

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CLEARH2O, INC.,
Petitioner,

v.

CEVA ANIMAL HEALTH INC.,
Patent Owner.

IPR2020-00039
Patent 8,794,185 B2

Before JAMES A. WORTH, MICHAEL L. WOODS, and
JAMES J. MAYBERRY, *Administrative Patent Judges*.

WOODS, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

ClearH2O, Inc., (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting *inter partes* review of claims 1–15 of U.S. Patent No. 8,794,185 B2 (“the ’185 patent”). Pet. 2. Ceva Animal Health Inc. (“Patent Owner”), filed a Preliminary Response (Paper 20, “Prelim. Resp.”) to the Petition, contending that the Petition should be denied as to all challenged claims. Prelim. Resp. 1.

We have authority under 37 C.F.R. § 42.4(a) and 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition “shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” Having considered the arguments and the evidence presented, for the reasons described below, we do not institute an *inter partes* review of any challenged claim.

A. Related Proceedings

The parties represent that *Biomune Company v. ClearH2O, Inc.*, C.A. No. 2:19-cv-00099, in the U.S. District Court for the District of Maine, is a related proceeding. Pet. 3; Paper 15, 1.

B. The ’185 Patent (Ex. 1001)

The ’185 patent, titled “Soft Gel Delivery System for Treating Poultry,” is “directed to a method of treating poultry hatchlings in a hatchling tray.” Ex. 1001, codes (54), (57). The ’185 patent further describes a method that provides a soft gel to be dispensed through a spray nozzle, and that the gel may include a therapeutic agent, such as a vaccine,

which the hatchlings consume. *See id.* at code (57), 1:23–29. To illustrate an apparatus that the '185 patent utilizes to deliver the soft gel, we reproduce Figure 2, below:

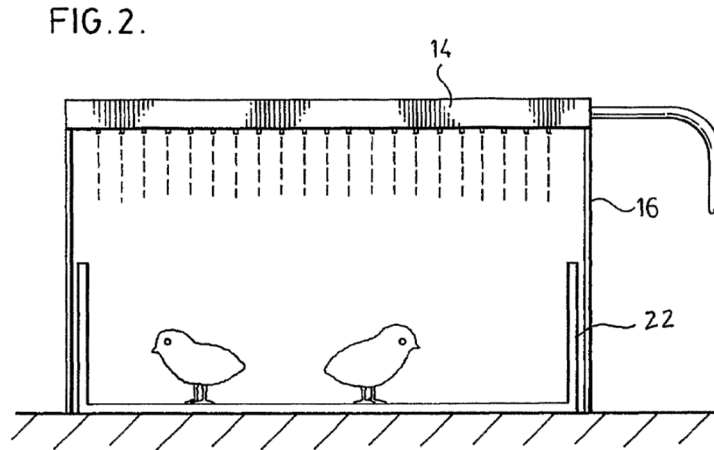


Figure 2 depicts an embodiment of the delivery apparatus including manifold 14 spaced above hatchling tray 22 by two supports 16. *Id.* at 6:35–37. We reproduce Figure 3, below, to better illustrate the manifold:

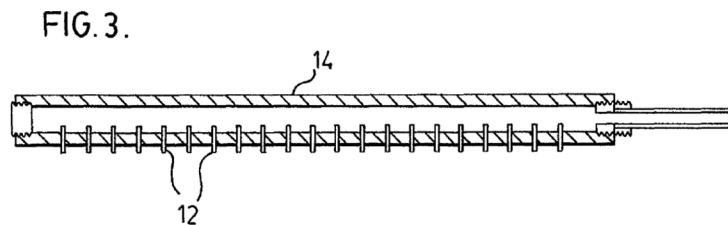


Figure 3 depicts manifold 14 with nozzles 12 located within the manifold. *Id.* at 6:41.

The '185 patent describes that the “method and soft gel vaccine of the present invention provides for an easy to use means of immunizing a large number of hatchlings by spraying the vaccine on the hatchlings in the tray.” *Id.* at 10:3–6.

C. Illustrative Claims

Claim 1 is the sole independent claim. *Id.* at 10:14–11:6. We reproduce claim 1, below:

1. A method of treating poultry hatchlings in a hatchling tray, the method comprising:
 - providing a soft gel for dispensing through a nozzle opening,
 - providing a dispensing apparatus, the apparatus for delivering a predetermined volume of the soft gel as a plurality of small beadlets through a plurality of nozzle openings of uniform size and uniform spacing therebetween along a manifold nozzle head wherein the plurality of nozzle openings on the manifold nozzle head approximately spans the length or width of a hatchling tray,
 - placing the hatchling tray containing poultry hatchlings beneath the nozzle openings of the dispensing apparatus,
 - dispensing the predetermined volume of the soft gel as small beadlets onto the hatchlings in the hatchling tray at approximately a constant rate,
 - passing the hatchling tray beneath the nozzle openings for even distribution of the beadlets to the hatchlings contained therein,
 - and
 - allowing the hatchlings to consume the beadlets.

Id. at 10:15–36.

D. References Relied Upon

Petitioner's challenges rely on the following references (Pet. 4):

Name	Reference	Ex. No.
Lewis	US Pub. No. 2002/0104485 A1, published Aug. 8, 2002	Ex. 1003
Goff	U.S. Pat. No. 883,132, issued Mar. 24, 1908	Ex. 1004
Lee	WO 99/08704, published Feb. 25, 1999	Ex. 1005
Lopez	U.S. Pat. No. 5,474,102, issued Dec. 12, 1995	Ex. 1006
Johnston	U.S. Pat. No. 6,910,446 B2, issued June 28, 2005	Ex. 1007

E. Alleged Grounds of Unpatentability

Petitioner contends that claims 1–15 of the '185 patent are unpatentable under the following grounds:

References	Basis	Claims
Lewis, Goff	§ 103(a) ¹	1, 2, 9, 12–15
Lewis, Goff, Lee	§ 103(a)	3–6, 8, 11
Lewis, Goff, Lopez	§ 103(a)	7, 10
Johnston, Lee	§ 103(a)	1–6, 8, 9, 11–15
Johnston, Lee, Lopez	§ 103(a)	7, 10

Pet. 4.

Petitioner also relies on the declaration testimony of Fernando J. Muzzio, Ph. D., (Ex. 1002) in support of its Petition. *See* Pet. 4.

¹ Because the challenged claims of the '185 patent have an effective filing date before the effective date of the applicable AIA amendment, we refer to the pre-AIA version of 35 U.S.C. § 103.

II. ANALYSIS

A. Claim Construction

We determine that no claimed limitation requires express construction for purposes of this Decision. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (noting that “we need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’”) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

B. Original Examination of the ’185 Patent

During the original examination of the ’185 patent, the examiner rejected the claims in at least six different office actions, in which the examiner relied on either Johnston or Lewis for teaching or disclosing a majority of the limitations of the issued claims. We summarize the relevant portions of these office actions, below.²

1. Office Action Dated April 28, 2009

In an office action dated April 28, 2009, the examiner rejected claim 1 under 35 U.S.C. § 103(a) as unpatentable over Johnston in view of U.S. Patent No. 6,908,620 (“McDougald”). Ex. 2001, 84. The examiner found that Johnston discloses the invention substantially as claimed, except for a soft gel, for which the examiner relied on McDougald. *Id.* at 84–85. Specifically, the examiner found that:

Johnston discloses a method of treating poultry hatchlings in a hatchling tray, the method comprising:

² Our citations to the prosecution history will be to Exhibit 2001.

providing a fluid spray, such as a medicament, a vaccine or a mixture thereof, capable of being dispensed through a spray nozzle . . . providing a spray dispensing apparatus . . . , the apparatus being capable of delivering a predetermined volume of a vaccine as a plurality of small beadlets through a plurality of spray nozzles arranged along a manifold . . . , placing the hatchling tray containing the hatchlings beneath the spray nozzles of the dispensing apparatus . . . , dispensing the predetermined volume of a vaccine as small beadlets into the hatchling tray . . . , and allowing the hatchlings to consume the beadlets.

Id. at 84–85 (citations omitted). The examiner acknowledged that Johnson did not disclose the fluid spray for treating poultry as a “soft gel,” however, and relied on McDougald for teaching the administration of a soft gel to poultry hatchlings. *See id.* at 85 (citation omitted). The examiner reasoned that a skilled artisan would have modified Johnston’s method to use a soft gel, as taught by McDougald, to provide “easy handling, aid in hydration and induce the feeding response in the birds.” *Id.*

2. Office Action Dated July 30, 2010

In an office action dated July 30, 2010, the examiner rejected claim 1 under 35 U.S.C. § 103(a) as being unpatentable over Lewis in view of U.S. Patent No. 2,034,968 (“Bartlett”). Ex. 2001, 149. The examiner found that Lewis discloses the invention substantially as claimed, except for a plurality of nozzle openings arranged approximately evenly apart along a manifold, for which the examiner relied on Bartlett. *Id.* In particular, the examiner found that:

Lewis et al. discloses a method of treating poultry hatchlings in a hatchling tray (Fig. 1), the method comprising: providing a soft get (28) capable of being dispensed through a nozzle opening . . . , providing a dispensing apparatus (18), the

apparatus being capable of delivering a predetermined volume of the soft gel as a plurality of small beadlets, placing the hatchling tray (14) containing the hatchlings (12) beneath the nozzle openings (openings of nozzle 18) of the dispensing apparatus (as shown in Fig. 1), dispensing the predetermined volume of the soft gel as small beadlets into the hatchling tray.

Id. (citations omitted).

As mentioned above, the examiner further found that Lewis “fails to specifically disclose a plurality of nozzle openings arranged approximately evenly apart along a manifold.” *Id.* To address this limitation, the examiner relied on Bartlett for teaching “a method of providing a dispensing apparatus . . . the apparatus comprising a plurality of nozzle openings . . . wherein the plurality of nozzle openings on the manifold approximately spans the length or width of a tray.” *Id.* In combining Lewis with Bartlett, the examiner reasoned that a skilled artisan would have modified Lewis to include Bartlett’s dispensing manifold to “evenly distribut[e] the soft gel.” *Id.* at 149–150.

3. *Office Action Dated October 15, 2010*

In an office action dated October 14, 2010, the examiner rejected claim 1 as unpatentable over Lewis and Bartlett. Ex. 2001, 317–318. As with the rejected dated July 30, 2010, the examiner found that Lewis discloses the invention substantially as claimed, except for a plurality of nozzle openings arranged approximately evenly apart along a manifold, for which the examiner relied on Bartlett. *Compare id., with id.* at 149–150.

4. *Office Action Dated February 24, 2011*

In an office action dated February 24, 2011, the examiner rejected claim 1 as unpatentable over Lewis in view of U.S. Patent No. 4,316,464 (“Peterson”). Ex. 2001, 357–358. As distinguished from the examiner’s rejection under Lewis and *Bartlett*, the examiner relied on *Peterson* for teaching “a dispensing apparatus . . . comprising a plurality of nozzle openings.” *Compare id.*, with *id.* at 149–150. The examiner reasoned that a skilled artisan would have modified Lewis’s method to include Peterson’s dispensing manifold to evenly distribute the soft gel. *Id.* at 358.

5. *Office Action Dated June 21, 2011*

In an office action dated June 21, 2011, the examiner rejected claim 1 under 35 U.S.C. § 103(a) as being unpatentable over Lewis in view of U.S. Patent No. 3,242,008 (“Kurtz”) and Peterson. Ex. 2001, 408. The examiner found that Lewis disclosed a method of treating poultry hatchlings, as similarly found in prior office actions. *Compare id.* at 409, with, e.g., *id.* at 149. The examiner relied on Peterson for disclosing “dispensing a predetermined volume of soft gel onto the hatchlings” and Kurtz for teaching “a dispensing apparatus . . . comprising a manifold nozzle head.” *Id.* at 409 (citations omitted). The examiner reasoned that a skilled artisan would have combined Lewis with Kurtz’s and Peterson’s teachings to arrive at the claimed method. *See id.* at 409–410.

6. *Office Action Dated January 4, 2012*

In an office action dated January 4, 2012, the examiner rejected claim 1 as unpatentable over Lewis in view of Kurtz. Ex. 2001, 467. The examiner found that Lewis disclosed the claimed method, as similarly

discussed above (*supra* Part II.B.2), but did not “specifically disclose a plurality of nozzle openings arranged approximately evenly apart along a manifold nozzle head.” Ex. 2001, 467. The examiner relied on Kurtz for teaching a manifold nozzle head with the claimed plurality of nozzle openings and reasoned that a skilled artisan would have modified Lewis’s nozzle head to include Kurtz’s manifold nozzle head “for the intended use of dispensing a flowable soft gel.” *Id.* at 468 (citations omitted).

7. Notice of Allowance Dated June 16, 2014

The examiner allowed the claims on June 16, 2014. Ex. 2001, 672.

In the examiner’s Reasons for Allowance, the examiner stated:

[T]he prior art of record fails to show or render obvious the limitations: a manifold nozzle head wherein the plurality of nozzle openings on the manifold nozzle head approximately spans the length or width of a hatchling tray, dispensing the predetermined volume of the soft gel as small beadlets onto the hatchlings in the hatchling tray at approximately a constant rate, passing the hatchling tray beneath the nozzle openings for even distribution of the beadlets to the hatchlings contained therein, and allowing the hatchlings to consume the beadlets, of the method of claim 1.

Id. at 677.

C. Asserted Art

Petitioner relies on the following references.

1. Lewis (Ex. 1003)

Lewis is a U.S. Patent Publication titled “Method and Apparatus for Dispensing Liquid Like Gel or the Like which may be Used to Treat

Dehydration in Animals such as Chicks and Which may be Used to Carry Other Biological Substances, for Example, Vaccines, Nutrients, Antibiotics and the Like for Other Treatment Purposes.” Ex. 1003, code (54). Lewis describes a dispensing device for discharging a substance or fluid for the treatment of animals. *Id.* ¶ 9. To illustrate an embodiment of Lewis’s device, we reproduce its Figure 1, below:

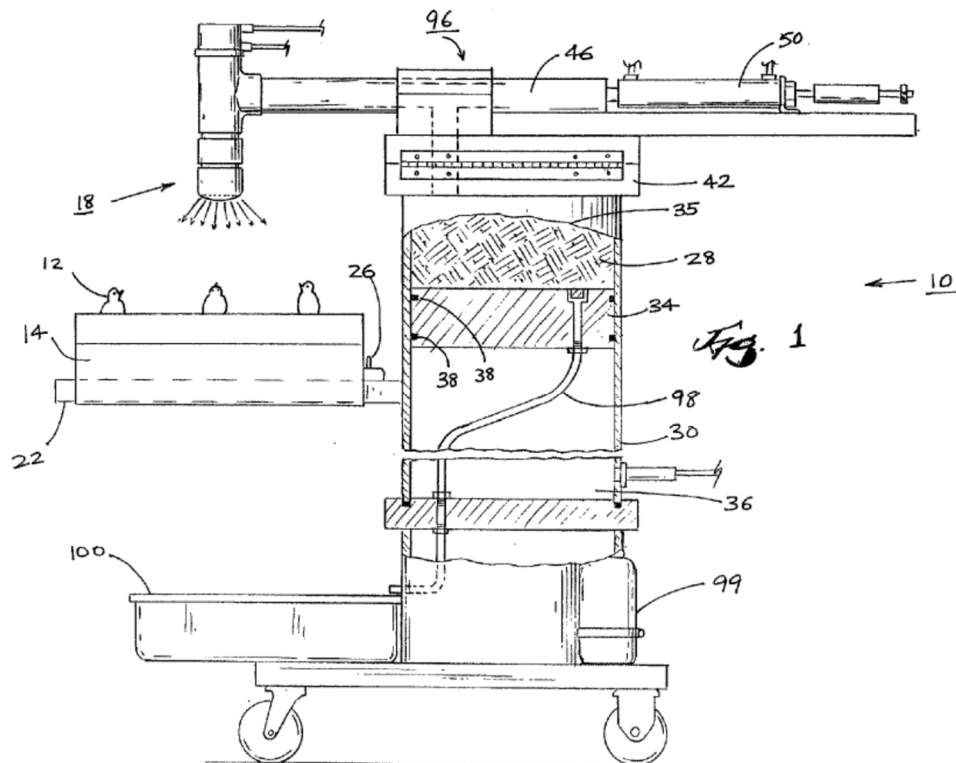
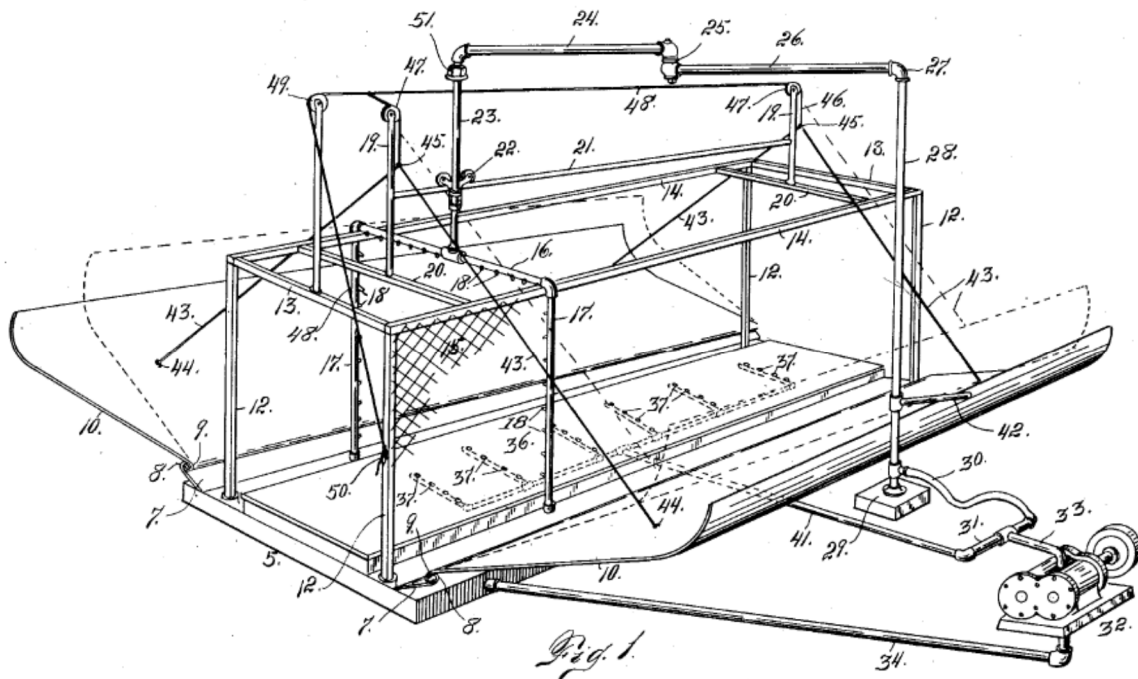


Figure 1 depicts Lewis’s dispensing machine 10. *Id.* ¶ 19. In particular, Figure 1 depicts chicks 12 placed in tray 14 below dispensing head/nozzle 18 of the dispensing machine. *Id.* ¶ 20. “A quantity of liquid like substance or gel” 28 is contained in tank 30. *Id.* Nozzle 18 includes a plurality of apertures, which are preferably equally spaced apart from each other. *Id.* ¶ 22. The locations of the apertures “ensure that the gel is evenly distributed over the tops of the chicks.” *Id.* ¶ 25.

As discussed above (*supra* Part II.B), Lewis was considered and applied in numerous rejections by the examiner during prosecution. *See, e.g.*, Ex. 2001, 149.

2. Goff (Ex. 1004)

Goff is a U.S. patent titled, “Apparatus for Treating Animals.” Ex. 1004, Title. In particular, Goff “relates to improvements in apparatus for treating animals” (*id.* at 1:15–16), such as by treating “various skin diseases . . . for the purpose of destroying the various insects which are lodged in the hair or wool . . . [of] the animals” (*id.* at 1:16–20). To illustrate an embodiment of Goff’s insect-destroying apparatus, we reproduce its Figure 1, below:



Goff describes Figure 1 as depicting an apparatus including a “spraying device [that] consists of a U-shaped pipe placed in the inverted position and composed of a transverse top member 16 and two depending member 17.

The member 16 extends entirely across the top of the frame work.” *Id.* at 1:92–98. Goff further discloses, “All the members of this spraying device are equipped with spray nozzles 18.” *Id.* at 1:100–102.

3. *Lee (Ex. 1005)*

Lee is an international patent publication titled, “Method of Protecting Against Chronic Infections.” Ex. 1005, code (54). Lee “is directed to a method of protecting an animal against a chronic disease . . . caused by an infectious organism.” *Id.* at code (57). Lee discloses that a “gel form of the vaccine is prepared by dissolving the gel power in water . . . at a concentration such that . . . a relatively soft gel results.” *Id.* at 8:1–8.

4. *Lopez (Ex. 1006)*

Lopez is a U.S. patent titled, “Fluid Distribution Manifold.” Ex. 1006, code (54). To illustrate an embodiment of Lopez’s manifold, we reproduce its Figure 1, below:

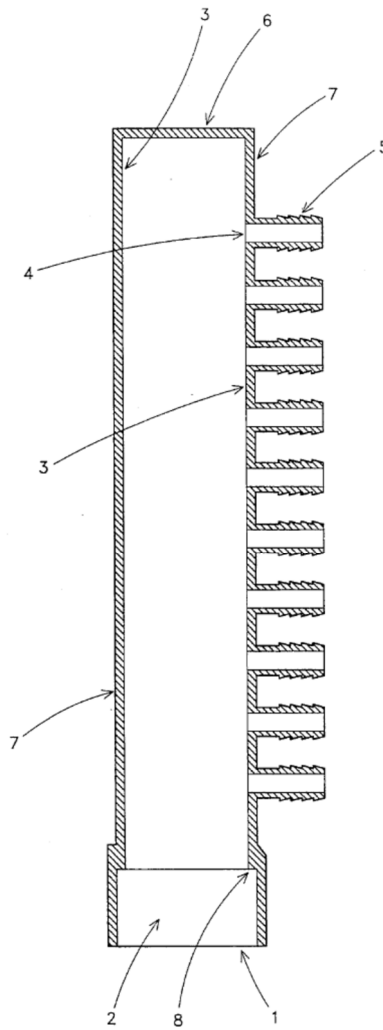


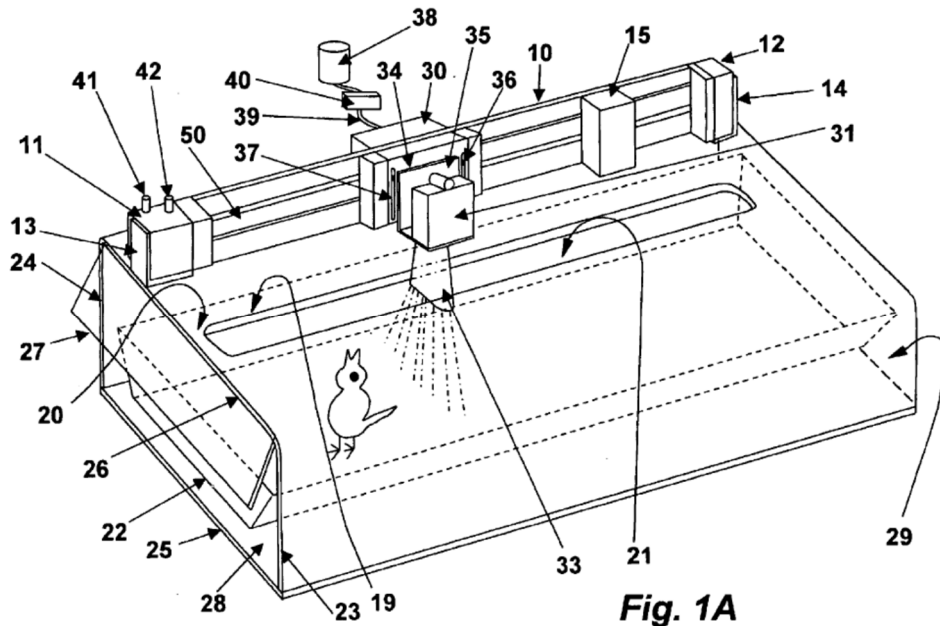
FIG. 1

Lopez describes Figure 1 as depicting a “sectional side view of the fluid distribution output manifold, with ten barbed distribution or output ports.” *Id.* at 4:11–12.

5. Johnston (Ex. 1007)

Johnston is a U.S. patent titled, “Vaccine Spray System.” Ex. 1007, code (54). Johnston describes a spray delivery system and methods of use thereof for delivering vaccine spray to birds or chicks, which are held within

an open-topped container. *Id.* at code (57). To illustrate an embodiment of Johnston's container, we reproduce its Figure 1A, below:



Johnston describes Figure 1A as depicting a fluid spray apparatus for delivering fluid spray, such as a vaccine, to small birds, including chicks. *Id.* at 3:6–7, 4:20–23. In particular, Figure 1A illustrates open topped container 22 with elongated guide rail 10 with first 11 and second 12 buff stops. *Id.* at 4:25–30. Entrance 28 and exit 29 of a tunnel may be sealed with hinged flap 27, which may help prevent the chicks from escaping. *Id.* at 4:42–46. Spray head 30 comprises nozzle assembly 31 to form a fan-shaped droplet, or mist, fluid spray. *Id.* at 5:40–43. The “fan-shaped spray of sufficient width in a long-axis to spray fluid droplets over substantially all of the width of . . . open topped container 22.” *Id.* at 5:47–49.

D. Asserted Grounds of Unpatentability

In its Petition, Petitioner presents five grounds, which we divide into two different groupings. *See* Pet. 4. In challenging sole independent claim

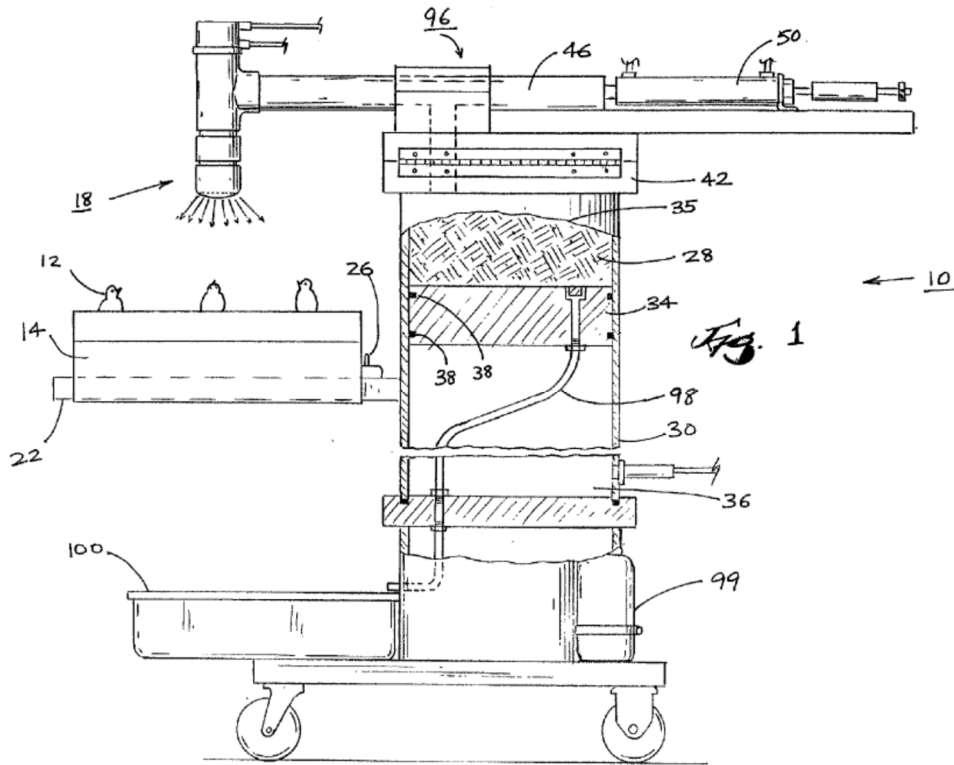
1, Petitioner presents two challenges based on the combined teaching of: (1) Lewis and Goff; and (2) Johnston and Lee. *See id.* We summarize each challenge separately, below.

1. Lewis and Goff

Petitioner contends that claims 1, 2, 9, and 12–15 are unpatentable over Lewis and Goff. Pet. 18. In particular, Petitioner asserts that Lewis discloses all of the claimed limitations of sole independent claim 1, but relies on Goff for teaching spray nozzles evenly spaced along a linear manifold. *Id.* at 18–24. We summarize Petitioner’s challenge of claim 1, below.

- a) *“A method of treating poultry hatchlings in a hatchling tray, the method comprising”*

Petitioner asserts that Lewis discloses this limitation, citing Lewis’s Figure 1. Pet. 18–20. We reproduce Lewis’s Figure 1, below:



According to Petitioner, Figure 1 “clearly illustrates that the disclosed gel is dispensed onto poultry hatchlings . . . in a hatchling tray.” *Id.* at 19.

b) “providing a soft gel for dispensing through a nozzle opening”

Petitioner asserts that Lewis describes dispensing a “liquid like substance or gel” from apertures 70 in nozzle 18 of dispensing machine 10. *Id.* at 20 (citing Lewis ¶¶ 10, 20, 22–26).

c) “providing a dispenser apparatus, the apparatus delivering a predetermined volume of the soft gel as a plurality of small beadlets through a plurality of nozzle openings of uniform size and uniform spacing therebetween along a manifold nozzle head”

Petitioner asserts that Lewis discloses this limitation, citing Lewis’s disclosure of “only a predetermined amount of gel” dispensed through “a plurality of apertures 70.” Pet. 21 (citing Ex. 1003 ¶¶ 22, 25).

d) “*wherein the plurality of nozzle openings on the manifold nozzle head approximately spans the length or width of a hatchling tray*”

Petitioner cites to Lewis’s teaching that “the location of the apertures 70 ensure that the gel is evenly distributed over the tops of the chicks.” Pet. 21 (quoting Ex. 1003 ¶ 25). Petitioner also cites to Lewis’s teaching that “the number of apertures, the shape of the apertures and the location of the apertures are relevant in setting the rate and amount of discharge of the gel 28 from the dispensing machine 10.” *Id.* at 22 (quoting Ex. 1003 ¶ 22).

Petitioner further cites to Goff’s teaching of “an apparatus for spraying animals that includes spray nozzles 18 evenly spaced along a linear manifold (top member 16).” *Id.* (citing Ex. 1004; Fig. 1, 1:72–105, 2:20–58).

Based on the teachings of Goff and Lewis, Petitioner reasons that:

It would have been obvious to one skilled in the art at the time of the invention to modify the nozzle openings of the preferred embodiment disclosed in *Lewis* to span the length or width of the hatchling tray in order *to* ensure even distribution of the dispensed gel onto the hatchlings.

...

and it would have been obvious to modify the apparatus machine 10 of *Lewis* to include the manifold and nozzle opening configuration of *Goff* to arrive at a device with uniformly spaced nozzle openings along a manifold nozzle head since this structure was a well-known alternative to be effective for uniformly distributing substances onto living animals.

Id. at 22–23 (citing Ex. 1002 ¶¶ 71, 82).

- e) *“placing the hatchling tray containing poultry hatchlings beneath the nozzle openings of the dispensing apparatus”*

To address this limitation, Petitioner cites to Lewis’s disclosure that hatchling tray 14 containing poultry hatchlings is placed beneath nozzle openings 18 of the dispensing apparatus. Pet. 23 (citing Ex. 1003 ¶ 10).

- f) *“dispensing the predetermined volume of the soft gel as small beadlets onto the hatchlings in the hatchling tray at approximately a constant rate”*

To address this limitation, Petitioner refers to Lewis’s disclosure that “only a predetermined amount of gel” is dispensed. Pet. 24 (citing Ex. 1003 ¶ 25). Petitioner further refers to Lewis’s teaching that “[a]ctivation of the gel dispensing machine causes a certain amount of gel to be dispensed out of the nozzle through a plurality of apertures in the dispensing head at a certain discharge rate.” *Id.* (quoting Ex. 1003 ¶ 11).

- g) *“passing the hatchling tray beneath the nozzle openings for even distribution of the beadlets to the hatchlings contained therein”*

In addressing this limitation, Petitioner cites to Lewis’s teaching that “[t]he gel is sprayed over the top of the chicks in a uniform fashion to better ensure uniform distribution of the gel.” Pet. 24 (citing Ex. 1002 ¶ 11). Petitioner further refers to Lewis’s Figure 1 and asserts, “the tray 14 is located beneath nozzle 18 so that the drops of gel 28 (i.e., beadlets) are distributed onto the hatchlings.” *Id.*

- h) *“allowing the hatchlings to consume the beadlets”*

Petitioner asserts, “Although not explicitly stated, *Lewis* strongly implies that the hatchlings consume gel 28.” Pet. 24. Dr. Muzzio testifies

that “the hatchlings onto which the gel is dispensed consume the soft gel in beadlet form.” Ex. 1002 ¶ 70.

2. *Johnston and Lee*

Petitioner asserts that claims 1–8, 9, and 11–15 are unpatentable over Johnston and Lee. Pet. 32. In presenting this alternative challenge, Petitioner asserts that Johnston discloses all of the claimed limitations of sole independent claim 1, but relies on Lee for teaching spray nozzles evenly spaced along a linear manifold. *Id.* at 18–24. We summarize Petitioner’s challenge of claim 1, below.

a) “A method of treating poultry hatchlings in a hatchling tray, the method comprising”

Petitioner cites to Johnston’s Figure 1A, which we reproduce, below (Pet. 32):

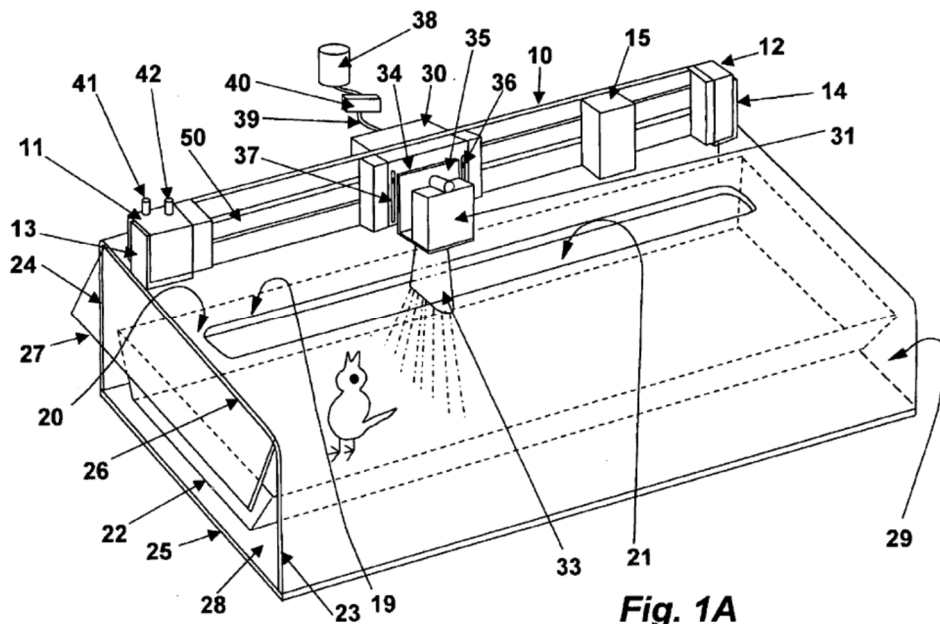


Fig. 1A

According to Petitioner, and as shown in Figure 1A, container 22 satisfies the claimed “hatchling tray.” *Id.*

b) “providing a soft gel for dispensing through a nozzle opening”

Petitioner cites to Johnston’s disclosure of dispensing a “fluid spray,” but acknowledges that it is not clear if this spray is a gel. *See* Pet. 32–33 (citing Ex. 1007, 4:19–25, 5:40–54).³ To address the claimed “soft gel,” Petitioner refers to Lee. *Id.* at 33 (citing Ex. 1005 (8:5–8)).⁴ The cited portion of Lee teaches, “The gel form of the vaccine is prepared by dissolving the gel powder in water at a suitable temperature . . . such that . . . a relatively soft gel results.” Ex. 1005, 8:1–8.

In combining Johnston with Lee, Petitioner reasons that “it would have been obvious to use the vaccine gel of Lee in the method and dispensing apparatus of Johnston.” *Id.* at 33 (citing Ex. 1002 ¶¶ 86, 87). Dr. Muzzio testifies, “Lee proposes a solution to the problem of oocyst settling by forming a soft gel,” and that the soft gel delays or prevents settling while still being able to flow through nozzles. *See* Ex. 1002 ¶ 86.

³ Although Petitioner cites to Exhibit 1006 (Lopez) rather than Exhibit 1007 (Lewis), we understand this to be an inadvertent typographical error and Petitioner intended to cite to Lewis. *See* Pet. 32.

⁴ Although Petitioner cites to Exhibit 1007 (Lewis) rather than Exhibit 1005 (Lee), we understand this to be an inadvertent typographical error and Petitioner intended to cite to Lee. *See* Pet. 33.

c) “providing a dispenser apparatus, the apparatus delivering a predetermined volume of the soft gel as a plurality of small beadlets through a plurality of nozzle openings of uniform size and uniform spacing therebetween along a manifold nozzle head”

Petitioner asserts that “fan-shaped spray nozzle 33 of Johnston includes a plurality of nozzle openings, which appear to be of uniform size and uniform spacing, as illustrated in FIG 1A.” Pet. 33–34.

In the alternative, Petitioner reasons that even if Johnston’s nozzle openings were not of uniform size and spacing, “it would have been obvious to modify the spray nozzle assembly 31 of Johnston to have uniform size and spacing to provide even and complete delivery coverage of the vaccine to the hatchlings in the underlying tray.” *Id.* at 34 (citing Ex. 1002 ¶¶ 86, 87). Dr. Muzzio testifies that the modification would have provided “even and complete delivery of the vaccine gel to the hatchlings in the underlying tray.” Ex. 1002 ¶ 87.

d) “wherein the plurality of nozzle openings on the manifold nozzle head approximately spans the length or width of a hatchling tray”

Petitioner cites to Johnston’s disclosure that its guide rail is “mounted on a cover that has an elongated slot that permits the spray nozzle assembly to extend below the plane of the cover, while allowing the spray nozzle assembly to freely traverse the length of an open-topped container placed beneath the cover.” Pet. 34–35 (citing Ex. 1007, 2:13–23).

- e) *“placing the hatchling tray containing poultry hatchlings beneath the nozzle openings of the dispensing apparatus”*

To address this limitation, Petitioner refers, in part, to Johnston’s Figure 1A, which depicts open-topped container 22 placed beneath nozzle openings of fan-shaped spray nozzle 33. Pet. 35 (citing Ex. 1007; Fig. 1A, 7:66–8:15).

- f) *“dispensing the predetermined volume of the soft gel as small beadlets onto the hatchlings in the hatchling tray at approximately a constant rate”*

Petitioner asserts, “If the soft gel of Lee were dispensed according to the method of Johnston, as it would have been obvious to do, the method would include dispensing a predetermined volume of soft gel as small beadlets onto hatchlings in a hatchling tray at an approximately constant rate, as claimed.” Pet. 35–36 (citing Ex. 1002 ¶¶ 86, 87).

- g) *“passing the hatchling tray beneath the nozzle openings for even distribution of the beadlets to the hatchlings contained therein”*

In addressing this limitation, Petitioner asserts that the “dispensed beadlets are thus inherently evenly distributed on the hatchlings in the method of *Johnston*.” Pet. 36.

- h) *“allowing the hatchlings to consume the beadlets”*

Petitioner cites to Johnston’s disclosure that some of the chicks will “inhale the fluid droplets into the respiratory system, or ingest by oral contact with fluid droplets.” Pet. 36 (citing Ex. 1007, 2:52–57).

E. Discretionary Denial Under 35 U.S.C. § 325(d)

Patent Owner contends that we should exercise our discretion and deny institution under 35 U.S.C. § 325(d). PO Prelim. Resp. 11.

We agree.

Institution of *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a) (stating “[t]he Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition” (emphasis added)); *see also Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“the PTO is permitted, but never compelled, to institute an IPR proceeding”). The exercise of our discretion to institute an *inter partes* review is informed by 35 U.S.C. § 325(d), which requires us to “take into account whether, and reject the petition . . . because, the same or substantially the same prior art or arguments previously were presented to the Office.” In evaluating whether to exercise our discretion under § 325(d), we weigh the following non-exclusive factors:

(a) the similarities and material differences between the asserted art and the prior art involved during examination;

(b) the cumulative nature of the asserted art and the prior art evaluated during examination;

(c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;

(d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;

(e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and

(f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments.

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, slip op. at 17–18 (Paper 8) (PTAB Dec. 15, 2017) (precedential-in-part, indentations added for clarity).

Upon reviewing the factors enumerated in *Becton, Dickinson*, we find that, on balance, the factors weigh in favor of exercising our discretion to deny institution under 35 U.S.C. § 325(d).

1. The similarities and material differences between the asserted art and the prior art involved during examination

The primary references relied upon by Petitioner—Johnston and Lewis—were primarily relied on by the examiner during the initial prosecution. *See supra* Parts IIB, IID.

As to the secondary references relied upon by Petitioner—Goff, Lopez, and Lee—the examiner did not rely on these references in rejecting the claims. A patent application with a disclosure similar to Lee (WO 96/25951), however, was cited and considered by the Examiner. *See* Ex. 2001, 327; *see also* Ex. 1001, code (56); *see also* PO Prelim. Resp. 15 (confirming the same). Indeed, we find that the disclosure of WO 96/25951 is almost identical to Lee. *Compare* Ex. 2004, *with* Ex. 1005.

Although the examiner did not consider secondary references Lopez and Goff during prosecution, because Petitioner’s primary references (Johnston and Lewis) were also the primary references involved during the original examination, this factor weighs in favor of denying institution.

2. *The cumulative nature of the asserted art and the prior art evaluated during examination*

As explained above, Petitioner’s primary references (Johnston and Lewis) were also two primary references relied on by the examiner during prosecution. *See supra* Parts II.B1–6. As to Petitioner’s secondary references, we find that these are merely cumulative to references relied upon by the examiner.

Petitioner relies on Lee for teaching a “soft gel.” Pet. 33. Similarly, the examiner relied on McDougald for teaching a “soft gel.” Ex. 2001, 85.

Petitioner relies on Goff for teaching “spray nozzles 18 evenly spaced along a linear manifold (top member 16).” Pet. 22 (citations omitted). The examiner similarly relied on Bartlett, Kurtz, and Peterson for teaching nozzles “of approximately uniform size arranged approximately evenly apart along a manifold.” Ex. 2001; 149, 317, 358, 409.

We find the asserted art to be identical (Johnston and Lewis) or cumulative (Goff and Lee) to the art evaluated during prosecution (Johnston, Lewis, Bartlett, Peterson, Kurtz, McDougald).

This factor weighs in favor of denying institution.

3. *The extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection*

Johnston and Lewis—the primary references relied upon by Petitioner—were the basis of at least six different office actions during the original prosecution. *Supra* Parts II.B.1–6.

As to Lewis, the examiner rejected independent claim 1 as unpatentable over Lewis and a combination of Bartlett, Peterson, and Kurtz. *See id.* at II.B.2–6. In particular, the examiner relied on Lewis for disclosing

the majority of the limitations of then-pending claim 1, with the exception of a plurality of nozzles arranged evenly apart along a manifold. *See id.*; *see also, e.g.*, Ex. 2001, 358 (“Lewis . . . fails to specifically disclose a plurality of nozzle openings arranged approximately evenly apart along a manifold” but “Peterson teaches . . . the plurality of nozzle openings on the manifold.”)

As to Johnston, the examiner rejected then-pending claim 1 as unpatentable over Johnston in view of McDougald. *See* Ex. 2001, 84. The examiner found that Johnston discloses the invention substantially as claimed, except for a soft gel, for which the examiner relied on McDougald. *See id.* at 85.

This factor weighs in favor of denying institution.

4. The extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art

Petitioner relies on either Johnston or Lewis for teaching a majority of the limitations for independent claim 1. *See supra* Parts II.D.1–2.

In combining Johnston with Lee, Petitioner relies on Lee’s teaching of a “soft gel,” and reasons that a skilled artisan would have used a soft gel with Johnston’s method. Pet. 33. This challenge largely overlaps the examiner’s rejection from the office action dated April 28, 2009. Ex. 2001, 85–89. In that office action, the examiner relied on Johnston for teaching the claimed limitations with the exception of the “soft gel,” for which the examiner relied on McDougald. *See id.* at 85. The examiner reasoned that a skilled artisan would have modified Johnston to include McDougald’s “soft gel” to provide for “easy handling, aid in hydration and induce the feeding response in the birds.” *Id.*

In combining Lewis with Goff, Petitioner relies on Goff's teaching of "spray nozzles 18 evenly spaced along a linear manifold" and reasons that a skilled artisan would have modified Lewis to use this type of manifold "to ensure even distribution of the dispensed gel." Pet. 22. This contention largely overlaps the examiner's five rejections from the office actions dated July 30, 2010, October 14, 2010, February 24, 2011, June 21, 2011, and January 4, 2012. *See supra* Parts II.B.2–6. In particular, in combining Lewis with Bartlett, Kurtz, and Peterson, the examiner relied on Bartlett, Kurtz, or Peterson for teaching the claimed "nozzle openings of approximately uniform size arranged approximately evenly apart along a manifold" and reasoned that a skilled artisan would have modified Lewis based on these teachings for the purpose of distributing or dispensing the soft gel. *See id.*

In a notice of allowance, the examiner indicated that the prior art failed to "show or render obvious" multiple limitations, including "a manifold nozzle head wherein the plurality of nozzle openings on the manifold nozzle head approximately spans the length or width of a hatchling tray." Ex. 2001, 677. Notably, the examiner found that the cited art did not disclose the claimed manifold nozzle. This limitation relates to an argument that Patent Owner presents in its Preliminary Response. *See* PO Prelim. Resp. 29. In particular, Patent Owner contends that Petitioner "failed to adequately address the 'manifold nozzle head' limitation in claim 1." *Id.*

We find that Petitioner's challenges are similar to the rejections made by the examiner during the initial prosecution. We also find that the examiner's reasons for allowance identify a limitation that Patent Owner contends is not adequately addressed.

This factor weighs in favor of denying institution.

5. *Whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art*

Petitioner acknowledges that Lewis and Johnston were “made of record during prosecution” and states that “the Examiner did not consider either reference in combination with the other presently identified prior art references.” Pet. 5.

Although the examiner did not consider Goff or Lee during the original examination, Petitioner fails to explain adequately that Goff or Lee are not cumulative of the prior art considered by the examiner.

Because we find that Goff and Lee are largely cumulative to other references relied upon by the examiner during prosecution—namely, Bartlett, Peterson, Kurtz, and McDougald—we are not persuaded that application of Goff and Lee would lead to a result different from that reached by the examiner.

This factor weighs in favor of denying institution.

6. *the extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments*

Petitioner contends that—during prosecution—the applicant misrepresented Lewis’s nozzles as being unable to present a “uniform spray pattern.” See Pet. 22 (“applicant argued—without support—[Lewis] results in a ‘conical spray pattern’ and therefore ‘cannot produce the uniform spray pattern of the instant claims’ (in direct contravention of the plain language of *Lewis*)).”

Even if Petitioner’s accusation were true, in that applicant mischaracterized Lewis during prosecution, we do not find this fact to support reconsideration of the prior art.

We agree with Petitioner’s assertion that Lewis discloses that “the location of the apertures 70 ensure that the gel is evenly distributed over the tops of the chicks.” Pet. 21 (quoting Ex. 1003 ¶ 25). If anything, however, this disclosure cuts against Petitioner’s reasoning that a skilled artisan would have modified Lewis’s nozzle openings “to span the length or width of the hatchling tray in order to ensure even distribution of the dispensed gel onto the hatchlings.” Pet. 22. In other words, if Lewis’s apertures already “ensure that the gel is evenly distributed over the tops of the chicks” (Ex. 1003 ¶ 25), we are not persuaded by Petitioner’s reasoning that a skilled artisan would have modified Lewis’s nozzles in order to “ensure even distribution of the dispensed gel onto the hatchlings” (Pet. 22).

This factor weighs in favor of denying institution.

III. CONCLUSION

After balancing the factors enumerated in *Becton, Dickinson*, we exercise our discretion to deny institution under 35 U.S.C. § 325(d).

IV. PETITIONER’S MOTION

Petitioner filed a motion to correct a mistake in Dr. Muzzio’s declaration. Paper 16 (“Motion”). Because we deny institution, we dismiss the Motion as moot.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, no *inter partes* review is instituted; and

FURTHER ORDERED that Petitioner's Motion (Paper 16) is
dismissed as moot.

IPR2020-00039
Patent 8,794,185 B2

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