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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL L. JONES, PAUL LUBOCK, and JOHN MERRITT[1]

Appeal 2018-006342
Application 12/317,339
Technology Center 1600

Before DONALD E. ADAMS, ERIC B. GRIMES, and
ROBERT A. POLLOCK, *Administrative Patent Judges.*

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a system for delivering a marker to a biopsy site, which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

STATEMENT OF THE CASE

> The invention is generally directed to a remotely imageable marker system suitable for deployment at a site within a patient's body, particularly a biopsy site such as in a patient's

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[1] Appellant identifies the real party in interest as SenoRx, Inc. Appeal Br. 3. We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42(a).

> breast. The imageable marker system includes a mass of powdered starch or other polysaccharide sufficient to accelerate thrombus formation at the site where tissue has been removed. . . . The marker system also includes a radiopaque element preferably coupled to or disposed within a pellet formed of bioabsorbable material.

Spec. ¶ 13.

Claims 35–52 are on appeal. Claims 35 and 38, reproduced below, are illustrative:

> 35. A biopsy site marker delivery system, comprising:
>
> a hollow shaft which has a distal end, a proximal end, and a distal opening;
>
> a plunger disposed in the hollow shaft;
>
> a bioabsorbable marker element, the bioabsorbable marker element being disposed in the hollow shaft distal to the plunger;
>
> a radiopaque marker element coupled to the bioabsorbable marker element; and
>
> a powdered polysaccharide material disposed in the hollow shaft distal to the plunger, the powdered polysaccharide material including:
>
> a first aliquot of the powdered polysaccharide material disposed distal to the bioabsorbable marker element; and
>
> a second aliquot of the powdered polysaccharide material disposed proximal to the bioabsorbable marker element, wherein the first aliquot of the powdered polysaccharide material and the second aliquot of the powdered polysaccharide material converge around the bioabsorbable marker element.

> 38. The biopsy site marker delivery system of claim 35, wherein the powdered polysaccharide material is a starch powder.

Claims 41 and 47 are also independent. Claim 41 is directed to a system like that of claim 35, except that it comprises "a radiographically detectable pellet disposed in the hollow shaft distal to the plunger" instead of the coupled "bioabsorbable" and "radiopaque" markers recited in claim 35. Claim 47 is directed to a similar system, except that it comprises "a marker body that carries a radiopaque element, the marker body being disposed in the hollow shaft distal to the plunger" instead of claim 35's coupled "bioabsorbable" and "radiopaque" markers. The limitations of the dependent claims will be addressed below to the extent they are relevant to Appellant's arguments.

The claims stand rejected as follows:

Claims 35–37, 39–41, 43–47, and 49–52 under 35 U.S.C. § 103(a) as obvious based on Burbank '196[2] and Burbank '241[3] (Ans. 2);

Claims 38, 42, and 48 under 35 U.S.C. § 103(a) as obvious based on Burbank '196, Burbank '241, Klaveness,[4] and Madison[5] (Ans. 4); and

Claims 35–52 under 35 U.S.C. § 103(a) as obvious based on Fallon,[6] Lee,[7] Burbank '241, and Burbank '034[8] (Ans. 5).

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[2] US 2002/0188196 A1 published Dec. 12, 2002.
[3] US 6,347,241 B2 issued Feb. 12, 2002.
[4] US 5,928,626 issued July 27, 1999.
[5] US 2,899,362 issued Aug. 11, 1959.
[6] US 6,027,471 issued Feb. 22, 2000.
[7] US 5,236,693 issued Aug. 17, 1993.
[8] US 6,161,034 issued Dec. 12, 2000.

OPINION

Obviousness: Burbank '196 and Burbank '241

The Examiner has rejected claims 35–37, 39–41, 43–47, and 49–52 as obvious based on Burbank '196 and Burbank '241. The Examiner finds that "Burbank'196 discloses ultrasound detectable bio-resorbable powders . . . with a tube configured to hold the powder and ejected via action of a syringe," to allow localization of a biopsy site. Ans. 2. The Examiner finds that "[t]he compositions are intended to be introduced at a biopsy site" and "[p]olysaccharides are among the bio-resorbable materials that can be used . . . for ultrasound detectable marker materials." *Id*.

The Examiner finds that Burbank '196 discloses that "[t]he material can further comprise radiopaque materials," but "does not disclose one or more radiographically detectable markers coupled to or disposed within a pellet formed of a bioabsorbable material." *Id*. at 2–3. The Examiner finds that "Burbank'241 discloses small bodies or pellets of gelatin that . . . have a radiopaque material that is coupled to or disposed within the pellet." *Id*. at 3. "An object of the invention is to mark [a] biopsy site with a material that will not migrate from the site even when the surrounding tissue is moved, manipulated or compressed." *Id*. The Examiner also finds that Burbank '241 discloses that multiple gelatin pellets containing a radiopaque marker can be loaded into a syringe for delivery. *Id*.

The Examiner concludes that it would have been obvious

> to incorporate pellets with a radiopaque maker as in Burbank'241 into the composition of Burbank'196 . . . because the material of Burbank'196 can contain a radiographically detectable marker element and Burbank'241 discloses that such elements can be provided in a pellet form and the radiopaque

> material delivered to the site as pellets will not migrate from the biopsy cavity.

Id. at 3–4.

Regarding the requirement in claim 35 for two aliquots of powdered polysaccharide material, the Examiner reasons that "[w]hen a pellet as in Burbank'241 is added [to the powder of Burbank '196], the powdered mass can be placed both distal and proximal to the pellet, . . . forming two 'aliquots' of the media as required by claims such as claim 35." *Id*. at 4. The Examiner finds that "[t]his arrangement can allow for complete filling of the site around the pellet as powder is delivered to the site both before and after the pellet." *Id*.

We agree with the Examiner that the system of claim 35 would have been obvious based on the cited references. Burbank '196 discloses "materials, devices, and methods for marking intracorporeal locations such as biopsy sites." Burbank '196 ¶ 11. For example, "a system 10 embodying features of the invention, includ[es] a delivery tube 14 containing a quantity of an ultrasound-detectable bio-resorbable particulate material 16 . . . and a syringe 18." *Id*. ¶ 23.

"The marking material comprises an ultrasound-detectable bio-resorbable finely-divided particulate material (such as a powder)." *Id*. ¶ 11. "Thus, much or all of the biopsy cavity may be filled with an ultrasound-detectable marker material, creating an ultrasound-detectable marker that can be as large as the biopsy sample that was removed." *Id*. ¶ 13.

Burbank '196 discloses that "particularly suitable materials include bio-resorbable polymers including" polysaccharides, among others. *Id*. ¶ 43. The "biopsy marker materials . . . may also include radiopaque materials or

radiopaque elements, so that the biopsy site may be detected both with ultrasound and with X-ray." *Id*. ¶ 41. "Radiopaque materials and markers may include metal objects . . . and may also include powders or particulate masses of radiopaque materials." *Id*.

Although Burbank '196 suggests including radiopaque elements in its composition, it does not expressly suggest including a bioabsorbable marker element (pellet) with a radiopaque marker element coupled to it. However, Burbank '241 discloses "a biopsy site marker that comprises small bodies or pellets of gelatin which enclose substantially in their interior a radio (X-ray) opaque object." Burbank '241 at 3:45–48. Burbank '241 states that "[t]ypically, several gelatin pellets, only some of which typically do, but all of which may contain the radio opaque object, are deposited sequentially from the applicator into the site through the tube." *Id*. at 3:52–55. Burbank '241 discloses that its invention "provide[s] a biopsy site marker that does not migrate from the biopsy cavity even when the surrounding tissue is moved, manipulated or decompressed." *Id*. at 3:28–31.

Based on these teachings, it would have been obvious to combine the biopsy site markers disclosed by Burbank '241—gelatin pellets containing a radiopaque object—with the powdered polysaccharide biopsy site marking material disclosed by Burbank '196, because Burbank '196 expressly suggests including radiopaque elements in its material, and Burbank '241 discloses a form of radiopaque biopsy site marker material that will not migrate from the biopsy cavity even when the surrounding tissue is moved.

Claim 35 further requires that the powdered polysaccharide material is disposed in two aliquots, one distal to the marker element and one proximal

to it, which converge around the marker element. That is, some of the powder is in front of the pellet, some is around the pellet, and some is behind the pellet, relative to the end of the shaft. Since neither of the Burbank references expressly describes the combination of a pellet and a powder, neither reference describes this configuration of a pellet and a powder.

However, we agree with the Examiner that the claimed arrangement of the powder of Burbank '196 and the gelatin pellets of Burbank '241 would have been obvious to those of ordinary skill in the art. The question of how to combine pellets and a powder, in a tube, is amenable to only a limited number of answers. The pellets could go in first, followed by all of the powder; all of the powder could go in first, followed by the pellets; or the pellets and powder could go in together, mixed. The latter arrangement meets the limitations of claim 35 and it would have been an obvious way to combine the teachings of Burbank '196 and Burbank '214, because it is one of only three ways in which to do so.

Appellant argues that "notably absent from Burbank '196 is any disclosure, teaching, or suggestion of separating the particulate material 16 into first and second aliquots," and "Burbank '196 does not disclose, teach, or suggest the addition of another bioabsorbable marker element to the particulate material 16." Appeal Br. 18. "Thus, notably absent from Burbank '196 is any disclosure, teaching, or suggestion of a concept wherein first and second aliquots converge around a bioabsorbable marker element." *Id*.

Appellant also argues that "notably absent from Burbank '241 is any disclosure, teaching, or suggestion of separating a powdered material into

first and second aliquots." *Id*. Thus, Appellant argues, Burbank '196 and Burbank '241 do not disclose or suggest *all of the elements* of claim 35." *Id*.

This argument is unpersuasive, because it addresses the teachings of the cited references only in isolation, while "[t]he test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art." *In re Young*, 927 F.2d 588, 591 (Fed. Cir. 1991). Here, while neither Burbank '196 nor Burbank '241 individually discloses all of the limitations of claim 35, for the reasons discussed above, when viewed together they would have made obvious the claimed system as a whole.

Appellant also argues that the Examiner's reason for combining the references is based on "advantages [that] are identified in Appellant's specification." Appeal Br. 21.

This argument is unpersuasive, because the Examiner explained that a person of ordinary skill in the art would have been motivated to make the combination based on the disclosure in Burbank '241 that its "pellets will not migrate from the biopsy cavity." Ans. 4. The Examiner's reason for combining the references was based on the teachings of the references, not those of Appellant's Specification.

Appellant also argues that "there would have been no reason to attempt to combine Burbank '196 and Burbank '241" because each of the references "is self-sufficient for its respective type of marker delivery." Appeal Br. 22.

This argument is also unpersuasive because, as the Examiner pointed out (Ans. 11), the references disclose different advantages for their

respective systems. Burbank '196 discloses that its powdered material can create an ultrasound-detectable marker as large as the biopsy sample that was removed (Burbank '196 ¶ 13), while Burbank '241 discloses that its radiopaque biopsy site marker does not move from the biopsy site (Burbank '241 at 3:28–31). Thus, in view of the express suggestion in Burbank '196 to include radiopaque elements in its composition, it would have been obvious to use the radiopaque elements disclosed by Burbank '241 because they will not move from the biopsy site.

Finally, Appellant argues that the rejection "is founded upon . . . an assumption that the size of the particles of powdered marker mass taught in Burbank '196 are much smaller than the diameter of the delivery tube and also much smaller than the added Burbank '241 pellets, in order to create the two aliquots of claim 35." Appeal Br. 23. Appellant points to the suggestion in Burbank '196 that, when "the particle size is significant relative to the diameter of a delivery tube," or is "about 60% to about 90% of the inner diameter of the delivery tube bore," the powder "may be expelled by direct action of a plunger," without the need for a liquid or gas. *Id*. at 23–24, citing Burbank '196 ¶ 78. Appellant points out that the system of claim 35 requires a plunger. *Id*. at 24.

Appellant also points to the statement in Burbank '241 that the size of its pellets is coordinated with the inner diameter of the delivery tube. *Id*. Appellant concludes that "the individual particles of the Burbank '196 powdered marker mass would have been about the same size as the Burbank '241 gelatin pellets." *Id*.

This argument is also unpersuasive. Burbank '196 discloses that its "powders may be composed of particles having sizes typically less than about 2000 microns, and typically between about 20 microns and about 2000 microns, preferably between about 20 microns and about 800 microns, more preferably between about 300 microns and about 500 microns." Burbank '196 ¶ 11.

Burbank '196 discloses that its powder may be ejected from a delivery tube using gas pressure, acoustic pressure, hydraulic pressure, or mechanical pressure. *Id*. ¶ 77. Burbank '196 discloses that, for example,

> a syringe filled with air or other gas may be connected to a tube or chamber containing an ultrasound-detectable bioresorbable powder and the syringe plunger depressed so as to force the air or gas, and the powder, through a needle or catheter attached to the tube or chamber and having an orifice within a biopsy site.

Id.

Thus, although Burbank '196 discloses one embodiment in which particles with a size that is significant relative to the delivery tube are expelled by *direct* action of a plunger (*id*. ¶ 78), it also discloses an embodiment in which a plunger is used to compress air in order to expel smaller particles. We also note that Burbank '241 states that, in dehydrated form, its pellets are about 1–3 mm in diameter and about 5–10 mm long. Burbank '241 at 4:59–62. We therefore do not agree with Appellant's position that the particles of the Burbank references would have been about the same size.

Appellant separately argues independent claims 41 and 47. Appeal Br. 29–31, 32–34. However, the arguments merely incorporate by reference the

arguments made for claim 35. *See id*. Those arguments are unpersuasive for the reasons discussed above.

Claim 36

Claim 36 reads:

> 36. The biopsy site marker delivery system of claim 35, wherein the bioabsorbable marker element is a first bioabsorbable marker element of a plurality of bioabsorbable marker elements disposed in the hollow shaft distal to the plunger, the plurality of bioabsorbable marker elements further comprising a second bioabsorbable marker element disposed proximal to the second aliquot of the powdered polysaccharide material in the hollow shaft, and wherein the powdered polysaccharide material further includes a third aliquot of the powdered polysaccharide material disposed proximal to the second bioabsorbable marker element, wherein the second aliquot of the powdered polysaccharide material and the third aliquot of the powdered polysaccharide material converge around the second bioabsorbable marker element.

Claim 36 thus adds to claim 35 the requirement for a second pellet ("bioabsorbable marker element"), and for additional powder behind both pellets (relative to the end of the shaft), with the powder between the pellets and the powder behind both pellets converging around the second pellet.

As relevant to claim 36, the Examiner finds that Burbank '241 discloses that "multiple gelatin pellets 20 containing the radiopaque or X-ray detectable marker 22 can be loaded into the barrel of a syringe with a plunger for delivery." Ans. 3. The Examiner reasons that "the use of more than 2 of such pellets results in the formation of additional aliquots of the powdered polysaccharide material that converge around each pellet as required by claim 36." *Id*. at 12.

We agree with the Examiner's fact-finding, reasoning, and conclusion.

Appellant argues that,

> [s]ince the cited references do not disclose, teach, or suggest the "second aliquot of the powdered polysaccharide material" as in claim 35, Appellant respectfully submits that the cited references also do not disclose, teach, or suggest the arrangement of "**a second bioabsorbable marker element** disposed proximal to the second aliquot of the powdered polysaccharide material in the hollow shaft" nor "a **third aliquot** of the powdered polysaccharide material disposed proximal to the second bioabsorbable marker element" as in claim 36. (Emphasis added).

Appeal Br. 28.

This argument is not persuasive because, for the reasons discussed above, we agree with the Examiner that the Burbank references would have made obvious the second aliquot of powdered material recited in claim 35, as well as the second bioabsorbable marker element and the third aliquot of powdered material recited in claim 36.

Claims 39, 43 and 52

Claims 39, 43, and 52 depend from claims 35, 41, and 47, respectively, and require that the pellet directly contacts each of the first and second aliquots of powdered polysaccharide material. Appellant argues that "[s]ince the cited references do not disclose, teach, or suggest the 'second aliquot of the powdered polysaccharide material' as in" the independent claims, they do not suggest a pellet "**directly contacting each of**" the first and second aliquots of powdered polysaccharide material. Appeal Br. 28; *see also id*. at 31–32, 34–35.

This argument is unpersuasive because, as discussed above, we conclude that the cited references would have made obvious the claimed arrangement of the powdered polysaccharide material of Burbank '196 and the pellet(s) of Burbank '241.

For the reasons discussed above, we affirm the rejection of claims 35, 36, 39, 41, 43, 47, and 52 under 35 U.S.C. § 103(a) based on Burbank '196 and Burbank '241. Claims 40, 44–46, and 49–51 fall with claims 35, 41, and 47. Claim 37 falls with claim 36. 37 C.F.R. § 41.37(c)(1)(iv).

Obviousness: Burbank '196, Burbank '241, Klaveness, and Madison

The Examiner has rejected claims 38, 42, and 48 as obvious based on Burbank '196, Burbank '241, Klaveness, and Madison. Ans. 4. The Examiner relies on the Burbank references for the teachings discussed above, but finds that they do not teach using "starch as a polysaccharide suitable for use in the short term marker detectable by ultrasound." *Id*.

The Examiner finds that Klaveness teaches "contrast agents for applications such as ultrasound that comprise a carbohydrate (abstract). In the examples, echogenic particles comprised galactose and starch were prepared." *Id*. at 5. The Examiner also finds that Madison "discloses that starch is a polysaccharide that exhibits hemostatic properties." *Id*.

The Examiner concludes that it would have been obvious "to select starch as the particular polysaccharide used in the biopsy marker device disclosed by Burbank'196 . . . because Burbank'196 discloses that ultrasound detectable powdered polysaccharides can be used to fill a biopsy site and Klaveness et al. discloses that powders of starch will be echogenic." *Id*. The Examiner reasons that, since a biopsy is a surgical procedure and

Madison teaches that starch is hemostatic, "introduction of a starch material would not only mark the biopsy site with an echogenic material but could also stop any bleeding at the site." *Id*.

We agree with the Examiner that claim 38 would have been obvious based on the cited references. Klaveness discloses that "contrast agents comprising microparticles of a water-soluble carbohydrate admixed with a substantial proportion (e.g. at least 10% w/w relative to the overall composition) of a less water-soluble non-surface active material . . . exhibit[] useful levels of contrast effect and/or stability" in the ultrasound field. Klaveness 2:5–10. "The non-surface active material may, for example, be a high molecular weight polysaccharide such as starch or dextran." *Id*. at 2:57–59. Klaveness provides working examples of galactose/starch mixtures. *Id*. at 4:19–35.

Thus, it would have been obvious to combine Klaveness' starch-containing composition with the biopsy-marking system made obvious by the combination of the Burbank references, because Burbank '196 discloses that its biopsy site-marking powder should be detectable by ultrasound (Burbank '196 ¶ 13) and Klaveness discloses that its composition is useful as a contrast agent in ultrasound imaging (Klaveness 1:9–11, 2:4–15).

Appellant argues the Examiner erred in relying on Madison, because "[t]he passage referenced by the Examiner is directed to a discussion of a prior art sponge having flaws," and would not have led a person of ordinary skill in the art to starch "for application at a biopsy site." Appeal Br. 37.

This argument is unpersuasive. The Examiner cited Madison only for an additional reason to use starch, for its hemostatic properties, in addition to

the echogenic properties disclosed by Klaveness. But whether or not Madison would have provided additional motivation, Klaveness itself provides adequate reason to combine its starch-containing powder with the system of the Burbank references because it teaches that its powder is useful as an ultrasound contrast agent.

We affirm the rejection of claim 38 under 35 U.S.C. § 103(a) based on Burbank '196, Burbank '241, Klaveness, and Madison. Claims 42 and 48 fall with claim 38. 37 C.F.R. § 41.37(c)(1)(iv).

Obviousness: Fallon, Lee, Burbank '241, and Burbank '034

The Examiner rejected all of the claims on appeal as obvious based on Fallon, Lee, Burbank '241, and Burbank '034. The Examiner finds that Fallon discloses a tube, with a plunger, filled with a hemostatic agent to allow accurate placement of the agent at a bleeding site or within a cavity. Ans. 6. "The hemostatic agent is particles such as powders or fibers . . . that are sufficiently small to flow when pressure is applied . . . and examples of suitable material include non-soluble polysaccharides." *Id*. "Lee evidences that such particles would be echogenic and therefore capable of being visualized using ultrasound." *Id*.

The Examiner relies on Burbank '241 for its disclosure of gelatin pellets with radiographic markers in them, as discussed above. The Examiner finds that "Burbank'034 discloses detectable markers that are introduced into a cavity following removal of a biopsy specimen." *Id*. The material "can be in forms such as powders" with a solubility that allows it to remain at the biopsy site for a predetermined amount of time. *Id*. "For

markers that are detectable by imaging, the marker can be radiographically visible, or other means such as ultrasound or MRI." *Id*.

The Examiner concludes that it would have been obvious "to include a radiopaque maker [sic] such as the pellets as in Burbank'241 in the composition of Fallon . . . because the material of Fallon can be used to fill a wound site and act to stop bleeding due to the hemostatic nature of the powder but would also be detectable by ultrasound as evidenced by Lee." *Id*. at 7. "Burbank'034 disclosed that such a material would also be useful to mark a biopsy location and that a combination of detectable materials can be used as disclosed by Burbank'241." *Id*.

Appellant argues, among other things, that "prior to the present invention, there was no reason for one of ordinary skill in the art to have been motivated to attempt to combine the teachings of Fallon, Lee, Burbank '034, and Burbank '241 to develop the presently claimed invention." Appeal Br. 43. Appellant argues that "Fallon does not disclose or suggest any consideration of a remote detection, i.e., imaging, or the use of a powdered material in transporting/delivering a bioabsorbable marker element to a biopsy site." *Id*. at 44.

In this case, we agree with Appellant that the Examiner has not persuasively shown that Fallon, Lee, Burbank '241, and Burbank '034 would have made obvious the claimed system.

Fallon discloses "an apparatus and method for applying a particulate hemostatic agent onto living tissue." Fallon 1:38–40. The hemostatic agent can be directed from a tapered tube onto the tissue. *Id*. at 1:46–47. Fallon states that its invention "allow[s] accurate placement by a surgeon of the

hemostatic agent onto a bleeding site or within an abdominal cavity." *Id*. at 1:55–58. Fallon states that its hemostatic agent can be a nonsoluble polysaccharide and in the form of particles, among other agents and forms. *Id*. at 3:32–40.

However, as Appellant has pointed out, Fallon does not disclose that its hemostatic agent is detectable by any imaging method, and the Examiner has not pointed to any disclosure that would provide a reason to modify it so as to make it detectable by imaging. Thus, even if Lee provides evidence that crosslinked starch or polymerized carbohydrates would be echogenic if used as the hemostatic agent in Fallon's system (*see* Ans. 6), the Examiner has not shown that the cited references would have provided a reason to modify Fallon's hemostatic agent to include the radiographically detectable gelatin beads disclosed by Burbank '241. Burbank '034 does not provide the missing reason, because its disclosure relates only to the need for imaging, not hemostasis, of a biopsy site. *See* Burbank '034 at 3:65 to 4:11.

In a nutshell, Fallon is addressed to hemostasis with no concern for imaging, while Burbank '241 and Burbank '034 are addressed to imaging with no concern for hemostasis. Lee does not provide a reason to combine hemostasis and imaging, because it is cited only as evidence of the echogenic properties of crosslinked starch and polymerized carbohydrates, and thus does not show that a skilled artisan would have had a reason to add a radiographic marker to Fallon's hemostatic agent.

We therefore reverse the rejection of claims 35–52 under 35 U.S.C. § 103(a) based on Fallon, Lee, Burbank '241, and Burbank '034.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
35–37, 39–41, 43–47, 49–52	103(a)	Burbank ’196, Burbank ’241	35–37, 39–41, 43–47, 49–52	
38, 42, 48	103(a)	Burbank ’196, Burbank ’241, Klaveness, Madison	38, 42, 48	
35–52	103(a)	Fallon, Lee, Burbank ’241, Burbank ’034		35–52
Overall Outcome			35–52	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED