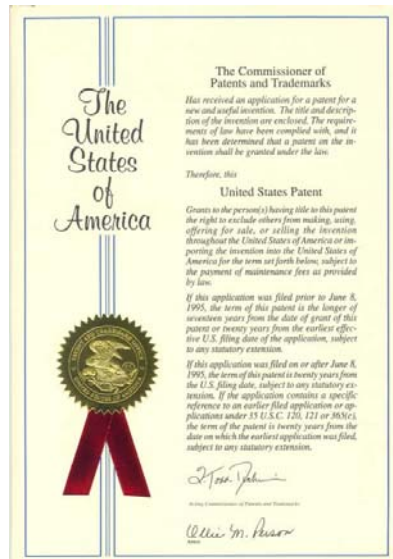


I have to tell the Examiner what?!?!?

The Duty of Disclosure in Light of McKesson v. Bridge Medical



November 14, 2007 HIPLA Monthly Luncheon

Special thanks to Richard F. Phillips for his support in sponsoring this presentation



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Overview

- **Background**
 - Duty of Disclosure
 - Unenforceability
- *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*
 - U.S. District Court for Eastern District of California
 - U.S. Court of Appeals for the Federal Circuit
- **Summary & Recommendations**
- **Discussion**

Background

- Courts apply an unenforceability standard in patent litigation based on the PTO's refusal to grant patents on applications where fraud on the PTO is practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct [37 C.F.R. § 1.56(a)]
- Patent may be rendered unenforceable if, with intent to deceive, applicant fails to disclose material information [*Norian Corp. v. Stryker Corp.*, 363 F3d 1321 (Fed. Cir. 2004)]



37 C.F.R. § 1.56 Duty of Disclosure

§ 1.56 Duty to disclose information material to patentability.

- (a) ... Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. ... The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office
- (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
- (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
 - (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.



McKesson Info. Solutions, Inc. v. Bridge Medical, Inc.

District Court

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- 2006 WL 1652518 (E.D. Cal. June 13, 2006)
- Patent at issue was for patient identification and linking system for use in hospital settings
 - U.S. Patent No. 4,857,716 (patent in suit)
 - 3-node communication system (handheld portable unit, base station, central computer)
 - Unique identifier for linking portable unit to base station
 - U.S. Patent Nos. 4,850,009 and 4,835,372 (related patents)



McKesson Info. Solutions, Inc. v. Bridge Medical, Inc.

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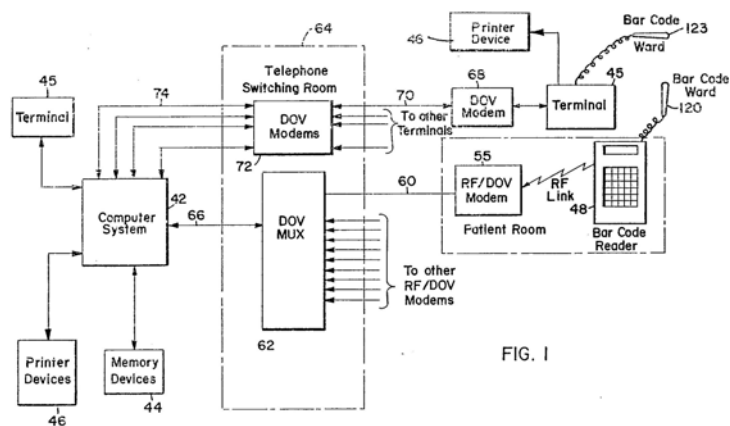


FIG. 1

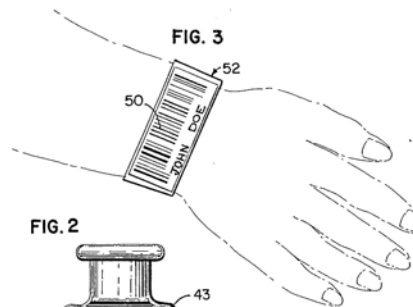


FIG. 2

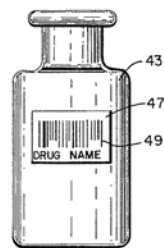


FIG. II

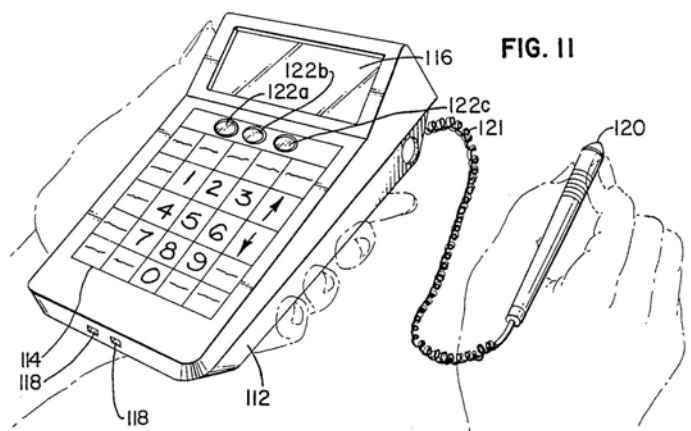
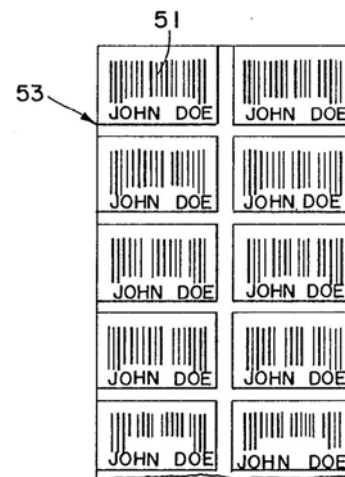


FIG. 4



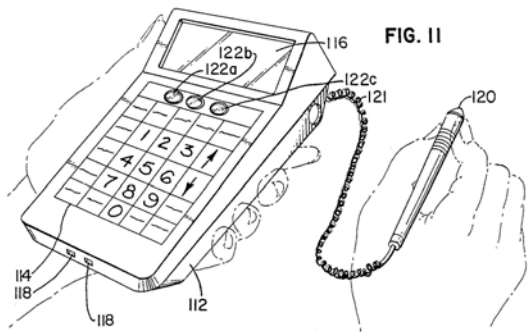


McKesson Info. Solutions, Inc. v. Bridge Medical, Inc. District Court



Handheld portable unit

'716 Patent Summary



Patent Prosecution History

*Wireless
Communication*



Base Station
(in patient room)



*Wired
Communication*

Central Computer
(remote location)



ExxonMobil
Chemical

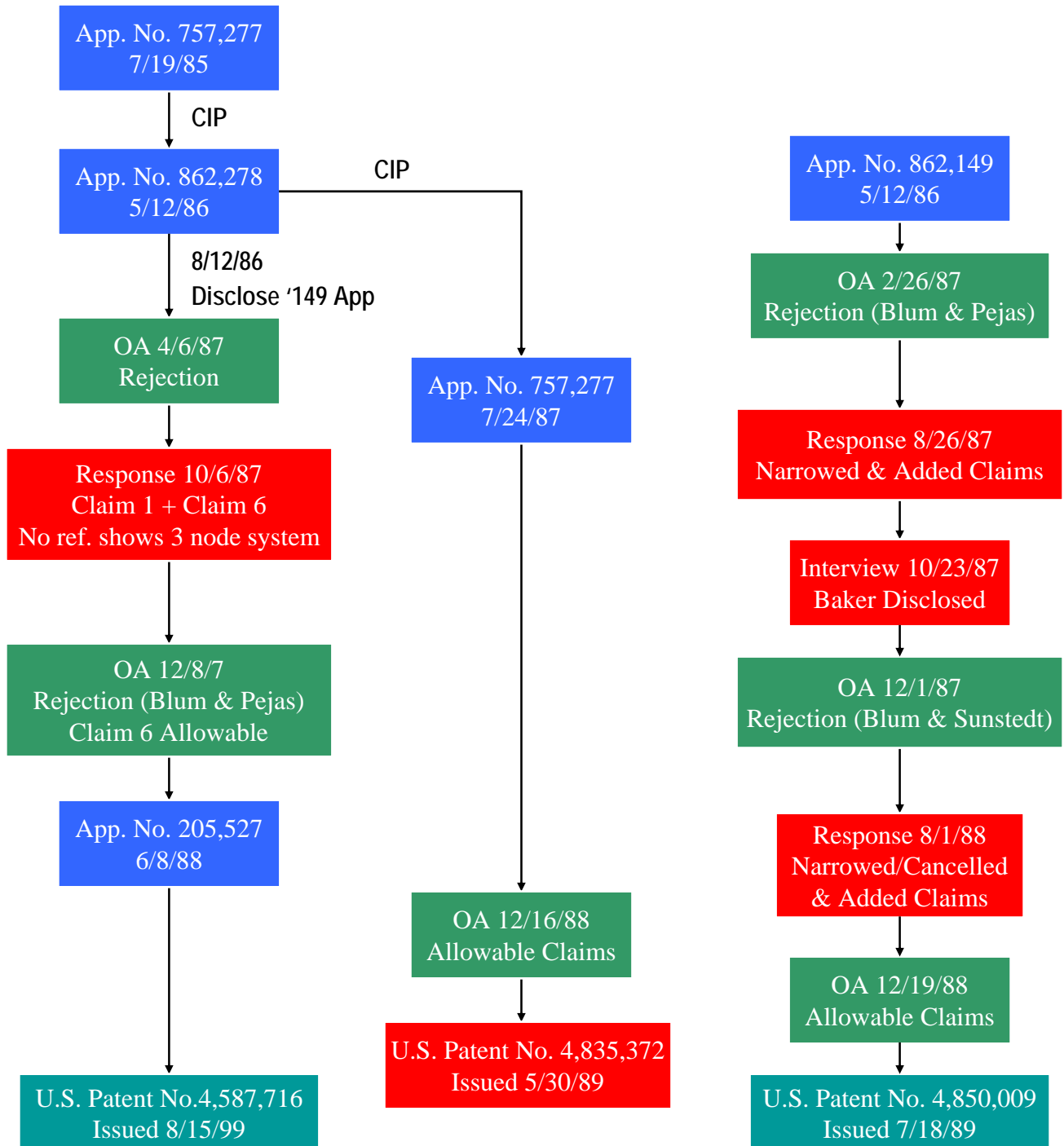


Patent Prosecution Timeline



Examiner A

Examiner B





McKesson Info. Solutions, Inc. v.
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District Court

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Omissions during prosecution of '716 Patent were failures to disclose ...

- Existence of Baker patent
- Rejection of broad claims in '009 Patent prosecution
- Allowance of '372 Patent

Omissions were material and done with intent to deceive...

Therefore, U.S. Patent 4,857,716 is unenforceable for inequitable conduct



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Existence of Baker patent

- Examiner B cited Baker in interview in '009 Patent prosecution
 - Attorney disclosed existence of '009 Patent (then an application) during prosecution of '716 Patent
- Prosecuting attorney believed that Baker was cumulative of Pejas, Hawkins & Koenig (already of record)
 - Baker & Pejas disclosed a 3-node system and a unique identifier
- Notable that Baker was only disclosed to prosecuting attorney in related case 17 days after statement regarding lack of prior art disclosing a 3-node system
 - District Court said this made Baker that much more material b/c attorney should have had the prior statement fresh in his mind
 - Attorney testified he was "over inclusive" in citing art, but non-disclosure is inconsistent with this testimony



McKesson Info. Solutions, Inc. v. Bridge Medical, Inc.

Federal Circuit

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Existence of Baker patent Con't

- Rejected argument that Baker was cumulative of Pejas because disclosure in Baker was 11 columns, whereas Pejas was only 2
- Attorney knew of materiality of Baker b/c of cancellation of claims 19-24 in '009 Patent prosecution & thus, withholding is evidence of intent to deceive
- Contemporaneous notes should be placed in file regarding specific consideration of information and reasons why it is not material
 - Attorney here had no such notes & said he "did not remember prosecution"
- Duty of disclosure goes beyond simply identifying co-pending and related applications
- Disclosure of co-pending application provided *some* evidence of lack of intent



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District Court

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Rejection of broad claims in '009 Patent prosecution

- *Dayco* did not create a new disclosure requirement (office actions), it just further explained the existing ones
- '009 Patent disclosed 3-node system with identical means of communication among the core structures & unique identifier
- Rejection was contradictory of attorney's statement regarding no prior art teaching 3-node system
- Attorney argued disclosure of application was sufficient (which was done early on in '716 Patent prosecution)
 - Duty of disclosure goes beyond mere citation of co-pending applications
 - This provided *some* evidence of lack of intent, but not enough



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Federal Circuit

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Rejection of broad claims in '009 Patent prosecution con't

- Rejection of a “substantially similar” claim by another Examiner meets the *Akron Polymer* reasonable examiner standard for materiality
 - Substantial similarity may be found among claims that “were in some respects substantially identical”
 - Substantial similarity is not required, but if present, then claims are material
- '009 Patent limited to “real time” communication, and just over a month later, '716 Patent limited to “real time, interactive 3-node communication” (evidence of materiality)
- '009 Patent Blum & Sunstedt rejection material b/c '716 Patent Examiner never cited Sunstedt before allowing '716 Patent
- Method v. system claim difference is unimportant & can still be material
- Even specifically reserving right to re-file cancelled claims in continuing application is insufficient to remove inference of materiality of office action created by cancellation



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District Court

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Allowance of '372 Patent

- '372 Patent prosecuted concurrently before same Examiner as '716 Patent and allowances were only a few months apart
- Notice of allowance is material if allowed claims "could conceivably" give rise to double patenting rejection
- '372 Patent claims do not have "unique identifier" of '716 Patent
- Unique identifier was rejected as obvious in '009 Patent prosecution, therefore it was conceivable to issue DP rejection
- Issued means plus function claims defined by specification and whole '716 Patent specification was contained in '372 Patent



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Allowance of '372 Patent con't

- Allowance need not lead to substantial likelihood of a double patenting rejection, only conceivability of the rejection is relevant
- Timing of allowances is not relevant to materiality or intent inquiries
 - Argument that allowance was cumulative b/c Examiner would have remembered issuing it when allowing '716 Patent not assessable b/c no evidence is on record on this point
 - Attorney testified he did not consider identity of Examiner in deciding to disclose, thus the issue of memory cannot contradict evidence of intent
- Attorney should not assume an Examiner retains details of all pending files before him when reviewing other applications
 - All disclosures must be in writing



McKesson Info. Solutions, Inc. v.
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District Court

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HOLDING

- Weighing materiality against intent, the court finds that **each of the nondisclosures** set forth above, the Baker patent, the '009 rejections, and the '372 allowance, **individually would support judgment of unenforceability.**
- The record compels a finding that the '716 patent was procured through inequitable conduct, thereby rendering the '716 patent unenforceable.

McKesson Information Solutions, Inc. v. Bridge Medical, Inc., No.
CIVS022669FCDKJM, 2006 WL 1652518 at *24 (E.D. Cal. June 13, 2006)



McKesson Info. Solutions, Inc. v.
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Federal Circuit

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HOLDING

- It is not necessary to decide whether any one of the three nondisclosures, standing alone, would have been sufficient to justify a judgment of unenforceability; in light of the district court's finding that there was inequitable conduct in all three instances, we hold that the court did not abuse its discretion in holding the patent unenforceable.
- Having found no clear error ... we must therefore affirm

McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897, 926 (Fed. Cir. 2007)



McKesson Info. Solutions, Inc. v. Bridge Medical, Inc.

Federal Circuit

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JUDGE NEWMAN'S DISSENT

- It is not clear and convincing evidence of deceptive intent that the applicant did not inform the examiner of the examiner's grant of a related case of common parentage a few months earlier, a case that was examined by the same examiner and whose existence has previously been explicitly pointed out by the same applicant.
- This court returns to the 'plague' of encouraging unwarranted charges of inequitable conduct, spawning the opportunistic litigation that here succeeded despite consistently contrary precedent.

McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897, 926 (Fed. Cir. 2007)

So what does it all mean for us?



- ANY ONE OF THE FAILURES TO DISCLOSE WAS SUFFICIENT FOR INEQUITABLE CONDUCT & THUS UNENFORCEABILITY
- Simply disclosing the existence of related & co-pending applications is not enough
- If co-pending cases have “substantially similar” claims, then cite rejections as well
- Two references describing the same thing may not be cumulative of each other if one provides more information or a longer disclosure than the other
- Contemporaneously record assessments of prior art & the reasons they are not cited

I have to tell the Examiner what?!?!

The Duty of Disclosure in Light of McKesson v. Bridge Medical

0.5 hrs Participatory including

0.5 hrs Ethics

Texas MCLE

Course No. 900033388

Questions?

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