J.T. McConville, Dissolution Testing for Inhalation Formulations, *Inhalation*, 2:6(2009) 8-11.
20. Invited article: Y-J. Son, M. Horng, M. Copley, J.T. McConville, Optimization of an *In Vitro* Dissolution Test Method for Inhalation Formulations, *Dissolution Technologies*, 17(2010), 6-13.
21. Member of the Society for Teaching Excellence, *University of Texas at Austin*, September, 2011.
22. Corresponding author for the most downloaded article in *European Journal of Pharmaceutics and Biopharmaceutics*: "Manufacture and Characterization of Mucoadhesive Buccal Films", January-March 2011.
23. Invited article: T.C. Carvalho, S.R. Carvalho, J.T. McConville, Formulations for Pulmonary Administration of Anticancer Agents to Treat Lung Malignancies, *Journal of Aerosol Medicine and Pulmonary Drug Delivery*, 24 (2011), 61-80.
24. Nomination: University of Texas System Regents' Outstanding Teaching Award, December 2011.
25. Research Presentation Award: Influence of particulate API in Eudragit® RS and RL films for buccal delivery, *International Pharmaceutical Excipients Council (IPEC Americas 2012)*, San Juan, Puerto Rico, 2012.
26. Invited article: S. Thitinan, J.T. McConville, Development of a Gastroretentive Pulsatile Drug Delivery Platform, *Journal of Pharmacy and Pharmacology*, 64 (2012), 505-516.
27. Invited article: Y-J. Son, J.T. McConville, Preparation of Sustained Release Rifampicin Microparticles for Inhalation, Special Edition: *Journal of Pharmacy and Pharmacology*, 64 (2012), 1291-1302.

28. Research Presentation Award: “Antisolvent Co-Precipitation Synthesis of D,L-Valine/Lysozyme”, *International Pharmaceutical Excipients Council (IPEC Americas 2014)*, Raleigh-Durham, NC, April, 2014.
29. Invited article: J.O. Morales, J.T. McConville, Novel Strategies for the Buccal Delivery of Macromolecules, *Drug Development and Industrial Pharmacy*, 40 (2014), 579–590.
30. Best Inter-Departmental Collaborative Research Award: “Polymeric Coating of Endotracheal Tubes for Local Drug Delivery”, *University of New Mexico College of Pharmacy Research and Scholarship Day*, Albuquerque, NM, September, 2015.
31. Invited article: J.E. Hasted P. Bäckman, A.R. Clark, W. Doub, A. Hickey, G. Hochhaus, P.J. Kuehl, C-M. Lehr, P. Mauser, J. McConville, R. Niven, M. Sakagimi and J.G. Weers, Scope and relevance of a pulmonary biopharmaceutical classification system AAPS/FDA/USP Workshop March 16-17th, 2015 in Baltimore, MD, *AAPS Open*, 2 (2016), 1-20.
32. Invited article: T.C. Carvalho, J.P. McCook, N.R. Narain, J.T. McConville, Development of Aqueous Dispersions of Coenzyme Q10 for Pulmonary Delivery and the Dynamics of Active Vibrating-Mesh Aerosolization, Special Issue: Staniforth Festschrift, *International Journal of Pharmaceutics*, 514 (2016), 514(2), 407-419.
33. Invited article: J.O Morales, K.R. Fathe, A. Brunaugh, S. Ferrati, S. Li, M. Montenegro-Nicolini, Z. Mousavikhamene, J.T. McConville, M.R. Prausnitz, H.D.C. Smyth, Challenges and Future Prospects for the Delivery of Biologics: Oral Mucosal, Pulmonary, and Transdermal Routes, *The AAPS Journal*, 2017, 1-17.
34. Guest Editor: Formulation and Delivery of Macromolecules, Special Edition: *AAPS PharmSciTech* 18 (2017).
35. Abstract Reviewer and Publication Coordinator for the Taylor & Francis Group and ExcipientFest 2017, Providence, RI.
36. Invited Article: I. Rossi, F. Sonvico, J. McConville, F. Rossi, E. Fröhlich, S. Zellnitz, A. Rossi, E. Del Favero, R Bettini, F. Buttini, Nebulized Coenzyme Q10 Nanosuspensions: A Versatile Approach for Pulmonary Antioxidant Therapy, *European Journal of Pharmaceutical Sciences*, 113 (2017), 159-170.
37. Session Judge: Academic and Industrial Posters, *Drug Delivery to the Lungs (DDL2017)*, Edinburgh, UK, December, 2017.
38. Session Judge: Pat Burnell Young Investigator Prize, *Drug Delivery to the Lungs (DDL2017)*, Edinburgh, UK, December, 2017.
39. Inducted as a member of the Tom L. Popejoy Society, *University of New Mexico*, 2018.

40. Elected: Member at Large Faculty Senate Health Sciences Center Council, *University of New Mexico*, July, 2018.
41. Session Judge: Academic and Industrial Posters, *Drug Delivery to the Lungs (DDL2018)*, Edinburgh, UK, December, 2018.
42. Session Judge: Academic and Industrial Posters, *Drug Delivery to the Lungs (DDL2018)*, Edinburgh, UK, December, 2018.
43. Keynote Speaker, *4th World Congress & Expo on Pharmaceuticals and Drug Delivery Systems*, Milan, Italy, March, 2019.
44. Special Issue Guest Editor, Thin Film Technologies, *International Journal of Pharmaceutics*, November, 2019.
45. Session Judge: Academic and Industrial Posters, *Drug Delivery to the Lungs (DDL2019)*, Edinburgh, UK, December, 2019.

#### VIII. University Service and Committees Served

1. Chemical, Radiological, & Biohazard Safety Committee, University of Texas at Austin, College of Pharmacy, 2006-2008.
2. Pharmacokinetics Task Force, University of Texas at Austin, College of Pharmacy, 2006-2008.
3. Curriculum Committee, University of Texas at Austin, College of Pharmacy, 2009-2010.
4. Program Assessment Team, University of Texas at Austin, College of Pharmacy, 2009-2010.
5. Financial Aid Committee (Professional Student), University of Texas at Austin, College of Pharmacy, 2006-2012.
6. Admissions Committee, University of Texas at Austin, College of Pharmacy, 2008-2012.
7. Cultural Proficiency Committee, University of Texas at Austin, College of Pharmacy, 2008- 2012.
8. Pharmaceutics Division Graduate Advisor, University of Texas at Austin, College of Pharmacy, 2008-2012.

9. Promotion and Tenure Committee, Department of Pharmaceutical Sciences, University of New Mexico, 2012-present.
10. Web Re-Design Committee, College of Pharmacy, University of New Mexico, 2012-2013.
11. Staff Excellence Award Committee, College of Pharmacy, University of New Mexico, 2012-2013.
12. Faculty Development Committee, College of Pharmacy, University of New Mexico, 2012-Present. (2014-2015 -Vice Chair; 2015-2017 - Chair).
13. Institutional Animal Care and Use Committee (IACUC), Health Science Center, University of New Mexico, 2013-Present.
14. Accreditation Committee, College of Pharmacy, University of New Mexico, 2014-2016.
15. Graduate and Postdoctoral Affairs Committee, College of Pharmacy, University of New Mexico, 2015-2017.
16. Student Pharmacist Research Interest Group (SPRIG), College of Pharmacy, University of New Mexico, 2015 – 2017.
17. Pharmacy Year 1 Faculty Advisor, College of Pharmacy, University of New Mexico, Academic year 2017 - 2018.
18. Pharmacy Year 2 Faculty Advisor, College of Pharmacy, University of New Mexico, Academic year 2018 - 2019.
19. Pharmacy Year 3 Faculty Advisor, College of Pharmacy, University of New Mexico, Academic year 2019 - 2020.
20. Graduate Affairs Committee, College of Pharmacy, University of New Mexico, 2018 – 2019.
21. Office of Research and Compliance Academic Misconduct Special Investigation Committee, University of New Mexico, 2018 – 2019.
22. Research and Scholarship Committee, College of Pharmacy, University of New Mexico, 2018 – 2020.
23. Faculty Senate Health Sciences Center Council, University of New Mexico, 2018 – 2020.
24. Faculty Senate, University of New Mexico, 2020 – Present.

25. Health Science Library and Informatics Center Advisory Council, Health Science Center, University of New Mexico, 2019 – Present.
26. UNM 2040 Steering Committee, University of New Mexico, 2021 – Present.

IX. Scientific Advisory Roles

1. Editorial Board Member of *Drug Development and Industrial Pharmacy*, 2007 – Present.
2. Editorial Advisory Board Member of *Inhalation*, 2007 – Present.
3. Prosolv® Advisory Board, JRS Pharma, Patterson, NY, 2009-2012.
4. Review Panel Member (*Ad-hoc*): National Institutes of Health, Center for Scientific Review, Nanotechnology Study Section, 2011.
5. Scientific Advisor for Respiratory Drug Delivery 2012, Phoenix, AZ, 2012.
6. American Association for the Advancement of Science, Research Competitiveness Program Review Committee (*Ad-Hoc*), New York Ave NW, Washington, DC, 2014.
7. Associate Editor of Special and Themed Issues for *Drug Development and Industrial Pharmacy*, 2015 – 2019.
8. Review Panel Member (*Ad-hoc*): National Institutes of Health, Center for Scientific Review, Special Emphasis Panel Study Section, 2017.
9. Scientific Advisor for the Aerosol Society, Drug Delivery to the Lungs (DDL), 2016 – Present.
10. Scientific Advisor for the International Pharmaceutical Excipients Council (IPEC) of the Americas, 2017 – 2019.
11. Editorial Board Member of the *Journal of Biopharmaceutics and Therapeutic Challenges*, 2017 – Present.
12. Review Panel Member (*Ad-hoc*): National Institutes of Health, Center for Scientific Review, Preclinical Services for HIV Therapeutics Special Emphasis Panel Study Section, 2020.
13. Associate Editor for *Drug Development and Industrial Pharmacy*, 2019 – Present.
14. Editorial Board Member of *Pharmaceutics*, 2020 – Present.

X. Teaching Experience

1. PHR352C (Lecture), Biopharmaceutics and Pharmacokinetics, Course Instructor, University of Texas at Austin, College of Pharmacy, 2007 - 2009.
2. PHR152P (Laboratory), Biopharmaceutics and Pharmacokinetics, Course Instructor, University of Texas at Austin, College of Pharmacy, 2007 - 2009.
3. PHR390S, Applied Pharmacokinetics, Course Coordinator, University of Texas at Austin, College of Pharmacy, 2007-2009.
4. PHR382R, Recent Advances in Pharmaceutics, Course Instructor, University of Texas at Austin, College of Pharmacy, 2007.
5. PHR380Q, Advanced Pharmaceutical Processing, Course Instructor, University of Texas at Austin, College of Pharmacy, 2008.
6. PHR380M, Drug Development, Course Instructor, University of Texas at Austin, College of Pharmacy, 2008.
7. PHR252C, Biopharmaceutics, Course Instructor, University of Texas at Austin, College of Pharmacy, 2009-2011.
8. PHR386Q, Preclinical and Clinical Drug Development, Course Instructor, University of Texas at Austin, College of Pharmacy, 2010-2012.
9. PHRM593, Pharmaceutical Sciences and Toxicology Seminar, Instructor of the Record (IOR), University of New Mexico, College of Pharmacy, 2014.
10. PHRM726, Biopharmaceutics and Pharmacokinetics, Course Instructor/Instructor of the Record (IOR), University of New Mexico, College of Pharmacy, 2012 – 2017.
11. PHRM702, Pharmaceutics II, Course Instructor, University of New Mexico, College of Pharmacy, 2013 – 2017.
12. PHRM598, Pharmaceutics & Drug Delivery Course Instructor/Instructor of the Record (IOR), University of New Mexico, College of Pharmacy, 2014.
13. PHRM701, Pharmaceutics I, Course Instructor, University of New Mexico, College of Pharmacy, 2016-2017.
14. PHRM802, Physical Pharmacy and Biopharmaceutics, Course Instructor/Instructor of the Record, University of New Mexico, College of Pharmacy, (IOR: 2017-Present).
15. PHRM824, Dosage Forms, Course Instructor, University of New Mexico, College of Pharmacy, 2017 – Present.

16. PHRM576, Molecular and Cellular Pharmacology, University of New Mexico, College of Pharmacy, 2017 – Present.

## XI. Mentoring

### *Graduate Students and Postdoctoral Fellows*

1. Yoen-Ju Son, Ph.D., Pharmaceutics Graduate Program, 2006-2010.  
*Post-Doctoral fellow under supervision of Dr. Michael Hindle, Virginia Commonwealth University, 2011-2013.*
2. Sumalee Thitinan, Ph.D., Pharmaceutics Graduate Program, University of Texas at Austin 2007-2011. Funded by a Thailand Government Pharmaceutical Organization Scholarship,  
*Employer: Thailand Government Pharmaceutical Organization, 2011-present.*
3. Thiago Carvalho Ph.D., Pharmaceutics Graduate Program, University of Texas at Austin, 2007-2011.  
*Employer: Bristol-Myers Squibb, New Brunswick, New Jersey, 2011-present.*
4. Matt Herpin, Pharmaceutics Graduate Program, University of Texas at Austin, 2011-2012.
5. Ping Du, Pharmaceutics Graduate Program, University of Texas at Austin, 2011-2012.
7. Ashkan Yazdi. Pharm.D./Ph.D Student Rotation, Pharmaceutics Graduate Program, University of Texas at Austin, 2011-2012.
8. Shih-Fan Jang, Ph.D., Pharmaceutics Graduate Program, University of Texas at Austin 2007-2013.
9. Javier Morales, Ph.D., Pharmaceutics Graduate Program, University of Texas at Austin 2008-2012. Funded by a Fulbright Organization Scholarship.  
*Assistant Professor, Department of Pharmaceutical Sciences and Technology, University of Chile, 2013-present.*
10. Simone Carvalho, Ph.D., Pharmaceutics Graduate Program, University of Texas at Austin 2009-2013.
11. Audrey Smith, Biomedical Sciences Graduate Program (BSGP) Student Rotation, University of New Mexico, Spring, 2013.
12. Dominique Perez, Biomedical Sciences Graduate Program (BSGP) Student Rotation, University of New Mexico, Spring, 2013.
13. Joseph Castillo, Biomedical Sciences Graduate Program (BSGP) Student Rotation, University of New Mexico, Fall, 2013.
14. Kai Berkenfeld Ph.D., Graduate Student, Department of Pharmaceutical Technology Graduate Program, University of Bonn, 2012-2019.

15. Anh-Le Dung, Nanoscience and Microsystems Engineering Graduate Program, University of New Mexico, 2013-2016.
16. Kristina Schönhoff M.S., Graduate Student, Department of Pharmaceutical Technology Graduate Program, University of Bonn, 2014-2016.
17. Sudha Ananthakrishnan M.S., Nanoscience and Microsystems Engineering Graduate Program, University of New Mexico, 2013-2016.
18. Elnaz Sadeghi M.S., Biomedical Engineering Graduate Program, University of New Mexico, 2016-2018.
19. Rikhav Gala, Ph.D., Research Scientist I, University of New Mexico, 2017-2018.

*Pharm.D Students*

1. Ashkan Yazdi, UT Pharm.D./Ph.D Student Rotation, 2008. (Honors Project)
2. Michelle Horng, UT Pharm.D. Student, 2008-2011.
3. Rajesh Peddaiahgari, UT Pharm.D. Student, 2009.
4. Yi Guo, UT Pharm.D. Student, 2009.
5. Tian Tian, UT Pharm.D./Ph.D Student Rotation, 2010/2011. (Honors Project)
6. Ashley Jewitt, UT B.S. Student, 2011-2012.
7. Nicole Wesley, UT Pharm.D. Student, Fall 2011.
8. Lessel Lamkin, UNM Pharm.D. Student, Spring 2012 – Spring 2014.
9. Colin Williams, UNM Pharm.D. Student, Spring 2012.
10. Michael Bernauer, UNM Pharm.D. Student, Spring 2013-Fall 2015.
11. Maria Gabriela Cabanilla, UNM Pharm.D. Student, Fall 2014 – Spring 2016.
12. Christina Clise, UNM Pharm.D. Student, Spring 2012 – Spring 2016.
13. Meghan Bass, UNM Pharm.D. Student, Spring 2016 – Spring 2017.
14. Jarrid Young, UNM Pharm.D. Student, Fall 2016 – Fall 2017.
15. Jason Solano, UNM Pharm.D. Student, Spring 2017-2018.
16. Joseph Dinallo, UNM Pharm.D. Student, Spring 2016-2017.
17. Anh Le, UNM Pharm.D. Student, Summer 2018 – Summer 2019.
18. Victoria Lopez, UNM Pharm.D. Student, Summer 2018 – Spring 2019.
19. Aaron Rodriguez, UNM Pharm.D. Student, Summer 2018 – Spring 2019.
20. Haya Albazzaz, UNM Pharm.D. Student, Spring 2020 – Present.
21. Erena Hovhannisyan, UNM Pharm.D. Student, Spring 2020 – Present.
22. Madison Robinette, UNM BSPS Student, Summer 2021 – Present.

*Visiting Scholars*

1. Simone Dietz, Pharmaceutics Intern from University of Bonn, Germany. Fall/Spring 2010/2011.
2. Christine Joseph, Pharmaceutics Intern from University of Bonn, Germany. Spring/Summer 2011.
3. Gero Joks, Pharmaceutics Intern from University of Bonn, Germany. Summer 2011.
4. Professor Alf Lamprecht, Visiting Professor from University of Bonn, Germany. Fall 2016.
5. Ian Morales, Pharmaceutics Intern from Department of Chemistry, University of Puerto Rico. Summer 2017.
6. Yousef Abugalyon, National Institute of Health (NIH) The University of Texas at El Paso BUILDing Scholars Program. Summer 2017.
7. William Mclain, Visiting Scholar from Master of Pharmacy degree programme in the Department of Pharmacy & Pharmacology at the University of Bath. Fall 2017.
8. Adnan Hassan, Visiting Scholar from Master of Pharmacy degree programme in the Department of Pharmacy & Pharmacology at the University of Bath. Fall 2017.
9. Liam Wade, Visiting Scholar from Master of Pharmacy degree programme in the Department of Pharmacy & Pharmacology at the University of Bath. Fall 2018.
10. Haya Albazzaz, Volunteer Pre-Pharmacy Undergraduate Student, UNM, Fall 2018 – Summer 2019.
11. Hannah Avery, Visiting Scholar from Master of Pharmacy degree programme in the Department of Pharmacy & Pharmacology at the University of Bath. Fall 2019.
12. Chrystabel Chinye, Visiting Scholar from Master of Pharmacy degree programme in the Department of Pharmacy & Pharmacology at the University of Bath. Fall 2019.

*Dissertation Committees Served*

1. Justin Tolman, Ph.D., UT Pharmaceutics Graduate Program, 2009.
2. Piynauch Wonganan, Ph.D, UT Pharmaceutics Graduate Program, 2010.
3. Yoen-Ju Son, Ph.D., UT Pharmaceutics Graduate Program, 2010. (Chair)
4. Sumalee Thitinan, Ph.D., UT Pharmaceutics Graduate Program, 2011. (Chair)
5. Nicole Nelson, Ph.D, UT Pharmaceutics Graduate Program, 2011.
6. Martin Donovan, Ph.D, UT Pharmaceutics Graduate Program, 2011.
7. Shayna McGill, Ph.D, UT Pharmaceutics Graduate Program, 2011.
8. Nicole Nelson, Ph.D., UT Pharmaceutics Graduate Program, 2011.

9. Loti David King'ori, M.Sc., Pharmacy, Rhodes University, South Africa, 2011.
10. Thiago Carvalho Ph.D., UT Pharmaceutics Graduate Program, 2011. (Chair)
11. Helen Lirolla, Ph.D., UT Pharmaceutics Graduate Program, 2012.
12. Prinda Wanakule, Ph.D., UT BME Graduate Program, 2012.
13. Mehra Haghi, Ph.D., Pharmacy, University of Sydney, 2012.
14. Letty Rodriguez, Ph.D., UT Pharmaceutics Graduate Program, 2012.
15. Javier Morales, Ph.D., UT Pharmaceutics Graduate Program, 2012. (Chair)
16. Shih-Fan Jang, Ph.D., UT Pharmaceutics Graduate Program, 2013. (Chair)
17. Eileen Dawson, Ph.D., UT BME Graduate Program, 2013.
18. Amit Kumar, Ph.D., UT Pharmaceutics Graduate Program, 2013.
19. Simone Carvalho, Ph.D., UT Pharmaceutics Graduate Program, 2013. (Co-Chair)
20. Amber McBride, Ph.D., UNM NSME Graduate Program, 2014.
21. Kristina Schönhoff, M.S., Pharmaceutical Technology Graduate Program, University of Bonn, 2014. (Co-Chair)
22. Ashmita Ramanah, Pharmacy, Rhodes University, 2016.
23. Elnaz Sadeghi, M.S. UNM Biomedical Engineering Graduate Program, 2018. (Chair)
24. Kai Berkenfeld Ph.D., University of Bonn, Pharmaceutical Technology Graduate Program, 2019. (Co-Chair)
25. Sudha Ananthakrishnan M.S., UNM NSME Graduate Program, 2019. (Chair)

## XII. Peer Reviewing

1. Drug Development and Industrial Pharmacy, Taylor & Francis Group, Abingdon, UK.
2. European Journal of Pharmaceutical Sciences, Elsevier, Amsterdam, Netherlands.
3. European Journal of Pharmaceutics and Biopharmaceutics, Elsevier, Amsterdam, Netherlands.
4. International Journal of Pharmaceutics, Elsevier, Amsterdam, Netherlands.
5. Journal of Controlled Release, Elsevier, Amsterdam, Netherlands.
6. Journal of Pharmaceutical Sciences, Elsevier, Amsterdam, Netherlands.
7. Pharmaceutical Research, Springer Nature, Basel, Switzerland.
8. Molecular Pharmaceutics, American Chemical Society, Washington, DC.

9. Ashley Publications Ltd., London, UK.
10. Drug Delivery, Taylor & Francis Group, Abingdon, UK.
11. Journal of Pharmacy and Pharmaceutical Sciences, Edmonton, Alberta, Canada.
12. Informa Healthcare USA, New York, NY
13. Pharmaceutical Press, London, UK
14. Journal of Pharmacy and Nutrition Science, Lifescience Global, Mississauga, Ontario, Canada.
15. Inhalation, CSC Publishing, St. Paul, MN.

### XIII. Publications

1. J.T. McConville, N. Patel, N. Ditchburn, P. Woodcock, M.J. Tobyn, J.N. Staniforth, Use of a Novel Modified TSI for the Evaluation of Controlled-Release Aerosol Formulations, *Drug Development and Industrial Pharmacy*, 26(2000) 1191-1198.
2. J.T. McConville, A.C. Ross, A.R. Chambers, G. Smith, A.J. Florence, H.N.E. Stevens, The Effect of Wet Granulation on the Erosion Behavior of an HPMC–Lactose Tablet, Used as a Rate-Controlling Component in a Pulsatile Drug Delivery Capsule Formulation, *European Journal of Pharmaceutics and Biopharmaceutics*, 57(2004) 541-549.
3. J.T. McConville, A.C. Ross, A.J. Florence, H.N.E. Stevens, Erosion Characteristics of an Erodible Tablet Incorporated in a Time-Delayed Capsule Device, *Drug Development and Industrial Pharmacy*, 31(2005) 79-89.
4. J.T. McConville, Recent Trends in Oral Drug Delivery, *The Drug Delivery Companies Report*, PharmaVentures, Oxford, UK, Autumn/Winter (2005) 24-27.
5. J.T. McConville, T.C. Carvalho, A.N. Iberg, R.L. Talbert, D.S. Burgess, J.I. Peters, K.P. Johnston, R.O. Williams III, Design and Evaluation of a Restraint-Free Small Animal Inhalation Dosing Chamber, *Drug Development and Industrial Pharmacy*, 31(2005) 35-42.
6. B.J. Hoebe, D.S. Burgess, J.T. McConville, L.K. Najvar, R.L. Talbert, J.I. Peters, N.P. Wiederhold, B.L. Frei, J.R. Graybill, R. Bocanegra, K.A. Overhoff, P. Sinswat, K.P. Johnston and R.O. Williams III, *In Vivo* Efficacy of Aerosolized Nanostructured Itraconazole Formulations for the Prevention of Invasive Pulmonary Aspergillosis, *Antimicrobial Agents and Chemotherapy*, 50(2006) 1552-1554.

7. J.M. Vaughn, J.T. McConville, X. Gao, M.T. Crisp, K.P. Johnston, R.O. Williams III, Supersaturation Produces High Bioavailability of Amorphous Danazol Particles Formed by Evaporative Precipitation into Aqueous Solution and Spray Freezing into Liquid Technologies, *Drug Development and Industrial Pharmacy*, 32(2006) 559-567.
8. J.T. McConville, K.A. Overhoff, P. Sinswat, J.M. Vaughn, B.L. Frei, D.S. Burgess, R.L. Talbert, J.I. Peters, K.P. Johnston, R.O. Williams III, Targeted High Lung Concentrations of Itraconazole Using Nebulized Dispersions in a Murine Model, *Pharmaceutical Research*, 23(2006) 901-911.
9. J.M. Vaughn, J.T. McConville, D.S. Burgess, J.I. Peters, K.P. Johnston, R.L. Talbert, R.O. Williams III, Single Dose and Multiple Dose Studies of Aerosolized Itraconazole Nanoparticles, *European Journal of Pharmaceutics and Biopharmaceutics*, 63(2006) 95-102.
10. T. Purvis, J.M. Vaughn, T.L. Rogers, X. Chen, K.A. Overhoff, P. Sinswat, J. Hu, J.T. McConville, K.P. Johnston, R.O. Williams III, Cryogenic liquids, Nanoparticles, and Microencapsulation, *International Journal of Pharmaceutics*, 324(2006) 43-50.
11. J.T. McConville, N.P. Wiederhold, Antifungal Prophylaxis to the Lung Using Itraconazole, *Inhalation*, 1(2007) 6-9.
12. J.T. McConville, Targeted Lung Delivery of Antifungals: Preclinical Studies Using Itraconazole Nanoparticles, *RDD Europe 2007*, 1(2007) 43-50.
13. D.A. Miller, J.T. McConville, W. Yang, R.O. Williams III, J.W. McGinity, Hot-Melt Extrusion for Enhanced Delivery of Drug Particles, *Journal of Pharmaceutical Sciences*, 96(2007) 361-76.
14. J.M. Vaughn, N.P. Wiederhold, Jason T. McConville, J.J. Coalson, R.L. Talbert, D.S. Burgess, K.P. Johnston, R.O. Williams III, Murine Airway Histology and Alveolar Macrophage Uptake of Inhaled Amorphous Itraconazole, *International Journal of Pharmaceutics*, 338(2007) 219-224.
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16. M. T. Carvajal, D. Cipolla, M. Copley, J.T. McConville, Highlights from RDD 2008: *Inhalation* Reports on Some of the Most Interesting Research Presented at the Most Recent Respiratory Drug Delivery Meeting, *Inhalation*, 2:3(2008) 18-20.

17. K.A. Overhoff, J.T. McConville, W. Yang, K.P. Johnston, J.I. Peters, R.O. Williams, Effect of Stabilizer on the Maximum Degree and Extent of Supersaturation and Oral Absorption of Tacrolimus Made by Ultra-Rapid Freezing, *Pharmaceutical Research*, 25(2008) 167-175.
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19. J. Tam, J.T. McConville, R.O. Williams III, K.P. Johnston, Amorphous Cyclosporin-A Nanodispersions for Enhanced Pulmonary Deposition and Dissolution, *Journal of Pharmaceutical Sciences*, 97(2008) 4915-4933.
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21. Y-J. Son, J.T. McConville, Advancements in Dry Powder Delivery to the Lung, Special Edition: Innovative Inhalation Technologies, *Drug Development and Industrial Pharmacy*, 34(2008) 948-959.
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26. J.T. McConville, L. Hodges, T. Jones, J.P. Band, B. O'Mahony, B. Lindsay, A.C. Ross, A.J. Florence, A.J. Stanley, M.J. Humphrey, C.G. Wilson, H.N.E. Stevens, A Pharmacoscintigraphic Study of Three Time-Delayed Capsule Formulations in Healthy Male Volunteers, *Journal of Pharmaceutical Sciences*, 98(2009) 4251-4263.
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28. J.A. Tolman, N.P. Wiederhold, J.T. McConville, L.K. Najvar, R. Bocanegra, J.I. Peters, J.J. Coalson, J.R. Graybill, T.F. Patterson, R.O. Williams III, Inhaled Voriconazole for the Prevention of Invasive Pulmonary Aspergillosis, *Antimicrobial Agents and Chemotherapy*, 53(2009) 2613-2615.
29. Y-J. Son, J.T. McConville, A Standardized Dissolution Test Method for Inhaled Pharmaceutical Formulations, *International Journal of Pharmaceutics*, 382(2009) 15-22.
30. J.O. Morales, M. Horng, A.M. Gregg, J.T. McConville, Development of Orally-Disintegrating Tablets using Starch and Fructose, *Pharmaceutical Technology*, 34(2010), 92-99.
31. Y-J. Son, M. Horng, M. Copley, J.T. McConville, Optimization of an *In Vitro* Dissolution Test Method for Inhalation Formulations, *Dissolution Technologies*, 17(2010), 6-13.
32. M. Copley, Y-J. Son, J. McConville, Dissolution Testing for Inhaled Drugs, *Pharmaceutical Technology Europe*, 22(2010), 37-38, 40-43.
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36. T. Carvalho, M. Horng, J.T. McConville, Application of a Pull on a Disk Method to Measure Surface Tension of Liquids, *AAPS PharmSciTech*, 13 (2012), 305-312.
37. Y-J. Son, J.T. McConville, A Prospective Dissolution Test Design: Controlling the Important Variables, *Respiratory Drug Delivery 2012*, 1(2012) 177-184.
38. S. Thitinan, J.T. McConville, Development of a Gastroretentive Pulsatile Drug Delivery Platform, *Journal of Pharmacy and Pharmacology*, 64 (2012), 505-516.
39. Y-J. Son, J.T. McConville, Preparation of Sustained Release Rifampicin Microparticles for Inhalation, Special Edition: *Journal of Pharmacy and Pharmacology*, 64 (2012), 1291-1302.
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43. J.O. Morales, G.R. Joks, A. Lamprecht, J.T. McConville A design of experiments to optimize a new manufacturing process for high activity protein-containing submicron particles, *Drug Development and Industrial Pharmacy*, 39 (2013), 1793-1801.
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45. T.C. Carvalho, J.P. McCook, N.R. Narain, J.T. McConville, Development and Characterization of Phospholipid-Stabilized Submicron Aqueous Dispersions of Coenzyme Q<sub>10</sub> Presenting Continuous Vibrating-Mesh Nebulization Performance, *Journal of Liposome Research*, 23 (2013), 276-290.
46. J. Hautmann, S.E. Godoy, P. Marshik, R. Chand, J. McConville, S. Krishna, S. Krishna, P. Muttill, Effect of Time Between Actuation on the Dose Variability for Three Metered Dose Inhalers, *Respiratory Drug Delivery 2013*, 2 (2013), 429-434.
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48. J.O. Morales, S. Huang, R.O. Williams III, J.T. McConville, Films loaded with Insulin-coated nanoparticles (ICNP) as potential platforms for peptide buccal delivery, *Colloids and Surfaces B: Biointerfaces*, 122 (2014), 38–45.
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54. J.O Morales, K.R. Fathe, A. Brunaugh, S. Ferrati, S. Li, M. Montenegro-Nicolini, Z. Mousavikhamene, J.T. McConville, M.R. Prausnitz, H.D.C. Smyth, Challenges and Future Prospects for the Delivery of Biologics: Oral Mucosal, Pulmonary, and Transdermal Routes, *The AAPS Journal*, (2017), 1-17.
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61. R.T. Sterk, A. Battle, H. Albazaz, M.A. Ozbun, J.T. McConville, The Effect of Thermal Gelation Agents on Aerosolization Properties of Viscous Liquids – In Preparation.

XIV. Published Abstracts

1. An *In Vitro* Method for Evaluation of Dry Powder Inhaler Formulations using a Novel Modified Twin Stage Impinger, Annual Meeting of the American Association of Pharmaceutical Scientists, Boston, MA, November, 1997.
2. A Novel *Ex Vivo* Method for Determining Diffusion Rates of Dry Powder Inhaler Formulations using an Isolated Perfused Guinea Pig Lung Model, Annual Meeting of the American Association of Pharmaceutical Scientists, Boston, MA, November, 1997.
3. The Comparison of Two Delivery Techniques for Dosing an Isolated Perfused Guinea Pig Lung (IPGPL), Annual Meeting of the American Association of Pharmaceutical Scientists, San Francisco, CA, November, 1998
4. An *In Vitro* Method for Evaluation of Lung Deposition and Drug Diffusion from Dry Powder Formulations using a Modified Twin Stage Impinger, Annual Meeting of the American Association of Pharmaceutical Scientists, San Francisco, CA, November, 1998.
5. Preclinical Evaluation of an Isotretinoin (iso) Powder Formulation for Aerosol Administration in Lung Cancer Chemoprevention, 90th American Association of Cancer Research, Philadelphia, PA, April, 1999.
6. Effect of Process Variables on the Time-delayed Release from a Capsule Based Delivery Device, 23rd Joint Research Seminar, Dublin, Ireland, June, 2000.
7. Effect of Process Variables on Drug Release from a Time-Delayed Capsule Delivery System, 137th British Pharmaceutical Conference, Birmingham, United Kingdom, September, 2000.
8. Processing Induced Variability of Time-delayed Delivery from a Pulsatile Capsule Device, Annual Meeting of the American Association of Pharmaceutical Scientists, Indianapolis, IN, October, 2000.
9. Microwave Dielectric Analysis of Wet Granulations for Erodible HPMC Tablets, 138th British Pharmaceutical Conference, Glasgow, United Kingdom, September, 2001.
10. The use of Microwave Analysis to Describe the Effect of a Wet Granulation Processing Technique, Annual Meeting of the American Association of Pharmaceutical Scientists, Denver, CO, October, 2001.
11. Gamma Scintigraphic Visualisation of Drug Release from a Time-Delayed Capsule, 6th US-Japan Drug Delivery Symposium, Honolulu, HI, November, 2001.
12. Gamma Scintigraphic Investigation of Drug Release from a Time-Delayed Capsule, 29th International Symposium on Controlled Release of Bioactive Materials, Seoul, Korea, June, 2002.
13. Preparation of Water-impermeable Capsule Bodies for a Pulsatile Drug Delivery System, 139th British Pharmaceutical Conference, Manchester, United Kingdom, September, 2002.
14. Time Delayed Delivery of Theophylline, 139th British Pharmaceutical Conference, Manchester, United Kingdom, September, 2002.

15. The Suitability of a Capsule Component for use with a Pulsed Release Drug Delivery Device, Annual Meeting of the American Association of Pharmaceutical Scientists, Toronto, Canada, November, 2002.
16. Gastrointestinal Transit and Release of Time-Delayed Delivery Capsules, Annual Meeting of the American Association of Pharmaceutical Scientists, Toronto, Canada, November, 2002.
17. A Study to Investigate the effects of Food Administration Post-Gastric Emptying on a Time-delayed Formulation in Healthy Volunteers using Gamma Scintigraphy, 30th International Symposium on Controlled Release of Bioactive Materials, Glasgow, United Kingdom, June, 2003.
18. Physiochemical Properties of Itraconazole Produced by Spray-Freezing into Liquid Process, 1st European Federation for Pharmaceutical Sciences Conference on Optimizing Drug Delivery and Formulation: New Challenges in Drug Delivery, Versailles, France, September, 2003.
19. Controlling Particle Characteristics of Itraconazole Powders Produced by Spray-freezing into Liquid - Organic Solution Versus Emulsion Liquid Feed Solutions, Annual Meeting of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October, 2003.
20. Nebulization of a Suspension Containing Itraconazole Prepared by Evaporative Precipitation into Aqueous Solution, Annual Meeting of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October, 2003.
21. Spray Freezing into Liquid of Itraconazole for Pulmonary Delivery, Annual Meeting of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October, 2003.
22. Enhanced Solubility and Dissolution of Itraconazole Prepared by the Spray Freezing into Liquid Technique, 31st International Symposium on Controlled Release of Bioactive Materials, Honolulu, HI, June, 2004.
23. The Use of Antioxidants to Stabilize Ethyl Lactate, Annual Meeting of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
24. Design of a Restraint-Free Small Animal Dosing Chamber for Inhalation and Investigation of Drug Distribution Within the Chamber, Annual Meeting of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
25. Miscibility of Hydrophilic Polymers and Surfactants with Polyethylene Oxide in Hot-melt Extruded Tablets Containing Poorly Water Soluble Drug, Annual Meeting of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
26. Delivery of Poorly Water Soluble Drugs using Nebulization, 15th Drug Delivery to the Lungs Conference, London, United Kingdom, December, 2004.
27. Improved Dissolution Rate and Bioavailability through the Formation of a Highly Miscible Binary Mixture, 32nd International Symposium on Controlled Release of Bioactive Materials, Miami, FL, June, 2004.
28. Delivery of Nebulized Itraconazole Nanoparticles in the Murine Model, Respiratory Drug Delivery Europe 2005, Paris, France, May, 2005.

29. Particle Engineering for Rapid Dissolution Rates of Poorly Water Soluble Drugs, American Institute of Chemical Engineers (AIChE) Annual Meeting, Cincinnati, OH, October, 2005
30. Investigation of Dissolution Properties of Microcrystalline or Stabilized Amorphous Particles of Itraconazole in Melt Extruded Solid Dispersions, Joint Symposium on the Future Prospects of Pharmaceutical Sciences, Hoshi University, Tokyo, Japan, October, 2005.
31. Characterization of Nebulized Itraconazole Nanoparticles and Delivery to the Murine Lung, Annual Meeting of the American Association of Pharmaceutical Scientists, Nashville, TN, November, 2005.
32. Treatment of Acute Pulmonary Aspergillosis with Nebulized Itraconazole in the Murine Model, Annual Meeting of the American Association of Pharmaceutical Scientists, Nashville, TN, November, 2005.
33. Improved Danazol Supersaturation and Oral Bioavailability via Formulation into an Amorphous Solid Solution, Annual Meeting of the American Association of Pharmaceutical Scientists, Nashville, TN, November, 2005.
34. Investigation of Dissolution Properties of Microcrystalline or Stabilized Amorphous Particles of Itraconazole in Melt Extruded Solid Dispersions, Annual Meeting of the American Association of Pharmaceutical Scientists, Nashville, TN, November, 2005.
35. Treatment of Pulmonary Aspergillosis using Nebulized Itraconazole Nanoparticles prepared using Particle Engineering Technologies, 16th Drug Delivery to the Lung Conference, London, United Kingdom, December, 2005.
36. *In Vivo* Efficacy of Aerosolized Nano-structured Itraconazole (ITZ) Formulations for the Prevention of Invasive Pulmonary Aspergillosis (IPA), 45th Interscience Conference on Antimicrobial Agents and Chemotherapy, Washington, DC, December 2005 (originally scheduled for New Orleans, September, 2005).
37. Single Dose Variability and Multi-Dose Studies of Nebulized Itraconazole in a Murine Model, Respiratory Drug Delivery (RDD X) Conference, Boca Raton, FL, April, 2006.
38. Murine Airway Histology and Alveolar Macrophage Uptake of Inhaled Amorphous Itraconazole (Itra), American Thoracic Society International Conference, San Diego, CA, May, 2006.
39. Particle Engineering and Formulation for Enhanced Bioavailability of Poorly Water Soluble Drugs, Particles 2006 Conference, Orlando, FL, May, 2006.
40. Sustained Lung Concentrations of Itraconazole using Nebulized Dispersions in a Murine Model, 32nd International Symposium on Controlled Release of Bioactive Materials, Vienna, Austria, July, 2006.
41. Aerosolized Itraconazole (ITZ) as Prophylaxis against Invasive Pulmonary Aspergillosis (IPA) due to *Aspergillus fumigatus*, American College of Clinical Pharmacy Annual Meeting, St. Louis, MS, October, 2006.
42. *In-vitro* and *In-vivo* Comparison of Melt Extruded Particulate Dispersions of PVP and HPMC-Stabilized Nano-Structured Amorphous Itraconazole Particles, Annual Meeting of the American Association of Pharmaceutical Scientists, San Antonio, TX, October, 2006.

43. Antisolvent Precipitation of Cyclosporin A Nanoparticles for Enhanced Pulmonary Delivery, Annual Meeting of the American Association of Pharmaceutical Scientists, San Antonio, TX, October, 2006.
44. Immunological Response and Alveolar Macrophage Uptake of Inhaled Amorphous ITZ, Annual Meeting of the American Association of Pharmaceutical Scientists, San Antonio, TX, October, 2006.
45. *In Vitro* and *In Vivo* Validation of a High-Concentration Pre-Clinical Rodent Dosing Apparatus for Inhalation, Annual Meeting of the American Association of Pharmaceutical Scientists, San Antonio, TX, October, 2006.
46. A Novel *In Vitro* Pulmonary Dissolution Testing Method for Controlled Release Inhalation Formulations, 34th International Symposium on Controlled Release of Bioactive Materials, Long Beach, CA, July, 2007.
47. The Swelling Properties of Walocel-HM (Hypromellose) in 100% Ethanol, Annual Meeting of the American Association of Pharmaceutical Scientists, San Diego, CA, November, 2007.
48. A Novel *In Vitro* Dissolution Testing Method for Inhalation Formulations, Annual Meeting of the American Association of Pharmaceutical Scientists, San Diego, CA, November, 2007.
49. *In Vitro* Determination of Gastric Mucoadhesion for Hypromellose Formulations, Annual Meeting of the American Association of Pharmaceutical Scientists, San Diego, CA, November, 2007.
50. Development of a Standardized *In Vitro* Pulmonary Dissolution Testing Method, 6th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Barcelona, Spain, April 2008.
51. Development of a Standardized Dissolution Test for Inhalable Formulations, Respiratory Drug Delivery (RDD XI) Conference, Scottsdale, AZ, May, 2008.
52. *In Vitro* Determination of Gastrointestinal Mucoadhesion Formulations, 35th International Symposium on Controlled Release of Bioactive Materials, New York, NY, July, 2008.
53. Aerosolized Voriconazole (VRC) as Prophylaxis against Invasive Pulmonary Aspergillosis (IPA) due to *Aspergillus fumigatus*, 48th Interscience Conference on Antimicrobial Agents and Chemotherapy/Infectious Diseases Society of America 46th Annual Meeting, Washington, DC, October, 2008.
54. Preliminary Studies for Rapidly Disintegrating Mini-Tablets for Enteric Coated Oral Delivery, Annual Meeting of the American Association of Pharmaceutical Scientists, Atlanta, GA, November, 2008.
55. Gender and Race-Based Disparities in the Proportion of Hepatitis C Patients that are Co-Infected with HIV/AIDS in The 1996-2005 US National Hospital Discharge Survey, Annual Meeting of the American Association of Pharmaceutical Scientists, Atlanta, GA, November, 2008.
56. Low Concentration Range Determination of API 31510 using High Performance Liquid Chromatography (HPLC), Annual Meeting of the American Association of Pharmaceutical Scientists, Atlanta, GA, November, 2008.
57. Major Sites of Pulmonary Malignancy and Associated Health Outcomes for Lung Cancer Patients in the 1996-2005 National Hospital Discharge Survey (NHDS),

- Annual Meeting of the American Association of Pharmaceutical Scientists, Atlanta, GA, November, 2008.
58. Improvements of an *In Vitro* Dissolution Test Method For Dry Powder Inhalation Formulations, Annual Meeting of the American Association of Pharmaceutical Scientists, Atlanta, GA, November, 2008.
  59. Aerosol Characterization and Single-Dose Pharmacokinetic Analysis of Nebulized Voriconazole Solution, Annual Meeting of the American Association of Pharmaceutical Scientists, Atlanta, GA, November, 2008.
  60. Investigation of Nebulized Dose and Inhaled Dose of Itraconazole Dispersions in a Nose-Only Rodent Dosing Chamber, Annual Meeting of the American Association of Pharmaceutical Scientists, Atlanta, GA, November, 2008.
  61. Characterization of Saccharide Derived Fast Disintegrating Tablets, ExcipientFest 2009, San Juan, PR, May, 2009.
  62. Manufacture and Characterization of Natural Polymer Based Films as Buccal Delivery Systems, ExcipientFest 2009, San Juan, PR, May, 2009.
  63. Development of Fast Disintegrating Tablets using Starch and Starch Derivatives, 36th International Symposium on Controlled Release of Bioactive Materials, Copenhagen, Denmark, July, 2009.
  64. An Investigation of Natural Based Films Suitable for Buccal Delivery, 36th International Symposium on Controlled Release of Bioactive Materials, Copenhagen, Denmark, July, 2009.
  65. Effect of Oral Candidiasis Co-Infection in HIV/AIDS and Hepatitis C Patients Admitted to Hospitals in The United States, Annual Meeting of the American Association of Pharmaceutical Scientists, Los Angeles, CA, November, 2009.
  66. Effect of Cooling Rate on the Particle Size of API31510 Emulsions, Annual Meeting of the American Association of Pharmaceutical Scientists, Los Angeles, CA, November, 2009.
  67. Investigation of nebulized itraconazole dispersions: *in-vitro-in-vivo* comparison of dose administered to mice in a nose-only dosing apparatus, Annual Meeting of the American Association of Pharmaceutical Scientists, Los Angeles, CA, November, 2009.
  68. Nanostructured Tacrolimus Produced by Ultra-Rapid Freezing for Dry Powder Inhalation, Annual Meeting of the American Association of Pharmaceutical Scientists, Los Angeles, CA, November, 2009.
  69. Development and Evaluation of a Manufacturing Process for Xanthan Gum-Based Films, Annual Meeting of the American Association of Pharmaceutical Scientists, Los Angeles, CA, November, 2009.
  70. Optimization of an In Vitro Dissolution Test Method for Inhalation Formulations, Annual Meeting of the American Association of Pharmaceutical Scientists, Los Angeles, CA, November, 2009.
  71. Low Density Chitosan-Based Particles Prepared by Spray Drying as a Pulmonary Drug Delivery Vehicle, Annual Meeting of the American Association of Pharmaceutical Scientists, Los Angeles, CA, November, 2009.

72. Particle Manufacture for Targeted Oral Delivery in a Rodent Model, Annual Meeting of the American Association of Pharmaceutical Scientists, Los Angeles, CA, November, 2009.
73. Development of Submicron Aqueous Formulations of API31510, Annual Meeting of the American Association of Pharmaceutical Scientists, Los Angeles, CA, November, 2009.
74. Manufacture and characterization of Fast Disintegrating Tablets, Annual Meeting of the American Association of Pharmaceutical Scientists, Los Angeles, CA, November, 2009.
75. Optimization of an In Vitro Dissolution Test Method for Inhalation Formulations, Proceeding of the Drug Delivery to the Lungs Conference (DDL20), Edinburgh, UK, December 2010.
76. The Use of Silicified Microcrystalline Cellulose and Fructose in the Development of Orally Disintegrating Tablets, 37th International Symposium on Controlled Release of Bioactive Materials, Portland, OR, July, 2010.
77. Rapidly Disintegrating Tablets for Targeted Oral Delivery, 37th International Symposium on Controlled Release of Bioactive Materials, Portland, OR, July, 2010.
78. Assessment of Student Performance in Biopharmaceutics using the TurningPoint Audience Response System, Proceedings of AACP Annual Meeting and Seminars, Seattle, WA, 2010.
79. Development and Characterization of Films for Buccal Delivery, Annual Meeting of the American Association of Pharmaceutical Scientists, New Orleans, LA, November, 2010.
80. Time Dependent Aerosolization Stability of Vibrating-Mesh Nebulizers with Submicron Lecithin Aqueous Dispersions of API31510, Annual Meeting of the American Association of Pharmaceutical Scientists, New Orleans, LA, November, 2010.
81. Nebulization Performance of Submicron Aqueous Dispersions of API 31510 prepared using High Pressure Homogenization, Annual Meeting of the American Association of Pharmaceutical Scientists, New Orleans, LA, November, 2010.
82. Measurement of Surface Tension of Liquids using Texture Analyzer, Annual Meeting of the American Association of Pharmaceutical Scientists, New Orleans, LA, November, 2010.
83. Manufacture of BSA Microcrystals by a Co-Precipitation Method, Annual Meeting of the American Association of Pharmaceutical Scientists, New Orleans, LA, November, 2010.
84. Stabilized Buoyancy and Optimal Loading Capacity of a Floating Gastric Device, Annual Meeting of the American Association of Pharmaceutical Scientists, New Orleans, LA, November, 2010.
85. Size Exclusion and Gastric Emptying in Rodent Models, Annual Meeting of the American Association of Pharmaceutical Scientists, New Orleans, LA, November, 2010.
86. Fighting Dysphagia with Orally Disintegrating Tablets, 8th International Conference on Functional Foods for Chronic Diseases: Science and Practice, Las Vegas, NV, March 2011.

87. Time Dependent Aerosolization Stability of a Vibrating-Mesh Nebulizer using API31510, Respiratory Drug Delivery Europe 2011, Berlin, Germany, May, 2011.
88. The Influence of Physicochemical Properties of Aqueous Dispersions on Active Vibrating-Mesh Nebulization, 18th Congress of International Society for Aerosols in Medicine, Rotterdam, Netherlands, June, 2011.
89. Orally Disintegrating Dietary Supplement Tablets, Institute of Food Technology Annual Meeting, New Orleans, LA, June, 2011.
90. A Gastric Retention Modeling Study of Floating Devices, 38th International Symposium on Controlled Release of Bioactive Materials, National Harbor, MD, July, 2011.
91. Impact of Drying Conditions on the Physicochemical and Aerodynamic Properties of Rifampicin Dihydrate (RFDH) Microcrystals, Annual Meeting of the American Association of Pharmaceutical Scientists, Washington DC, October, 2011.
92. BSA Microcrystals by a Co-Precipitation Method: The Effect of Solvent Type and Presence of Surfactant, Annual Meeting of the American Association of Pharmaceutical Scientists, Washington DC, October, 2011.
93. The Influence of Particles on Physical Properties of Films, Annual Meeting of the American Association of Pharmaceutical Scientists, Washington DC, October, 2011.
94. *In Vitro* Evaluation of Adhesion Properties of Mucoadhesive Pellets Using Artificial Agar/Mucin Gel, Annual Meeting of the American Association of Pharmaceutical Scientists, Washington DC, October, 2011.
95. The Influence of Physicochemical Properties of Aqueous Dispersions on Active Vibrating-Mesh Nebulization, Annual Meeting of the American Association of Pharmaceutical Scientists, Washington DC, October, 2011.
96. Dissolution Rate Comparison of Micronized and Spray-Dried Budesonide, Respiratory Drug Delivery 2012, Phoenix, AZ, May, 2012.
97. A Novel Method for the Manufacture of Protein-Coated Nanoparticles, 39th International Symposium on Controlled Release of Bioactive Materials, Quebec City, Canada, July, 2012.
98. Dissolvable Strip for Treatment of Oral Thermal Burns, Annual Meeting of the American Association of Pharmaceutical Scientists, Chicago, IL, October, 2012.
99. The Effect of pH on Protein-coated Submicron Particles Obtained by Antisolvent Co-precipitation, Annual Meeting of the American Association of Pharmaceutical Scientists, Chicago, IL, October, 2012.
100. Manufacture and Characterization of Films for Buccal Delivery of Protein-coated Submicron Particles, Annual Meeting of the American Association of Pharmaceutical Scientists, Chicago, IL, October, 2012.
101. Influence of Particulate API in Eudragit® RS and RL Films for Buccal Delivery, Annual Meeting of the American Association of Pharmaceutical Scientists, Chicago, IL, October, 2012.
102. Controlled Release Properties of Cellulose Processed by Rapid Freezing Technology, Annual Meeting of the American Association of Pharmaceutical Scientists, Chicago, IL, October, 2012.

103. Prediction of *In Vitro* Aerosolization Profiles Based on Rheological Behaviors for Aqueous Dispersions of API 31510, Annual Meeting of the American Association of Pharmaceutical Scientists, Chicago, IL, October, 2012.
104. Acoustic Levitation to Simulate Rifampicin Spray Drying Kinetics, Annual Meeting of the American Association of Pharmaceutical Scientists, Chicago, IL, October, 2012.
105. Multiple Dose Platforms for Once-Daily Administration of Ciprofloxacin or Verapamil, 3rd International Conference and Exhibition on Pharmaceutics & Novel Drug Delivery Systems, Northbrook, IL, April, 2013.
106. Effect of Time Between Actuation on the Dose Variability for Three Metered Dose Inhalers, Respiratory Drug Delivery Europe 2013, Berlin, Germany, May, 2013.
107. Controlled Release Mucoadhesive Films Containing Nanoparticles of Lysozyme, 40th International Symposium on Controlled Release of Bioactive Materials, Honolulu, HI, July, 2013.
108. Determination of Thermodynamic Characteristics of A Rifampicin Solvate Recrystallized from Ethanol, 31st Annual Meeting of the Mountain West Society of the Society of Toxicology, Albuquerque, NM, September, 2013.
109. Bioadhesive Films Containing Nanoparticles of Lysozyme, Annual Meeting of the American Association of Pharmaceutical Scientists, San Antonio, TX, November, 2013.
110. Development of Films of Insulin-coated Nanoparticles for Use in Buccal Delivery, Annual Meeting of the American Association of Pharmaceutical Scientists, San Antonio, TX, November, 2013.
111. Gastroretentive Capsules for Once-daily Administration of Ciprofloxacin or Verapamil, Annual Meeting of the American Association of Pharmaceutical Scientists, San Antonio, TX, November, 2013.
112. Preformulation Development Studies of Respirable Rifampicin Particles through Crystal Modification, Annual Meeting of the American Association of Pharmaceutical Scientists, San Antonio, TX, November, 2013.
113. Inhaled Therapeutics for Lung Cancer, Drug Delivery to the Lungs Conference (DDL24), Edinburgh, UK, December, 2013.
114. Antisolvent Co-Precipitation Synthesis of D,L-Valine/Lysozyme, ExcipientFest 2014, Raleigh, NC, April, 2014.
115. Antisolvent Co-precipitation Synthesis of D,L-Valine/Lysozyme (Encore Presentation), Annual Meeting of the American Association of Pharmaceutical Scientists, San Diego, CA, November, 2014.
116. Core Forming Antisolvent Co-precipitation of Protein Loaded Crystals, Annual Meeting of the American Association of Pharmaceutical Scientists, San Diego, CA, November, 2014.
117. Investigating of Protein-Coated Nanoparticles for Controlled Release Films, 42nd International Symposium on Controlled Release of Bioactive Materials, Edinburgh, UK, July, 2015.
118. Enhancing Macrophage Uptake of Rifampicin, 3rd International TB-Meeting, October, 2015 Parma, Italy

119. Development of Coenzyme Q10 Nano-emulsions for a Nebulization Delivery, Annual Meeting of the American Association of Pharmaceutical Scientists, Orlando, FL, October, 2015.
120. Formulation and Characterization of Dextromethorphan Thin Films, Annual Meeting of the American Association of Pharmaceutical Scientists, Orlando, FL, October, 2015.
121. Manufacture and Characterization of Rifampicin Particles for Aerosolization, Annual Meeting of the American Association of Pharmaceutical Scientists, Orlando, FL, October, 2015.
122. Polymeric Coating of Endotracheal Tubes for Local Drug Delivery, Annual Meeting of the American Association of Pharmaceutical Scientists, Orlando, FL, October, 2015.
123. Stability Characterization of Nano-Emulsions Intended as a Vehicle for Aerosol Formulations, Annual Meeting of the American Association of Pharmaceutical Scientists, Orlando, FL, October, 2015.
124. Preparation and Evaluation of Dextromethorphan Containing Thin Films, ExcipientFest 2015, Baltimore, MD, April, 2015.
125. Development of Coenzyme Q10 Nano-Emulsions for Nebulization Delivery, 43rd International Symposium on Controlled Release of Bioactive Materials, Seattle, WA, July, 2016.
126. Polyethylene Glycol Coating of Endotracheal Tubes for Local Delivery, 43rd International Symposium on Controlled Release of Bioactive Materials, Seattle, WA, July, 2016.
127. Manufacture and Assessment of a Novel 3D Printed Induction Port for Cascade Impactor Analysis, ExcipientFest 2017, Providence, RI, April, 2017.
128. Effect of Drug Concentration on Viscosity of Submicron Dispersions of Coenzyme Q10, ExcipientFest 2017, Providence, RI, April, 2017.
129. Investigating ACI Performance of a Salbutamol pMDI Formulation Using a Modified 3D Printed Induction Port, Annual Meeting of the American Association of Pharmaceutical Scientists, San Diego, CA, November, 2017.
130. Effect of Drug Concentration on surface tension and the rheology of Submicron Dispersions of CoenzymeQ10, Annual Meeting of the American Association of Pharmaceutical Scientists, San Diego, CA, November, 2017.
131. Reducing the Sol-Gel Transition of Hypromellose 2910 with Highly Electronegative Ion Containing Gelling Aids, ExcipientFest 2018, San Juan, PR, May, 2018.
132. Oral Gelling Liquid Formulations for Dental Remineralization, ExcipientWorld 2019, National Harbor, MD, May, 2019.
133. Preparation of Drug Containing Core Microparticles for use in Taste Masking Applications, 43th International Symposium on Controlled Release of Bioactive Materials, Las Vegas, NV, June, 2020.
134. Determining the design space of intermediate core microparticles obtained from spray dried acrylic polymers for taste masking bitter drugs, Annual Meeting of the American Association of Pharmaceutical Scientists, Virtual Meeting, October, 2020.
135. Enhanced Dissolution of a Poorly Soluble Drug Using a Spray Drying Technique, Annual Meeting of the American Association of Pharmaceutical Scientists, Philadelphia, PA, October, 2021.

136. The Effect of 3D Printed Mimetic Human Induction Ports on the Deposition of Inhalation Aerosols, UNM College of Pharmacy Annual Research Day, Albuquerque, NM, April, 2022.
137. Variability in 3D Print Weight for Novel Solid Oral Dosage Form Components, UNM College of Pharmacy Annual Research Day, Albuquerque, NM, April, 2022.
138. Modifying Drug Release from Microparticles Prepared by Spray Drying Using a 3-Fluid Nozzle, Annual Meeting of the American Association of Pharmaceutical Scientists, Boston, MA, October, 2022.
139. 3D Printed Mimetic Human Induction Ports Effects the Deposition of Inhalation Aerosols, American Society of Health-System Pharmacists (ASHP) Midyear Meeting, Las Vegas, NV, December, 2022.

XV. Book Contributions and Editorials

1. J.T. McConville, Preface for *Advanced Drug Formulation Design to Optimize Therapeutic Outcomes*, (Eds.) Robert O. Williams III, David R. Taft, J.T. McConville, Informa Healthcare, New York, NY, September, 2007.
2. J.T. McConville, N.P. Wiederhold, Invasive Pulmonary Aspergillosis: Therapeutic and Prophylactic Strategies, In *Advanced Drug Formulation Design to Optimize Therapeutic Outcomes*, (Eds.) Robert O. Williams III, David R. Taft, J.T. McConville, Informa Healthcare, New York, NY, September 2007.
3. J.T. McConville, F.J. McInnes, A.C. Ross, Preface for Innovative Inhalation Technologies: Special Edition, *Drug Development and Industrial Pharmacy*, 34(2008) 1-2.
4. S. Thitinan, J.T. McConville, Pulsatile Drug Delivery, In *Controlled Release: Oral Dosage Forms*, Eds. Patrick Crowley, Clive Wilson, Controlled Release Society Books, St. Paul, MN, 2011.
5. Y-Ju Son, J.T. McConville, In Vitro Performance Testing for Pulmonary Drug Delivery, In *Controlled Release Science and Technology: Pulmonary Delivery*, (Eds.) Hugh Smyth, Anthony Hickey, Controlled Release Society Books, St. Paul, MN, 2011.
6. J.O. Morales, A.B. Watts, J.T. McConville, Mechanical Particle Size Reduction Techniques, In *Formulating Poorly Water Soluble Drugs*, (Eds.) Dave Miller, Alan Watts, Robert O. Williams III, Springer Publishing Company, New York, NY, 2011.
7. J.O. Morales, J.T. McConville, Polymer Drug Delivery Systems for Sustained Mucoadhesion in the Respiratory Tract. In *Polymers for Pulmonary Drug Delivery*, (Eds.) H.D.C. Smyth, I. Saleem, J.T. McConville, iSmithers, Shrewsbury, UK, 2013.

8. P. Du, J.T. McConville, Regulatory Aspects of Pulmonary Delivery of Polymers. In *Polymers for Pulmonary Drug Delivery*, (Eds.) H.D.C. Smyth, I. Saleem, J.T. McConville, iSmithers, Shrewsbury, UK, 2013.
9. J.T. McConville, Polymer Drug Delivery Systems Targeting the Alveolar Macrophages. In *Polymers for Pulmonary Drug Delivery*, (Eds.) H.D.C. Smyth, I. Saleem, J.T. McConville, iSmithers, Shrewsbury, UK, 2013.
10. J.O. Morales, J.T. McConville, Preface for Buccal Drug Delivery Theme Issue, *Drug Development and Industrial Pharmacy*, 40(2014), 577–578.
11. J.T. McConville, Preface for Special Focus: Pharmaceutical Dosage Form Design Influence on Drug Pharmacokinetics, *Drug Development and Industrial Pharmacy*, 41(2015), 1921.
12. J.T. McConville, Preface for Special Focus: Transdermal, Topical and Follicular Drug Delivery Systems, 42(2016), 845.
13. J.T. McConville, Preface for Special Focus: Ocular and Ophthalmic Drug Delivery Systems, 42(2016), 513.
14. J.T. McConville, Preface for Special Focus: Current developments in oral drug administration, *Drug Development and Industrial Pharmacy*, 43 (2017), 699.
15. J.T. McConville, J.O. Morales, Preface for Selected abstracts from Excipient Fest 2017, *Drug Development and Industrial Pharmacy*, 44 (2018), 868.
16. J.T. McConville, R. Gala, J.O. Morales, Preface for Special Issue: Thin Film Technologies, *International Journal of Pharmaceutics*, November, 2019.

XVI. Invited Talks, Sessions, and Workshop Presentations

1. *Microwave Dielectric Analysis of Wet Granulations for Erodible HPMC Tablets*, Proceedings of the 138th British Pharmaceutical Conference, Glasgow, United Kingdom, September, 2001.
2. *Chronopharmaceutical Drug Delivery*, University of Texas at Austin, Austin, TX, October, 2001.
3. Workshop Presenter: *Particle Engineering Technologies: Theory and Practice*, Annual Meeting of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.

4. *Capsule Filling and Topical Formulations*, Science Camp Presentation, Priscilla Pond Flawn Child and Family Laboratory, University of Texas at Austin, Austin, TX, June, 2005.
5. *Pre-Clinical Development Studies with Poorly Water-Soluble Drugs*, Universidade Federal de Minas Gerais, Belo Horizonte, Brasil, June, 2005.
6. *Targeted High Lung Concentrations of Itraconazole using Nebulized Dispersions in a Murine Model*, 1<sup>st</sup> Joint Symposium on the Future Prospects of Pharmaceutical Sciences, Hoshi University, Tokyo, Japan, October, 2005.
7. *Pre-Clinical Development Studies with Poorly Water-Soluble Drugs*, University of Louisiana at Monroe, Monroe, LA, January, 2006.
8. *The Effective Delivery of Itraconazole for the Treatment of Acute Fungal Infections*, University of Mississippi, Oxford, MS, January, 2006.
9. *Targeted High Lung Concentrations of Itraconazole using Nebulized Dispersions in a Murine Model*, University of Texas at Austin, Austin, TX, February, 2006.
10. *Enhanced Therapeutic Outcomes using Targeted Itraconazole Delivery in a Murine Model*, Long Island University, Brooklyn, NY, February, 2006.
11. *Targeted Treatment of Infectious Diseases to the Lung*, Virginia Commonwealth University, February, 2007.
12. *Targeted Lung Delivery of Antifungals: Preclinical Studies using Itraconazole Nanoparticles*, Respiratory Drug Delivery Europe 2007, Paris, France, April, 2007.
13. *Preclinical Studies with Poorly Water Soluble Drugs*, University of Strathclyde, Glasgow, UK, July, 2007.
14. *Antifungal Prophylaxis to Treat Pulmonary Aspergillosis*, GEA-NUS 10th Anniversary Celebration & Pharmaceutical Technology Seminar, Singapore, December, 2007.
15. *Novel In Vitro Dissolution Testing Methods for Inhalation Formulations*, Dissolution Testing, Bioequivalence & Bioavailability Strategies Meeting, London, United Kingdom, June 2008.
16. *Dissolution Testing of Inhalation Products*, Copley Scientific Ltd, London, United Kingdom, June 2008.
17. *Modification of the USP Type II Dissolution Testing Apparatus for Powder Formulations*, Novartis, Basel, Switzerland, July 2008.

18. *The Use of Renewable Ingredients for Pharmaceutical Formulations*, Tate & Lyle, Decatur, September 2008.
19. *Improved Therapy by Direct Lung Targeting for the Treatment of Pulmonary Aspergillosis*, Purdue University, September, 2008.
20. Attendee/Observer at the Aerosol Advisory Board Meeting, United States Pharmacopeia Headquarters, Rockville, MD, January, 2009.
21. *Formulation and Characterization of Prosolv® Fast Disintegrating Tablets*, Prosolv® Advisory Board Meeting, San Juan, Puerto Rico, April, 2009.
22. Workshop Presenter: Advances in the Development of Oral Controlled Release Pharmaceutical Forms and/or Site Specific Gastrointestinal Tract Delivery and Pulmonary Delivery Systems: *An Introduction to Pulmonary Drug Delivery*, Santiago, Chile, October, 2009.
23. *Formulation and Characterization of Fast Disintegrating Tablets Containing Renewable Ingredients*, 2<sup>nd</sup> Joint Symposium on the Future Prospects of Pharmaceutical Sciences, Hoshi University, Tokyo, Japan, October, 2009.
24. *Dissolution Testing of Aerosol Powder Formulations*, Novartis, Horsham, UK, December 2009.
25. Workshop Presenter: *An Introduction to Buccal Drug Delivery*, Advances in Pharmaceutical Technology and Pharmaceutical Engineering, Santiago, Chile, October, 2010.
26. *Fighting Dysphagia with Orally Disintegrating Tablets*, Functional Foods for Chronic Diseases: Science and Practice, Las Vegas, March, 2010.
27. *Formulation of Rapidly Disintegrating Tablets to Combat Dysphagia*, Prosolv® Advisory Board Meeting, Miami, FL, April, 2011.
28. Workshop Moderator and Presenter: *Developing Pharmaceutical Products for Controlled Pulmonary Delivery*, Annual Meeting of the American Association of Pharmaceutical Scientists, Washington, DC, October, 2011.
29. Workshop Presenter and Panel Discussion Member: *Dissolution Testing to Meet Formulation Challenges*, 39th International Symposium on Controlled Release of Bioactive Materials, Quebec City, Canada, July, 2012.

30. Speaker and Panel Discussion Member: *A Prospective Dissolution Test Design: Controlling the Important Variables*, Respiratory Drug Delivery 2012, Phoenix, AZ, 2012.
31. Workshop Presenter and Panel Discussion Member: *Setting Release Specifications for in vitro Testing of Controlled Release Dosage Forms: Dissolution Testing to meet Formulation Challenges*, 39th International Symposium on Controlled Release of Bioactive Materials, Quebec City, Canada, July, 2012.
32. Visiting Professor and Workshop Presenter: *An Introduction to Pulmonary Drug Delivery*, Advances in Pharmaceutical Technology and Pharmaceutical Engineering, Santiago, Chile, April, 2013.
33. *Trans-Mucosal Buccal Drug Delivery*, New Mexico Society of Health-System Pharmacists (NMSHSP) Balloon Fiesta Symposium, Albuquerque, NM, October, 2013.
34. *Inhaled Therapeutics for Lung Cancer*, Drug Delivery to the Lungs Conference (DDL24), Edinburgh, UK, December, 2013.
35. *Development of a Single Capsule Multiple Dose Regimen*, (New Mexico Pharmacist Association (NMPhA) Mid-Winter Meeting, January, 2014.
36. Session Chair and Moderator: *Macromolecule Drug Delivery: Challenges and Triumphs*, AAPS National Biotechnology Conference, San Diego, CA, May, 2014.
37. *Use of Cationic Polymethacrylate Derivatives for Oral Mucosa Drug Delivery*, 1st International Society for Biomedical Polymers and Polymeric Biomaterials Conference, Washington DC, July, 2014.
38. *Enhancing Macrophage Uptake of Rifampicin*, 3rd International TB-Meeting: Inhaled Therapies for Tuberculosis and Other Infectious Diseases, October, 2015, Parma, Italy.
39. Session Chair and Moderator: *Challenges and Future Prospects of Alternative Delivery of Biologics*, American Association of Pharmaceutical Sciences Annual Meeting, Orlando, FL, October, 2015.
40. *Development of a Buoyant Gastroretentive Dosage Form*, University of Sarajevo, Sarajevo, Bosnia and Herzegovina, June, 2016.
41. *Cascade Impactor Performance using 3D Printed Induction Port Designs*, American Association of Pharmaceutical Scientists Rocky Mountain Discussion Group 5th Annual Meeting, Albuquerque, NM, October, 2017.

Curriculum Vitae

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42. *Using Highly Electronegative Gelling Aids with Hypromellose 2910*, 4th World Congress & Expo on Pharmaceuticals and Drug Delivery Systems, Milan, Italy, March, 2019.
43. *Cascade Impactor Performance using Anatomically Appropriate 3D Printed Induction Port Designs*, University of Cork, Cork, Ireland, August, 2019.
44. *Taking it Slow: Reduced Velocity Aerosols*, Inspire Me, San Francisco, CA, June, 2019.
45. *Oral Gelling Liquid Formulations*, Rainforest Innovations, Albuquerque, NM, August, 2021.

XVII. Intellectual Property

1. Enhanced Delivery of Drug Compositions to Treat Life Threatening Infections, United States Patent US9061027 B2 (WO2006026502A1), Issue date: Jun 23, 2015.
2. Enhanced Delivery of Immunosuppressive Drug Compositions for Pulmonary Delivery, United States Patent US9044391 B2, Issue Date: Jun 2, 2015.
3. Stabilized Hot Melt Extrusion Composition with Small Drug Particles, United States Patent US9504658 B2 (WO2007001451A9), Issue date: Nov 29, 2016.
4. Enhanced Delivery of Immunosuppressive Drug Compositions for Pulmonary Delivery, United States Patent US10231955 B2, Issue Date: Mar 19, 2019.
5. Treatment of Pulmonary Fungal Infection with Voriconazole via Inhalation, Non-Provisional Patent Application (PCT/US2009/043027), filed: May 6, 2009.
6. Bioadhesive Films for Local and/or Systemic Delivery: Non-Provisional Patent Application (PCT/US2013/032490 - WO 2014/065870), filed: March 15, 2013.
7. Wireless Dispensing Device Monitor: Provisional Application (US62/796,678), filed: Jan 25, 2019.
8. Coenzyme Q10 Aerosol: Non-Provisional Application (PCT/US2016/039173 - WO 2016/210226), filed: June 24, 2016.
9. Coenzyme Q10 Aerosol: National Application (15/738,512), filed Dec 20, 2017.
10. Drug-eluting medical devices coatings: Provisional Application (US62/948,469), filed: Dec 16, 2019.
11. Oral Gelling Liquid Formulations: Non-Provisional Application (US16/839,385), filed Feb 13, 2020.
12. Thermally Gelling Drug Formulations: Non-Provisional Application (US16/947,224), filed Jul 13, 2020.