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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ROLAND H. JOHNSON, DOUGLAS I. HEPLER, KATHLEEN G. PALMA, and WILLIAM R. CAMPBELL

Appeal 2020-001513
Application 15/730,565
Technology Center 1600

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and JOHN G. NEW, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal[1,2] under 35 U.S.C. § 134(a) involving claims to a chewable solid dosage form containing imidacloprid. The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse and enter a new ground of rejection.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the Real Party in Interest as Bayer Healthcare LLC, (*see* Appeal Br. 1).

[2] We have considered and herein refer to the Specification of Oct. 11, 2017 ("Spec."); Non-Final Office Action of Mar. 11, 2019 ("Non-Final Act."); Appeal Brief of July 10, 2019 ("Appeal Br."); Examiner's Answer of Oct. 22, 2019 ("Ans."); and Reply Brief of Dec. 20, 2019 ("Reply Br.").

Statement of the Case

Background

"[T]he market for ectoparasite control in mammals has long been dominated by compositions for topical administration" (Spec. ¶ 3). Known topical compositions for use on dogs and cats include imidacloprid for treating fleas and fipronil for treating fleas, ticks, and scabies (*id.*). However, topical compositions have various disadvantages, including toxicity to humans and environmental contamination (*id.* ¶ 4). "It is therefore desirable to provide an orally deliverable compound for control of targeted parasites. It is especially desirable to provide such a compound in a readily consumable dosage form" (*id.* ¶ 5).

The Claims

Claims 1–6, 8–15, 19, 21–24, and 26–28 are on appeal.[3] Independent claim 1 is representative and reads as follows:

> 1. A chewable solid dosage form comprising an ectoparasiticidally effective amount of imidacloprid, wherein the chewable solid dosage form comprises from about 1.75 mg to about 108 mg of imidacloprid.

(Appeal Br. 30).

[3] Claims 7, 16–18, 20, and 25 are cancelled. Claim 9 appears to depend on cancelled claim 7. Should prosecution be re-opened, we encourage Appellant to address the dependency of claim 9.

The Rejection

The Examiner rejected claims 1–6, 8–15, 19, 21–24, and 26–28 as unpatentable under 35 U.S.C. § 103(a) as obvious over Hershberger,[4] Mencke,[5] Dryden,[6] and Solecki.[7]

The Examiner finds Hershberger teaches a liquid composition that "can be admixed, topped, or otherwise added to solid pet food, which can thus be prepared as a . . . chewable soft treat" for pets that may contain imidacloprid, for treating flea or tick infestations (Ans. 6–7; emphasis omitted). The Examiner relies on Mencke, Solecki, and Dryden to teach safe amounts of imidacloprid (*id.* at 11–12).

Appellant asserts "no combination of prior art suggests the claimed chewable solid dosage form comprising an ectoparasiti[ci]dally effective amount of imidacloprid" (Appeal Br. 12). Specifically, Appellant contends "Hershberger's oral dosage form is indisputably a liquid" (*id.*). Appellant contends that "Hershberger discloses pouring the liquid over solid food for immediate consumption by the pet, not for further processing into tablets/soft treats" (*id.* at 14). Appellant further contends that "[t]he ordinary meaning of solid does not include a liquid as in Hershberger" (*id.* at 15).

The Examiner responds "in Hershberger the composition itself is liquid, but Hershberger provides that it can be admixed, topped, or otherwise

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[4] Hershberger, US 2005/0158367 A1, published July 21, 2005.
[5] Mencke et al., US 5,712,295, issued Jan. 27, 1998.
[6] Dryden et al., *Comparative Speed of Kill of Selamectin, Imidacloprid, and Fipronil-(S)-Methoprene Spot-On Formulations against Fleas on Cats*, 6 Veterinary Therapeutics *1–5 (2005).
[7] Solecki, *Pesticide residues in food, the International Programme on Chemical Safety, Toxicological Evaluations, IMIDACLOPRID*, Joint Meeting on Pesticide Residues 1-28 (2001).

added to solid pet food, which can thus be prepared as a tablet, capsule, chewable soft treat" (Ans. 6).

We begin with claim interpretation, since before a claim is properly interpreted, its scope cannot be compared to the prior art. The term in dispute is "chewable dosage form" as recited in claim 1. We first turn to the Specification which is, "[i]n most cases, the best source for discerning the proper context of claim terms." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1360 (Fed. Cir. 2004).

The Specification discloses:

> The parasiticidal compositions of the invention can be provided in any therapeutically acceptable pharmaceutical form. For example, the compositions can be formulated for oral administration as drug powders . . . beads, microbeads, pellets, pills, microtablets, compressed tablets or tablet triturates, molded tablets or tablet triturates, and in capsules, which are either hard or soft and contain the composition as a powder, particle, bead, solution or suspension. The parasiticidal compositions can also be formulated for oral administration as a solution or suspension in an aqueous liquid, as a liquid incorporated into a gel capsule.

(Spec. ¶ 30). The Specification discloses "[o]ne especially useful delivery format for animals is the soft (mildly friable under pressure) chewable treat for edible consumption" (Spec. ¶ 40). The Specification discloses a process for manufacturing a chewable dosage vehicle wherein:

> dry ingredients of the chew mixture are blended first, then an oil suspension of the active blended therein, followed by admixture with the liquid ingredients (e.g., humectants and softening agents) to form a thoroughly blended mixture. After blending, the chew mixture is discharged without compression from a port through the blender into a suitable container for processing into individual dosage units with a forming machine.

(Spec. ¶ 66).

Therefore, in light of the Specification, we interpret the phrase "chewable dosage form" in claim 1 as a pharmaceutical form that is distinct from liquid or gel capsule forms, and that is provided in a solid and chewable formulation for administration to animals.

We find the Examiner's arguments to the contrary unpersuasive. The Examiner finds the "term 'solid' does not exclude the presence of liquids ingredients" (Ans. 4). Although we agree with the Examiner the claimed chewable solid dosage form may contain liquid ingredients, the resulting dosage form is unambiguously solid in its final composition. Moreover, the Specification itself distinguishes between a chewable solid dosage form and a gelatin capsule which may contain the medicament in a liquid solution or suspension. Accordingly, to the extent that the Examiner is reading "solid dosage form" out of the claims, that interpretation is not reasonable.

The Examiner also finds "in Hershberger the composition itself is liquid, but Hershberger provides that it can be admixed, topped, or otherwise added to solid pet food, which can thus be prepared as a tablet, capsule, chewable soft treat" (Ans. 6; emphasis omitted).

We also find this interpretation unpersuasive. When Hershberger teaches "a liquid composition that can be admixed, topped, or otherwise added to a pet food" (Hershberger 7), we appreciate that the pet might then chew the resultant treated pet food. But that interpretation also reads the concept of "solid dosage form" out of the claim, relying solely on the word "chewable" because any medicament, liquid, gel, or solid, could be added to food and thereby be transmuted to a "chewable solid dosage form." However, "the broadest reasonable interpretation must be *reasonable* in light

of the claims and specification." *PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 815 F.3d 747, 755 (Fed. Cir. 2016).

Because Hershberger does not teach a "chewable solid dosage form" and that missing element is not supplied by Mencke, Dryden, or Solecki, the references do not render the claims obvious.

Conclusion of Law

The evidence of record does not support the Examiner's finding that Hershberger, Mencke, Dryden, and Solecki render the claims obvious.

New Ground of Rejection

Under the provisions of 37 C.F.R. § 41.50(b), we enter the following new ground of rejection. Claims 1–6, 8–15, 19, 21–24, and 26–28 are rejected under 35 U.S.C. § 103 as obvious over Cleverly[8] and CN'620.[9]

Findings of Fact

1. Cleverly teaches a solid chewable veterinary formulation containing an effective amount of at least one pharmaceutical agent; at least one filler; at least one disintegrant; at least one non-animal product containing flavor; at least one binder; at least one humectant; and at least one granulating solvent (Cleverly 17, claim 1).

2. Cleverly teaches the pharmaceutical agent may be imidacloprid (Cleverly 18–19, claims 12, 25).

[8] Cleverly et al., US 2004/0037869 A1, published Feb. 26, 2004 (of record Oct. 11, 2017). We note that Cleverly was previously applied against the significantly-narrower "single dose" method claims of the parent application No. 12/471,129.

[9] CN 1386420 A, published Dec. 25, 2002 (of record Oct. 11, 2017).

3. Cleverly teaches administering insecticides, including substituted pyridylmethyl derivatives such as imidacloprid for treating blood-sucking pests including fleas (Cleverly ¶¶ 87–88).

4. CN'620 teaches an antiparasitic composition for pets that contains imidacloprid and is highly effective on fleas (CN'620, 1).

5. CN'620 teaches a solid oral preparation of imidacloprid for a cat or dog, providing a daily dose of 0.2–7 mg/kg (CN'620, 1).

6. CN'620 teaches preparing an oral tablet having a weight of 1 g containing 0.12% (w/w) imidacloprid (CN'620, 4 (Example 5)).

Principles of Law

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious," the answer depends on "whether the improvement is more than the predictable use of prior art elements according to their established functions." *KSR*, 550 U.S. at 417.

Analysis

Cleverly teaches a chewable solid dosage form containing imidacloprid effective for treating fleas (FF 1–3). Cleverly does not teach an amount of imidacloprid. CN'620 teaches solid oral dosage forms for treating fleas in cats and dogs, containing 0.2–7 mg/kg imidacloprid (FF 4–5). CN'620 teaches a specific tablet composition containing 1.2 mg imidacloprid (1 g x 0.12%) (FF 6). A person of ordinary skill in the art would have been motivated to use the dose amounts taught by CN'620 with

Cleverly's chewable solid dosage form as both references teach imidacloprid solid oral dosage forms for treating fleas in pets (FF 3, 6).

The resulting combination teaches a chewable solid dosage form containing 0.2–7 mg/kg imidacloprid, i.e., an ectoparasiticidally effective amount. Applying the Examiner's uncontested finding that the average size of a domestic house cat is 5 kg (Ans. 10), a person of ordinary skill in the art would have had a reasonable expectation of success in preparing a chewable solid dosage form containing about 1–35 mg of imidacloprid. Accordingly, the prior art teaches the chewable solid dosage form of claim 1, including a dose amount that overlaps the claimed dose amount. "[T]he existence of overlapping or encompassing ranges shifts the burden to the applicant to show that [the] invention would not have been obvious." *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003).

With regard to claims 2, 3, 8, 19, 21–24, and 26, CN'620 teaches solid oral dosage forms for treating fleas in cats and dogs, containing 0.2–7 mg/kg imidacloprid, a range that overlaps the claimed range (FF 3–6).

With regard to claim 4, Cleverly teaches a chewable solid dosage form containing imidacloprid effective for treating fleas (FF 1–3).

With regard to claims 5 and 9[10], Cleverly teaches treatment of fleas (FF 1). As to the packaging and label, these simply represent printed matter that does not patentably distinguish the invention from claim 1. *See In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004) ("All that the printed matter does is teach a new use for an existing product. . . . He is not, however, entitled to patent a known product by simply attaching a set of instructions to that product.")

[10] We note that claim 9 depends from cancelled claim 7.

With regard to claims 6 and 10–14, CN'620 teaches overlapping solid oral dosage forms for treating cats and dogs, containing 0.2–7 mg/kg imidacloprid, a range that overlaps the claimed range (FF 5) and therefore necessarily comprise doses effective to kill fleas, flea larvae or eggs, ticks, helminthes, and scabies. "Products of identical chemical composition can not have mutually exclusive properties." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990).

With regard to claim 15, Cleverly teaches including "product containing flavor or flavor derived from a non-animal source" (Cleverly ¶ 14).

With regard to claim 27, claim 12 of Cleverly suggests a formulation with a single pharmaceutical agent that may be imidacloprid as does CN'620 (FF 2, 6).

With regard to claim 28, Cleverly teaches dosage form components including pregelatinized starch (Cleverly ¶ 230), glycerin (Cleverly, Claim 2), croscarmellose sodium (Cleverly ¶ 242), corn oil and polyethylene glycol (Cleverly ¶ 189). "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850 (C.C.P.A. 1980).

We note that Appellant argues that the Specification provides evidence of unexpected results (Appeal Br. 23–26). Appellant's evidence of unexpected results relies on compositions containing 5 mg and 3 mg of imidacloprid (*See id.* at 24–25). Appellant's evidence does not provide a

reasonable basis for concluding that embodiments within the entire range of the claimed amount (about 1.75 mg to about 108 mg) would behave in the same manner as the tested embodiments. Accordingly, Appellant's evidence of alleged unexpected results is not commensurate with the scope of the claims. *See In re Lindner,* 457 F.2d 506, 508 (CCPA 1972).

Appellant also argues that the present invention solves a long-felt need (Appeal Br. 27). However, Appellant's argument does not include any evidence of either a long-felt need, or that the claimed composition meets that need. "Attorneys' argument is no substitute for evidence." *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989).

Considering the prior art and Appellant's evidence of unexpected results, we conclude that the claims would have been obvious over Cleverly and CN'620.

CONCLUSION

In summary:

Claims Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**	**New Ground**
1–6, 8–15, 19, 21–24, 26–28	103	Hershberger, Mencke, Dryden, Solecki		1–6, 8–15, 19, 21–24, 26–28	
1–6, 8–15, 19, 21–24, 26–28	103	Cleverly, CN'620			1–6, 8–15, 19, 21–24, 26–28
Overall Outcome				1–6, 8–15, 19, 21–24, 26–28	1–6, 8–15, 19, 21–24, 26–28

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). Section 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review." Section 41.50(b) also provides:

> When the Board enters such a non-final decision, the appellant, within two months from the date of the decision, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:
>
> (1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the prosecution will be remanded to the examiner. The new ground of rejection is binding upon the examiner unless an amendment or new
>
> Evidence not previously of Record is made which, in the opinion of the examiner, overcomes the new ground of rejection designated in the decision. Should the examiner reject the claims, appellant may again appeal to the Board pursuant to this subpart.
>
> (2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same Record. The request for rehearing must address any new ground of rejection and state with particularity the points believed to have been misapprehended or overlooked in entering the new ground of rejection and also state all other grounds upon which rehearing is sought.

Further guidance on responding to a new ground of rejection can be found in the Manual of Patent Examining Procedure § 1214.01.

REVERSED, 37 C.F.R. § 41.50(b)