IP Alert: Can Challengers Now Attack Subject Matter Eligibility in Inter Partes Reviews?



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The statute authorizing inter partes reviews (IPR) explicitly limits the grounds for cancellation to Sections 102 and 103 of the patent statute:

> Section 311(b). Scope. A petitioner in an IPR may request to cancel as unpatentable 1 or more claims of a patent only on a ground raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.

In a recent appeal of an IPR decision, a panel majority of the Court of Appeals for the Federal Circuit may have opened the gates for Section 101 challenges to be made in IPRs under the guise of printed matter/obviousness challenge.

The Federal Circuit struck down all claims in U.S. Patent 8,846,112 of Mallinckrodt Hospital Products IP Ltd., as obvious on May 16, 2018. Praxair Distribution, Inc., v. Mallinckrodt Hospital Products IP Ltd.'s, Case Numbers 2016-2616, 2016-2656. The decision affirmed the U.S. Patent and Trademark Office Patent Trial and Appeal Board (PTAB)'s final written decision in an IPR with regard to most claims. The Federal Circuit went further than the PTAB in also finding claim 9 unpatentably obvious, which the board had not found.

Mallinckrodt's '112 patent claims generally were directed to supplying a medical provider with (a) a cylinder of nitric oxide gas and (b) information on dosage and treatment parameters. Claim 9 additionally required discontinuing treatment under certain conditions based on the information provided. The court, following the PTAB's analysis, interpreted the providing of information to be printed matter or purely mental steps, not

entitled to patentable weight. Only if the printed matter is functionally related to its "substrate" is it given patentable weight. The PTAB found that only in claim 9 was the printed matter functionally related to its substrate.

Although all three judges of the panel[1] concurred in the judgment, Judge Newman penned a separate concurring opinion in which she disagreed with the panel majority's application of the printed matter doctrine and its obviousness analysis. Perhaps most importantly, Judge Newman faulted the majority opinion, written by Judge Lourie, for converting a patentability analysis under Section 103 into a subject matter eligibility analysis under Section 101.

The majority's analysis employed two steps that could be used to convert many Section 102/103 challenges into challenges under Section 101. First, the court held that any claim limitation that relies on the content of information, whether printed or not, now falls under the rubric of printed matter. This includes mental steps. Second, the court held that such elements or steps lack patentable weight and may be disregarded in an obviousness analysis. Only if the information is "functionally related to the substrate" will the element or step be considered for obviousness.

Quoting In re Gulak,[2] Judge Newman particularly objected to an obviousness analysis that dissects a claim, excises printed matter, and declares the remaining portion of the mutilated claim to be unpatentable. A claim, she urged, must be viewed as a whole in determining obviousness.

A patent challenger seeking to cancel claims for lack of subject matter eligibility may now consider using an IPR to do so. Take as an example claim 1 of Myriad Diagnostics' U.S. Patent 5,753,441.[3]

> A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises
>
> > comparing (a) germline sequence of a BRCA1 gene or BRCA1 RNA from a tissue sample from said subject or a sequence of BRCA1 cDNA made from mRNA from said sample with (b) germline sequences of wild-type BRCA1 gene, wild-type BRCA1 RNA or wild-type BRCA1 cDNA,
>
> wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject.

A patent challenger could now attack the Myriad claim in a hypothetical IPR under Sections 102 or 103 and the printed matter doctrine. The step of comparing could be characterized under the Praxair holding as printed matter, which only has patentable weight if functionally linked to its substrate, i.e., other claim elements. Once that step is characterized as printed matter, no other step of the claim remains to which it can be functionally linked. Moreover, no other step or element remains for which a reference teaching must be found. Another example to consider is claim 1 of U.S. Patent No. 6,355,623.[4] The claim recited:

> A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
>
> (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8.times.10.sup.8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per 8.times.10.sup.8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

A patent challenger could assert in a hypothetical IPR that step (b) is a mental step and therefore a form of printed matter. Once it is accorded no patentable weight, any reference teaching of administering known drug 6-thioguanine to treat an immune-mediated gastrointestinal disorder could be applied as invalidating.

Thus, claims with "information" or "mental steps" as the basis for invention are now likely to be subjected to IPR challenges using the printed matter doctrine.

Click here to download the decision in Praxair Distribution, Inc., v. Mallinckrodt Hospital Products IP Ltd.

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Click here to read our report on the oral hearing in this case at the Federal Circuit.

[1] Chief Judge Prost, Judge Lourie, and Judge Newman

[2] 703 F.2d 1381, 1385 (Fed. Cir. 1983)

[3] The Federal Circuit held this claim subject-matter ineligible because it claimed an abstract mental process of comparing and analyzing two gene sequences. Association for Molecular Pathology v. Myriad Diagnostics, Inc., 689 F.3d 1303, 1334 (Fed. Cir. 2012) aff'd in part, rev'd in part, 133 S. Ct. 2017 (2013)

[4] Invalidated in Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289 (2012).

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