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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* RALPH V. RUDZINSKI and RALPH A. LESSOR

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Appeal 2017-003075[1]
Application 13/196,884
Technology Center 1600

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Before FRANCISCO C. PRATS, ULRIKE W. JENKS, and JOHN G. NEW, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims to a pharmaceutical product composed of an inhaled anesthetic contained within a lined aluminum container. The Examiner rejected[2] the claims for obviousness.

We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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[1] Appellants state that the "real parties in interest in this appeal are Baxter International Inc. and Baxter Healthcare S.A., the assignees of record." Appeal Br. 4.

[2] We herein refer to the Specification, filed Aug. 2, 2011 ("Spec."); Final Office Action, mailed Aug. 14, 2015 ("Final Act."); Appeal Brief, filed Jul. 19, 2016 ("Appeal Br."); and the Reply Brief, filed Dec. 27, 2016 ("Reply Br."). The Examiner's Answer, mailed Oct. 27, 2016, has not been cited in this Decision.

STATEMENT OF THE CASE

The following rejections are before us for review:

(1) Claims 1–8, rejected under 35 U.S.C. § 103(a) as being unpatentable over Flament-Garcia, et al.,[3] Britto,[4] and Wu et al., [5] (Final Act. 2–8);[6] and.

(2) Claims 1, 3–6, and 8, rejected under 35 U.S.C. § 103(a) as being unpatentable over Bieniarz, et al.,[7] Ruebusch, et al.,[8] and Wu (Final Act. 8–11).

Claim 1, the only independent claim on appeal, is representative and reads as follows:

> 1. A pharmaceutical product comprising an inhalation anesthetic stored within an aluminum container,
>
> the interior of the aluminum container provided with an inert lining comprising an epoxyphenolic resin, and
>
> the inhalation anesthetic selected from the group consisting of sevoflurane, desflurane, isoflurane, enflurane, methoxyflurane and halothane, and present therein as a liquid, a vapor, or a combination thereof.

Appeal Br. A-1 (Claims App'x).

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[3] US 6,162,443 (issued Dec. 19, 2000) ("Flament-Garcia")).
[4] US 6,253,762 B1 (issued Jul. 3, 2001).
[5] US 6,315,985 B1 (issued Nov. 13, 2001) ("Wu")).
[6] Final Office Action entered August 14, 2015.
[7] US 5,990,176 (issued Nov. 23, 1999) ("Bieniarz")).
[8] US 6,045,784 (issued Apr. 4, 2000) ("Ruebusch")).

OBVIOUSNESS—
FLAMENT-GARCIA, BRITTO, AND WU

*The Examiner's Prima Facie Case*

The Examiner cited Flament-Garcia as disclosing a pharmaceutical product composed of a fluoroether anesthetic, such as sevoflurane, enflurane, isoflurane, methoxyflurane, or desflurane, enclosed within a container lined with polypropylene, polyethylene, or an ionomeric resin. Final Act. 3. The Examiner noted, in particular Flament-Garcia's teaching that the material lining the container should not be reactive with the anesthetic enclosed within the container. *Id.* at 3–4.

The Examiner found that Flament-Garcia's container differed from the container recited in Appellants' claims in that Flament-Garcia "lacks specific disclosure on the containers being made of aluminum and the resin being epoxy phenolic resin in the lining of the inner surface." *Id.* at 4.

As evidence that the product recited in Appellants' claims would nonetheless have been obvious, the Examiner cited Britto as disclosing that it was known in the art to use aluminum to construct containers for inhaled drugs, noting in particular that strengthened aluminum cans "are capable of withstanding particularly stressful coating and curing conditions (see col. 4, lines 34-50)." *Id.* at 5. The Examiner also noted Britto's teaching of including an inert polymer lining in containers for inhaled drugs. *Id.*

The Examiner cited Wu as also disclosing the use of lined aluminum cans as containers for inhaled drugs, noting in particular Wu's disclosure that its most preferred type of container was "a conventional aluminum (or aluminum alloy) aerosol canister, but with an interior coating of an inert

material, such as a spray-coated, baked epoxy-phenolic lacquer (col. 3, lines 48–53; col. 7, lines 43–55)." *Id.*

Based on the references' combined disclosures, the Examiner reasoned that an ordinary artisan would have considered it obvious "to have selected the inert epoxyphenolic resins to coat the inner lining of an aluminum container disclosed within the prior art disclosures (Britto and Wu et al), to arrive at a product/process 'yield[ing] no more than one would expect from such an arrangement.'" *Id.* at 7 (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007)).

*Analysis*

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

Having carefully considered all of the evidence and arguments presented by Appellants and the Examiner, Appellants do not persuade us that the preponderance of the evidence fails to support the Examiner's conclusion of obviousness as to claim 1 in view of Flament-Garcia, Britto, and Wu.

As required by Appellants' claim 1, Flament-Garcia discloses a product composed of an inhaled fluoroether anesthetic enclosed within a container. *See* Flament-Garcia, abstract; *see also id.* at 3:12–16 ("Fluoroether-containing inhalation anesthetics useful in connection with the

present invention include, but are not necessarily limited to, sevoflurane, enflurane, isoflurane, methoxyflurane, and desflurane.").

As required by Appellants' claim 1, Flament-Garcia discloses that the container may be lined with an inert material that does not react with the inhaled anesthetic compounds. *See id.* at 4:30–32 (disclosing embodiment in which "interior surface **14** of container **12** is preferably constructed of a material containing polyethylene napthalate"); *id.* at 3:60–65 ("[C]ertain copolymers and blends of polyethylene napthalate can be used in connection with the present invention, provided they provide an adequate barrier to the transmission of vapors, e.g., inhalation anesthetic and water vapors, therethrough, and provided that they provide the desired strength and non-reactivity to inhalation anesthetic **18**.").

As the non-reactive container lining, in addition to polyethylene napthalate, Flament-Garcia discloses that, "[a]lternatively, interior surface **14** of container **12** is constructed of a material containing one or more of polypropylene, polyethylene, and ionomeric resins such as a SURLYN® ionomeric resin manufactured by DuPont." *Id.* at 4:58–61. Flament-Garcia discloses that, alternatively, the container liner may be composed of polycyclomethylpentene/polymethylpentene. *Id.* at 4:40–49.

Flament-Garcia's product thus differs from the product recited in Appellants' claim 1 only in that Flament-Garcia does not use an epoxyphenolic resin-lined aluminum container as the vessel for the fluoroether anesthetics.

As the Examiner found, however, Wu discloses that such containers were known in the art to be useful as vessels for inhaled drugs. *See* Wu, 3:48–52 ("The most preferred type of container for use in the present

invention is a conventional aluminum (or aluminum alloy) aerosol canister, but with an interior coating of an inert material, such as a spray-coated, baked epoxy-phenolic lacquer (available from Cebal Printal U.K. Ltd.)."); *see also id.* at abstract (Wu's invention is a "medicinal aerosol steroid solution formulation product with enhanced chemical stability. The steroid is a 20-ketosteroid having an OH group at the C-17 or C-21 position and the aerosol container has a non-metal interior surface which has been found to reduce chemical degradation of such steroids.").

Britto similarly discloses that polymer-lined aluminum cans were useful as vessels for inhaled drugs. *See* Britto, 4:34–5:38.

As the Supreme Court has explained, "when a patent claims a structure already known in the prior art that is altered by mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *KSR*, 550 U.S. at 416.

Here, as noted above, Flament-Garcia teaches that it was desirable to use containers lined with non-reactive polymers as vessels for inhaled fluoroether anesthetics, and Wu discloses that an aluminum container with an inert epoxyphenolic resin lining was useful as a vessel for inhaled drugs. We, therefore, agree with the Examiner that an ordinary artisan had good reason for, and a reasonable expectation of success in, using the epoxyphenolic resin-lined aluminum container disclosed in Wu as a vessel for the fluoroether anesthetics disclosed in Flament-Garcia, particularly given the advantages of aluminum containers taught in Britto. We, therefore, also agree with the Examiner that the product recited in Appellants' claim 1 would have been prima facie obvious to the ordinary artisan.

Appellants do not persuade us to the contrary. Appellants contend, based on Bieniarz, that an ordinary artisan would have been dissuaded from using an aluminum container because of the reactivity of aluminum oxides with fluoroether anesthetics. Appeal Br. 9–10.

As noted above, however, the Examiner's prima facie case posits using an aluminum container *with an inert lining* as the vessel for a fluoroether anesthetic. We are not persuaded that any alleged concerns about fluoroether anesthetics coming into contact with aluminum demonstrate that it would have been unobvious to coat the interior of an aluminum container with an inert material that would prevent the anesthetic compounds from coming into contact with the aluminum. Indeed, we conclude that the opposite is true—given the knowledge in the art that aluminum was a desirable material for inhaled drug containers (*see, e.g.,* Britto, Wu), we agree with the Examiner that an ordinary artisan, advised by Bieniarz and Flament-Garcia that fluoroether anesthetics should not contact aluminum oxides, would have considered it obvious to use a container with an inert lining in order to prevent such contact, for example the preferred container described in Wu, noted above.

Appellants contend that, given fluoroether anesthetics' known capacity to dissolve certain polymers, an ordinary artisan would have had no reasonable expectation of success in using any polymer as a liner for a container for fluoroether anesthetics, absent a prior showing of non-reactivity between the polymer and the anesthetic. Appeal Br. 9–10 (citing Spec. ¶ 6); Reply Br. 2. Similarly, Appellants contend, because fluoroether anesthetics were known to dissolve certain polymers, an ordinary artisan would have had no motivation for using any polymer as a liner for a

container for fluoroether anesthetics. Appeal Br. 10 (citing Spec. ¶ 6); Reply Br. 2.

Appellants' argument relies on the following statement in the Specification: "[I]nhalation anesthetics have strong organic solvent properties, which ***typically*** will dissolve and/or react with the plastic material, leading to measurable impurities in the inhalation anesthetic." Spec. ¶ 6 (emphasis added).

In addition to the fact that the relied-upon disclosure in the Specification relates to "plastic material," as opposed to polymers specifically, neither Appellants nor their Specification cites to any specific evidence that supports or explains the assertion that polymers "typically" would be expected to be dissolved by, or react with, fluoroether anesthetics. *See* Spec. ¶ 6. Nor do Appellants identify any evidence of record suggesting that the specific epoxyphenolic resin taught by Wu as lining its preferred inhaled drug container would have been expected to be reactive with Flament-Garcia's fluoroether anesthetics.

Indeed, as seen above, contrary to Appellants' contention that fluoroether anesthetics would typically be expected to react with polymers, Flament-Garcia discloses at least five types of polymers that are compatible with fluoroether anesthetics: polyethylene napthalate and copolymers and blends thereof, polypropylene, polyethylene, ionomeric resins, and polycyclomethylpentene/polymethylpentene. *See* Flament-Garcia, 4:30–66.

We are not persuaded, therefore, that the evidence of record supports Appellants' contention that an ordinary artisan would have expected the epoxyphenolic inner coating of Wu's aluminum container to react with Flament-Garcia's fluoroether anesthetics. To the contrary, given Flament-

Garcia's disclosure that a variety of different polymers were useful as an inert liner material for a container for inhaled fluoroether anesthetics, and given Wu's disclosure that a conventional aluminum aerosol container with an inert epoxyphenolic inner coating was a useful vessel inhaled drugs, and further given Wu's disclosure, discussed below, that its containers were compatible with ether as well as fluorocarbon propellants, Appellants do not persuade us that an ordinary artisan lacked adequate motivation for, or a reasonable expectation in, using Wu's container as a vessel for Flament-Garcia's inhaled fluoroether anesthetics.

We acknowledge the following statement in Wu identified by Appellants (*see, e.g.,* Appeal Br. 13–14; Reply Br. 5–6):

> As used herein, the terms "coated", "inert coating" and the like simply refer to a non-metal interior coating that does not promote degradation at the OH substituents on C-17/21 OH 20-ketosteroids. Inert coating materials include any suitable polymer, lacquer, resin, or other coating treatment that creates a barrier to chemical interaction of the dissolved C-17/21 OH 20-ketosteroid and metal on the container (especially metal oxides).

Wu, 7:35–42.

Appellants do not persuade us, however, that the above-quoted passage at column 7 of Wu would have suggested to an ordinary artisan that the "inert" epoxyphenolic inner coating of Wu's preferred container (*see id.* at 3:48–52) would only be non-reactive with the named steroid compounds, but would be expected to be chemically reactive with a number of other agents.

To the contrary, Wu discloses that its containers are compatible with, i.e., non-reactive with, a number of organic propellant compounds, including ethers and fluorocarbons:

> Preferred products/devices according to the present invention are pressurized aerosols such as MDIs [metered dose inhalers] that use liquefied gas propellants, including chlorofluorocarbons (CFCs), hydrofluorocarbons (HFCs), fluorocarbons (PCs), hydrocarbons (HCs), hydrochlorofluorocarbons (HCFCs), and dimethyl ether (DME). Propellants containing hydrogen are preferred. Ethanol may also be included to assist in solubilizing the 20-ketosteroid, preferably in an amount of about 1–25%.

*Id.* at 8:44–52.

Because Wu discloses that its containers are compatible with, i.e., non-reactive with, organic compounds including ethers and fluorocarbons, which share a number of functional groups with Flament-Garcia's fluoroether anesthetics, including an ether moiety and pendant fluorine atoms (*see, e.g.,* Spec. ¶ 11), Appellants do not persuade us that an ordinary artisan lacked adequate motivation for, or a reasonable expectation of success in, using Wu's containers as vessels for the anesthetic compounds taught in Flament-Garcia. Moreover, because Wu discloses that its containers are suitable vessels for pressurized aerosols containing liquefied organic gas propellants (*see* Wu, 8:44–52), Appellants do not persuade us that an ordinary artisan lacked a reasonable expectation that Wu's container would have the vapor barrier characteristics desired by Flament-Garcia. *See* Appeal Br. 11 (citing Flament-Garcia 2:20–24).

In addition, given the teachings discussed above suggesting that Wu's preferred epoxyphenolic resin-lined aluminum container would be useful as a vessel for Flament-Garcia's fluoroether anesthetics, we are not persuaded that the teachings in Flament-Garcia and Wu regarding Type III glass diverge to the extent that an ordinary artisan would have lacked a good reason for, or a reasonable expectation of success in, using Wu's preferred

container as a vessel for Flament-Garcia's anesthetics. *See* Appeal Br. 11–12, 14–15; Reply Br. 4–5.

We acknowledge Wu's disclosure, also identified by Appellants (*see, e.g.,* Appeal Br. 12; Reply Br. 3, 5, 7), that its epoxyphenolic coating is superior to a teflon-like "FEP" coating at improving the chemical stability of the steroid drugs present in its containers, because it adsorbs the steroid degradation products:

> [T]he data indicates the epoxy can is superior to the FEP in preventing degradation. Without wishing to be held to any particular mechanism to explain the difference in results between the two coating types, it is hypoth[e]sized that it is not that the phenolic epoxy provides a better barrier, but rather that some adsorption of degradation products is taking place. Essentially, the phenolic epoxy may be "soaking up" the degradates. A small amount of budesonide may also be adsorbed too, but the amount is apparently too small to affect the target content amount.

Wu, 13:33–42.

The fact that Wu's preferred container might be particularly suited as a vessel for steroid therapeutics does not persuade us that an ordinary artisan would have considered Wu's container unsuitable as a vessel for Flament-Garcia's fluoroether anesthetics. To the contrary, as discussed above, Wu teaches that its containers are compatible and non-reactive not only with steroid therapeutics, but also with a variety of organic propellant compounds, including ethers and fluorocarbons. That Wu's container might adsorb impurities only provides additional impetus for using the container as a vessel for Flament-Garcia's anesthetic compounds.

In sum, on the current record, Flament-Garcia discloses that that it was desirable to use containers lined with non-reactive polymers as vessels

for inhaled fluoroether anesthetics. And Wu discloses that an aluminum container having an inert epoxyphenolic resin lining, which is non-reactive to ethers and fluorocarbons, was useful as a vessel for inhaled drugs. We, therefore, agree with the Examiner that an ordinary artisan had good reason for, and a reasonable expectation of success in, using the epoxyphenolic resin-lined aluminum container disclosed in Wu as a vessel for the fluoroether anesthetics disclosed in Flament-Garcia, particularly given the advantages of aluminum containers taught in Britto.

Appellants do not persuade us, therefore, that the Examiner erred in concluding that the product recited in Appellants' claim 1 would have been prima facie obvious to the ordinary artisan. Because Appellants do not identify any specific objective evidence of nonobviousness that might outweigh the evidence of prima facie obviousness advanced by the Examiner, we affirm the Examiner's rejection of claim 1 over Flament-Garcia, Britto, and Wu. Because they were not argued separately, claims 2–8 fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

## OBVIOUSNESS— BIENIARZ, RUEBUSCH, AND WU

### *The Examiner's Prima Facie Case*

The Examiner cited Bieniarz as disclosing a pharmaceutical product composed of a fluoroether anesthetic, such as sevoflurane, enflurane, or isoflurane, enclosed within a container. Final Act. 8. The Examiner found that Bieniarz disclosed that "suitable containers include plastic, steel or other material that can be used for holding goods. Examples of containers include bottles, ampules, test tubes, beakers, etc, (see col. 5, lines 9-13)." *Id.*

The Examiner conceded, however, that Bieniarz differs from the rejected claims in that Bieniarz "lack[s] specific disclosure on the container being aluminum with an inner coating of an epoxyphenolic resin. This is taught by Ruebusch et al and Wu et al." *Id.*

Specifically, the Examiner cited Ruebusch as evidence that metal containers lined with inert polymeric materials including phenolic resin coatings, epoxy resin coatings, and mixtures thereof, were useful for preventing corrosion and/or rust in the metal caused by Lewis acids present in the contained material. *Id.* at 8–9. The Examiner cited Wu for its teachings relied upon the rejection discussed above. *Id.* at 9.

Based on the references' combined disclosures, the Examiner reasoned that an ordinary artisan would have considered it obvious to select the inert epoxyphenolic resin-lined aluminum container taught in Wu as the container for fluoroether anesthetics, as recited in Appellants claims, "because Bieniarz et al teach that [a] fluoroether anesthetic[] such as sevoflurane is a Lewis acid compound and a formulation comprising such [a] compound requires measures to prevent degradation" and because "Ruebusch et al teach that formulations comprising Lewis acid compounds require measure[s] to minimize degradation which include coating the inner surface of the metal canister with a suitable material such as epoxy and/or phenolic resins." *Id.* at 10.

*Analysis*

Having carefully considered all of the evidence and arguments presented by Appellants and the Examiner, Appellants do not persuade us that the preponderance of the evidence fails to support the Examiner's

conclusion of obviousness as to claim 1 in view of Bieniarz, Ruebusch, and Wu.

Bieniarz is directed to the discovery that the interior of glass vessels containing inhaled fluoroether anesthetics can become etched or altered, thereby exposing aluminum oxides in the glass to the contents of the vessels, which in turn generates Lewis acids that can cause degradation of the fluoroether anesthetics. Bieniarz, 1:50–67. Bieniarz discloses addressing this problem by including a Lewis acid inhibitor, such as water, in its vessel-enclosed fluoroether formulations. *Id.* at 2:50–67.

As required by Appellants' claim 1, Bieniarz discloses a product composed of an inhaled fluoroether anesthetic enclosed within a container:

> [A] container, such as a glass bottle, is first washed or rinsed with the Lewis acid inhibitor and then filled with the fluoroether compound. . . . [A]s used herein, the term "container" refers to a receptacle made from glass, plastic, steel or other material that can be used for holding goods. Examples of containers include bottles, ampules, test tubes, beakers, etc.

*Id.* at 5:2–13

The container/fluoroether anesthetic combination taught in Bieniarz, thus, differs from the product recited in Appellants' claim 1 in that Bieniarz's product does not include an aluminum container lined with an inert epoxyphenolic resin.

As discussed above, however, Wu discloses that such containers were known in the art to be useful as vessels for inhaled steroid drugs. *See* Wu, 3:48–52 ("The most preferred type of container for use in the present invention is a conventional aluminum (or aluminum alloy) aerosol canister, but with an interior coating of an inert material, such as a spray-coated, baked epoxy-phenolic lacquer (available from Cebal Printal U.K. Ltd.).")

Given Wu's teaching that an aluminum container with an inert epoxyphenolic resin lining was a particularly preferred vessel for certain inhaled drugs, we agree with the Examiner that an ordinary artisan had good reason for, and a reasonable expectation of success in, using the epoxyphenolic resin-lined aluminum container disclosed in Wu as a vessel for the inhaled fluoroether anesthetic drugs disclosed in Bieniarz, particularly given Bieniarz's teaching that it was desirable to minimize contact between fluoroether anesthetic formulations and Lewis acids generated by interactions with the container walls. In that regard, we note Ruebusch's disclosure, identified by the Examiner, that corrosion of metal aerosol containers caused by the presence of Lewis acids (*see* Ruebusch, 1:6–2:14) can be avoided by providing the containers with an inner lining composed of a thermoplastic resin coating, including "phenolic resin coatings, . . . epoxy resin coatings . . . and mixtures of these coatings" (*id.* at 6:36–38).

Because we agree with the Examiner that an ordinary artisan would have considered it obvious to use Wu's preferred inert epoxyphenolic resin-lined aluminum container as a vessel for Bieniarz's fluoroether anesthetics, particularly in view of the cited teachings in Ruebusch, we also agree with the Examiner that the product recited in Appellants' claim 1 would have been obvious over those references. Appellants' arguments do not persuade us to the contrary.

We acknowledge, as seen above, and as Appellants contend (*see* Appeal Br. 16; Reply Br. 8), that Bieniarz is directed to using Lewis acid inhibitors to avoid the undesired effects of inadvertently generated Lewis acids on fluoroether compositions, whereas Ruebusch is directed to using an

inner liner to prevent interaction between metal containers and Lewis acids intentionally placed within the containers. Those facts, however, fail to explain why it would have been unobvious to use a container, taught in Wu, known to be useful as an inert vessel for inhaled drugs, as a container for Bieniarz's inhaled fluoroether drugs.

As noted above, "when a patent claims a structure already known in the prior art that is altered by mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *KSR*, 550 U.S. at 416. In the present case, Appellants identify no unpredicted or unexpected result coming from the claimed used of Wu's container as a vessel for fluoroether anesthetics. Moreover, because both Bieniarz and Ruebusch suggest isolating Lewis acid-containing materials from metal container components, we do not find the references' teachings to be antithetical.

As to Appellants' contention, based on Bieniarz, that an ordinary artisan would have been dissuaded from using an aluminum container because of the reactivity of aluminum oxides with fluoroether anesthetics (*see* Appeal Br. 16–17), we note again that the Examiner's prima facie case posits using an aluminum container *with an inert lining* as the vessel for a fluoroether anesthetic. As discussed above, we are not persuaded that any alleged concerns about fluoroether anesthetics coming into contact with aluminum demonstrate that it would have been unobvious to coat the interior of an aluminum container with an inert material that would prevent the anesthetic compounds from coming into contact with the aluminum.

Indeed, as discussed above, we conclude that the opposite is true—given the knowledge in the art that aluminum was a desirable material for

inhaled drug containers (*see, e.g.,* Wu), we agree with the Examiner that an ordinary artisan, advised by Bieniarz that fluoroether anesthetics should not contact aluminum oxides, would have considered it obvious to use a container with an inert lining in order to prevent such contact, for example the preferred container described in Wu, noted above. Appellants do not persuade us, therefore (*see* Appeal Br. 17), that the cited references fail to provide a sufficient reason for, or a reasonable expectation of success in, using Wu's preferred container as a vessel for Bienarz's fluoroether anesthetics.

Appellants reiterate their contentions that an ordinary artisan would not have had motivation or a reasonable expectation of success in using Wu's container as a vessel for fluoroether anesthetics because fluoroether anesthetics were known to degrade plastics, and because Wu's disclosure only relates to its epoxyphenolic liner's inertness in relation to the disclosed steroid compounds, but not other materials. Appeal Br. 17–18.

As discussed above, however, in addition to expressly describing its epoxyphenolic liner as being inert, Wu discloses that its containers are compatible with, i.e., non-reactive with, a number of organic propellant compounds, including ethers and fluorocarbons (Wu, 8:44–52), which share a number of functional groups with Bieniarz's fluoroether anesthetics, including an ether moiety and pendant fluorine atoms (*see, e.g.,* Spec. ¶ 11). Appellants do not persuade us, therefore, that an ordinary artisan lacked adequate motivation for, or a reasonable expectation of success in, using Wu's containers as vessels for the anesthetic compounds taught in Bieniarz.

We find that Appellants' argument, that Ruebusch is non-analogous art (Reply Br. 9), is improperly presented for the first time in the Reply Brief, and we therefore decline to consider it.

As explained in 37 C.F.R. § 41.37(c)(1)(iv), except in certain circumstances not applicable here, "any arguments or authorities not included in the appeal brief will be refused consideration by the Board for purposes of the present appeal." We are not persuaded, therefore, that this new argument is properly presented for the first time in the Reply Brief, such that we should consider it. *See also* 37 CFR § 41.41(b)(2) ("Any argument raised in the reply brief which was not raised in the appeal brief, or is not responsive to an argument raised in the examiner's answer, including any designated new ground of rejection, will not be considered by the Board for purposes of the present appeal, unless good cause is shown."); *Ex parte Borden*, 93 USPQ2d 1473, 1477 (BPAI 2010) (The reply brief is not "an opportunity to make arguments that could have been made in the principal brief on appeal to rebut the Examiner's rejections, but were not.") ("Informative").

In any event, as discussed above, Bieniarz discloses that inhaled fluoroether drugs can be stored in any number of different types of containers, including metal containers. As also discussed above, Wu discloses that a preferred vessel for inhaled steroid drugs, an aluminum container with an inert epoxyphenolic lining, is compatible with a number of organic compounds, including an ether propellant, that share functional groups with fluoroether anesthetics. Thus, even if we were to consider and accept (which we do not) Appellants' argument that Ruebusch constitutes

non-analogous art, we would still conclude that the Examiner had shown the product of claim 1 to be obvious over Bieniarz and Wu.

In sum, for the reasons discussed, Appellants do not persuade us that the Examiner erred concluding in that the product recited in Appellants' claim 1 would have been prima facie obvious to the ordinary artisan in view of Bieniarz, Ruebusch, and Wu. Because Appellants do not identify any specific objective evidence of nonobviousness that might outweigh the evidence of prima facie obviousness advanced by the Examiner, we affirm the Examiner's rejection of claim 1 over Bieniarz, Ruebusch, and Wu. Because they were not argued separately, claims 3–6 and 8 fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

## SUMMARY

For the reasons discussed, we affirm both of the Examiner's obviousness rejections.

## TIME PERIOD

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

## AFFIRMED