

*Declaration-keyed Re-examination Anticipation
In re Natures Remedies (Fed. Cir. 2009)*



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Background of the Case

- Natures Remedies obtained US Pat. No. 5,945,107.
- A reference from Medi-Tab anticipated claim 2 of '107.
- Claim 2 of '107 was rejected as unpatentable under 102(b).
- Natures Remedies (NR) appealed by arguing that the Medi-Tab reference was not accessible to the public prior to the priority date of '107.

The Issue

- Whether the Medi-Tab reference was accessible to the public, i.e. printed publication under 102(b).

The Reference

- The Medi-Tab reference was an application submitted to the Scientific-Ethical Committee of Copenhagen in Denmark, seeking approval for clinical testing of Medi-tab capsules.
- The reference was dated April 10, 1996, which was more than one year prior to '107's priority date (Dec 8, 1997).
- The reference should be accessible to the public except for some condition as stipulated in Danish law*

* The Danish Open File Act, Art. 12(1)

The Rejection

- BPAI adduced a declaration from the Copenhagen Committee for the 102(b) rejection.
- The committee declaration confirmed:
 - That they oversees clinical studies
 - That the Medi-Tab reference was an clinical study application submitted to the Committee.
 - That the Medi-Tab reference was open to inspection by the public in view of the Danish Open File Act since April 10, 1996.
- The board thus determined that the declaration established a prima facie 102(b) rejection.

NR's Argument

- NR submitted another declaration from a Danish attorney to rebut BPAI's assertion.
- The NR declaration stated that Art. 12(1) of the Act provides exemption from disclosure of the files if it is "material importance to the economy of the person or enterprise".
- BPAI maintained the rejection. NR appealed.

Law Applicable to the case

- The “court must accord ‘substantial evidence’ deference to the factual components of the determination” as to whether a reference qualified as a printed publication under 102(b) (see. *Kyocera Wireless Corp v Int’l Trade Comm’n*, 545 F.3d 1340, 1350 (Fed. Cir. 2008))
- A reference was publically available where it was “classified and indexed... providing the roadmap that would [allow] one skilled in the art to locate [it]” (see *Bruckelmyer*, 445 F.3d at 1379)

Analysis from the Court of Appeal

- Fact founding:

- The committee declaration did not established whether the Medi-Tab reference was exempted from disclosure under Art. 12(1) of the Danish Open File Act.
- The NR declaration did not address what the “material importance” of the Medi-Tab reference is to Medi-Tab’s “economy”.
- The court also found that the Medi-Tab reference had indicated that the result of the study would be “published in an international gastro-enterological medical publication”. Medi-Tab therefore was initially not intended to keep the reference confidential.

Conclusion

- The evidence as presented by BPAI illustrated that the Medi-Tab reference is a prima facie evidence for 102(b) rejection.
- The Court held that BPAI was correct.

The End

