The Unenforceability Defense Based on Inequitable Conduct Should be Repealed

Current Law: The doctrine of unenforceability is a judicially-created doctrine under which accused infringers, in patent litigation, assert that otherwise valid patents should be declared unenforceable for reason of "inequitable conduct." While the validity inquiry asks whether individual claims of the patent meet the specific statutory requirements of patentability, e.g. novelty and unobviousness, the inequitable conduct inquiry asks whether there was an intentional misrepresentation or omission during the patent application process. If the accused conduct is found to be sufficiently culpable, a judge can then declare the patent unenforceable.

The doctrine of unenforceability does not exist under the patent laws of other industrialized nations. However, in U.S. patent litigation, accused infringers now routinely (A 1998 AIPLA study showed that 80% of cases included such charges) use accusations of inequitable conduct as a second prong of attack to eliminate the asserted patent for reasons unrelated to actual validity, particularly in the biopharmaceutical sector where patents are highly valuable. The subjective nature of the inquiry permits a fishing expedition into the patent owner's files, and drives up the cost and length of patent litigation. As noted in *Burlington Industries v. Dayco Corp.* 849 F.2d 1418 (Fed. Cir. 1988), "[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague."

The Unenforceability Defense Based on Inequitable Conduct Should be Repealed:

- The National Academies of Science have called for the elimination or reform of the doctrine of unenforceability as part of their recommendations to make the patent system more objective and efficient.

- The regulation of applicant conduct should be committed to the expert agency, the PTO, as is done in other areas of the law (e.g., misconduct before the FDA can lead to sanctions imposed by the FDA, but does not invalidate approvals unless the misconduct alters the FDA's safety or effectiveness analysis).

- Courts should address objective questions of patent validity, infringement, and anticompetitive behavior, and should no longer have authority to declare objectively valid patents unenforceable for reasons unrelated to actual invalidity.

- The aggressive use of inequitable conduct accusations in patent litigation chills communications between patent applicants and examiners during the patent application process and negatively impacts patent examination quality today.

- The U.S. Court of Appeals for the Federal Circuit has described the abuse of the unenforceability defense as a "plague," increasing the costs of litigation.

Egregious Examples of Inequitable Conduct Allegations

Purdue Pharma v. Endo

In this case, the judge determined that the patent was valid and infringed. However during the application process, the patent owner had explained to the patent examiner that they had unexpectedly found that the claimed drug formulation provided for effective pain control over a smaller range of doses (a four-fold dosage range) than prior formulations. This was based on the inventor's knowledge of drug formulation science and his knowledge about that specific claimed drug. The infringer then found memoranda from the company's FDA regulatory staff, which showed that, for purposes of getting this claim into the drug's approved labeling, large clinical trials would have to be conducted, in the absence of which the sponsoring company would not be able to prove its "four-fold dosage range" claim. This was then introduced as evidence that the applicant must have made a misrepresentation to the patent examiner, because, after all, here was an admission that the company was unable to prove its assertion. The Federal Circuit at first affirmed, the drug went generic, Purdue lost almost half its sales and laid off a very large proportion of its staff. The Federal Circuit then reversed itself, stating that the applicant's statements did not clearly rise to the level of inequitable conduct, and sent the case back to district court. The case then settled, but the patentee has suffered irreparable harm.

Ferring v. Barr

The case concerns Barr's ANDA to market a generic version of DDAVP (desmopressin acetate), a treatment for diabetes insipidus with annual sales of $200 million. In February 2006, the CAFC affirmed a lower court ruling that Ferring's patent was unenforceable due to inequitable conduct. In this case, the accused infringer asserted that the inventor had withheld material information from the patent office during the patent application process. The patent examiner had rejected the patent claims because, under the examiner's understanding of the claim language the claimed drug would not have been novel. At issue was whether an ordinary scientist would have understood the term "peroral" to mean, simply, administration of the drug by mouth (as the examiner understood it), or more specifically the absorption of the drug substance through the mucous membranes of the mouth cavity, without swallowing. The inventor submitted several declarations from fellow scientists who explained the ordinary scientific meaning of that term in this specific context. The inventor did not, however, tell the examiner that some of the experts had in the past had a consulting relationship with the sponsoring company, or had in the past participated in clinical trials sponsored by the pharmaceutical manufacturer. The substance of the declarations, however, was completely undisputed - nobody asserted that the experts had in any way provided false or perjured information. Accordingly, the information that was allegedly withheld had nothing to do whether the patent was objectively valid or not.

Takeda Pharmaceuticals

In this case the infringer asserted that Takeda had misrepresented the age and the type of rats used in tests to the patent examiner. The court had previously found Takeda's patent

valid, enforceable, and infringed by Alphapharm Pty. Ltd. and Mylan Laboratories, both of whom filed ANDAs for generic versions of ACTOS.The U.S. District Court for the Southern District of New York awarded attorneys' fees to Takeda Pharmaceutical Company in a case involving Takeda's blockbuster antidiabetic drug, ACTOS (pioglitazone hydrochloride). The court's ruling on attorneys' fees stated that Takeda showed by clear and convincing evidence that Alphapharm and Mylan filed baseless Paragraph IV certifications. Specifically, the Court found that "Alphapharm's certification, which asserted invalidity due to obviousness, was deeply flawed and Alphapharm revised its theory again and again in a futile effort to state a prima facie case of obviousness." The Court further found that "Mylan completely abandoned its Paragraph IV theory of invalidity and proceeded to trial on a contorted claim that Takeda had engaged in inequitable conduct before the Patent and Trademark Office." The Court stated that both Alphapharm and Mylan also engaged in other exceptional litigation misconduct. Based on this, the judge held that the generics' inequitable conduct claims were so baseless that they actually amounted to litigation misconduct, justifying an award of attorney fees.

McKesson Information Solutions v. Bridge Medical

The key facts in this case involved two similar applications pending before the PTO. The three documents from the first case that were not cited in the second included: a prior-art patent; offices-actions; and the grant of the first case. In this case, McKesson lost at the district court after the judge found that its patent was unenforceable due to inequitable conduct during prosecution. The alleged acts of inequitable conduct involved McKesson's patent attorney who failed to submit three material pieces of information. On appeal, the CAFC affirmed. The court found no clear error in the finding of materiality of these omissions or intent to deceive. McKesson had paid $14 billion nearly a decade after the misconduct to acquire the business owning the patent.