

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte HARRY S. SOWDEN, DAVID WYNN, SHUN-POR LI,
DER-YANG LEE, and MARTIN THOMAS

Appeal 2008-5113
Application 10/476,530
Technology Center 1600

Decided: November 21, 2008

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to dosage forms having cavities and partial coatings. The Examiner has rejected the claims as anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse the Examiner's anticipation rejection, and affirm the Examiner's obviousness rejections in part.

STATEMENT OF THE CASE

Claims 1, 2, 4-17, 19-21, 23-31, 33-42 and 45-48 are pending and on appeal (App. Br. 2). Claims 1, 8, and 20, the appealed independent claims, are representative and read as follows (indentations and paragraph formatting added):

1. A dosage form comprising:
 - (a) at least one active ingredient;
 - (b) a core having a first surface portion upon which resides a first coating and a second surface portion which is substantially free of the first coating; and
 - (c) a shell which resides upon at least a portion of the second surface portion,
 - wherein the shell comprises a different material from the first coating,
 - in which the core comprises a cavity therein, and the shell resides upon at least a part of the second surface portion of the core which is located within the cavity and the cavity is an aperture which extends entirely through the core.

8. A dosage form comprising:
 - (a) at least one active ingredient;
 - (b) a core comprising a center portion having an exterior surface and an annular portion having an exterior surface and an interior surface, wherein the annular portion interior surface is in contact with at least a portion of the center portion exterior surface, and a first coating resides on at least a portion of the annular portion exterior surface, and in which the core annular portion has the shape of a torus; and
 - (c) a shell which resides upon at least a portion of the exterior surface of the center portion, wherein the shell comprises a different material than the first coating.

20. A dosage form comprising:
 - (a) at least one active ingredient;

(b) a core having an outer surface and a cavity which extends through the core having the shape of a torus such that the core outer surface has at least a first opening therein;

(c) a first coating which resides on at least a portion of the core outer surface, wherein the first shell portion comprises a different material from the first coating; and

(d) a first shell portion which is adjacent to the first opening and covers at least the first opening.

The Examiner applies the following documents in rejecting the claims:

Shivanand et al.	US 6,110,499	Aug. 29, 2000
Newton	US 5,683,719	Nov. 4, 1997
Ritschel et al.	US 6,365,185 B1	Apr. 2, 2002

The following rejections are before us for review:

Claims 1, 2, 4-7, 9, and 21 stand rejected under 35 U.S.C. § 102(b) as anticipated by Shivanand (Ans. 3-5).

Claims 1, 2, 4-17, and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Shivanand and Newton (Ans. 5-6).

Claims 1, 2, 4-17, 19-21, 23-31, 33-42, and 45-48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Shivanand, Newton, and Ritschel (Ans. 6-9).

ANTICIPATION

ISSUE

The Examiner cites Shivanand as describing a dosage form “for administering phenytoin indicated for the management of epilepsy” (Ans. 3). The Examiner contends that Shivanand’s dosage form is a tablet or capsule with a single-layered or two-layered core, “and a drug resides in the core. The invention provides a dosage form comprising an external coat of

phenytoin for instant phenytoin therapy, an internal wall and a subcoat, positioned between the internal surface of the wall of the dosage form and the pharmaceutical phenytoin composition (see figures 1-4)” (Ans. 4).

The Examiner contends that “[a] passageway is laser or mechanically drilled through the wall to contact the drug layer (see drawings descriptions, col. 3-8) . . . , and the passageway, which is defined by Shivanand as aperture, orifice, bore, pore, or porous element includes also a compound that erodes (col. 9, lines 2-12)” (*id.* at 4-5).

Appellants contend that Shivanand does not meet all of the limitations of claim 1 because the Examiner’s “position that a passageway into the compartment is an aperture that passes through the core . . . is a flawed interpretation of the claims” (App. Br. 4). Specifically, Appellants urge:

[T]he claims define a dosage form in which a hole or opening extends entirely through the core. The contention that a passageway into a compartment reads on the claims herein ignores the condition that the aperture must extend entirely through the core. An opening that reaches or even extends into an compartment does [not] read or even suggest an aperture that extends entirely through a core.

(*Id.* at 5.)

The issue with respect to this rejection, then, is whether the Examiner has made a prima facie case that the passageway into the interior drug layer of Shivanand meets the limitation in claim 1 requiring the core to have “cavity [that] is an aperture which extends entirely through the core.”

FINDINGS OF FACT (“FF”)

1. Shivanand discloses “a phenytoin formulation that delivers in a controlled-continuous release dose phenytoin to a patient in need of phenytoin for maintaining an antiepileptic phenytoin level in the blood as a

function of the phenytoin-releasing formulation” (Shivanand, col. 3, ll. 24-25).

2. Figure 1 of Shivanand, reproduced below, is a “general view” of Shivanand’s a dosage form, “designed and shaped for the oral administration of phenytoin for the treatment of epilepsies at a controlled rate over time to a patient in need of therapy for the management of epilepsies” (Shivanand, col. 3, ll. 59-63):

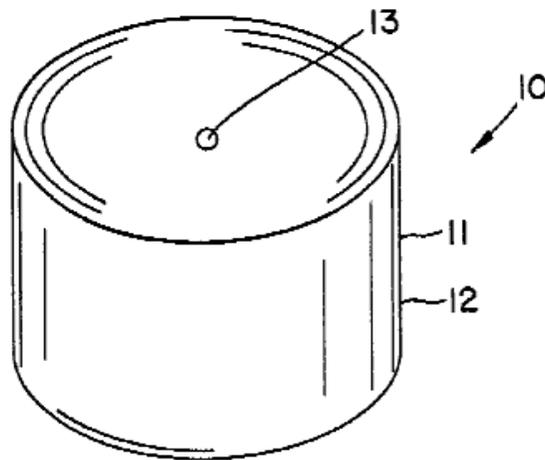


FIG. 1

Figure 1 “illustrates a controlled-release dosage form that delivers phenytoin over an extended time” (*id.* at col. 4, ll. 43-45). Thus, dosage form 10 has a body member 11, which “comprises wall 12. Wall 12 is an exterior wall and it surrounds and forms an internal area, not seen in drawing FIG. 1. Drawing FIG. 1 comprises at least one exit 13 that connects the exterior of drawing FIG. 1 with the interior of dosage form 10” (*id.* at col. 4, ll. 37-42).

3. Figure 4 of Shivanand, reproduced below, is an “opened view” of the dosage form shown in Figure 1, and shows a dosage form “comprising an

internal wall and a subcoat, positioned between the internal surface of the wall of the dosage form and the pharmaceutical phenytoin composition and the composition for pushing the pharmaceutical composition from the dosage form” (Shivanand, col. 4, ll. 7-12):

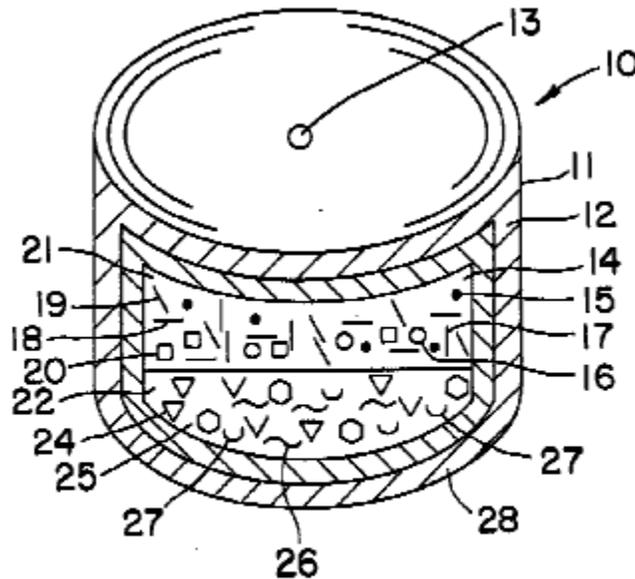


FIG. 4

Figure 4 shows wall 12, “which surrounds and defines internal compartment 14, [and] comprises totally or in at least a part a semipermeable composition. The semipermeable composition is permeable to the passage of an exterior fluid, such as an aqueous fluid, and it is permeable to biological fluid present in the gastrointestinal tract” (*id.* at col. 4, ll. 62-67). Shivanand discloses that wall 12 “is nontoxic and it is impermeable to the passage of antiepileptic phenytoin 15, represented by dots, present in compartment 14. Wall 12 is inert, and it maintains its physical and chemical integrity during the dispensing life of antiepileptic phenytoin 15” (*id.* at col. 4, l. 67 through col. 5, l. 5).

4. Shivanand also discloses that “compartment **14** comprises an expandable composition **22**, also identified as expandable layer **22**. Expandable layer **22** cooperates with phenytoin layer **21** for delivering phenytoin **15** from dosage form **10**” (Shivanand, col. 7, ll. 29-33). Specifically, “[t]he osmopolymers used for the expandable layer exhibit an osmotic pressure gradient across semipermeable wall **12**; they imbibe fluid into compartment **14**; and, thereby expand and push the phenytoin from the osmotic dosage form” through exit passageway **13** (*id.* at col. 7, ll. 49-53).
5. Shivanand discloses that “[t]he expression ‘passageway’ . . . includes aperture; orifice; bore; pore; porous element through which phenytoin drug **15** can be pumped, diffuse or migrate through a fiber; capillary tube; porous overlay; porous insert; microporous member and porous composition” (Shivanand, col. 9, ll. 2-8). Shivanand further discloses that “[t]he passageway includes also a compound that erodes or is leached from wall **12** in the fluid environment of use to produce at least one passageway” (*id.* at col. 9, ll. 8-10).
6. Shivanand discloses that the “passageway is laser or mechanically drilled through the wall to contact the drug layer” (Shivanand, col. 10, ll. 16-17).
7. Shivanand discloses a number of examples of preparing a dosage form in accordance with Figure 4 in which the passageway is drilled into, but which does not extend entirely through, the drug layer of the dosage form (*see, e.g.*, Shivanand, col. 12, ll. 55-57; col. 14, ll. 46-47; col. 16, ll. 9-10; col. 17, ll. 62-64; col. 19, ll. 47-48). Thus, Example 3 of Shivanand discloses preparing a two-layer core composition by compressing a layer of sodium phenytoin-containing material with a layer of an osmotically

expandable polymer in an 8 millimeter cavity of a die, and then coating the resulting bilayer core with a subcoat of polymeric material (Shivanand, col. 12, ll. 23-43). The resulting dosage form is then coated with a wall-forming composition, after which “a 50-mil (1.27 mm passageway is drilled through the semipermeable wall and subcoat into the sodium phenytoin side of the dosage form” (*id.* at col. 12, ll. 55-57).

PRINCIPLES OF LAW

“[T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). “To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently.” *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

During examination, the PTO must interpret terms in a claim using “the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant’s specification.” *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

ANALYSIS

We agree with Appellants that the Examiner has not made a *prima facie* case that the passageway into the interior drug layer of Shivanand meets the limitation in claim 1 requiring the core to have a “cavity [that] is an aperture which extends entirely through the core.”

As argued by the Examiner, Shivanand discloses that its dosage form has a passageway that passes through the outer semipermeable wall into the interior portion of the dosage form (*see* FF 2). However, rather than

disclosing that the passageway extends through the entire core, Shivanand discloses that the passageway is drilled *into* the drug layer of the core (*see* FF 5-7). We do not see, and the Examiner does not explain, where Shivanand discloses that the passageway “extends entirely through the core” as required by claim 1.

Rather, the Examiner argues, “Shivanand discloses an embodiment where the core is bilayered and every layer has a different active agent. This embodiment reveals that the passageway reaches through the core to let the base layer out of the dosage form (see Shivanand, col. 10, line 1+)” (Ans. 10). We do not agree with the Examiner’s interpretation of Shivanand.

Specifically, Shivanand discloses a dosage form having a core with a drug layer that contains phenytoin, and a “push” layer that contains an expandable polymer (*see, e.g.*, FF 3, 4). The two-layered core is surrounded by a semipermeable wall that allows passage of aqueous fluid, but not the phenytoin drug (FF 3). Shivanand discloses that a “passageway is laser or mechanically drilled through the wall to contact the drug layer” (Shivanand, col. 10, ll. 16-17 (FF 6); *see also* FF 7). When the expandable polymer in the push layer imbibes aqueous fluid through the semipermeable outer wall and expands, the drug is forced out of the exit passageway, because it cannot pass through the semipermeable wall (FF 4, 5).

Thus, we do not agree with the Examiner that when Shivanand discloses drilling a passageway to contact the drug layer, Shivanand discloses that the passageway “extends entirely through the core” as required by claim 1. Moreover, we do not agree with the Examiner that it is reasonable to interpret the language in claim 1 requiring the core to have “an aperture which extends entirely through the core” as encompassing

Shivanand's passageway, which only extends into a single layer, i.e. the drug layer, of the disclosed dosage form core.

Therefore, because we do not agree with the Examiner that Shivanand discloses a dosage form having all of the elements recited in claim 1, we reverse the Examiner's anticipation rejection of claim 1, and its dependent claims 2, 4-7, and 9.

The Examiner also rejected claim 21 as being anticipated by Shivanand (Ans. 3). We reverse this rejection as well.

Claim 21 depends from independent claim 20, which was not rejected as anticipated. Because claim 21 contains all of the limitations of claim 20, it is unclear why the Examiner rejected claim 21 as anticipated, but not claim 20.

At any rate, similar to claim 1 discussed above, claim 21 recites a dosage form that has a "cavity [which] extends entirely through the core such that the core has first and second openings therein." As discussed above with respect to claim 1, Shivanand does not disclose such a dosage form. We therefore reverse the Examiner's rejection of claim 21 as anticipated by Shivanand.

OBVIOUSNESS -- SHIVANAND AND NEWTON

ISSUE

Claims 1, 2, 4-17, and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Shivanand and Newton (Ans. 5-6).

In rejecting the cited claims, the Examiner concedes that Shivanand does not disclose the annular core recited in claim 8 and its dependent claims (*see id.* at 5). To meet that limitation, the Examiner cites Newton as disclosing a controlled release dosage form having "an extruded core of

active material and excipients, said core being coated in a water insoluble coating Cores may be circular or annular (col. 3, lines 57, and 58), and may contain more than one active agent (col. 5, 19)” (*id.*). The Examiner further cites Newton as disclosing that

[U]sually the coating will extend over the majority of the surface area of the extrudate leaving an area uncoated or coated with a permeable material through which the active material is released (col. 4, lines 34-37). The outer exterior surface of the tube is coated with a water insoluble coating and the inner surface is coated with a water permeable coating (claim 25).

(Ans. 6.)

In view of these teachings, the Examiner finds that the particular shape of the dosage form core recited in claim 8 “does not constitute a patentable distinction absent a showing of criticality or unexpected results supported by scientific and or clinical data. The prior art shows the same dosage form irrespective of shape formulated to provide modified release of an active agent” (*id.*). Therefore, the Examiner contends:

The configuration of an article such as a tablet is a matter of choice, which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the tablet is significant. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). It would have been obvious to one of ordinary skill in the art to modify the core shape to conform to other shapes including that of an annular body or a torus. The motivation being a desire to tailor the dosage form for optimum release of specific drugs.

(*Id.*)

Appellants present separate arguments with respect to claims 1, 2, 4, 5, and 8. Appellants argue that the combination of Shivanand and Newton does not render claim 1 obvious because Shivanand is a specific osmotic

dosage form requiring a closed compartment, and that therefore, “one skilled in the art would not have been motivated to modify Shivanand to include an aperture that extends entirely through the device” (App. Br. 7). Moreover, Appellants argue “[a]n opening that passes entirely through the core, as contemplated by the Examiner, would prevent any increase in osmotic pressure and render the dosage form inoperative” (*id.*).

Appellants argue that claim 2 requires the shell to extend into the cavity in the dosage form core, and that the coating of Shivanand cannot meet this limitation because Shivanand’s passageway is produced by laser or mechanical means, which “would preclude the presence of any shell portion extending into the cavity” (App. Br. 8). Appellants contend that the same reasoning applies to claims 4 and 5 (*id.*).

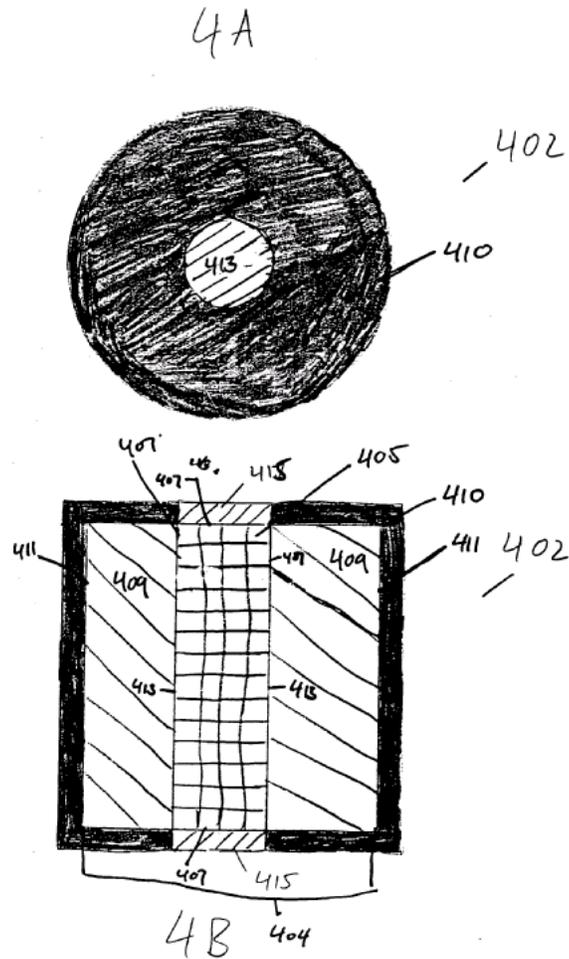
Appellants argue that the Examiner erred in maintaining that the torus shape of the core recited in claim 8 is meaningless because the principal way that active ingredient is released in such dosage forms “is erosion of the center core. The erosion rate for such a dosage form depends, at least in part, on the surface area that is exposed to the eroding medium. As noted in the specification, this shape has been particularly conducive to controlled release of an active ingredient,” as evidenced by teachings in a number of patents (App. Br. 8).

Moreover, Appellants contend, “[t]he mechanism for the release of active ingredients in Shivanand is diffusional that is caused by internal osmotic pressure,” whereas “[t]he advantage of annular cores relates to controlled release during erosion. One skilled in the art would not utilize an internal core designed for controlled release by erosion in a device that depends upon diffusion and internal osmotic pressure” (App. Br. 9).

The issue with respect to this rejection, then, is whether the Examiner has made a prima facie case that one of ordinary skill in the art would have considered claims 1, 2, 4, 5, and 8 obvious in view of Shivanand and Newton.

FINDINGS OF FACT

8. Appellants' Figures 4A and 4B, reproduced below, show an embodiment of the dosage form encompassed by claim 8, and "depict overhead and side views of dosage form 402, which comprises a core 404 made up of a center portion 405 surrounded by an annular portion 409" (Spec. 16):



Figures 4A and 4B show:

The center portion 405 has a surface 407, while the annular portion 409 has an exterior surface 411 and an interior surface 413. The annular portion interior surface 413 is in contact with a portion of the center portion surface 407. The annular portion exterior surface 410 is covered by a first coating 410. A shell, divided into first and second shell portions 415 reside upon a portion of the center portion surface 407[.]

(Spec. 16.)

9. Appellants' Figure 7A, reproduced below, "depicts another embodiment of the invention" (Spec. 16):

FIG. 7A

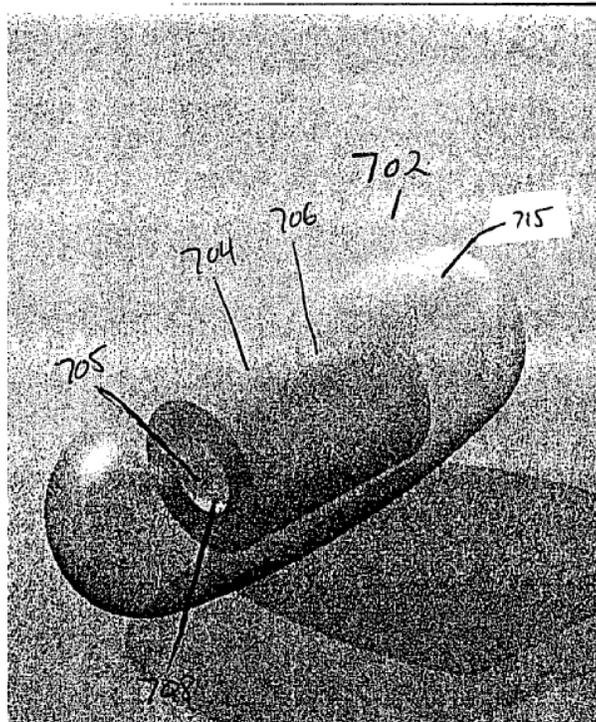


Figure 7A shows "dosage form 702 compris[ing] a core 704 having the shape of a torus" (Spec. 16).

10. Newton discloses “a wet mixture of an active material and excipient [which] can be extruded to produce an extruded core having a smooth surface, which when coated in a water insoluble coating will retain its structural integrity upon exposure to an aqueous medium” (Newton, col. 1, ll. 21-25). Newton states that “[t]he coated extruded compositions provide a controlled release of active material, i.e. when exposed to an aqueous medium the active is released into that medium over a prolonged period” (*id.* at col. 1, ll. 25-28).

11. To make the dosage forms, Newton discloses that a “wet mass is formed into the core of the controlled release dosage form by extrusion through a die. The nature of the die will influence the shape and hence the release characteristics of the extruded core” (Newton, col. 3, ll. 52-55). Accordingly, “[f]or example, the active wet mass can be extruded through circular, elliptical or annular dies. Thus, the extruded cores may be circular or annular in cross-section, i.e. rods or hollow tubes” (*id.* at col. 3, ll. 55-58).

12. Newton discloses that the extruded dosage forms must be coated with a water insoluble material to retain their structural integrity “during the period over which the active material is to be released” (Newton, col. 4, ll. 28-31). While the coating may extend over the entire extrudate, “usually the coating will extend over the majority of the surface area of the extrudate leaving an area uncoated or coated with a permeable material through which the active material is released” (*id.* at col. 4, ll. 34-37).

13. Newton discloses that the hollow tube-shaped extrudates “can be coated and chopped to produce dosage forms in which the cut ends and interior surfaces of the tube are uncoated or coated in a permeable material, and release may take place through these areas” (Newton, col. 4, ll. 47-50).

“Thus, cores of a hollow cylindrical form may have their outer exterior surface coated in a water insoluble material and the inner exterior surface uncoated, or coated in a water soluble or water permeable material” (*id.* at col. 4, l. 65, through col. 5, l. 1).

14. Newton also discloses extruded cores which are “hollow tubes wherein the hollow centre is filled by a second pharmaceutically acceptable material. Preferably the second pharmaceutically acceptable material is co-extruded with the extruded core. In such a case the interior extruded form may be of the kind of the present invention or of any other extrudable kind” (Newton, col. 5, ll. 18-23).

15. Thus, Newton discloses:

A cylindrical extruded core of the present invention may be co-extruded with a second pharmaceutically acceptable material such as the core fills the hollow centre of the second active material. In such a case the coating may be applied to the exterior surface of the co-extrudate, or the co-extrudate may act as a coating in itself.

(Newton, col. 5, ll. 24-30.)

PRINCIPLES OF LAW

“[A]nticipation is the epitome of obviousness.” *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).

“[O]bviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). While emphasizing a flexible approach to the obviousness question, the Supreme Court has nonetheless similarly noted that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to

combine the elements *in the way the claimed new invention does* . . . because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (emphasis added); *see also id.* at 1740-41 (requiring a determination of “whether there was an apparent reason to combine the known elements *in the fashion claimed by the patent at issue*”) (emphasis added).

ANALYSIS

We agree with Appellants that the Examiner has not made a prima facie case that one of ordinary skill in the art would have considered claims 4, 5, and 8 obvious in view of Shivanand and Newton. However, we do not agree with Appellants that the Examiner erred in concluding that claims 1 and 2 would have been obvious to a person of ordinary skill in the art in view of the cited references.

Regarding claim 1, Newton discloses a controlled release dosage form comprised of an “active material” in the shape of hollow tubes (FF 10-11). Moreover, Newton discloses that its hollow tube-shaped dosage forms “may have their outer exterior surface coated in a water insoluble material and the inner exterior surface uncoated, or coated in a water soluble or water permeable material” (Newton, col. 4, l. 65, through col. 5, l. 1 (FF 13)).

Thus, Newton clearly meets claim 1’s limitation requiring an active ingredient. Moreover, Newton’s water insoluble material on the exterior surface of the hollow tube (FF 13) meets the limitation requiring the core to have “a first surface portion upon which resides a first coating.” Newton’s disclosure that its tubes’ inner exterior surface is “coated in a water soluble

or water permeable material” (Newton, col. 5, l. 1 (FF 13)) meets the limitation in claim 1 requiring “a shell which resides upon at least a portion of the second surface portion, wherein the shell comprises a different material from the first coating.”

Also, because the water soluble material is on the inner exterior surface of the hollow tube (FF 13), Newton meets the limitation in claims 1 and 2 requiring the shell to “reside[] upon at least a part of the second surface portion of the core which is located within the cavity.” Lastly, because the dosage form is a hollow tube, it meets claim 1’s limitation that “the cavity is an aperture which extends entirely through the core.”

Thus, because Newton meets all of the limitations in claims 1 and 2, Newton renders claims 1 and 2 obvious. *See Connell v. Sears, Roebuck & Co.*, 722 F.2d at 1548 (“[A]nticipation is the epitome of obviousness.”). We therefore affirm the Examiner’s rejection of claims 1 and 2 as obvious over Newton and Shivanand. Because they were not argued separately from claim 1, we also affirm the Examiner’s rejection of claims 6, 7, 9, 13, and 14 over these references. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Claims 4 and 5 read as follows:

4. The dosage form of Claim 2, in which the shell resides upon at least part of both the first coating and the second surface portion of the core.
5. The dosage form of Claim 1, in which the shell resides over all the first coating and the second surface of the core.

The Examiner has not explained where or why either of the cited references teaches or suggests the configurations of shell and coating recited

in these claims. We therefore reverse the Examiner's rejection of claims 4 and 5 over Newton and Shivanand.

Regarding claim 8, the claim recites a dosage form that has a core that includes a center portion and an annular portion. The center portion has an exterior surface. The annular portion also has an exterior surface, and an interior surface, and the annular portion's interior surface is in contact with at least a portion of the center portion exterior surface.

The core of claim 8 has a first coating that resides on at least a portion of the annular portion exterior surface. The core annular portion has the shape of a torus. The core also has a shell which resides on at least a portion of the exterior surface of the center portion, and the shell comprises a different material than the first coating.

Appellants' Figures 4A and 4B show an embodiment of a dosage form core encompassed by claim 8 (FF 8). As seen from Figures 4A and 4B, the core is essentially a tube 402 filled with a pharmaceutical composition 407 (corresponding to claim 8's center portion), that is distinct from the composition 409 (corresponding to claim 8's annular portion) that comprises the surrounding tube (FF 8).

Newton discloses that one embodiment of its invention is a hollow tube "wherein the hollow centre is filled by a second pharmaceutically acceptable material. Preferably the second pharmaceutically acceptable material is co-extruded with the extruded core" (Newton, col. 5, ll. 18-21 (FF 14)). Thus, Newton meets claim 8's limitations requiring the core to have an annular portion (Newton's drug-containing tube) and a center portion (the tube-filling center material), both of which have exterior

surfaces, the annular portion also having an interior surface which contacts an exterior surface of the center portion.

While Newton does not describe its dosage form as being in the shape of a torus, Appellants' Figure 7A shows that tube-shaped dosage form cores can be considered to be in the shape of a torus (*see* FF 9). Thus, when claim 8 is properly read in light of the Specification, Newton's tube-shaped dosage form core meets claim 8's limitation requiring the core to be torus-shaped.

Newton does not, however, meet claim 8's limitation that the shell must reside on at least a portion of the exterior surface of the center portion, with the shell comprising a different material than the first coating. Specifically, Newton discloses that if the center core and surrounding tube are co-extruded, "the coating may be applied to the exterior surface of the co-extrudate, or the co-extrudate may act as a coating in itself" (Newton, col. 5, ll. 24-30 (FF 15)).

Thus, rather than disclosing a separate coating (i.e. "shell" of claim 8) for the center and annular portions of the dosage form core, Newton discloses applying a single coating to its entire tube/cylinder co-extruded core, or allowing the co-extruded tube/cylinder to act as its own coating. Moreover, the Examiner has not explained where either of the cited references would have suggested to one of ordinary skill in the art that it would be suitable or desirable to provide the exterior surface of the center portion of Newton's tube/cylinder embodiment with a coating or shell that is different than the coating on the other surfaces of the core.

We therefore agree with Appellants that the Examiner has not made a *prima facie* case that claim 8 would have been obvious to a person of ordinary skill in the art in view of the cited references. Accordingly, we

reverse the Examiner's obviousness rejection of claim 8 and its dependent claims 10-12, 15-17, and 19.

In sum, we reverse the Examiner's obviousness rejection of claims 4, 5, 8, 10-12, 15-17, and 19 over Shivanand and Newton. However, we affirm the Examiner's rejection of claims 1, 2, 6, 7, 9, 13, and 14 over those references.

Because our rationale in affirming the obviousness rejection of claims 1, 2, 6, 7, 9, 13, and 14 is different than that applied by the Examiner, we designate our affirmance a new ground of rejection under 37 C.F.R. § 41.50(b).

OBVIOUSNESS -- SHIVANAND, NEWTON, AND RITSCHEL
ISSUE

Claims 1, 2, 4-17, 19-21, 23-31, 33-42, and 45-48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Shivanand, Newton, and Ritschel (Ans. 6-9). The Examiner concedes that Shivanand and Newton "were deficient in disclosing the double pulse release, the pore sizes of the shell, and the shell dissolution rate," and did not disclose the use of polycaprolactone (*id.* at 7).

To meet those limitations, the Examiner cites Ritschel as disclosing tablets capable of time-controlled release of active agent at different rates, the tablets "consisting of a solid core comprising an active agent together with a hydrogel, with the solid core being coated with a semi-permeable, self-destructing membrane which is optionally drilled to provide a release orifice, and then optionally further coated with the same or different active agent material" (*id.* at 8).

The Examiner concludes that one of ordinary skill in the art would have considered it obvious to “use the tablet or capsule designs disclosed by Shivanand, or Newton and expand it with the designs given by Ritschel, and use one or more active agents in the core, coat it with one or more coatings, regulate the shell dissolution time, and the double pulse release” (*id.* at 9).

The Examiner reasons that:

The motive would be the disclosure of Ritschel that the invention is to design a system or device which contains, instead of an osmotically active agent, a dry swelling material and instead of a semipermeable membrane by spray-or dip-coating, a semipermeable shell by press-coating and an exit means through which the drug solution is expelled at a predetermined rate over a period of 8 or 14 hours for a 12 or 24 hours duration of effect (col. 1, lines 51-58).

(*Id.*)

Appellants present separate arguments with respect to claims 1, 2, 4, 5, 8, 20, and 21 (App. Br. 9-11). Regarding claim 1, Appellants argue that Ritschel does not remedy the previously argued deficiencies of Shivanand and Newton, and that, therefore, “even assuming that Ritschel could be combined with one of the primary references, the result does not disclose the instantly claimed inventions of claims 1-19, 30 and 32-48” (*id.* at 9).

Regarding claims 2, 4, and 5, Appellants repeat the previous contention that the use of a laser or mechanical means to produce the hole in Shivanand’s dosage form precludes the presence of the shell portion extending into the cavity, even when Shivanand is viewed in light of Newton or Ritschel (*id.* at 10). Regarding claim 8, Appellants repeat the previous contention that the Examiner erred in finding the torus shape of the article to be non-critical, as well as the contention that “[o]ne skilled in the art would

not utilize an internal core designed for controlled release by erosion in a device that depends upon diffusion and internal osmotic pressure” (*id.* at 11).

Regarding claim 20, Appellants contend that “the prior art alone or together would not lead one to a dosage form having a core in the shape of a torus with a cavity that extends through the core” (*id.*). Regarding claim 21, Appellants similarly argue that “the prior art alone or together would not lead one to a dosage form having a core in the shape of a torus or first and shell portions that covers corresponding first and second openings” (*id.*).

The issue with respect to this rejection, then, is whether the Examiner has made a *prima facie* case that one of ordinary skill in the art would have considered claims 1, 2, 4, 5, 8, 20, and 21 obvious in view of Shivanand, Newton, and Ritschel.

FINDINGS OF FACT

16. Ritschel discloses an orally administered drug delivery that “delivers a compound in a sustained manner to the upper portion of the gastrointestinal tract and then a greater burst of release at the lower small intestine and the colon, more particularly to the colon” (Ritschel, col. 3, ll. 33-36).

17. Figure 7 of Ritschel, reproduced below, is “a side cutaway view of a further embodiment of the dispensing system in accordance with the principles of the invention, comprising a self-destructing wall, an active agent core, a push means, and a delay jacket, and which system is useful for delivering a beneficial agent to the digestive tract” (Ritschel, col. 2, ll. 50-55):

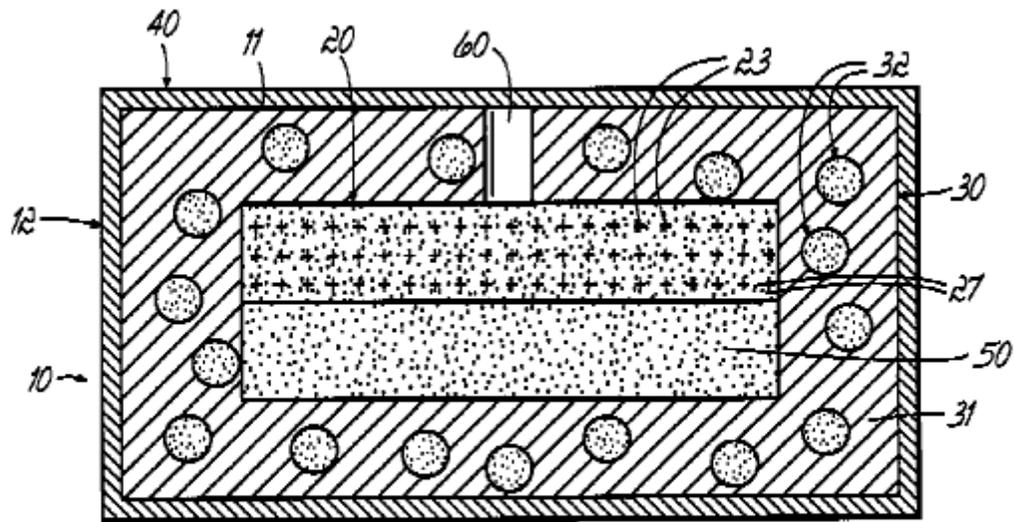


FIG. 7

Figure 7 shows:

[S]ystem **10** . . . in opened section with a portion of wall **12** removed at **21**. In FIG. 7, system **10** comprises body **11**, wall **12**, orifice **60**, and internal compartment **20**. Wall **12** of the delivery system illustrated in FIG. 7 comprises a composite formed essentially of a semipermeable matrix **31**, that is permeable to the passage of an external fluid and it is essentially impermeable to the passage of active agent **23**, and a multiplicity of embedded disintegrants **32**. Disintegrants **32** comprises a swelling agent **34** which is coated by a delay jacket **33**. Compartment **20** of delivery device **10** shown in FIG. 7 comprises a beneficial agent **23**, and, optionally, an osmotically effective compound **27**.

(Ritschel, col. 4, ll. 53-65.)

18. Regarding the dosage form shown in Figure 7, Ritschel states:

During operation, when the delivery system **10** is in the environment of use dispensing beneficial agent **23**, compartment **20** contains also imbibed external fluid **25**.

Generally, wall **12** is a semipermeable composite having a wall thickness of 25 to 800 microns. FIG. 7 shows an optional push means **50** which, upon contact with imbibed fluid, consumes volume inside the core compartment by swelling and thereby pushes the active agent formulation through the exit means.

(Ritschel, col. 4, l. 65, through col. 5, l. 6.)

ANALYSIS

We agree with Appellants that the Examiner has not made a prima facie case that one of ordinary skill in the art would have considered claims 4, 5, 8, 20 and 21 obvious in view of Shivanand, Newton, and Ritschel. However, for the reasons discussed previously, we do not agree with Appellants that the Examiner erred in concluding that claims 1 and 2 would have been obvious to a person of ordinary skill in the art in view of the cited references.

As discussed above, because Newton discloses controlled release dosage form cores in the shape of hollow tubes having different coatings on the exterior and interior portions of the tubes (FF 11-13), Newton meets all of the limitations of claims 1 and 2. As also discussed above, “anticipation is the epitome of obviousness.” *Connell v. Sears, Roebuck & Co.*, 722 F.2d at 1548.

Therefore, because we do not agree with Appellants that the cited references fail to teach or suggest the subject matter recited in claims 1 and 2, we affirm the Examiner’s obviousness rejection of those claims. Moreover, because they were not argued separately, we also affirm the Examiner’s rejection of claim 1’s dependent claims 6, 7, 9, 13, 14, 30, 34-42, and 45-48 over these references. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Because our rationale in affirming the obviousness rejection of claims 1, 2, 6, 7, 9, 13, 14, 30, 34-42, and 45-48 is different than that applied by the Examiner, we designate our affirmance a new ground of rejection under 37 C.F.R. § 41.50(b).

With respect to claims 4 and 5, as pointed out above, the Examiner has not explained where or why Shivanand or Newton teaches or suggests the configurations of shell and coating recited in these claims. Because we do not see, and the Examiner has not explained, how Ritschel remedies the deficiencies of Shivanand and Newton with respect to claims 4 and 5, we reverse the Examiner's rejection of claims 4 and 5 over Newton, Shivanand, and Ritschel.

With respect to claim 8, as discussed above, Newton discloses a dosage form core having the claimed center and annular portions, and the claimed shapes (FF 8-15). However, the Examiner has not specifically explained why either of the other cited references would have suggested placing a coating or shell on the center portion of Newton's core that is different than the coating on the other surfaces of the dosage form. We therefore reverse the Examiner's obviousness rejection of claim 8, and its dependent claims 10-12, 15-17, 19, and 33.

Claim 20 recites a dosage form having a core with an outer surface and a cavity which extends through the core having the shape of a torus such that the core outer surface has at least a first opening. The core must also have a first coating that resides on at least a portion of the core outer surface, and a first shell portion that comprises a different material from the first coating. The first shell

portion must be adjacent to the first opening and cover at least the first opening.

As discussed above, Newton discloses controlled release dosage form cores in the shape of hollow tubes having different coatings on the exterior and interior portions of the tubes (FF 11-13). As also discussed above, Newton's tube-shaped dosage forms can be considered to be torus-shaped when the claims are interpreted in light of the Specification (*see* FF 9). We therefore do not agree with Appellants that the cited references fail to disclose a dosage form having the claimed shapes and different coatings.

However, the Examiner does not point to, and we do not see, where Newton discloses its dosage form cores as having claim 20's shell portion that covers at least one opening. We note that Shivanand and Ritschel teach osmotic dosage forms that use expanding polymers to push active ingredients through small exit ports, thereby providing controlled release of the active ingredient (*see* FF 2-7, 16-18).

However, the Examiner has not provided a specific explanation as to how or why those disclosures would have prompted a person of ordinary skill to cover at least one of the openings of Newton's hollow tube-shaped cores with a shell composition that is different from the coating on the remainder of the core, as required by claim 20. We therefore reverse the Examiner's obviousness rejection of claim 20, and its dependent claims 21, 23-29, and 31.

SUMMARY

We reverse the Examiner's rejection of claims 1, 2, 4-7, 9, and 21 under 35 U.S.C. § 102(b) as anticipated by Shivanand.

We affirm the Examiner's rejection of claims 1, 2, 6, 7, 9, 13, and 14 under 35 U.S.C. § 103(a) as obvious over Shivanand and Newton. Because our affirmance of this rejection relies on a different rationale than that applied by the Examiner, we designate our affirmance a new ground under 37 C.F.R. § 41.50(b).

We reverse the Examiner's rejection of claims 4, 5, 8, 10-12, 15-17, and 19 under 35 U.S.C. § 103(a) as obvious over Shivanand and Newton.

We affirm the Examiner's rejection of claims 1, 2, 6, 7, 9, 13, 14, 30, 34-42, and 45-48 under 35 U.S.C. § 103(a) as obvious over Shivanand, Newton, and Ritschel. Because our affirmance of this rejection relies on a different rationale than that applied by the Examiner, we designate our affirmance a new ground under 37 C.F.R. § 41.50(b).

We reverse the Examiner's rejection of claims 4, 5, 8, 10-12, 15-17, 19-21, 23-29, 31, and 33 under 35 U.S.C. § 103(a) as obvious over Shivanand, Newton, and Ritschel.

Time Period for Response

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.

37 C.F.R. § 41.50(b) also provides that the appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

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(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record

AFFIRMED-IN-PART, 37 C.F.R. § 41.50(b)

lp

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