

Dr. Falk Pharma GmbH
v.
Ellodi Pharmaceuticals, L.P.

Case IPR2024-01197

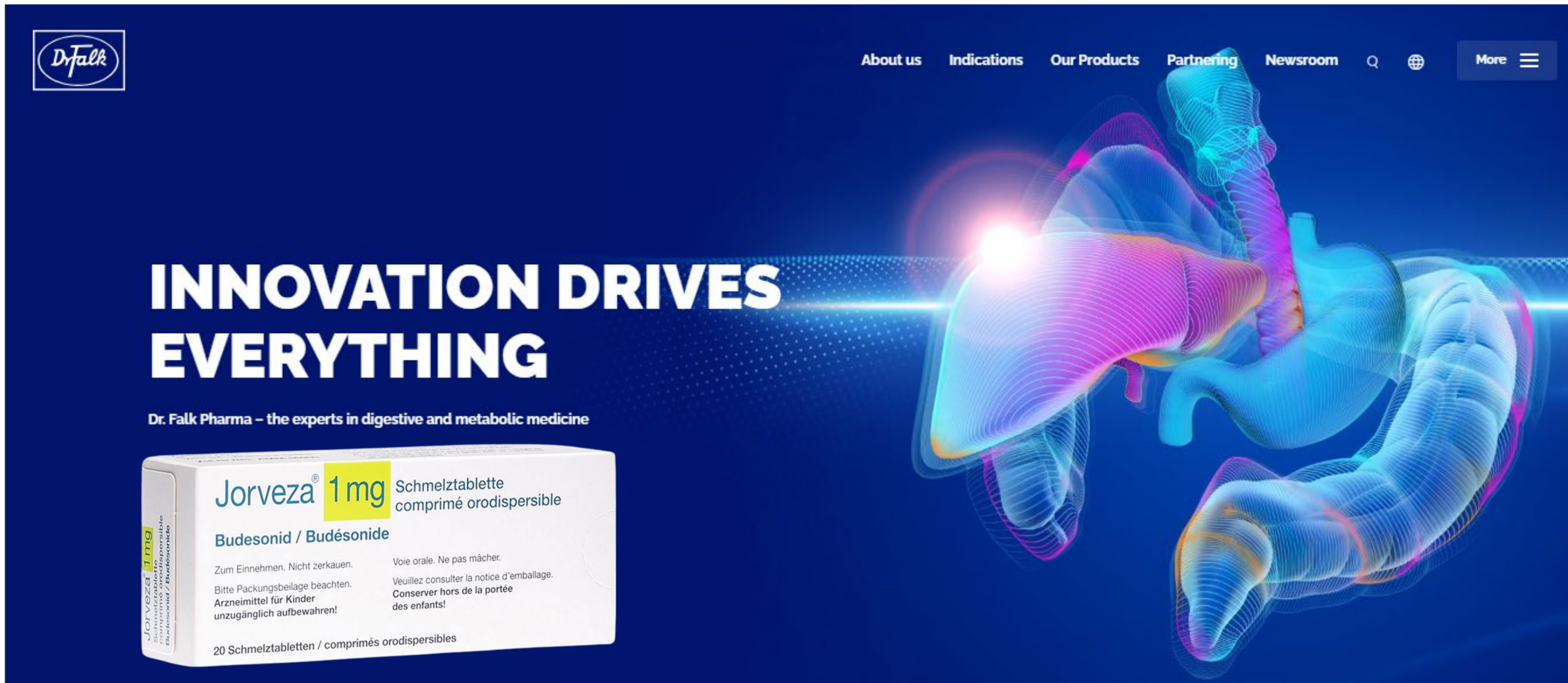
U.S. Patent 8,771,729

Petitioner's Demonstratives For Oral Hearing

Judge John G. New
Judge Zhenyu Yang
Judge Tawen Chang

October 27, 2025

Dr. Falk Pharma Ex. 1095
IPR Petition – USP 8,771,729



The banner features a dark blue background with a glowing, wireframe illustration of a human digestive system (stomach, intestines, and liver) on the right side. A bright light source is positioned near the stomach, casting a glow across the organs. On the left, the text 'INNOVATION DRIVES EVERYTHING' is prominently displayed in white. Below this, the tagline 'Dr. Falk Pharma – the experts in digestive and metabolic medicine' is shown. At the bottom left, a white box of Jorveza 1mg is depicted, showing its packaging details in multiple languages.

Dr. Falk

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INNOVATION DRIVES EVERYTHING

Dr. Falk Pharma – the experts in digestive and metabolic medicine

Jorveza® 1 mg Schmelztablette
comprimé orodispersible

Budesonid / Budésonide

Zum Einnehmen. Nicht zerkauen.
Bitte Packungsbeilage beachten.
Arzneimittel für Kinder
unzugänglich aufbewahren!

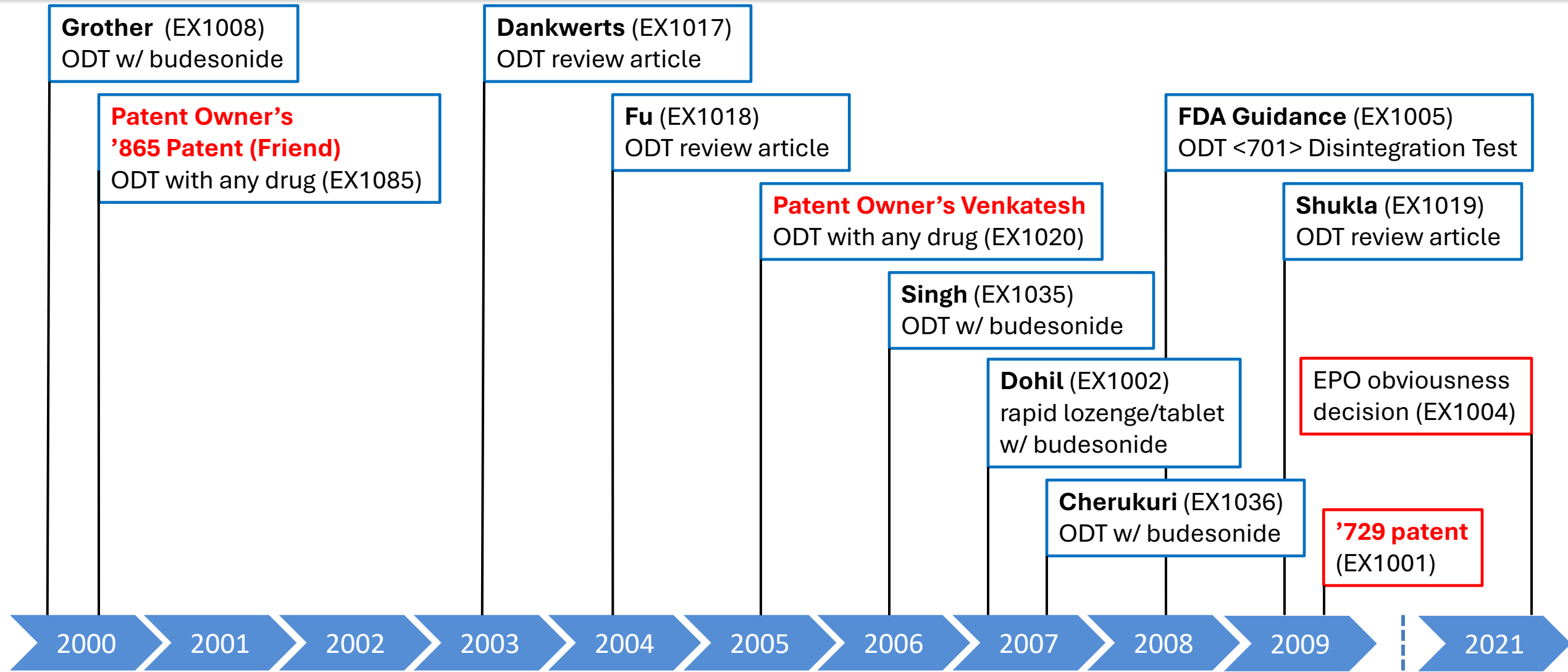
Voie orale. Ne pas mâcher.
Veuillez consulter la notice d'emballage.
Conserver hors de la portée
des enfants!

20 Schmelztabletten / comprimés orodispersibles

Obviousness Grounds

Ground	Reference(s)	Challenged Claims
1	Dohil in view of the knowledge of a POSA	1-7, 15, 20-21, 27, 29-36
2	Grother in view of the FDA Guidance	1-7, 9-15, 20, 27-28, 35-36, 38-40
3	Dohil and Venkatesh in view of the knowledge of a POSA	8, 16-18
4	Grother, the FDA Guidance, and Venkatesh	8, 16-26, 37

Prior Art Timeline



'729 Patent Claim 1

1. An orally disintegrating solid pharmaceutical composition comprising less than or equal to about 20 mg of a topically administrable corticosteroid and at least one disintegrant, wherein the solid pharmaceutical composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration, wherein the solid pharmaceutical composition disintegrates within 60 seconds when tested using the USP <701> Disintegration Test, and wherein upon administration the corticosteroid is deposited topically in the upper gastrointestinal tract.

Fu Review Article On ODTs

During the last decade, fast disintegrating tablet (FDT) technologies that make tablets disintegrate in the mouth without chewing and additional water intake have drawn a great deal of attention. The FDT is also known as *fast melting*, *fast dispersing*, *rapid dissolve*, *rapid melt*, and/or *quick disintegrating tablet*. All FDTs approved by the Food and Drug Administration (FDA) are classified as orally disintegrating tablets. Recently, the European Pharmacopeia adopted the term *orodispersible tablet* for a tablet that disperses or disintegrates in less than 3 minutes in the mouth before swallowing. Such a tablet disintegrates into smaller granules or melts in the mouth from a hard solid to a gel-like structure, allowing easy swallowing by patients. The disintegration time for good FDTs varies from several seconds to about a minute.

Ground 1: Obviousness over Dohil

Dohil's Rapidly Dissolving Lozenge/Tablet

[0032] In other illustrative embodiments of the invention, the Budesonide is provided in the form of a lozenge which may be dissolved in the mouth, thus reaching and coating the esophagus. The lozenge or other similar tablet, capsule, or other solid, would dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus. Or, for children or other patients that may have difficulty with a dissolving lozenge, the lozenge may be ground or otherwise dissolved in a small volume of water or other pharmaceutically suitable liquid, for example, reaching a total volume presented in embodiments herein. In other illustrative embodiments of the invention, the Budesonide is provided in the form of a tablet, a capsule, or, for example a gel capsule, designed for slow release and delivery to the esophagus.

FDA Guidance On ODTs

Guidance for Industry Orally Disintegrating Tablets

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

The products are designed to disintegrate or dissolve rapidly on contact with saliva, thus eliminating the need to chew the tablet, swallow an intact tablet, or take the tablet with liquids. This mode of administration was initially expected to be beneficial to pediatric and geriatric patients, to people with conditions related to impaired swallowing, and for treatment of patients when compliance may be difficult (e.g., for psychiatric disorders).

FDA Guidance On ODTs

Based on the original product rationale and Agency experience, we recommend that, in addition to the original definition, ODTs be considered solid oral preparations that disintegrate rapidly in the oral cavity, with an in-vitro disintegration time of approximately 30 seconds or less, when based on the United States Pharmacopeia (USP) disintegration test method or alternative (see section IV).

IV. DISINTEGRATION TESTING

Part of the process of determining if a product is an ODT involves testing a product to see how long it takes to disintegrate. Determination of disintegration time appears to be method dependent. Some methods are more discriminating than others. To provide both a standard for and consistency in disintegration testing, we recommend that applicants use the USP method for disintegration testing.³ However, other methods that can be correlated with or are demonstrated to provide results equivalent to the USP method also can be used and submitted to determine disintegration time.

³ USP 29, <701> *Disintegration*, pp. 2670-2672.

Dr. Parr (Petitioner's Expert)



Dr. Parr

Pharm.D, Ph.D.

Expert Witness

30+ Years Experience

The FDA Guidance provides the agency's thinking and recommendations on the topic of orally disintegrating pharmaceutical compositions. *Id.* at 1. ... The FDA regulates the use of pharmaceutical compositions in the United States. Dohil's formulations were intended to "be used in therapy for human patients," EX1002 (Dohil) at ¶[0028] ... and the initial testing of its formulations was conducted within the United States, *id.* at ¶[0049]. ... A person of ordinary skill in the art seeking to formulate budesonide into an orally disintegrating pharmaceutical composition would be highly motivated to follow the FDA Guidance that such a composition should disintegrate within 30 seconds or less when tested using the USP <701> Disintegration Test.

EPO Decision

[Dohil ¶0032] clearly describes a lozenge or similar tablet, which rapidly dissolves in the mouth. The OD [Opposition Division] is persuaded that said tablet is not interpreted by the skilled person as being a conventional tablet to be swallowed, simply because the latter is not meant to dissolve in the mouth. On the contrary, in view of its general knowledge, the skilled person would understand that the tablets addressed in [0032] of D1 [Dohil] necessarily require an excipient which facilitates their dispersion and dissolution. This consideration is consistent with the analysis under point 23.5 above, which led to a positive conclusion on the requirements of Article 123(2) EPC for claim 1 of the MR [Main Request]. As a consequence, the OD [Opposition Division] concludes that the dosage forms described in [0032] of D1 [Dohil] at least overlap the ODT addressed in claim 1....

Dr. Davies (Patent Owner's Supposed "Expert")



Dr. Davies

Q. Are you aware that the European patent office has found that Dohil's disclosure in paragraph 32 does clearly disclose an ODT?

A. I do not know. I have been told the European patent office has -- there's a European patent case, but I haven't read it.

That doesn't change my view. This is this patent, and this litigation and this jurisdiction. And when I read Dohil and I read about that lozenge, a person of skill -- I believe a person of ordinary skill would understand what a lozenge is, and it's not an ODT, for all the reasons that I have described.

Dr. Davies (Patent Owner's Supposed "Expert")



Dr. Davies

Q. And have you ever been involved with formulating an orally disintegrating tablet?

A. I have not. But I have been involved in the testing formulations, particularly those that are used and designed for the mouth. And, of course, I've taught them at the graduate course.

Q. When you said you've been involved with testing formulations, is that testing formulations of orally disintegrating tablets?

A. No, that was testing formulations which were related to formulations that were designed for the use in the mouth for systemic absorption. I tested and characterized those formulations.

Prior Art Rapidly Dissolving Lozenges

Reference	Rapidly Dissolving Lozenge	Time	Citation
(1) Mezaache	“lozenges, which... quickly dissolve in the mouth”	less than 30 seconds	Ex. 1077 ¶¶[0002], [0003], [0040]
(2) McEntee	“lozenges that dissolve or disperse... within a minute”	within a minute	Ex. 1075 at 3:20-28
(3) Augsburg	“lozenges which have rapid disintegration rates”	within 60 seconds	Ex. 1078 ¶¶[0043], [0061]
(4) Tang	“lozenge that dissolve or disperse... within a minute”	within a minute	Ex. 1079 at 14:9-14
(5) Barman	“fast dissolving lozenge”	5 minutes	Ex. 1081 Claims 31, 33, ¶¶[0036],[0044]
(6) Singh	“quick-dissolving lozenge”	2-3 min., or 5 or 6 min. or less	Ex. 1080 Claim 11-12, ¶¶[0057], [0104]-[0105]
(7) Martin	“lozenge should dissolve or disintegrate quickly”	about 20 to 120 seconds	Ex. 1076 ¶¶[0060], [0067]
(8) Than	“quick dissolving lozenge”	quickly	Ex. 1082 at 2

Dr. Davies (Patent Owner's Supposed "Expert")

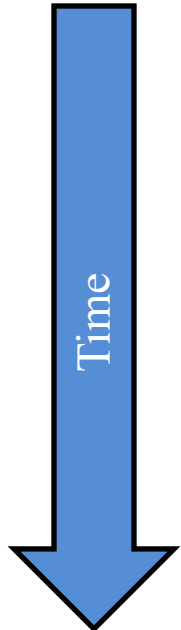


Dr. Davies

Q. Did you do any literature searches to prepare your declaration for this case? Key word searches? That's what I'm looking for.

A. I just responded. No, I just responded to Dr. Parr.

Rapid Disintegration Rate Leading Up To The FDA Guidance



Reference	Priority Date	Rapid Disintegration Rate	Citation
Mezaache	Oct. 1998	less than 30 seconds	Ex. 1077 ¶[0040]
McEntee	Mar. 2002	within a minute	Ex. 1075 at 3:20-28
Augsburger	Dec. 2002	within 60 seconds	Ex. 1078 ¶¶[0043], [0061]
Tang	Feb. 2004	within a minute	Ex. 1079 at 14:9-14
Barman	Oct. 2006	5 minutes	Ex. 1081 ¶[0036]
Singh	Nov. 2006	2-3 minutes, or 6 minutes or less	Ex. 1080 ¶¶[0104]-[0105], Claim 12
Martin	Dec. 2007	about 20 to 120 seconds	Ex. 1076 ¶[0067]

FDA Guidance	Dec. 2008	30 seconds or less	Ex. 1005 at 2
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However, as firms started developing additional products using different technology and formulations, many of these later products exhibited wide variation in product characteristics from the initial products. *Because this shift* in product characteristics can affect suitability for particular uses, *the Agency developed this guidance for industry.*

Institution Decision On Dohil

Dohil teaches that this composition may be in liquid form, but also provides corticosteroid compositions in the form of “a dissolving tablet, a dissolving wafer, a capsule, or a gel capsule,” including embodiments wherein such “tablets, wafers, and capsules are formulated with at least one excipient to deliver a viscous form of the corticosteroid to the esophagus.”

In re Applied Materials

A reference must be considered for everything that it teaches, not simply the described invention or a preferred embodiment.

In re Applied Materials, Inc., 692 F.3d 1289, 1298 (Fed. Cir. 2012)
Petitioner Reply at 4

Dohil Treats EOE

[0010] Provided herein are methods for preventing and alleviating any chronic inflammatory or malignant state that involves the esophagus and responds to steroid therapy. The methods of the present invention are useful, for example, for preventing and alleviating the symptoms and inflammation of eosinophilic esophagitis

[0015] The pharmaceutical composition in certain embodiments comprises a therapeutically effective amount of corticosteroid to prevent or alleviate esophageal inflammation. In certain embodiments, 1-2 mg or 2-3 mg or corticosteroid per day is administered to said individual.

Difficulty In Swallowing For EOE Patients Motivates An ODT

[D]ysphagia [difficulty swallowing] is the most frequent complaint of adult EOE patients.

Ex. 1073 at 1478; *see also* Ex. 1033 at 1218 (Table 1); Ex. 1001 at 1:24-28; Ex. 1072 at 22:16-23:5; Ex. 1093 ¶¶16-18
Petitioner Reply at 4-5

[ODTs] are designed to disintegrate or dissolve rapidly on contact with saliva, thus eliminating the need to chew the tablet, swallow an intact tablet, or take the tablet with liquids. This mode of administration was initially expected to be beneficial to pediatric and geriatric patients, to people with conditions related to impaired swallowing, and for treatment of patients when compliance may be difficult (e.g., for psychiatric disorders).

Ex. 1005 1; *see also* Ex. 1018 at 434
Petition at 7-12; Petitioner Reply at 4-5

Budesonide Was Known To Treat Inflammation Of The Esophagus

Patent Owner admits “budesonide has previously been used to treat EOE.”

Patent Owner Corrected Sur-Reply at 12 n.2
(citing Ex. 1014 and Ex. 1015)

In 2005 and 2007, Aceves et al. reported that a viscous suspension of budesonide was orally administered as a topical formulation to successfully treat eosinophilic esophagitis (EOE or EE).

Petition at 5
See also Ex. 1014 at 706; Ex. 1015 at 1, 6, 8; Ex. 1030 ¶¶50-51

Advantages Of ODTs Over Liquid Formulations

Advantages of ODTs include:

Convenience of administration and accurate dosing as compared to liquid formulations.

Ex. 1019 at 311; Ex. 1030 ¶71
Petitioner Reply at 5

[ODTs] have all the advantages of solid dosage forms, such as good stability, accurate dosing, easy manufacturing, small packaging size, and easy handling by patients.

Ex. 1018 at 434; Ex. 1030 ¶71; Ex. 1093 ¶19
Petition at 7-10; Petitioner Reply at 5

Larger Clinical Trials And Dohil's Liquid Suspension

[0067] These data suggest that oral viscous budesonide would be an effective and safe treatment for individuals, for example children, for example, young children, with proven EE. It may have advantages over other therapies in that it is palatable, its volume (8-12 ml) provides pan-esophageal mucosal coverage and it requires only once daily administration. A larger placebo-controlled clinical trials would provide more information about dosing, efficacy and long-term safety of this treatment.

[0046] ... [The patient] was placed on a regimen of twice daily oral budesonide suspension (Pulmicort®) 500 micrograms (4 ml) mixed with about 10 packets (1 gram each) sucralose, (Splenda®), a non-absorbed sugar in order to increase fluid viscosity to be swallowed twice daily.

Dr. Davies Admits Larger Clinical Trials Use Hundreds To Thousands Of Patients



Dr. Davies

Q. You mentioned there were 20 children in [Dohil's initial] study. How many people would be included in the larger placebo-controlled clinical trial referenced in paragraph 67?

A. It says "would provide," so that typically is -- that has a much larger patient base. ...

Q. You mentioned a much larger patient base. Would that be 100 patients? How many patients?

A. It could be 100 -- It depends on the trial they are doing. It could be 100, 300, and then to the final stage, it's thousands. Yeah. If they wanted to commercialize it. So, yeah, in that context.

The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art. Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 420 (2007).
Petitioner Reply at 6

Lozenges For Sore Throats

Oral lozenges have been used for many years and have proved to be a very popular drug delivery system for treating local mouth diseases and sore throats.

Ex. 1017 at 181
Petitioner Reply at 8-9

Dohil's Lozenge/Tablet Rapidly Dissolves And Coats The Esophagus

[0032] In other illustrative embodiments of the invention, the Budesonide is provided in the form of a lozenge which may be dissolved in the mouth, thus reaching and coating the esophagus. The lozenge or other similar tablet, capsule, or other solid, would dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus. Or, for children or other patients that may have difficulty with a dissolving lozenge, the lozenge may be ground or otherwise dissolved in a small volume of water or other pharmaceutically suitable liquid, for example, reaching a total volume presented in embodiments herein. In other illustrative embodiments of the invention, the Budesonide is provided in the form of a tablet, a capsule, or, for example a gel capsule, designed for slow release and delivery to the esophagus.

Dohil's Liquid Suspension

[0053] Treatment. ... Viscous budesonide was made by mixing each 0.5 mg PulmicortTM respule with 5 grams (5 packets) of sucralose (SplendaTM) to create a volume of 8-12 ml.

Dohil's Tablets Deliver Corticosteroid To The Esophagus

[0013] ... Also provided are pharmaceutical compositions comprising a corticosteroid, for example a topical corticosteroid, such as, for example, Budesonide, in the form of a dissolving tablet, a dissolving wafer, a capsule, or a gel capsule. In certain embodiments, these tablets, wafers, and capsules are formulated with at least one excipient to deliver a viscous form of the corticosteroid to the esophagus.

[0037] ... For dissolving tablets, appropriate excipients include those that increase the resulting liquid viscosity of the dissolved tablet, enabling it to reach the esophagus, for example, to coat the esophagus.

Saliva Production

The whole unstimulated saliva flow rate is approximately 0.3-0.4 ml / min. This rate decreases to 0.1 ml / min during sleep and increases to about 4,0-5,0 ml / min during eating, chewing and other stimulating activities. ...

When a substance is placed in the oral cavity, the flow of saliva will increase depending on its taste, consistency and concentration. When the volume of saliva is approximately 1.1 ml, a swallowing reflex is triggered.

Dr. Davies Admits 1-2 mL Of Saliva Is “Clearly” Sufficient



Dr. Davies

Q. And a volume of 1 to 2 milliliters of saliva is sufficient for allowing the corticosteroid to be deposited topically in the upper gastrointestinal tract?

A. Well, the volume clearly is sufficient volume such that the drug would be deposited topically in the upper GI tract. You know, that's what the inventors are teaching you, that they have developed a formulation for the first time which can deposit the drug topically in the upper gastrointestinal tract. ...

The OD [Opposition Division] acknowledges that D1 [Dohil] offers several starting points for assessing inventive step, and that, even if less preferred, the dosage forms disclosed in [0032] represent the closest starting point to the claimed subject-matter, as the dosage form in [0032] and the claimed ODT have same release mechanism. In fact, said rapidly dissolving solid compositions are proposed in D1 [Dohil] as an alternative, indirect way of forming a budesonide-containing liquid in situ in the mouth, which is able to coat the esophagus.

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one [composition], and a person of ordinary skill in the art would recognize that it would improve similar [compositions] in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 417 (2007).
Petitioner Reply at 6

Dohil's Alternative Embodiments Of Administration

[0032] In other illustrative embodiments of the invention, the Budesonide is provided in the form of a lozenge which may be dissolved in the mouth, thus reaching and coating the esophagus. The lozenge or other similar tablet, capsule, or other solid, would dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus. Or, for children or other patients that may have difficulty with a dissolving lozenge, the lozenge may be ground or otherwise dissolved in a small volume of water or other pharmaceutically suitable liquid, for example, reaching a total volume presented in embodiments herein. In other illustrative embodiments of the invention, the Budesonide is provided in the form of a tablet, a capsule, or, for example a gel capsule, designed for slow release and delivery to the esophagus.

first embodiment

“Or”

second embodiment

Motivation To Use ODTs For Patients With Difficulty Swallowing

Dysphagia, or difficulty in swallowing, is common among all age groups. ... Common complaints about the difficulty in swallowing tablets in the order of frequency of complaints are size, surface, form, and taste of tablets. ... These studies show an urgent need for a new dosage form that can improve patient compliance. Solid dosage forms that can be dissolved or suspended with water in the mouth for easy swallowing are highly desirable for the pediatric and geriatric population, as well as other patients who prefer the convenience of readily administered dosage forms.

Considering the many benefits of [ODTs], it is only a matter of time until a majority of oral formulations are prepared in [ODT] forms.

ODTs For Topical (Local) Administration

Fast dissolving tablets are also applicable when local action in the mouth is desirable such as local anesthetic for toothaches, oral ulcers, cold sores, or teething, and to those who cannot swallow intact sustained action tablets/capsules.

There Was A Reasonable Expectation Of Success

Prior Art ODTs with budesonide: (1) Dohil, (2) Grother, (3) Singh, and (4) Cherukuri.

Ex. 1002, Ex. 1008, Ex. 1035, Ex. 1036
Petition at 10-11, 40-41

TABLE 2. Examples of Commercially Available, Preapproval, or Submitted Orally Disintegrating Tablet Products

Brand name	Active ingredient	Brand name	Active ingredient	Brand name	Active ingredient
Claritin [®] RediTabs [®]	Loratadine	Children's Dimetapp [®] ND	Loratadine	Benadryl [®] Fastmelt [®]	Diphenhydramine citrate
Feldene Melt [®]	Piroxicam	Imodium Instant Melts	Loperamide HCl	Nasea OD	Ramosetron HCl
Maxalt [®] -MLT [®]	Rizatriptan benzoate	Propulsid [®] Quicksolv [®]	Cisapride monohydrate	Gaster D	Famotidine
Pepcid [®] ODT	Famotidine	Tempra Quicklets Tempra FirsTabs	Acetaminophen	Excedrin [®] QuickTabs	Acetaminophen
Zyprexa [®]	Olanzapine	Remeron [®] SolTab [®]	Mirtazapine	Ralivia FlashDose [®]	Tramadol HCl
Zofran [®] ODT [®]	Ondansetron	Triaminic [®] Softchews [®]	Various combinations	Zolpidem ODT	Zolpidem tartrate
Risperdal [®] M-Tab [™]	Risperidone	Zomig-ZMT [®] and Rapimelt [®]	Zolmitriptan	Fluoxetine ODT	Fluoxetine
Zubrin [™] (pet drug)	Tepoxalin	Alavert [®]	Loratadine	Nurofen [®] Flashtab [®]	Ibuprofen
Zelapar [™]	Selegiline	NuLev [®]	Hyoscyamine sulfate	Hyoscyamine Sulfate ODT	Hyoscyamine sulfate
Klonopin [®] Wafers	Clonazepam	Kemstro [™]	Baclofen	Cibalgina due FAST	Ibuprofen

Ex. 1018 at 438-439
Petition at 8-10

Dohil Discloses Dosage Amounts

[0015] The pharmaceutical composition in certain embodiments comprises a therapeutically effective amount of corticosteroid to prevent or alleviate esophageal inflammation. In certain embodiments, 1-2 mg or 2-3 mg or corticosteroid per day is administered to said individual.

Table 1

Age					Prior**		PPI before	Budes Dose	Age					Prior**		PPI before	Budes Dose
Pt.	mths	Res***	Sex	ΔWt****	IgE*	mths	Budes.	mths	Pt.	mths	Res***	Sex	ΔWt****	IgE*	mths	Budes.	mths
1	42	R	M	-0.1	F, A	ELIM (4)	No	1 mg (4)	11	201	R	F	0.1	A		No	2 mg (4)
2	33	R	M	0.15	X		No	1 mg (3)	12	34	R	M	-0.15	X		No	1 mg (3)
3	71	R	M	0.73	F, A		Yes	1 mg (3)	13	51	R	F	0.08	F	ELIM (5)	No	1 mg (6)
4	109	R	M	0.85	X	FLU (3)	Yes	1 mg (4)	14	48	R	M	1.5	F	ELIM (5)	No	1 mg (3)
5	41	R	M	-0.07	F, A	ELIM (2)	Yes	1 mg (3)	15	31	R	M	0.2	F	ELIM (3)	Yes	1 mg (4)
6	66		M		F, A	FLU (3)		1 mg (3)	16	121	R	M	0.13	F, A		Yes	2 mg (3)
		R	M	0.5	F, A		Yes	2 mg (3)	17	36	P	M	0.46	F, A	FLU (12)	No	0.5 mg (3)
7	88		M		F, A	FLU (12)	Yes	1 mg (3)	18	32	N	M	0.83	F		No	1 mg (3)
		R		0.375			Yes	2 mg (3)	19	68	N	F	0.15	F	ELIM (2)	Yes	1 mg (4)
8	90	R	F	0.65	X		No	1 mg (4)	20	93	N	M	0.15	F, A	FLU	No	1 mg (4)
9	41	R	M	0.18	A		Yes	1 mg (4)									
10	20	R	M	0.03	F		Yes	1 mg (4)									

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Ex. 1002 ¶[0015], Table 1
Petition at 20-21

Hybritech and Merck

[A] patent need not teach, and preferably omits, what is well known in the art.

Hybritech Inc v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986)
Petitioner Reply at 19

[Holding claims to be obvious where] the claimed invention adds nothing beyond the teachings of [the prior art].

Merck & Co. Inc. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1374 (Fed. Cir. 2005)
Petitioner Reply at 25

ODT Versus Liquid Formulations And Same Dosage Amounts

	ODT and Liquid forms dosed at same amounts?
CLARITIN [®]	Yes
ZOFRAN [®]	Yes
CLARINEX [®]	Yes
PEPCID [®]	Yes

Dr. Davies Admits Budesonide Was Known To Treat The Upper GI Tract



Dr. Davies

[I]t is my understanding that there is no dispute that budesonide, fluticasone, or other topical corticosteroids could be used to treat inflammation of the upper gastrointestinal tract. In fact, the '729 patent describes both being used to treat EoE in the background of the invention section.

Ex. 2007 ¶65
Petitioner Reply at 26

[T]here is no dispute that budesonide was known for treating inflammatory conditions of the gastrointestinal tract, including the upper gastrointestinal tract.

Ex. 2007 ¶76
Petitioner Reply at 26

'729 Patent Prosecution History

Dissolution within sixty seconds is an important feature of the invention. As discussed in this Application, corticosteroids are known to suppress immune function, thus, prolonged contact of corticosteroids to the mouth or throat can lead to an oral yeast infection. In order to minimize contact with the mouth, thereby minimizing the chance of an oral yeast infection, claims 1 and 27 provide a composition that disintegrates within sixty seconds; after the composition disintegrates, the remnants of the composition can be swallowed thus minimizing both contact between the drug and the mouth and the likelihood of developing a yeast infection.

Dr. Parr (Petitioner's Expert)



Dr. Parr

Pharm.D, Ph.D.

Expert Witness

30+ Years Experience

For a drug to be in solution -- if it's in a dosage form, a tablet, a wafer, or a lozenge, that dosage form has to first disintegrate to make the drug available to be dissolved.

So if it dissolves within 10 to 120 seconds, it would have had to have disintegrated long before that for the drug to be dissolved.

Ground 2: Obviousness over Grother in view of the FDA Guidance

Grother Discloses ODTs

Summary of the Invention

There is disclosed a fast dispersing solid dosage form designed to release an active ingredient rapidly in the oral cavity characterized in that said dosage form is essentially free of mammalian gelatin and comprises:

- at least one active ingredient;

- at least one modified starch at a concentration of from 20 to 90% by weight of said solid dosage form; and

- at least one matrix forming agent;

wherein said solid dosage form is obtainable by removing a solvent from a mixture comprising said active ingredient, said modified starch and said matrix forming agent.

Grother Discloses ODTs With Budesonide

Abstract

The present invention relates to fast dispersing solid dosage forms that preferably dissolve in the oral cavity within sixty (60), more preferably within thirty (30), most preferably within ten (10) seconds.

Ex. 1008 at Abstract; *id.* at 13:19-22
Petition at 34-35, 39

Any drug may be used as the active ingredient in the composition of the present invention. Examples of suitable drugs include but are not limited to those listed below:

Corticosteroids: beclomethasone, betamethasone, budesonide, cortisone acetate, desoxymethasone, dexamethasone, fludrocortisone acetate, flunisolide, flucortolone, fluticasone propionate, hydrocortisone, methylprednisolone, prednisolone, prednisone, triamcinolone.

Ex. 1008 at 15:19-20, 18:15-18
Petition at 35-36

Dr. Davies Admits Grother's ODT Works With Any Class Of Drugs



Dr. Davies

As discussed above, a POSA would understand that Grother is concerned with creating an ODT formulation that eliminates mammalian gelatin from ODT formulations and works with any class of drugs.

Ex. 2007 ¶118
Petitioner Reply at 27

Boston Sci. and Acoustic

Combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness.

Boston Scientific Scimed, Inc. v. Cordis Corp., 554 F.3d 982, 991 (Fed. Cir. 2009)
Petition at 36

The motivation to combine prior art references can come from the knowledge of those skilled in the art, from the prior art reference itself, or from the nature of the problem to be solved.

Acoustic Tech., Inc. v. Itron Networked Sols., 949 F.3d 1366, 1375 (Fed. Cir. 2020)
Petitioner Reply at 22

In re Young and In re Fulton

Patents are part of the literature of the art and are relevant for all they contain.

In re Young, 927 F.2d 588, 591 (Fed. Cir. 1991)
Petitioner Reply at 22-23

[A] finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggests that the combination claimed by the patent applicant is the preferred, or most desirable, combination.

In re Fulton, 391 F.3d 1195, 1200 (Fed. Cir. 2004)
Petitioner Reply at 23

Institution Decision On Grother

Grother teaches that “[a]ny drug may be used as the active ingredient in the composition of [its] invention.” Ex. 1008, 15:19–20. Grother teaches that examples of suitable drugs include corticosteroids including, e.g., budesonide. *Id.* at 15:20–21, 18:15–18.

Dr. Davies' Own "Platform Technology" Works With All Classes Of Drugs



Dr. Davies

US 20110189299A1

(19) **United States**
(12) **Patent Application Publication** (10) **Pub. No.: US 2011/0189299 A1**
Okubo and Davies et al. (43) **Pub. Date: Aug. 4, 2011**

[0043] Examples of drugs include, but are not limited to, antihypertensive agent, antihypotensive agent, analgesic, antipsychotic agent, antidepressant, antimanic, antianxiety agent, sedative, hypnotic, antiepileptic, opioid agonist, therapeutic agent for asthma, anesthetic, antiarrhythmic agent, therapeutic agent for arthritis, anticonvulsant, ACE inhibitor, decongestant; antibiotic, antianginal agent, diuretic, antiparkinson agent, bronchodilator, oxytocic, antidiuretic, antileptic agent, immunosuppressant, immunity regulator, antiemetic, antiinfective agent, antineoplastic, antifungal agent, antiviral agent, antidiabetic agent, antiallergic agent, fever reducer, antitumor agent, antigout agent, antihistamine agent, antipruritic agent, bone regulator, cardiovascular agent, hypocholesterolemic agent, antimalarial agent, pharmaceutical agent for ceasing smoking, antitussive agent, expectorant, mucolytic agent, nasal decongestant, dopamine agonist, pharmaceutical agent for digestive tract, muscle relaxant, neuromuscular blocker, parasympatholytic, prostaglandin, stimulant drug, anorectic agent, thyroid agent or antithyroid agent, hormone, antimigraine agent, antiobesity agent, antiinflammatory agent and the like. The drug may also be selected from a variety of peptides, proteins, polysaccharides, antigens, antibodies, DNAs, RNAs, siRNAs, low-molecular weight drugs and the like, which are intended for prophylactic vaccination, immunotherapy, antibody therapy, gene therapy, suppression of gene expression and the like.

[0044] Specific examples of the drug include, but are not limited to, insulin, glucagon, leuprolide, growth hormones, parathyroid hormones, calcitonin, vascular endothelial growth factor, erythropoietin, heparin, cyclosporin, oxytocin, tyrosine, enkephalin, tyrotropin releasing hormone, follicle-stimulating hormone, leuteinising hormone, vasopressin, vasopressin analogs, catalase, superoxide dismutase, interleukin II, interferons, colony stimulating factor, tumor necrosis factor, melanocyte stimulating hormone, glucagon-like peptide-1, glucagon-like peptide-2, katecholamine, cholecystekinin-12, cholecystekinin-8, exendin, gonadoliberin-related peptide, insulin-like protein, leucine-enkephalin, methionine-enkephalin, leuromorphine, neurophysin, copeptin, neuropeptide Y, neuropeptide AF, PACAP-related peptide, pancreatic hormone, peptide YY, urotensin, intestinal peptide, adrenocorticotrophic peptide, epidermal growth factor, prolactin, luteinising hormone releasing hormone (LHRH), LHRH agonist, growth hormone releasing factor, somatostatin, gastrin, tetragastrin, pentagastrin, endorphins, angiotensins, tyrotropin releasing hormone, granulocyte-colony stimulating factor, granulocyte-macrophage-colony stimulating factor, heparinase, antigens for influenza vaccine, tetanus toxins, peptides for cancer vaccine, β -amyloid, immunoglobulins, siRNAs for treatment of cirrhosis, siRNAs for treatment of cancer, low-molecular weight drugs such as bromhexine, granisetron, zolmitriptan, sumatriptan and the like, and pharmaceutically acceptable salts thereof, and the like.

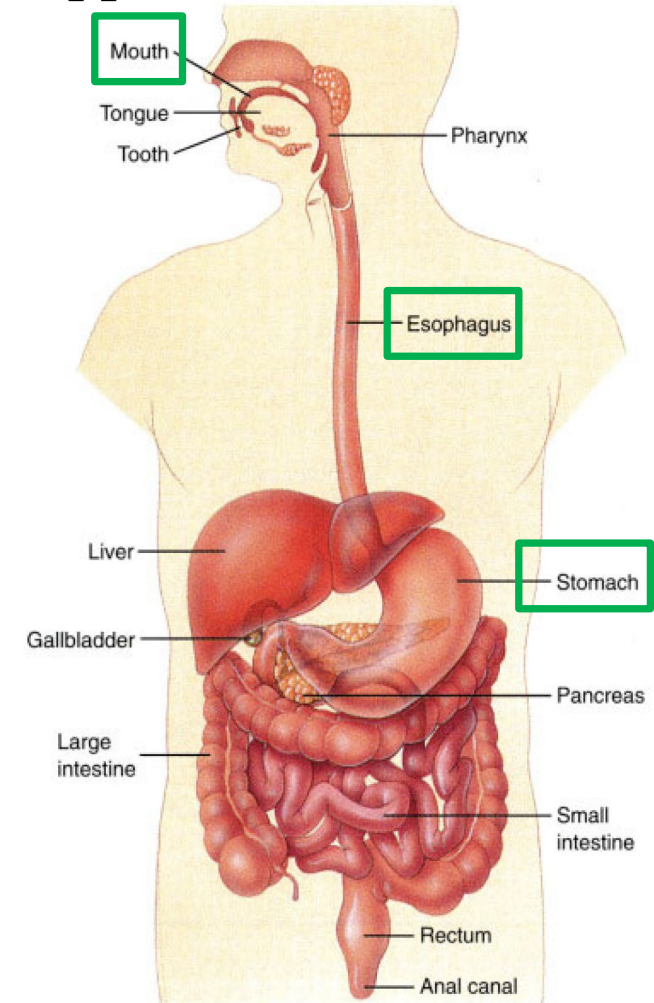
Grother Deposits Active Ingredient In The Upper GI Tract

Grother

According to the present invention there is therefore provided a pharmaceutical composition for oral administration in the form of a fast dispersing dosage form **designed to release an active ingredient rapidly in the oral cavity** characterized in that the essentially gelatin free composition comprises a modified starch and at least one matrix forming agent.

Ex. 1008 at 3:18-20; *id.* at 13:19-22
Petition at 41; Petitioner Reply at 24

Components of the upper GI tract include:



Ex. 1093 ¶60
Petitioner Reply at 24

FDA Guidance

In an effort to develop drug products that are more convenient to use and to address potential issues of patient compliance for certain product indications and patient populations, pharmaceutical manufacturers have developed products **that can be ingested simply by placing them on the tongue**. The products are designed to disintegrate or dissolve rapidly on contact with saliva, thus eliminating the need to chew the tablet, swallow an intact tablet, or take the tablet with liquids.

Dr. Parr (Petitioner's Expert)



Dr. Parr

Pharm.D, Ph.D.

Expert Witness

30+ Years Experience

Budesonide was known to be a potent anti-inflammatory glucocorticoid before October of 2009. For example, Goodman & Gillman's explains that budesonide "is proposed to deliver adequate steroid therapy to a specific portion of inflamed gut while minimizing systemic side effects owing to extensive first pass hepatic metabolism to inactive derivatives. Topical therapy (e.g., enemas and suppositories) also is effective in treating colitis limited to the left side of the colon. While the topical potency of budesonide is 200 times higher than hydrocortisone, its oral systemic bioavailability is only 10%." *Id.* ... A person of ordinary skill in the art would have considered budesonide to be a desirable drug for treating inflammation of the gastrointestinal tract.

Randall and Verve

[T]he Board failed to account for critical background information that could easily explain why an ordinarily skilled artisan would have been motivated to combine or modify the cited references to arrive at the claimed inventions. As *KSR* established, the knowledge of such an artisan is part of the store of public knowledge that must be consulted when considering whether a claimed invention would have been obvious.

Randall Mfg. v. Rea, 733 F.3d 1355, 1362 (Fed. Cir. 2013)
Petitioner Reply at 23

Patent documents are written for persons familiar with the relevant field; the patentee is not required to include in the specification information readily understood by practitioners, lest every patent be required to be written as a comprehensive tutorial and treatise for the generalist, instead of a concise statement for persons in the field.

Verve, LLC v. Crane Cams, Inc., 311 F.3d 1116, 1119 (Fed. Cir. 2002)
Petitioner Reply at 23

Ground 3: Obviousness over Dohil and Venkatesh

Ground 4: Obviousness over Grother, FDA Guidance, and Venkatesh

Venkatesh And The '729 Patent

(19) **United States**

(12) **Patent Application Publication**

Venkatesh et al.

(10) **Pub. No.: US 2005/0232988 A1**

(43) **Pub. Date: Oct. 20, 2005**

(54) **ORALLY DISINTEGRATING TABLETS AND METHODS OF MANUFACTURE**

(76) **Inventors:** **Gopi M. Venkatesh**, Vandalia, OH (US); **Ken Kangyi Qian**, Cincinnati, OH (US); **Shyam Vangala**, Huber Heights, OH (US); **James M. Clevenger**, Vandalia, OH (US); **Donald Guenther**, Brookville, OH (US)

Ex. 1020 at title page

(12) **United States Patent**
Perrett et al.

(10) **Patent No.: US 8,771,729 B2**

(45) **Date of Patent: Jul. 8, 2014**

(54) **ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS**

(75) **Inventors:** **Stephen Perrett**, Princeton, NJ (US); **Fredric Jay Cohen**, Washington Crossing, PA (US); **Gopi Venkatesh**, Vandalia, OH (US)

Ex. 1001 at title page
Petition at 52

Venkatesh On Taste And Mouthfeel

An ideal orally disintegrating tablet formulation rapidly disintegrates in the buccal cavity dispersing the contents and has a pleasant taste and smooth creamy mouthfeel (no grittiness), and complete drug release occurs in the gastrointestinal tract so as to be bioequivalent to the reference immediate release product.

Ex. 1020 ¶[0002]

For use in an orally disintegrating tablet, the particle size of most of the taste-masked microcapsules should be less than 400 um or less to avoid gritty mouthfeel.

Ex. 1020 ¶[0012]

These granules can be obtained with an average particle size of 200 um and can be effectively taste masked by coacervation by phase separation to produce taste-masked particles with optimum size distribution (e.g., mean particle size of not more than 400 um) for incorporation into tablets, which rapidly disintegrate in the buccal cavity with a smooth creamy mouthfeel.

Ex. 1020 at ¶[0015]; *id.* ¶¶[0009], [0018]-[0019]

Petition at 55-57, 60-62

Venkatesh And The '729 Patent Incorporate Friend By Reference

Venkatesh

The present invention provides a method for the manufacture of resilient microgranules with most desired particle size distributions, which are suitable for effectively taste masking by coacervation in accordance with methods disclosed in U.S. Pat. No. 6,139,865 [Friend], which is incorporated in its entirety by reference.

Ex. 1020 ¶[0012]; *id.* ¶[0027]
Petitioner Reply at 14

'729 Patent

All documents (e.g., patents, patent publication, journal articles, etc.) cited in the present application are incorporated by reference in their entirety for all purposes.

Examples of such a coacervation process are disclosed in U.S. Pat. Nos. 5,252,337, 5,639,475, 6,139,865 [Friend] and 6,495,160.

Ex. 1001 at 2:32-34, 14:44-46
Petitioner Reply at 14

Friend Teaches Taste Masking Achieves Virtually Immediate Release Of Drug

Although the use of polymeric materials, particularly cellulosic polymers, to taste mask bitter tasting drugs is known... the present invention provides for far more effective taste masking than previously possible, using high coating levels while nevertheless achieving virtually immediate release of drug.

Ex. 1085 at 2:65-3:3

The composition comprises microcapsules of drug and a substantially water-insoluble polymeric material, typically a cellulosic polymer.... These high coating levels give rise to effective taste masking, while nevertheless allowing targeted release of drug, so that the drug is released shortly after passage through the mouth.

Ex. 1085 at Abstract

[T]he invention provides for extremely effective taste masking while also providing for release of drug shortly after the drug passes through the mouth.

Ex. 1085 at 1:67-2:2
Petitioner Reply at 15

Friend Explains Dissolution Occurs Via Pores And Is Adjustable

[I]t is believed that the polymeric walls of the microcapsules, particularly those formed by coacervation, typically have pores. It is further believed that drug dissolution from the microcapsules occurs through these pores. Thus, it is believed that water enters the pores and forms a highly concentrated solution of drug and water inside the microcapsule, and that the resulting concentration gradient from the highly concentrated solution to the surrounding aqueous fluid drives diffusion of the drug out through the pores to the surrounding aqueous fluid. Another mechanism of release which is believed to occur is breakage of the coating on the microcapsule, possibly caused or promoted by swelling of the core material due absorption of water.

Ex. 1085 at 9:31-45; *id.* at 7:52-56, 15:60-63
Petitioner Reply at 15-16

Regardless of the reasons for these effects, these effects can be used to adjust the release rate for a particular drug.

Ex. 1085 at 9:54-55
Petitioner Reply at 15-16

Dr. Parr (Petitioner's Expert)



Dr. Parr

Pharm.D, Ph.D.

Expert Witness

30+ Years Experience

In the '865 patent [Friend], Adare/Ellodi explained that taste-masking with a water-insoluble polymer does not prevent topical disposition of drug in the upper gastrointestinal tract. Rather, the taste-masking allows the drug to be released “virtually immediate[ly]” and “shortly” after passage through the mouth such that the drug is deposited in the upper gastrointestinal tract. ...

The Adare/Ellodi '865 patent [Friend] explains that the water-insoluble coating has a porous structure that facilitates the rapid release of the drug from the microparticles. ...

The Adare/Ellodi '865 patent [Friend] further teaches that the release rate for a particular drug can be adjusted. [Ex. 1085] at 9:54-55 (“Regardless of the reasons for these effects, these effects can be used to adjust the release rate for a particular drug.”).

Dr. Davies Did Not Consider Friend



Dr. Davies

Q. I'm looking at line 44 [of column 14 of the '729 patent]. It says: "Examples of such a coacervation process are disclosed in U.S. Patent Nos. 5,252,337, 5,639,475, 6,139,865 [Friend], and 6,495,160." Do you see that?

A. I do.

Q. Did you review any of those patents in preparing your opinions in this case?

A. I don't believe I did, in the context, but I understand that the patent in this column 14 is talking about using ethylcellulose to -- coacervation using ethylcellulose to -- for the taste-masking of the corticosteroid.

'729 Patent Utilizes Taste-Masking

In one embodiment, the method of preparing the compositions of the present invention includes a taste-masking step. The taste-masked corticosteroid-containing particles of the compositions of the present invention (e.g., corticosteroid crystals, corticosteroid-containing microgranules or drug layered beads) of the present invention can be prepared by various methods, including solvent coacervation with a water-insoluble polymer such as ethylcellulose. ... Examples of such a coacervation process are disclosed in U.S. Pat. Nos. 5,252,337, 5,639,475, 6,139,865 [Friend] and 6,495,160. ...

Institution Decision On Venkatesh

Venkatesh teaches that “[a]n ideal orally disintegrating tablet formulation rapidly disintegrates in the buccal cavity dispersing the contents and has a pleasant taste and smooth creamy mouthfeel (no grittiness), and complete drug release occurs in the gastrointestinal tract.” Ex. 1020 ¶ 2. Venkatesh teaches that “[t]his convenience leads to better compliance with dosing regimen and as a consequence, to enhanced therapy.” *Id.*

Patent Owner's Motion To Strike Should Be Denied

Petitioner's Reply Responds To The Patent Owner Response (POR)

Patent Owner Argued:

In its Response, PO provided evidence that lozenges dissolve slowly, over time, to provide continuous treatment—not within 60 seconds as claimed.

Motion to Strike at 2

Because lozenges and similar tablets are designed to dissolve slowly (Ex. 2013, 413; Ex. 2014, 201), modifying these dosage forms to disintegrate within 60 seconds based on the FDA Guidance would render the lozenge and similar tablet unsatisfactory for its intended purpose or change the principal operation of dissolving slowly to provide a continuous treatment.

POR at 30; *see id.* at 13, 14, 20, 25-27, 36

Dr. Davies: “I am also not aware of any fast or quick dissolving lozenges.”

Ex. 2007 ¶83
POR at 14

***Apple* and Rule 42.23(b)**

As we have regularly held, the petitioner in an inter partes review proceeding may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner.

Apple Inc. v. Andrea Elec. Corp., 949 F.3d 697, 706-07 (Fed. Cir. 2020)
Petitioner Opp'n at 2

A reply may only respond to arguments raised in the corresponding opposition, patent owner preliminary response, patent owner response, or decision on institution.

37 C.F.R. § 42.23(b)
Petitioner Opp'n at 2

Trial Practice Guide

In most cases, the Board is capable of identifying new issues or belatedly presented evidence when weighing the evidence at the close of trial, and disregarding any new issues or belatedly presented evidence that exceeds the proper scope of reply or sur-reply. As such, striking the entirety or a portion of a party's brief is an exceptional remedy that the Board expects will be granted rarely.

Moderna and Burt

Petitioner's arguments on Reply may be considered properly responsive to Patent Owner's arguments [and] any surprise or prejudice to Patent Owner based on the allegedly new arguments is mitigated in this case because Patent Owner substantively responded to those arguments in its Sur-Reply.

Moderna Therapeutics, Inc. v. Arbutus Biopharma Corp., IPR2019-00554, Paper 40, at 36 (PTAB 2020)
Petitioner Opp'n at 6-7

There is a difference between evidence that brings unfair prejudice and evidence that is damning. ... The [evidence] may well have been damning, but we do not see how it created unfair prejudice.

United States v. Burt, 495 F.3d 733, 740 (7th Cir. 2007)
Petitioner Opp'n at 6

Shockwave

We have explained that although the prior art that can be considered in IPRs is limited to patents and printed publications, it does not follow that we ignore the skilled artisan's knowledge when determining whether it would have been obvious to modify the prior art. This is because the obviousness analysis “requires an assessment of the ‘background knowledge possessed by a person having ordinary skill in the art.’” *Dow Jones & Co. v. Abblaise Ltd.*, 606 F.3d 1338, 1349 (Fed. Cir. 2010) (quoting *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 401 (2007)).

Shockwave Medical, Inc. v. Cardiovascular Systems, Inc., 142 F.4th 1371, 1378 (Fed. Cir. 2025)
Responding to Patent Owner Corrected Sur-Reply at 13 n.3

As we explained in *Qualcomm I*, our case law has long recognized numerous permissible uses for general background knowledge in an IPR such as, “for example, furnishing a motivation to combine, or supplying a missing claim limitation.” 24 F.4th at 1376 (first citing *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013); and then citing *Koninklijke*, 948 F.3d at 1337-38)).

Shockwave, 142 F.4th at 1378-78