

Courtesy of Hauptman Ham, LLP

Vol. 9, No. 8

AUGUST 2023

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## PROCEDURAL DUE PROCESS IN IPR PROCEEDINGS

By [Michael McComas](#)

[Axonics, Inc. v. Medtronic, Inc.](#), Appeal Nos. 2022-1532, 2022-1533  
(Fed. Cir. August 7, 2023, Lourie, [Dyk](#), and Taranto, precedential)

- An inter partes review (IPR) petitioner is entitled to notice of, and an opportunity to respond to, a new claim construction adopted by the Patent Trial and Appeal Board (“the Board”) after institution of the IPR, at least where the petitioner relies on the same prior art embodiments for each invalidity ground, under the new construction, as were relied on in the petition.
- 至少在根据请愿书中所依据的内容，请愿者针对每个无效理由都依赖相同的现有技术实施例的情况下，多方复审 (IPR) 申请人有权收到专利审判和上诉委员会 (“委员会”) 在 IPR 提出后采用的新权利要求解释的通知，并有机会对其作出回应。
- 当事者系レビュー(IPR)の申立人は、少なくともその申立人が各無効の根拠として申立書の中で依拠したものと同一先行技術の実施例に依拠する際、IPR開始後に特許公判審判部 (PTAB: 審判部) が採用した新たなクレーム解釈を通知する権利および応答する機会を有する。
- 당사자계 심판(IPR) 신청인은 적어도 신청인이 각 무효의 근거로 신청서에서 의존한 것과 동일한 선행기술의 실시예에 의존할 때, IPR 개시 후 특허심판위원회 (“위원회”)가 채택한 새로운 청구항 해석을 통지하고 대응할 수 있는 권리와 기회를 가진다.

## Background

Axonics, Inc. (“Axonics”) initiated inter partes review of Medtronic, Inc. (“Medtronic”) patents 8,457,758 and 8,738,148 (“the ‘758 and ‘148 patents”). The patents share a common specification, and are directed to transcutaneous charging of implanted medical devices (from an “external power source”

to an “internal power source”). Claim 1 of the ‘758 patent, designated by the parties as representative of the case, includes two clauses reciting that the external power source automatically varies power output in response to inputs from the internal power source. The first clause recites that the power is varied based on a “value associated with” current passing through the internal power source, and the second clause recites that the power is varied based on a “measured current associated with” the current passing through the internal power source.

In the petition, Axonics argued that the claims were obvious by applying a “single input” interpretation in which the “measured current” of the second clause is a species of the “value” recited in the first clause, and therefore narrows the scope of the “value” to the “measured current.” After the Board’s institution decision, which was based on the single input construction of Axonics, Medtronic responded asserting a “two input” interpretation in which each clause recites a separate input on which variation of the power output is based, requiring that the “value” be something other than the “measured current.” Axonics replied, defending the single input construction, and additionally arguing that the cited references made the claims invalid even under the two input construction, and submitting an expert declaration in support. Medtronic filed a sur-reply supporting its position, and also arguing that Medtronic must be afforded an opportunity to submit its own expert declaration, without expressly seeking leave to do so.

The Board adopted the two input construction in its final decision, and refused to consider Axonics’ invalidity arguments under that construction as improper reply arguments not submitted with the original petition.

### Holding

The Court of Appeals for the Federal Circuit (“Federal Circuit”) remanded the case for the Board to consider invalidity arguments under the two input construction.

### Discussion

In its final decision, adopting the new claim construction, the Board stated that a reply “may not offer an entirely new rationale based on a new combination of elements in the asserted references to show unpatentability based on what amounts to a new ground not set forth in the Petition.”

The Federal Circuit countered that “where a patent owner in an IPR first proposes a claim construction in a patent owner response, a petitioner must be given the opportunity in its reply to argue...under the new construction, at least where it relies on the same embodiments for each invalidity ground as were relied on in the petition.” The court reviewed numerous cases in which the Board had adopted a claim construction in its final decision that was different from a claim construction adopted at institution. In all cases, the Federal Circuit had repeatedly held that parties must be given notice and an opportunity to argue under the new construction. The court cautioned, however, that “[w]e leave for

another day the question of whether, when presented with a new claim construction, a petitioner can rely in its reply on new embodiments from the prior art references that were relied on in the petition.”

## UNCLEAR SALES DATA FAILED TO SHOW COMMERCIAL SUCCESS

By [Josh Hauptman](#)

[Incept LLC v. Palette Life Scis., Inc.](#), Appeal No. 2021-2063  
(Fed. Cir. Aug. 16, 2023, Newman, [Schall](#), Taranto, precedential)

- In appeals, avoid issues subject to extensive substantial evidence review. Commercial success arguments should be based on actual product sales, and establishing a showing of commercial success should be supported by clear accounting records.
- 在上诉中，避免需要大量实质性证据审查的问题。商业成功的论据应该以实际的产品销售为基础，建立商业成功的证明应该有清晰的会计记录支持。
- 控訴審において、広範囲に及ぶ証拠の実質検討の問題提起を避けるべきである。商業的成功の議論は実際の製品の販売に基づくべきであり、かつ商業的成功の証明の成立は明確な会計記録にて裏付けられるべきである。
- 항소심에서 광범위한 증거의 실질적 검토 문제를 제기하는 것은 피해야 한다. 상업적 성공에 대한 논의는 실제 제품 판매에 근거해야 하며, 상업적 성공의 입증은 명확한 회계 기록으로 뒷받침되어야 한다.

This case revolves around a legal dispute between Incept and Palette concerning patent claims centered on innovative methods for treating cancer using injected fillers. Incept owns patents outlining techniques to reduce radiation exposure to non-target tissue during cancer treatment by employing injected gel fillers that are biocompatible and biodegradable between specific tissue areas. Palette challenged the validity of these patents, arguing that the claimed methods were anticipated by, or obvious from, a prior patent by Wallace. Wallace teaches use of biocompatible gels for organ displacement, which include hydrolysable segments and are formed from injectible reaction mixtures. Wallace specifically teaches that such materials can be used for radiation treatment. The Board held all claims anticipated by, or obvious from, Wallace. The Court of Appeals for the Federal Circuit conducted a comprehensive review of the case and affirmed the holding by the Board.

Regarding anticipation, the court found no legal error in the Board’s conclusion. The central question in reviewing the Board’s decision was whether the Board’s approach in combining various teachings from Wallace’s patent to find anticipation of Incept’s claims was flawed and whether Wallace teaches all elements recited in Incept’s claims. The court determined that the Board had not committed any legal errors in basing a conclusion of anticipation on different elements from Wallace, as Wallace’s patent indeed contained the features outlined in Incept’s claims. Noting that Incept claims are not drawn to a species of a genus disclosed by Wallace, but are directed to fillers having certain general qualities, the court explained that the compositions of Wallace are described as having those same general

qualities. The court also explained that Wallace teaches compositions that are "entirely removable by biodegradation" and could be placed "between an organ and nearby tissue," based on the evidence presented and expert testimonies.

Regarding obviousness, the primary inquiries included whether the Board's analysis of one patent's obviousness was compromised by a faulty anticipation analysis of another patent and whether the Board overlooked Wallace's alleged teachings that suitable polymers are nondegradable in vivo. The court stated that, having found the Board's anticipation analysis without flaw, it would not have been error to rely on such analysis to support its conclusion of obviousness. The court also clarified that Wallace's apparent preference for nondegradable polymers did not discourage or discredit degradable alternatives.

The court additionally addressed Palette's allegations that the Board had inadequately considered dependent claims' time limits for biodegradability and had established an unduly stringent standard for proving commercial success. The court supported the Board's finding that a teaching in Wallace of "suitable" polymers that are nondegradable in vivo "over a period of at least several months" amounts to at least a suggestion that those polymers are degradable in vivo after several months, and observed that Incept did not argue for patentability of these dependent claims before the Board. Regarding commercial success, the court agreed with the Board's assessment that Incept's evidence of shipment volume did not sufficiently identify how much of the volume was due to sales, free samples, or replacement shipments, and so did not adequately support a presentation of commercial success to counter the conclusion of obviousness.

In summary, the case underscored Incept's efforts to reinterpret the Board's findings and reevaluate prior art within the context of patent anticipation and obviousness. The Federal Circuit emphasized its role in reviewing existing evidence rather than generating new findings. Notably, arguments about evidence of commercial success required that the evidence identify actual sales of the product in question.

## WHEN NEW ARGUMENTS CAN BE RAISED IN IPR PROCEEDINGS

*By Bobbie Wu*

[\*Rembrandt Diagnostics, LP. v. Alere, Inc.\*](#), Appeal No. 2021-1796  
(Fed. Cir., August 11, 2023, Moore, Dyk, Reyna)

- An IPR petitioner can bring new theories and evidence if the new theories and evidence are responsive to arguments by the patentee or observations of the Board, and are sufficiently connected with previously raised arguments.
- 如果新的理论和证据能够回应专利权人的论点或委员会的意见，并且与先前提出的论点有充分的联系，知识产权申请人可以提出新的理论和证据。
- IPR 申立人は、特許権利者の反論あるいは審判部の所見に呼応しかつ以前提起された議論と関連しているのであれば、新たな理論と証拠を持ち出すことができる。

- IPR 신청인은 특허권자의 반론 또는 위원회의 판단에 호응하고 이전에 제기된 주장과 관련이 있는 경우 새로운 이론과 증거를 제시할 수 있다.
- In an IPR, a specific objection to one ground of invalidity newly presented in a reply might be insufficient to apply to all new grounds of invalidity presented in the reply.
- 在知识产权中，对答复中新提出的一种无效理由的具体反对可能不足以适用于答复中提出的所有新的无效理由。
- IPR において、答弁書の中で新たに示された 1 つの無効理由に対する特定の異議は、その答弁書の中で提起された新たな無効理由のすべてに適用するには不十分であろう。
- IPR 에서 답변서에 새롭게 제시된 하나의 무효사유에 대한 특정 이의제기는 답변서에 제기된 모든 무효사유에 적용하기에는 불충분할 수 있다.
- An expert declaration is helpful in rebutting an opponent’s expert declaration.
- 专家声明有助于反驳对方的专家声明。
- 専門家の宣誓供述書は、相手側の専門家の宣誓供述書に反駁するために有益である。
- 전문가 진술서는 상대방의 전문가 진술서를 반박하는 데 도움이 된다.

**Background:**

Rembrandt sued Alere for infringement of U.S. Patent No. 6,548,019, and Alere petitioned for IPR challenging the validity of claims 1-6 and 9-15 of the ‘019 patent. Initially, the Board instituted only on certain grounds and declined to review claims 6 and 10. After institution, Rembrandt disclaimed claims 1, 9, and 11-15, leaving claims 2-5 for the Board to review. In its final decision, the Board held that claim 2 was anticipated, but that Alere had failed to prove claims 3-5 were unpatentable. Alere appealed and the Court of Appeals for the Federal Circuit remanded for the Board to consider all challenged claims and grounds.

On remand to the Board, Rembrandt filed a patent owner response addressing those grounds without an accompanying expert declaration. Alere filed a reply with expert declaration responding both to Rembrandt’s arguments and to the observations the Board raised in its original institution decision. On sur-reply, Rembrandt argued that Alere proposed new theories in their reply which should be discarded by the Board as grounds not petitioned. Rembrandt’s argument regarding new theories of unpatentability submitted in a reply was only asserted, however, with respect to some grounds of unpatentability alleged by Alere. Rembrandt only made a general objection for other grounds of unpatentability, which were at issue in the present appeal. Eventually, the Board found claims 3-6 and 10 were unpatentable, and Rembrandt brought the present appeal.

**Holding:**

The Federal Circuit concluded that the Board could rely on Alere’s theories and evidence, and that substantial evidence supports the Board’s unpatentability determinations.

## Discussion:

The court agreed that Rembrandt forfeited its argument that Alere offered new theories with respect to the issues on appeal, because Rembrandt expressly objected to only one obviousness ground for allegedly raising new theories after institution, but did not make the same objection to other grounds at issue. Rembrandt's general objection was insufficient to constitute a proper objection to a new argument made in a reply. The court held that the general objection would provide inadequate notice of which theories are allegedly new, in the context of the specific ground of obviousness, and would provide the Board with inadequate basis to consider the question.

The court further concluded that Alere's responsive reply arguments do not constitute new theories, and the Board did not abuse its discretion in considering them. The court explained that there is no blanket prohibition on introducing new evidence in replies, so long as the new evidence is responsive or supportive to prior raised arguments, and so long as the opposite party has notice of the new evidence and opportunity to respond to it. The court found that Alere's reply argument discussing cost and efficiency was responsive to Rembrandt's prior argument questioning motivation to combine teachings and to the Board's observations. The court also found that Alere's reply argument involves the same legal ground based on the same prior art references and the same legal argument that was raised in the petition.

Finally, the court held that the Board's obviousness determinations are supported by substantial evidence, because Rembrandt provided no credible rebuttal to the conclusions of Alere's expert regarding how a skilled artisan would have interpreted disclosures of the prior art. The court found Alere's expert testimony adequate to support the Board's factual findings, and unrebutted by any similarly credible evidence from Rembrandt.

## **SOLICITOR GENERAL URGES NEW INTERPRETATIONS OF SECTION 101**

*By Bobbie Wu*

### *BRIEF FOR THE UNITED STATES AS AMICUS CURIAE RE: (1) Interactive Wearables, LLC v. Polar Electro Oy and (2) Tropp v. Travel Sentry, Inc.*

United States Supreme Court Appeal Nos. 21-1281 and 22-22

(Amicus Brief filed April 5, 2023)

(Cert denied in each appeal May 15, 2023)

- The Solicitor General argues that the claims in *Interactive Wearables v. Polar Electro Oy* are patent-eligible, that in the lower courts the claims were subjected to unreasonable abstraction at Alice Step Two, and that the lower court's § 101 analysis improperly conflated §§ 102, 103 and/or 112 with § 101.
- 副检察长辩称，*Interactive Wearables 诉 Polar Electro Oy* 案中的权利要求符合专利资格，在下级法院，这些权利要求在 Alice 准则第二步中被不合理的抽象化，并且下级法院的对于第101条的分析不恰当地将第102、103和/或112条与第101条混为一谈。

- 訴訟長官 ( Solicitor General ) は、Interactive Wearables 対 Polar Electro Oy事件においてクレームが、下級審ではそのクレームがAlice判決ステップ2において不合理な抽象的概念とされたが、特許適格性があるとされている、と反論している。また、その下級審の101条の解析は102条、103条および / あるいは112条と101条とを、不適切に融合している、と反論している。
- Solicitor General은 Interactive Wearables v. Polar Electro Oy 사건에서 하급심에서 해당 청구항이 Alice 판결 2단계에서 불합리한 추상적 개념으로 판단되었으나, 특허적격성이 있다고 판단하였다고 반박하고 있다. 또한, 그 하급심에서 101조에 대한 분석은 102조, 103조 및/또는 112조와 101조를 부적절하게 융합하고 있다고 반박하고 있다.
- The Solicitor General argues that the claims in Tropp v. Travel Security are not patent-eligible because the claims recite nothing that transforms non-technological abstract ideas at the core of the claimed method into something technological in character.
- 副檢察長辯稱・Tropp诉Travel Security案中的权利要求不符合专利资格，因为这些权利要求没有提及任何将所要求方法核心的非技术抽象概念转化为技术特征的内容。
- 訴訟長官 ( Solicitor General ) は、Tropp 対 Travel Security事件においてクレームが、クレームされた方法の核心において非技術的な抽象的概念を性質上技術的な何かに変換したに過ぎないことを理由として、特許適格性がないと反論している。
- Solicitor General은 Tropp v. Travel Security 사건에서 청구항이 청구된 방법의 핵심에서 기술적인 추상적 개념을 본질적으로 기술적 개념으로 변환한 것에 불과하다는 이유로 특허적격성이 없다고 반박하고 있다.
- In view of the positions taken by the Solicitor General in this brief, it may be beneficial to argue, in some cases, that Examiners improperly adopt a high degree of abstraction or emphasize prior art in section 101 analyses.
- 鉴于副檢察長在本摘要中所持的立场，在某些情况下，主张审查员在第101条分析中不恰当地采用高度抽象或强调现有技术可能是有益的。
- 訴訟長官 (Solicitor General) がこの書面の中で取った立場を考慮すると、ある場合においては、当該審査官が101条の解析において高度の抽象的概念を承認したことあるいは先行技術を強調したことが不適切である、と反論することは有益であろう。
- Solicitor General의 입장을 고려할 때, 어떤 경우에는 해당 심사관이 101조 분석에서 고도의 추상적 개념을 승인하거나 선행기술을 강조한 것이 부적절하다고 반박하는 것이 도움이 될 수 있다.

## Background

In *Interactive Wearables*, the Eastern District of New York (EDNY) found patent claims invalid as being directed to patent-ineligible subject matter and granted a motion to dismiss. The Federal Circuit

affirmed via nonprecedential, per curiam decision. Patent owner IW petitioned for a writ of certiorari, and the Supreme Court invited the Solicitor General (SG) to file an amicus brief.

In *Tropp*, the EDNY found patent claims invalid as being directed to patent-ineligible subject matter at summary judgment. The Federal Circuit affirmed via nonprecedential, per curiam decision. Patent owner Tropp petitioned for a writ of certiorari, and the Supreme Court invited Solicitor General to file an amicus brief.

The Supreme Court denied the certiorari petitions in each case.

## Discussion

Regarding unreasonable abstraction, and in the context of *Interactive Wearables*, the SG argues that any abstraction of a claim, for purposes of analysis under section 101, should be reasonable. In general, technologies and industrial processes are not abstract ideas. Accordingly, the abstract-idea exception does not apply to objects such as automobiles, remote controls, cameras, and the like. The claims in *Interactive Wearables* directly recite a receiver, a processor, a memory, a first display and an audio player, and indirectly recite a wireless remote-control device and a second display. The claims thus recite various electronic hardware that together make up a mechanical device. The lower court's *Interactive Wearables* characterization of the claims as directed to the abstract idea of "providing information in conjunction with media content" represents an unreasonable level of abstraction at Step Two of the *Alice* test, denying the technological core of the claims.

Regarding the conflation of analyses, and in the context of *Interactive Wearables*, the SG acknowledged that analyses under 35 U.S.C. §§ 102-103 may sometimes overlap with the patent-eligibility analysis under 35 U.S.C. § 101 in light of *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 90 (2012). The SG argued, however, that § 102, § 103 and/or § 112 analyses should not be conflated with § 101 analysis, i.e., the *Alice* test, as was done by the lower courts in *Interactive Wearables*. According to the SG, the decisions below apply modified versions of anticipation and obviousness doctrine in the guise of a Section 101 analysis, unmooring those doctrines from the statutory text and diminishing their analytical rigor. Section 101 and the abstract-idea exception screen out the sorts of nontechnological innovations that do not warrant patent protection even if they are novel and nonobvious, are enabled and have an adequate written description. Even assuming that the *Interactive Wearables* claims recite in part an abstract idea, the SG urges that the claims also recite elements that transform the abstract idea into a technological application which is patent eligible.

Regarding the transformation of a non-technological abstract idea into something technological in character, and in the context of *Tropp*, the SG argues that the abstract-idea exception includes methods of organizing human activity, e.g., strategies for achieving non-technical aims such as improved techniques for ordering economic relationships and fundamental economic practices. According to the SG, the claims in *Tropp* recite the abstract idea of coordinating luggage inspection by marketing to consumers a 'special' lock that the Transportation Security Administration (TSA) has agreed to treat in a particular way. However, the claims do not positively recite a physical device, i.e., do not positively recite the special lock. Rather, the claims are drawn to a method of improving airline inspection including steps of making the special lock available to consumers (offering for sale), marketing the special lock and alerting/reminding agreement participant (luggage screening entity) of contractual obligation (agreement to process in accordance with special procedure). As such, the SG argues that claims merely recite strategies for achieving non-technical aims.



It is worth noting certain correspondence between arguments made by the SG in this brief and older patent eligibility results from cases adhering to the Freeman-Walter-Abele doctrine. For example, *In re Iwahashi*, 12 USPQ2d 1908 (Fed. Cir. 1989) (claim reciting means plus function elements plus a read-only memory (ROM) held statutory because of ROM); and *In re Alappat*, 31 USPQ2d 1545 (Fed. Cir. 1994) (statutory claim reciting all mean plus function elements accorded substantial weight), may be viewed more favorably by the United States Patent and Trademark Office.

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