Appeal Nos. 22-1136, -1186

United States Court of Appeals

for the

Federal Circuit

C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.,

Plaintiffs-Appellants,

v.

MEDICAL COMPONENTS, INC.,

Defendant-Cross-Appellant.

Appeal from the United States District Court for the District of Utah,
Case No. 2:12-cv-00032-RJS-DAO, Judge Richard J. Shelby

RESPONSE AND REPLY BRIEF OF APPELLANTS C.R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.

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INTRODUCTION & SUMMARY OF ARGUMENT

MedComp and its amici strain to avoid this Court's decision in *C.R. Bard Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372 (Fed. Cir. 2020) ("*AngioDynamics*"), which rejected an almost identical eligibility challenge to the same technology at issue here. There is no principled distinction between this case and *AngioDynamics*. Even the district court acknowledged that its decision is in "tension" with *AngioDynamics* (Appx00028 n.138); that tension cannot be resolved. *AngioDynamics* controls and compels reversal of the district court's judgment.

In *AngioDynamics*, this Court applied well-established precedent of the Supreme Court and this Court to hold that Bard's claims reciting radiopaque identifiers affixed to power injectable ports were directed to patent-eligible subject matter at *Alice* step one as a matter of law. That decision is entirely correct and is the binding law.

MedComp repeatedly, and often subtly, asks this Court to revisit its § 101 and printed matter jurisprudence. It contends that a claim is not patent eligible if it includes or implicates printed matter. But this Court has squarely held that a claim must be "directed solely" to printed matter to warrant invalidation under § 101, *see AngioDynamics*, 979 F.3d at 1375, 1383. MedComp seeks to inject novelty into the § 101 analysis, when both

the Supreme Court and this Court have unambiguously held that questions of ***novelty*** are reserved for anticipation and obviousness challenges under § 102 and § 103, *see Diamond v. Diehr*, 450 U.S. 175, 188-90 (1981); *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1372 (Fed. Cir. 2020), *cert. denied sub nom.*, 141 S. Ct. 1266 (2021). MedComp argues that the ***means*** of conveying information constitute printed matter, when this Court has expressly held, in reviewing the eligibility of the same technology, that it is the ***content*** of information that implicates the printed matter doctrine, not the means of conveying information, *see AngioDynamics*, 979 F.3d at 1384. None of these *Alice* step one arguments has the slightest merit.

MedComp and its amici fall equally flat in defense of the district court's *Alice* step two ruling. In *AngioDynamics*, this Court held that evidence showing that radiographic identifiers were placed on various types of implantable medical devices was insufficient to establish as a matter of law that the "ordered combination" of a power injectable port and a radiographic marker identifying the port as power injectable lacked an inventive concept. 979 F.3d at 1384. Yet MedComp continues to insist that the Court should look to identification of any type of medical device when assessing *Alice* step two. Applying the correct legal standard, MedComp's *Alice* step two argument fails—MedComp cites to only a ***single*** prior art

patent that uses a radiographic marker for a ***different*** type of port and for a ***different*** purpose.

For these reasons, the judgment below cannot stand. And, because MedComp's barebones cross-appeal lacks any substantive argument, in no event should the judgment of invalidity as to MedComp's patents be disturbed.

ARGUMENT

I. MEDCOMP IS UNABLE TO DEFEND THE DISTRICT COURT'S *ALICE* STEP ONE RULING AS TO BARD'S PATENTS

A. MedComp Cannot Avoid This Court's Controlling *AngioDynamics* Decision

This Court already has considered patent-eligibility issues on Bard patents directed to indistinguishable technology and held that the use of radiographic markers to identify a port as being power injectable is patent-eligible subject matter. *See AngioDynamics*, 979 F.3d at 1375, 1384. The district court's ruling below is irreconcilable with *AngioDynamics* and should be reversed.

1. *AngioDynamics* Is Directly On Point

In *AngioDynamics*, this Court held, as a matter of law, that claims reciting radiopaque identifiers affixed to power injectable ports were directed to patent-eligible subject matter at *Alice* step one. This Court

explained that "[w]hen each claim is read as a whole, the focus of the claimed advance is not solely on the content of the information conveyed, ***but also on the means by which that information is conveyed***." 979 F.3d at 1384 (emphasis added). Specifically,

> the claimed invention is described in the patents as satisfying a specific need for easy vascular access during CT imaging, and it is the radiographic marker in the claimed invention that makes the claimed port particularly useful for that purpose because the marker allows the implanted device to be readily and reliably identified via x-ray, as used during CT imaging.

Id.

Here, the asserted claims of the '302 and '022 patents also recite radiopaque identifiers affixed to power injectable ports. Appx00114-00115; Appx00177. Under *AngioDynamics*, those claims too are directed to patent-eligible subject matter at *Alice* step one. The same rationale at *Alice* step one applies to the '615 patent, which differs from the '302 and '022 patents only in the means used to convey information—an identifying structural feature rather than a radiographic marker. Appx00220-00221.

To conclude otherwise would not only create a conflict among panels of this Court, *see, e.g.*, *In re Rudy*, 956 F.3d 1379, 1383 (Fed. Cir. 2020), but also would wrongly allow patent eligibility to be "turned and twisted in any direction" so that patents directed to the same type of invention could have conflicting eligibility determinations, *Parker v. Flook*, 437 U.S. 584, 590

(1978); *see Accenture Glob. Servs., GmbH v. Guidewire Software, Inc.*, 728 F.3d 1336, 1344 (Fed. Cir. 2013) (where claims "contain only 'minor differences in terminology [but] require performance of the same basic process,' they should rise or fall together") (citing *CLS Bank Int'l v. Alice Corp.*, 717 F.3d 1269, 1291 (Fed. Cir. 2013)); *CLS Bank*, 717 F.3d at 1274 n.1 (Lourie, Dyk, Prost, Reyna, & Wallach, JJ., plurality opinion) ("[E]ight judges, a majority, have concluded that the particular method, medium, and system claims at issue in this case should rise or fall together in the § 101 analysis.").[1]

MedComp and amici concede, as they must, that the legal standard set forth in *AngioDynamics* is controlling here, but they nevertheless maintain (MedComp Br. 10-12, 31-33, 36-38; Smiths Br. 2-3; AngioDynamics Br. 4, 16, 26-27) that the result in *AngioDynamics* is not controlling here based on supposed differences in the factual records, claim scope, and theories of

[1] Neither of the two cases amicus Smiths cites (Br. 4) permits inconsistency in patent eligibility decisions of this Court, particularly with respect to *Alice* step one, a purely legal question. One case concerned the relationship between decisions of federal agencies and this Court. *See Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1428 (Fed. Cir. 1988) ("Once again, it is important that the district court and the PTO can consider different evidence. Accordingly, different results between the two forums may be entirely reasonable."). The second case dealt with the applicability of collateral estoppel to competing decisions of the CCPA and Ninth Circuit with respect to the validity of a patent. *Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 708-09 (Fed. Cir. 1983).

ineligibility. None of these arguments has merit. They are merely after-the-fact attempts to justify a result that is not reconcilable with the Court's precedent.

First, any alleged difference in the records of *AngioDynamics* and this case is irrelevant because "*Alice* step one presents a legal question that can be answered based on the intrinsic evidence." *CardioNet*, 955 F.3d at 1372; *see id.* at 1374 ("The [step one] analysis does not require a review of the prior art or facts outside of the intrinsic record regarding the state of the art at the time of the invention."). The operative records are the claims at issue in each of these cases and there is, for purposes of the *Alice* step one analysis, nothing different between these "records." *AngioDynamics* held that the claims there were patent eligible as a matter of law at *Alice* step one based on the specification and claims. 979 F.3d at 1384. That holding did not depend, in any way, on any particular evidence in the record there that is not present here.

Second, contrary to amicus Smiths' argument (Br. 4-5), there is no material difference between the scope of the claims here and in *AngioDynamics*. As a threshold matter, the Court should decline to consider this argument not presented by MedComp. *See, e.g.*, *Christian v. United States*, 337 F.3d 1338, 1345 (Fed. Cir. 2003) ("Since none of the parties has

made or adopted either argument [offered by amici], we decline to consider them."). Regardless, the minor differences in claim language that Smiths identifies (Br. 4-5)—the presence of "limitations to specific flow rates or pressures such that the port is capable for power injection" in the claims asserted in AngioDynamics but not here—are irrelevant given this Court's authoritative construction of the patents-in-suit in *Port I*. There, this Court "construe[d] [the asserted claims of the '302, '022 and '615 patents] to mean that the claimed access port is power injectable." *C.R. Bard, Inc. v. AngioDynamics, Inc.*, 748 F. App'x 1009, 1016 (Fed. Cir. 2018) ("*Port I*"). Smiths' purported distinction in the claim language is thus illusory.

Third, amicus Smiths also wrongly asserts (Br. 5; *see* Br. 17-20) that the district court "examined an issue not considered in *AngioDynamics*, i.e. whether the claims were directed to the abstract idea of communicating information." ***AngioDynamics made precisely that argument to this Court***, contending that "Bard's claims embrace the ***abstract idea of using associated markings to communicate information*** about a port." No. 19-1756, D.I. 43 at 52 (emphasis added). This was not a stray comment but was

the lodestar of AngioDynamics' appeal.[2] This Court considered it and reversed the judgment of invalidity.[3]

There thus is no relevant difference in the record, the claims, or the theory of eligibility that could support holding the *AngioDynamics* claims patent eligible while holding these Port ID patents ineligible. Thus, like *AngioDynamics*, the asserted claims here are eligible at step one.

2. MedComp, Like The District Court, Misplaces Reliance On *Secured Mail*

In conducting the *Alice* step one inquiry (Appx00030-00032), the district court did not cite *AngioDynamics* even once and instead analogized Bard's claims to the claims at issue in *Secured Mail Solutions LLC v. Univ.*

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[2] The briefing for *AngioDynamics* included headings titled: "The Claims Are ***Directed To The Abstract Idea Of Identifying*** A Port's Intended Use By Perceiving A Label" and "Bard's Claims Fail Step One Of The *Alice* Test Because They Are All ***Directed To An Abstract Idea.***" No. 19-1756, D.I. 43 at 51 (emphases added). AngioDynamics argued that "[t]he Asserted Claims were exposed at trial as an improper attempt to ensnare port structure long existing in the art by ***attempting to patent the mental step of identifying a port as power-injectable*** via a label" and were "***directed to identifying an access port's intended use via an 'identifiable feature'*** and … ***directed to the human mind***." *Id.* at 38, 41, 51 (emphases added).

[3] In petitioning for rehearing, AngioDynamics itself recognized that this Court's decision resolved its "communicating information" theory of ineligibility. *See* No. 19-1756, D.I. 76 at 4, 16 (arguing that "the panel's reversal of the trial court's § 101 judgment has the unjust effect of precluding AngioDynamics from raising its ineligibility defense at trial," and "is highly prejudicial because it forecloses [its] ability" to reargue patent eligibility).

Wilde, Inc., 873 F.3d 905 (Fed. Cir. 2017). That choice was erroneous given the clear similarity between the technology and issues here and in *AngioDynamics*. MedComp (Br. 24, 54-55) and amici (AngioDynamics Br. 5-7; Smiths Br. 17-20) attempt to justify the district court's choice to focus on that less relevant decision, but never even argue, let alone show, that the claims here are more analogous to the *Secured Mail* claims than to the claims in *AngioDynamics*. To do so would strain credulity given how closely the claims here parallel those at issue in *AngioDynamics* (*see supra*, at 4-7).

In *Secured Mail*, the claims were directed to "[a] method of verifying mail identification data" and "[a] method for providing electronic data to a receipt of a mail object" and focused on using generic computer technology to perform "tasks for which a computer is used in its ordinary capacity." 873 F.3d at 908-11 (claim limitations included: "[g]enerating, by a processor," data; "storing" data; "receiving" data; and "providing" data "via said network."). For those claims, "***each step*** of the process [was] directed to the abstract process of communicating information about a mail object using a personalized marking." *Id.* at 911 (emphasis added). In contrast, the claims here, like those in *AngioDynamics*, when "read as a whole," do not focus "solely on the content of the information conveyed, but also on the

means by which that information is conveyed." 979 F.3d at 1384.[4] The claims here, unlike those in *Secured Mail*, also contain structural limitations defining a power injectable port. *Port I*, 748 F. App'x at 1016; Appx00115; (e.g., limitations including "a housing having an outlet" and "a needle-penetrable septum").

Similarly, MedComp's (Br. 24, 54-55) and amici's (Smiths Br. 17-20; AngioDynamics Br. 5-7) attempts to defend the district court's conclusion that, like the claims in *Secured Mail*, Bard's claims "are not directed to an improvement in port technology" (Appx00031) are without merit. Bard's patents claim an important new functionality—the ability to determine the type of port after implantation. As this Court recognized in *Port I*, this new functionality is critical for patient safety: "[P]ower injecting a non-power injectable port can cause serious injury or death. Distinguishing between the two types of ports is the crux of what the patents claim." 748 Fed. App'x at

[4] AngioDynamics itself extensively relied on *Secured Mail* to make the same analogy as the district court did here, arguing that Bard's claims at issue there bore "a striking resemblance" to the *Secured Mail* claims. No. 19-1756, D.I. 43 at 52-53. Yet, this Court rejected that argument and held that Bard's claims, unlike the *Secured Mail* claims, were patent eligible.

1016.[5] Similarly, in *AngioDynamics*, this Court recognized the added functionality that the radiopaque marker provides:

> [T]he claimed invention is described in the patents as satisfying a specific need for easy vascular access during CT imaging, and it is the radiographic marker in the claimed invention that make the claimed port particularly useful for that purpose because the marker allows the implanted device to be readily and reliably identified via x-ray, as used during CT imaging.

979 F.3d at 1384.

Smiths (Br. 19-20) wrongly argues that this new functionality is no different than the mail identifier in *Secured Mail*. But, in *Secured Mail*, "[t]he claims of the three sets of patents [were] *not* limited by rules or steps that establish how the focus of the methods is achieved." 873 F.3d at 911 (emphasis added). In contrast, Bard's claims are directed to the specific means—radiopaque markers and unique structural features—that enable the port to become identifiable post-implantation.

B. MedComp's Proposed Printed Matter Standard Is Riddled With Legal Errors

Unable to support the district court's judgment of invalidity under existing law, MedComp and amici push for a fundamental expansion of the

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[5] Additionally, on remand, the PTAB found that each of the claims asserted here were patentable over the cited prior art based, *inter alia*, on the claim requirement limiting the asserted claims to power injectable ports. *See See AngioDynamics, Inc. v. C.R. Bard, Inc.*, Appeal 2015-001533, 2019 WL 411125, at *3; Appeal 2015-004506, 2019 WL 411126, at *2; Appeal 2015-004554, 2019 WL 411127, at *3 (P.T.A.B. Jan. 28, 2019).

printed matter doctrine in no fewer than four ways. Most of their arguments are foreclosed by binding precedent, and all of them are inconsistent with the focus of the printed matter doctrine—which is to ascribe no patentable weight to elements that claim the content of information, not to act as a poison pill to invalidate claims to a physical apparatus like a power injectable port.

1. A Claim Is Not Invalid Under Section 101 Simply Because It Includes Printed Matter

MedComp's efforts to lower the high bar for ineligibility fail. In *AngioDynamics*, this Court held that "a claim may be found patent ineligible under § 101 on the grounds that it is *directed solely* to non-functional printed matter and the claim contains no additional inventive concept." 979 F.3d at 1383 (emphasis added). This makes sense; printed matter is entitled to no patentable weight when distinguishing the prior art because the printed matter is, itself, not patent eligible. *Praxair Distribution, Inc. v. Mallinckrodt Hosp. Prod. IP Ltd.*, 890 F.3d 1024, 1032 (Fed. Cir. 2018) ("Claim limitations directed to the content of information and lacking a requisite functional relationship are not entitled to patentable weight because such information is not patent eligible subject matter under 35 U.S.C. § 101."). But the addition of an element claiming the content of information does not render elements not directed to informational content ineligible.

Unless the entirety of a claim is "directed solely" to printed matter, the claim as a whole still is patent eligible.

Under that standard, Bard's claims are plainly not patent ineligible due to printed matter. The asserted claims recite radiopaque identifiers or identifying structural features on a power injectable port. Appx00114-00115; Appx00177; Appx00220-00221. Neither the identifiers nor the port itself is printed matter. The only portion of the claims that implicates the printed matter doctrine is the informational content conveyed by the identifiers. A claim is not solely directed to printed matter because it relates to or implicates informational content. *See, e.g.*, *In re Lowry*, 32 F.3d 1579, 1583 (Fed. Cir. 1994) ("Lowry's invention manages information"; "[w]hile the information content affects the exact sequence of bits stored in accordance with Lowry's data structures, the claims require specific electronic structural elements which impart a physical organization on the information stored in memory.").

Unable to prevail under the "directed solely to" standard, MedComp subtly seeks (*e.g.*, Br. 35) to rewrite that standard to require invalidation whenever claims "include" patent-ineligible matter, in effect allowing an ineligibility determination based on the mere presence of printed matter in a claim. Not only is this argument foreclosed by *AngioDynamics*, but it runs

headlong into other decisions of this Court holding that "to preclude the patenting of an invention simply because it touches on [patent ineligible subject matter] would 'eviscerate patent law.'" *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016) (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012)); *see id.* ("it is not enough to merely identify a patent-ineligible concept underlying the claim; we must determine whether that patent-ineligible concept is what the claim is 'directed to'"). Courts "must consider the claim ***as a whole*** to determine whether the claim is ***directed to*** [patent ineligible subject matter] or something more." *Data Engine Techs. LLC v. Google LLC*, 906 F.3d 999, 1011 (Fed. Cir. 2018) (emphasis added).[6] *AngioDynamics* establishes that "something more" is present here.

Nor do this Court's decisions in *ChargePoint, Inc. v. SemaConnect, Inc.* 920 F.3d 759 (Fed. Cir. 2019), and *Yu v. Apple Inc.*, 1 F.4th 1040 (Fed.

[6] *Cf. In re TLI Commc'ns LLC Pat. Litig.*, 823 F.3d 607, 611 (Fed. Cir. 2016) ("[I]n determining whether the claims are directed to an abstract idea, [courts] must be careful to avoid oversimplifying the claims because '[a]t some level, 'all inventions ... embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.'"") (citations omitted); *FairWarning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089, 1094 (Fed. Cir. 2016) ("even though a claim can be abstracted to the point that it reflects a patent-ineligible concept … that claim may nevertheless be patent eligible if the claim language is directed to a patent-eligible *application* of that concept") (quotation marks, alterations, and citation omitted).

Cir. 2021) (both cited in AngioDynamics Br. 9), support MedComp's and amici's argument that claims are directed to patent-ineligible subject matter wherever they merely implicate an abstract idea. In *ChargePoint*, this Court held that method claims reciting "a communication network for [vehicle] charging stations" were directed to an abstract idea because "the broad claim language would cover ***any mechanism*** for implementing network communication on a charging station, thus *preempting the entire industry*'s ability to use networked charging stations." *Id.* at 768, 770, 773 (emphasis added); *see id.* at 773 ("[c]ommunication over a network for that purpose has been and continues to be a 'building block of the modern economy'"). Similarly, in *Yu*, this Court held that claims reciting an "improved digital camera" were directed to "the abstract idea of taking two pictures … and using one picture to enhance the other in some way," 1 F.4th at 1043, not to a particular configuration of which the abstract idea would be but a part, and thus the claimed invention "[wa]s simply a generic environment in which to carry out the abstract idea," *id.* at 1044.[7]

[7] *See also Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285, 1298 (Fed. Cir. 2020) (cited in AngioDynamics Br. 9) ("Claim 22 here simply instructs the reader to tune the liner to achieve a claimed result, without limitation to particular ways to do so. This holding as to step 1 of *Alice* extends only where, as here, a claim on its face clearly invokes a natural law, *and nothing more*, to achieve a claimed result.") (emphasis added).

Thus, *Alice* step one turns not on whether a claim includes or implicates patent-ineligible subject matter, but whether the claim ***as a whole***, assessing both breadth and preemption concerns, is directed to patent-ineligible subject matter.

2. Novelty Is Irrelevant To The Section 101 Analysis

MedComp (Br. 39-41, 51-54) and amici (AngioDynamics Br. 7-8; Smiths Br. 11) are also wrong to the extent they maintain that Bard's claims are directed solely to printed matter because the novelty lies in the identifiers. Those features are not printed matter (*see infra*, at 18-23), but even if they were this effort to import novelty into the § 101 inquiry is contrary to well-established law. "The 'novelty' of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter." *Diehr*, 450 U.S. at 188-89. Rather, the question of novelty "is reserved for §§ 102 and 103." *Data Engine*, 906 F.3d at 1011. As this Court recently reiterated in *CardioNet*:

> [S]ubject matter eligibility under § 101 ordinarily is merely the first step in determining the patentability of a claim. A patent claim must meet other statutory criteria to be valid, including that its claimed invention be novel and nonobvious over the prior art, as well as described adequately to enable its use. While "it may later be determined that [the claimed invention] is not deserving of patent protection because it fails to satisfy the statutory conditions of novelty under § 102 or

> nonobviousness under § 103," based on prior art not yet part of the record, the novelty or nonobviousness of the invention has little to no bearing on the question of what the claims are "directed to."

955 F.3d at 1372 (quoting *Diehr*, 450 U.S. at 191) (internal citations omitted).

Thus, although MedComp and amici repeatedly characterize the § 101 analysis as turning on novelty, the law is clearly otherwise: "The analysis under *Alice* step one is whether the claims as a whole are 'directed to' an abstract idea, regardless of whether the prior art demonstrates that the idea or other aspects of the claim are known, unknown, conventional, unconventional, routine, or not routine." *Id.* at 1372; *Data Engine*, 906 F.3d at 1011 ("The eligibility question is not whether anyone has ever used tabs to organize information. That question is reserved for §§ 102 and 103").

None of the cases on which MedComp and amici rely (MedComp Br. 38-40; AngioDynamics Br. 5) supports importing novelty into *Alice* step one.[8] *Boggs v. Robertson*, 13 U.S.P.Q. 214 (D.C. Sup. Ct. 1931), simply stands for the foundational principle that claims directed ***solely*** to printed

[8] Under long-established precedent, the printed matter doctrine is applicable to the separate inquiries of anticipation and obviousness under §§ 102 and 103. Printed matter is not given patentable weight when assessing anticipation and obviousness. *Praxair*, 890 F.3d at 1031 ("Claim limitations directed to printed matter are not entitled to patentable weight unless the printed matter is functionally related to the substrate on which the printed matter is applied").

matter or an abstract idea are not patentable. There, the claims recited "a system of lines without reference to any tangible article"—"the so-called manufacture [wa]s completely lacking in material substance." *Id.* at 214. The court held the claims patent ineligible because they were "worded so as to cover a mere mental vision." *Id.*

Novelty likewise played no part in this Court's *Alice* step one analysis in *PersonalWeb Technologies, LLC v. Google*, LLC, 8 F.4th 1310 (Fed. Cir. 2021), *cert. denied*, No. 21-1093, 2022 WL 994366 (Apr. 4, 2022). There, the claims were directed to "algorithm-generated content-based identifier to perform the claimed data-management functions," such as "controlling access to data items," "retrieving and delivering copies of data items," and "marking copies of data items for deletion." *Id.* at 1316. The claims recited purely "mental processes that 'can be performed in the human mind' or 'using a pencil and paper[]'—a telltale sign of abstraction." *Id.* (citations omitted). This Court held that the claims were directed to an abstract idea because the claimed advance over the art, what the applicant regarded as his invention, was "a medley of mental processes that, taken together, amount only to a multistep mental process." *Id.* at 1318.

Nor does *Simio, LLC v. FlexSim Software Prod., Inc.*, 983 F.3d 1353 (Fed. Cir. 2020), support MedComp's and amici's position. There, the claim

was "directed to the abstract idea of using graphics instead of programming to create object-oriented simulations." *Id.* at 1360. This Court explained that "characterizing the claim as being directed to an abstract idea is appropriate" because "the abstract idea tracks the claim language and accurately captures what the patent asserts to be [his invention.]" *Id.* (citation omitted). The claims failed step one because they were limited to an abstract idea.

The novelty of Bard's claims or any portion thereof thus has no relevance to this Court's review of the district court's § 101 ruling.

3. The Means Of Conveying Information Is Not Printed Matter

MedComp again misstates the law in contending (Br. 52; *see* Br. 3, 20-21) that Bard's claims are invalid under the printed matter doctrine because they are "directed to … the radiopaque alphanumeric characters [or concave side(s)] that ***convey*** that the port is power injectable." (Emphasis added.) That argument is irreconcilable with *AngioDynamics*, which held that Bard's claims there were "patent eligible under 35 U.S.C. § 101" precisely because they were directed to the ***means*** of conveying information—the radiopaque markers. 979 F.3d at 1375 (emphasis added). This Court explained:

> When each claim is read as a whole, ***the focus of the claimed advance*** is not solely on the content of the information conveyed, but also ***on the means by which that information is conveyed***. In particular, the claimed invention is described in the patents as satisfying a specific need for easy vascular access during CT imaging, and ***it is the radiographic marker in the claimed invention that makes the claimed port particularly useful for that purpose*** because the marker allows the implanted device to be readily and reliably identified via xray, as used during CT imaging.

Id. at 1384 (emphases added). The same is true here.

AngioDynamics addressed claims which "recite an assembly, system, or method for identifying a vascular access port as power injectable using multiple means for conveying the device's functionality, including, specifically, a radiographic marker." 979 F.3d at 1383-84. Here, as the district court explained, "[e]ach of the independent and dependent claims in the '302 and '022 Patents require the presence of a type of radiopaque marker identifying the claimed port as power injectable." Appx00003. Thus, the '302 and '022 patents at issue here mirror those adjudicated in *AngioDynamics*—both sets of claims are directed to radiopaque identifiers on power injectable ports, with the same informational content (identification of a vascular access port as power injectable) and the same means through which that information is conveyed (radiopaque marks on power injectable ports). The printed matter inquiry for the '302 and '022 patents is therefore indistinguishable from *AngioDynamics*.

Although *AngioDynamics* did not address claims comprising identifying structural features like the '615 patent, its reasoning applies with equal if not greater force to such claims. Just like the radiopaque markers, "the claimed invention is described in the patents as satisfying a specific need for easy vascular access during CT imaging, and it is the [identifying structural feature] in the claimed invention that makes the claimed port particularly useful for that purpose because the marker allows the implanted device to be readily and reliably identified [post-implantation]." 979 F.3d at 1384. Moreover, those structural features cannot fairly be analogized to "labels" or other traditional forms of printed matter. Appx03737 (Judge Nielson: "the same analysis [for radiopaque markers] would apply [to the identifying structural features] as well").

MedComp also maintains (Br. 36) that "[t]he District Court provided a partial list of Federal Circuit cases that addressed printed matter, and not one contemplated a distinction between the printed matter itself and the information conveyed by it." But those cases do not purport to address the distinction between the means of communicating information and the content of the information conveyed. For example, *In re McKee*, 64 F.2d 379 (C.C.P.A. 1933), the CCPA addressed a claim directed to identifying marks placed on cuts of meat. The claims at issue there had no limitations

directed to how the meat was marked, *i.e.*, the means of communication. *Id.* at 379. Rather, the sole focus of the claims was on the printed matter itself: "We see nothing more in appellant's alleged invention than the arrangement of printed matter upon meat." *Id.* at 380. And both *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042 (Fed. Cir. 2010), and *In re Ngai*, 367 F.3d 1336 (Fed. Cir. 2004), involved informational content printed on a non-technological substrate, where the claimed substrate existed only to communicate information. *AstraZeneca*, 633 F.3d at 1064-65 (informational content and the label upon which it is printed were printed matter; "the instructions do nothing more than explain how to use the known drug"); *Ngai*, 367 F.3d at 1339 (informational content and the instruction sheet upon which it is printed were printed matter; "[a]ll that the printed matter does is teach a new use for an existing product").[9]

[9] Contrary to MedComp's suggestion (Br. 35-36), this Court has long held that "a limitation is printed matter ***only if it claims the content of information***," such that the technological means of conveying information necessarily fall outside the doctrine. *In re Distefano*, 808 F.3d 845, 848-49 (Fed. Cir. 2015) (emphasis added) (citing Chisum on Patents § 1.02[4] (2015)); *see, e.g.*, *Praxair*, 890 F.3d at 1032 ("merely adding an instruction sheet ***or other informational content*** to a drug product is not sufficient to create a functional relationship, even if required by the FDA for approval") (emphasis added); *In re Ockman*, 833 F.2d 1023, 1023 (Fed. Cir. 1987) ("Insofar as the claims involve no more than printed matter, ***gathering data and forwarding information to others***, those claims are non-statutory under § 101.") (emphasis added).

Moreover, contrary to MedComp's assertion (Br. 37), the identifying structural feature is nothing "like … a peace sign made of metal." This Court's decision in *Lowry*, 32 F.3d 1579, is illustrative. There, this Court rejected the "analog[y] to printed matter" because "Lowry's data structures [were] physical entities that provide [additional functionality or] increased efficiency in computer operation." *Id.* at 1584. The claimed structural features, unlike printed matter, were "[m]ore than mere abstraction, [rather they were] specific … structural elements." *Id.* at 1583-54. So too here, the identifying structural features plainly are not printed matter.

Nor is it significant that, as MedComp puts it (Br. 34), the claims "require[] a mental step by the [medical] practitioner based on after-acquired knowledge." Although a human must view the x-ray or feel the port and identify the structural feature, such indirect mental steps are "not the type of human activity that § 101 is meant to exclude." *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1304 (Fed. Cir. 2019) (rejecting argument that asserted claims "encompass steps that people can 'go through in their minds,' allegedly confirming that they are directed to an abstract concept"); *see, e.g., CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1373 (Fed. Cir. 2011) ("Methods which can be performed entirely in the human mind are unpatentable not because there is anything wrong with claiming mental

method steps as part of a process containing non-mental steps, but rather because computational methods which can be performed *entirely* in the human mind are the types of methods that embody the 'basic tools of scientific and technological work' that are free to all men and reserved exclusively to none.") (citation omitted); *cf. PersonalWeb*, 8 F.4th at 1318 ("The claims as a whole, then, are directed to a medley of mental processes that, taken together, amount only to a multistep mental process."). Were it otherwise, the rule would swallow every invention that requires thought by its user.

Finally, MedComp's preemption concerns are based on the erroneous premise (Br. 37-38; *see* Br. 33-34) that the claimed subcutaneous radiopaque markers and structural identifiers are indistinguishable from "all [other] markings on medical devices for its purpose." Bard's claims do not "cover any characters or letters that anyone ever uses," as MedComp wrongly asserts (Br. 37), but rather are limited to radiopaque identifiers that are located on power injectable ports and observable via x-ray. Nor do the claims preempt all "symbols or shapes to indicate function," as MedComp again wrongly assert (*id.*), but rather only those radiopaque identifiers on the housing base for the purpose of identifying ports as being power injectable post-implantation (Appx00114-00115; Appx00177). And likewise, the

claims in the '615 patent are directed to a physical assembly, comprising tangible structural features in specific locations on the port. Appx00220-00221. There should be no concern about preemption here. *See, e.g.*, *ChargePoint*, 920 F.3d at 768, 770 ("consider[ing] the extent to which the claim would preempt building blocks of science and technology" and holding claims patent ineligible where they would "preempt[] the entire industry's ability to use networked charging stations."); *In re Marco Guldenaar Holding B.V.*, 911 F.3d 1157, 1160-61 (Fed. Cir. 2018) ("[p]remption is the underlying concern behind the abstract idea exception"; holding method claims "directed to the abstract idea of 'rules for playing a dice game'" patent-ineligible).

4. MedComp's Functional Relationship Argument Disregards This Court's Construction Of Bard's Patents

Under this Court's precedent, "[p]rinted matter that is functionally related to its substrate is given patentable weight." *Praxair*, 890 F.3d at 1032. Here, there is a direct functional relationship between the printed matter—information identifying the port as being power injectable—and the substrate on which the printed matter is written—a power injectable port. This relationship provides an independent reason that Bard's claims are not invalid under the printed matter doctrine. MedComp's argument (Br. 47)

that there is no functional relationship because "the claims do not specifically recite power injectable ports at all" ignores this Court's prior construction of the Bard asserted claims.

In *Port I*, this Court determined that the substrate—the port—is limited to power injectable ports. There, a key claim construction issue was whether the claimed ports were so limited or, as the PTAB had found, the claims covered both power injectable and non-power injectable ports. 748 F. App'x at 1016. Relying on references to power injectability in limitations containing printed matter,[10] this Court found that the content of that printed matter was "definitional" and thus this claim language "mean[s] that the claimed access port is power injectable." *Id.* And this Court rejected the PTAB's conclusion that "the claims would contemplate a falsely labeled access port." *Id.*

Here, the specific claimed substrate and the specific claimed printed matter combine to create an improved functionality that is a key feature of the claimed invention. By putting the printed matter identifying the port as power injectable on the power injectable port, the port can "readily and reliably identified" as power injectable. *AngioDynamics*, 979 F.3d at 1384.

[10] For instance, claim 5 of '302 patent mentions power injectability only in a limitation requiring that "the alphanumeric message indicat[es] that the assembly is power injectable." Appx00115 (13:8-18).

Printed matter identifying the port as power injectable that is not located on the port itself does not result in the same functionality—an identifier that is separate from the port can be lost and or forgotten at the time of the procedure. The placement of the printed matter on the port ensures that a healthcare practitioner can identify the port as power injectable every time a procedure is performed and with 100% accuracy. It is also particularly convenient because power injectable ports are used in connection with CT scans, a procedure that utilizes X-rays.

The functional relationship between the power-injectable port and the message identifying port as power injectable is analogous to *In re Miller*, 418 F.2d 1392 (CCPA 1969), and *In re Gulack*, 703 F.2d 1381 (Fed. Cir. 1983), both of which held the printed matter was entitled to patentable weight. In *Miller*, the claims were directed to a measuring cup with volumetric indicia (the printed matter) included on the measuring cup in a manner that allowed measurement of a half recipe. 418 F.2d at 1394. Thus, for example, an indicator stating "2 cups" actually measured only half that volume. *Id*. The CCPA gave patentable weight to the printed matter, concluding "there is a new and unobvious functional relationship between a measuring receptacle, volumetric indicia thereon indicating volume in a

certain ratio to actual volume, and a legend indicating the ratio, and in our judgment the appealed claims properly define this relationship." *Id.* at 1396.

Similarly, in *Gulack*, this Court found a functional relationship between a band of concentric circles and the sequence of digits printed on the band such that the digits are presented "as an endless sequence with no discrete beginning or end." 703 F.2d at 1382. This Court explained "the critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate." *Id.* at 1386. Here, the claims require that the printed matter identifying the port as power injectable be placed on a specific substrate (a port injectable port) to convey information about that substrate. *See id.* (noting that *Miller* found a functional relationship "to size or to type of substrate, or conveying information about substrate").

Finally, MedComp misplaces reliance (Br. 45-46) on the portion of this Court's decision in *AngioDynamics* that held the printed matter at issue there was not functionally related to the substrate. *See* 979 F.3d at 1382. The claims at issue in *AngioDynamics* included some printed matter that was ***not*** located on the port. For example, claim 1 of the '417 patent requires, *inter alia*, an "identifiable feature separated from the subcutaneously implanted access port… confirming that the implanted port is both suitable

for flowing fluid at a rate of at least 1 milliliter per second through the access port and for accommodating a pressure within the cavity of at least 35 psi." *Id.* at 1376.[11] Thus, in *AngioDynamics*, the printed matter identifying the port as power injectable was ***not*** always placed on the port itself. In contrast, all the claims here require that the printed matter be on the power injectable port.

For all these reasons, the judgment of invalidity fails at *Alice* step one.

II. MEDCOMP IS UNABLE TO DEFEND THE DISTRICT COURT'S *ALICE* STEP TWO RULING AS TO BARD'S PATENTS

The district court's judgment should be reversed at *Alice* step one and thus the Court need not address *Alice* step two. However, if the Court reaches step two, it should reverse the district court's conclusion that the use of radiographic markers and identifying structural features was, as a matter of law, routine and conventional. Contrary to MedComp's assertions (Br. 14-18), the record here evidences, at most, the ***generic*** use of radiopaque markers on ***different*** medical devices with ***different*** purposes. That is insufficient to establish as a matter of law that Bard's claims lack an inventive concept.

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[11] The dependent claims specify that the separate identifiable feature is "a key chain, a bracelet, a wrist band, a sticker provided on a patient's chart, a patient ID card, or a label provided on the product packaging." *AngioDynamics*, 979 F.3d at 1376.

A. MedComp's Evidence Relating To Implantable Medical Devices Generally Is Legally Insufficient To Establish The Lack Of An Inventive Concept

MedComp wrongly argues (Br. 62; *see* AngioDynamics Br. 21-23) that the "relevant audience" for *Alice* step two is medical practitioners generally who would consider all types of implantable medical devices. This Court has previously rejected that very argument. In *AngioDynamics*, this Court accepted *arguendo* AngioDynamics' evidence that "the use of radiographically identifiable markings on implantable medical devices was known in the prior art"—"including one vascular port with an x-ray tag that identified the port's flow rate"—but held that "AngioDynamics's evidence [was] not sufficient to establish as a matter of law, at *Alice* step two, that the use of a radiographic marker, in the 'ordered combination' of elements claimed, was not an inventive concept." 979 F.3d at 1384.

As in *AngioDynamics*, the "ordered combination" of elements claimed here is a power injectable port with a radiographic marker identifying the port as power injectable. *See* Appx00114-00115; Appx00177; Appx00220-00221.[12] MedComp, however, presented no evidence that radiographic

[12] Other decisions of this Court are in accord. For example, in *BASCOM Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016), this Court reversed a summary judgment of patent ineligibility because the claimed invention was based on a "particular arrangement of elements [that was] a technical improvement over prior art."

markers were used on a power injectable port. Indeed, MedComp's only supposed evidence that radiographic markers were used on ports of any type was a single prior art patent relating to *non*-power injectable ports that used the radiographic marker to identify a flipped port. Appx00870-00871; Appx00881. MedComp offered no evidence that this port had ever been commercialized or even made. And though MedComp complains (Br. 59) that there is no "commercialization" requirement, it disregards that not all prior art establishes that something is routine and conventional. *See, e.g.*, *Exergen Corp. v. Kaz USA, Inc*., 725 F. App'x 959, 965-66 (Fed. Cir. 2018) ("There are many obscure references that nonetheless qualify as prior art … [but] would not suffice to establish that something is 'well-understood, routine, and conventional activity previously engaged in by scientists who work in the field.'") (quoting *Mayo*, 566 U.S. at 79). Citing a single prior art patent, without more, is insufficient to show as a matter of law that placing a

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Id. at 1350. AngioDynamics (Br. 22) attempts to distinguish *BASCOM* on the grounds the claimed invention "improve[s] the performance of the computer system itself." But the improved performance was directly tied to the specific arrangement of claimed elements. *BASCOM*, 827 F.3d at 1350 ("[T]he patent describes how its particular arrangement of elements is a technical improvement over prior art ways of filtering such content."). The same is true here—a radiographic marker allows the port to be reliably and easily identified as being power injectable at the time of the power injection.

radiographic identifier on a port, let alone a power-injectable port, was routine and conventional.

Finally, MedComp (Br. 16-17) and AngioDynamics (Br. 12, 14-15) both wrongly rely upon Bard's supposed "admission" in the Eliasen declaration submitted during prosecution of the '302 patent. That declaration makes no admission regarding what was routine and conventional in the prior art; rather, in the context of provoking an interference proceeding, Mr. Eliasen's statements concern what was ultimately determined to be Bard's own invention.

Specifically, during prosecution of the '302 patent, Bard sought to provoke an interference with MedComp's '287 Application, proposing that both independent claim 1 of the '287 Application and all dependent claims of the '287 Application be included in the interference proceeding. To do so, Mr. Eliasen treated claim 1, which is directed to the use of a radiographic marker on a power injectable port, as if it were prior art. Appx02857-02859; *see Maier v. Hanawa*, 26 U.S.P.Q.2d 1606, 1992 WL 475809, *5-6 (Com'r Pat. & Trademarks March 21, 1992) ("In determining whether it is proper to designate a claim as corresponding to the Count, the pertinent inquiry is whether that claim and the Count define the same patentable invention, i.e., whether they are patentably distinct."); *see also* 37 C.F.R. § 1.601(n)

("Invention 'A' is the 'same patentable invention' as an invention 'B' when invention 'A' is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention 'B' assuming invention 'B' is prior art with respect to invention 'A.'"). Relying on claim 1 as "prior art," Mr. Eliasen opined that the dependent claims were obvious: "Why Claims 2-12 of the '287 Application Would Have Been Obvious in View of Claim 1 of the '287 Application." Appx02857.

The Patent Office ultimately declared an interference where claim 1 of the '287 Application and claim 1 of the '302 patent were defined as the count, and the Patent Office awarded priority to Bard. *Zinn v. Powers*, No. 105,860, 2012 WL 4043190, *1 (B.P.A.I. Sept. 11, 2012). Thus, the Patent Office decided that ***Bard*** was the first to invent the subject matter of claim 1 of the '287 Application; Mr. Eliasen's supposed admissions are therefore premised upon Bard's own invention, and the Eliasen Declaration provides no support for the district court's *Alice* step two ruling.

B. MedComp Makes No Attempt To Defend The District Court's Error In Disregarding Identification Of Structural Features Through Palpation

In its opening brief (Br. 50-52), Bard showed that the district court erred by ignoring the teachings in the specification of Bard's patents that one way the identifying structural features of the '615 patent work is through

touch (palpation). MedComp ignores this argument and makes no attempt to defend the district court's analysis. Instead, MedComp (Br. 58-59) simply block quotes the district court's ruling and asks this Court to adopt it. But the record contains absolutely no evidence that using structural features to identify a port (or any other type of medical device) through palpation was routine and conventional. This deficiency provides an independent basis to reverse as to the '615 patent.

AngioDynamics (Br. 23-24) wrongly contends that *Two-Way Media Ltd. v. Comcast Cable Communications, LLC*, 874 F.3d 1329 (Fed. Cir. 2017), supports the district court's decision to discount using the structural feature to identify a port via palpation. But that decision simply holds that the "inventive concept must be evident in the claims." *Id.* at 1338. The '615 claims explicitly recite a "structural feature" used for "identifying the access port as being power injectable subsequent to subcutaneous implantation." Appx00220 (12:61-62). It is bedrock patent law that the claims are read in light of the specification. *See, e.g.*, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). The specification makes clear that the claimed identifying structural features can work via palpation and by reciting the structural feature, the "inventive concept [is] evident in the claims." *Two-Way Media*, 874 F.3d at 1338.

C. MedComp's Waiver Arguments Are Without Merit

MedComp fares no better in asserting (Br. 60) that Bard waived its *Alice* step two arguments by "not fully develop[ing]" them in the district court.

The sole case that MedComp cites to support a waiver simply reiterates hornbook appellate procedure: "absent extraordinary circumstances, we will not consider arguments raised for the first time on appeal." *McDonald v. Kinder-Morgan, Inc.*, 287 F.3d 992, 999 (10th Cir. 2002). MedComp does not suggest that Bard has raised new issues on appeal. Nor could it; Bard raised the same legal issues before the district court that it raises here. Specifically, Bard argued below that MedComp's evidence relating to implantable medical devices generally was insufficient to establish a lack of inventive concept as a matter of law. Appx02680-02681. Indeed, the district court considered and rejected this argument. Appx00035-00037. Similarly, Bard argued below that MedComp had presented no evidence regarding the use of structural features to identify a port via palpation. Appx00038; Appx02647-02648. There has been no waiver.

III. THE INVALIDITY JUDGMENT AS TO MEDCOMP'S PATENTS SHOULD BE AFFIRMED

Regardless of how the Court resolves Bard's appeal, it should affirm the district court's judgment of invalidity as to MedComp's '324 patent.

In the single paragraph that it devotes to its cross-appeal, MedComp maintains (Br. 63) that it should get the benefit of any reversal of the district court's invalidity judgment as to Bard's claims. MedComp refers to the district court's law-of-the-case ruling, but offers no argument in support of its position. As such, it has waived any challenge to the judgment. *See, e.g.*, *Braun v. Dep't of Health & Hum. Servs.*, 983 F.3d 1295, 1305 (Fed. Cir. 2020) ("For reasons of fairness to appellees and of judicial efficiency, we generally refuse to consider an appellant's challenge to particular rulings in a decision under review unless the challenge was raised and properly developed in the appellant's opening brief—for which the reply brief and oral argument are not adequate substitutes."); *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 n.9 (Fed. Cir. 2006) ("When a party includes no developed argumentation on a point ... we treat the argument as waived under our well established rule.") (internal quotation marks and citation omitted)).

MedComp wrongly asserts (Br. 63) that "[t]he District Court only held that the '324 Patent was ineligible under Section 101 because its 'prior

Order' was 'now law of the case.'" The district court did not simply invoke the law-of-the-case doctrine. It first analyzed the parties' respective statement of facts (Appx00049-00051) and applied the undisputed facts and its understanding of the applicable law to the claims of the '324 patent. Appx00051-00055. MedComp acknowledges (Br. 62-63) that "[t]he asserted claims of MedComp's '324 Patent are *somewhat different* than the Bard Port ID claims" (emphasis added), and it made a similar argument below (Appx04211-04215). Yet MedComp provides no explanation as to what those differences are, let alone present a well-developed argument as to why those differences are so insignificant that its claims "should rise or fall" with Bard's claims.

MedComp thus has provided no basis to reverse the district court's judgment of invalidity as to its patents. This Court instead should affirm that judgment or at the very least dismiss the cross-appeal for failure to present any developed arguments.

CONCLUSION

The judgment of invalidity as to Bard's patents should be reversed or, alternatively, vacated, and the case remanded for further proceedings on Bard's infringement claims. The judgment of invalidity as to MedComp's

patents should be affirmed or, alternatively, MedComp's cross-appeal should be dismissed.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 27, 2022, I electronically filed the Response And Reply Brief of Appellants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to any of the following counsel registered as CM/ECF users:

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CERTIFICATE OF COMPLIANCE

Counsel for Appellants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. certifies that the brief contained herein has a proportionally spaced 14-point typeface, and contains 8485 words, based on the "Word Count" feature of Word for Microsoft 365 MSO, including footnotes and endnotes, excluding the parts of the brief exempted by Fed. R. App. 32(a)(7) and Fed. Cir. R. 32(b).

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