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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/840,758	08/31/2015	Frederick E. Shelton IV	END7634USNP/171F01US	7429

123907 7590 09/14/2020

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EXAMINER
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ART UNIT	PAPER NUMBER
3731	

NOTIFICATION DATE	DELIVERY MODE
09/14/2020	ELECTRONIC

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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 FREDERICK E. SHELTON IV and
JASON L. HARRIS

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Appeal 2020-001178
Application 14/840,758
Technology Center 3700

_____

Before CHARLES N. GREENHUT, MICHAEL L. HOELTER, and ANNETTE R. REIMERS, *Administrative Patent Judges*.

GREENHUT, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1–3, 5–13, and 15–28. *See* Final Act. 1. Claims 4 and 14 have been canceled. *See* Appeal Br. 5. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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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 Ethicon LLC, a Johnson & Johnson company. Appeal Br. 1.

STATEMENT OF THE CASE

The claims are directed to surgical staples and adjuncts with medicants affected by activators. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A staple cartridge assembly for use with a surgical stapler, comprising:
>
> a cartridge body having a plurality of staple cavities, each staple cavity having a surgical staple disposed therein;
>
> a biocompatible, bioabsorbable adjunct material releasably coupled to the cartridge body and configured to be delivered to tissue within a body of a patient by deployment of the staples in the cartridge body; and
>
> an effective amount of at least one medicant disposed within and releasable from the adjunct material, the at least one medicant including an activator material configured to be activated within the body of the patient by an activator located outside the body of the patient, the activation of the at least one medicant allowing monitoring of the adjunct material after its delivery to the tissue, the activator material being configured to be activated by a magnetic field induced by the activator.

REFERENCES

The prior art relied upon by the Examiner is:

Name	**Reference**	**Date**
Schmid	US 2013/0256373 A1	Oct. 3, 2013
Dormer	US 8,740,872 B2	June 3, 2014

REJECTION

Claims 1–3, 5–13, and 15–28 are rejected under 35 U.S.C. § 103 as being unpatentable over Schmid and Dormer. Final Act. 2.

OPINION

In order to arrive at the claimed subject matter, the Examiner proposes modifying Schmid's staple cartridge assembly that has a cartridge body (staple cartridge body 126), a surgical staple (staple driver 130), a biocompatible, bioabsorbable adjunct material (tissue thickness compensator 200), and an effective amount of medicant, by adding Dormer's activator material that is configured to be activated within the body of a patient by an activator located outside the body of the patient. Final Act. 2–3 (citing Schmid ¶¶ 169, 170, 172, 173; Figs. 2–3; Dormer Abstr., 2:29–39, 9:52–55, 10:1–30). The Examiner reasons that it would have been obvious to a skilled artisan to "have provided Schmid's [staple cartridge assembly] with the features as taught by Dormer in order to target deliver[y] of a medicament." *Id.* at 3.

Appellant contends that the Examiner's proposed modification is based on improper hindsight reconstruction because there is no reason for the proposed modification of Schmid. *See* Appeal Br. 10. Appellant argues that "Schmid already provides targeted delivery of its medicament, so Dormer's magnetic targeted delivery is wholly unnecessary." *Id.* at 11.

In response, the Examiner modifies the rationale for the proposed modification by stating that Schmid already has "an activator, such as a fluid activator or an oxidizing agent, for a controlled release of the medicament as shown in paragraph 173" and "Dormer is relied upon to show the mode of activating a material, such as using a magnetic field." Ans. 4. The Examiner then reasons that it would have been obvious to "apply Dormer's mode of activation, i.e.[, a] magnetic field, to Schmid's adjunct material in order [to] control the release of the medicament." *Id.*

Appellant argues that "there is no objective reason for the Examiner's new basis of rejection" because, as the Examiner previously stated, Schmid already "discloses an effective amount of at least one medicament disposed within and releasable from an adjunct material." Reply Br. 3 (citing Final Act. 4).

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), cited with approval in *KSR Int'l. v. Teleflex*, 550 U.S. 398, 418 (2007). Further, our reviewing court has frequently cautioned that it is not proper to base a conclusion of obviousness upon facts gleaned only through hindsight. "To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction—an illogical and inappropriate process by which to determine patentability." *Sensonics Inc. v. Aerosonic Corp*., 81 F.3d 1566, 1570 (Fed. Cir. 1996) (citing *W.L. Gore & Assoc. v. Garlock*, *Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983)). "The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made." *Id.* (citing *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985)).

Dormer's use of "magnetically-susceptible nanoparticles" is for "targeted delivery" of medicants to "specific locations of the heart." Dormer Abstr. In other words, Dormer uses its magnetically-susceptible nanoparticles to move medicants from a site of delivery to a site of

treatment, in which the site of delivery is *different* from the site of treatment. Schmid, on the other hand, has its medicants already at the site of delivery *and* the site of treatment. Schmid ¶¶ 141, 149; Figs. 17, 18. Thus, in regards to the Examiner's first reason for modifying Schmid's staple cartridge assembly, i.e., "to target deliver[y] of a medicament" (Final Act. 3), we agree with Appellant that there is no reason to do that because "Schmid already provides targeted delivery of its medicament" (Appeal Br. 11).

Further, Dormer has a need to control the release of its medicant because the site of delivery and the "target" site, i.e., the site of treatment, are different. Dormer Abstr., 4:43–57, 5:28–35, 6:42–45, 7:14–23, 9:40–55, 10:4–15; Fig. 1. That is, once Dormer's magnetically-susceptible nanoparticles are drawn to the site of treatment in the heart, a magnetic force is then applied to oscillate the nanoparticles causing release of a bioactive agent from the nanoparticles' coatings. Dormer 10:4–15. As the Examiner acknowledges, Schmid already controls the release of its medicant at the treatment site using, for example, an oxidizing agent. Ans. 4; Schmid ¶ 173. Thus, there would appear to be no reason for modifying Schmid's "mode of activation" for that of Dormer's because Schmid does not need to "target" its medicant. If anything, it can be argued that Dormer's magnetically-susceptible nanoparticles and the equipment necessary to generate a magnetic force to move or oscillate the nanoparticles (Schmid 10:1–29, 12:6–29) seem more complex than Schmid's oxidizing agent. The Examiner does not provide a reason why it would be obvious to substitute a simple mode of activation for a more complex one. Thus, in regards to the Examiner's second reason for modifying Schmid's staple cartridge assembly, i.e., "in order [to] control the release of the medicament" or to

substitute one "mode of activating a material" for another (Ans. 4), we agree with Appellant that "there is no objective reason for the Examiner's new basis of rejection" (Reply Br. 2).

As such, because the Examiner has not articulated a persuasive reason supported by rational underpinnings for combining the referenced teachings in the manner proposed, we conclude that it is more likely than not that the Examiner improperly resorted to hindsight in reaching a conclusion of obviousness.

For the foregoing reasons, we do not sustain the Examiner's rejection.

CONCLUSION

The Examiner's rejection is reversed.

DECISION SUMMARY

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–3, 5–13, 15–28	103	Schmid, Dormer		1–3, 5–13, 15–28

REVERSED