



Minding Your Ps and Qs at the PTO

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Patent litigation can spawn a verdict of inequitable conduct. It may not sound that bad. Yet the ruling brands a patent unenforceable.

The verdict typically comes about like this. The defendant company in a patent infringement lawsuit alleges that the plaintiff company committed inequitable conduct during patent prosecution, the process of obtaining a patent. Inequitable conduct includes misrepresentation of a material fact, failure to disclose material information, or submission of false material information. Materiality is defined by what a reasonable examiner would have considered important in deciding whether to allow a patent application. The prohibited acts are coupled with intent to deceive, an intent that a judge may infer from the facts. If the judge decides that the plaintiff used deceit to obtain the patent, then the judge will issue the inequitable conduct verdict. It no longer matters that the defendant infringed, because courts will no longer enforce the patent.

An unenforceable patent still has uses – hiding unsightly cracks in a wall, for instance. An inventor who played a role in events leading to the patent-killing verdict may find fractures in his or her reputation. So, it's best to avoid those activities identified by courts as meriting the inequitable conduct death knell.

Mum's Not the Word: the Risk of Failing to Divulge Facts

A patent applicant must disclose prior art to the patent examiner, a rule neglected in *Bruno Independent Living Aids, Inc.* Here, the patent applicant failed to inform a patent examiner about a competitor's stairlift similar to its claimed stairlift, even though the company informed the US Food and Drug Administration while seeking approval to sell the product. The omission led to a finding of inequitable conduct.

Submitting prior art can create hazards as well. Semiconductor Energy Laboratory learned this lesson the hard way when the company submitted an untranslated 29-page Japanese reference with a concise explanation of its relevance and a one-page partial English translation. District and appellate judges concluded that untranslated portions of the reference contained information more relevant to Semiconductor's claimed invention than anything else considered by the patent examiner.

Patent prosecution can take a long time, particularly in the field of biotechnology. As one patent application undergoes examination, a related application may issue as a patent and become the subject of litigation. Patent applicants should not only update their examiners about prior art that an opposing party offers in court, but also keep in mind that they may need to inform a patent examiner about a ruling to narrow claim scope. In *Mallinckrodt, Inc. v. Masimo Corp.*, Masimo had not notified its patent examiner about a judge's decision that claims in a related patent must include certain limitations to avoid prior art.

The US patent office can assign two related applications to different patent examiners. When one examiner finds new prior art, the applicant may need to notify the other examiner about the discovery. In *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, the patent applicant had similar applications under review by two examiners. One examiner brought a newly-discovered prior art patent to the attention of McKesson. The company's failure to inform the other examiner about the prior art inspired the ruling of inequitable conduct.

Patent applicants can violate their duty of good faith by withholding information material to a determination about patentability. Merck lost a patent on a method of using cyclobenzaprine to treat certain types of skeletal muscle disorders, because a court found several examples of inequitable conduct. In one instance, Merck told the patent examiner that cyclobenzaprine did not cause drowsiness, even though the company had data showing that this assertion was untrue. In a dispute over *Taq* enzyme patent claims, a district court judge concluded that Cetus Corporation inventors withheld data that would have contradicted their arguments for patentability.

Information deemed material to patent examination can take many forms, as shown by *Monsanto v. Bayer Bioscience*. Here, the Court of Appeals for the Federal Circuit agreed with a district court's finding of inequitable conduct and the unenforceability of four Bayer patents. Plant Genetic Systems, a predecessor of Bayer Bioscience, had filed patent applications on *Agrobacterium tumefaciens* techniques for transforming plant cells with a fragment of a *Bacillus thuringiensis* toxin gene. During patent prosecution, the applicant disclosed an abstract of a poster presented at a conference by a scientist from a different organization. The patent applicant argued that the abstract did not render the claims obvious, because it failed to show that chimeric *Bt* toxin genes could be introduced into plant cells and would



direct the synthesis of toxin. However, one of the patent applicant's employees had attended the conference and taken notes about the poster. The notes revealed details on the construction of a *Bt* toxin chimeric gene and expression vector, evidence that the *Bt* toxin fusion protein functioned as an insecticide, and an indication that the scientist had transformed a plant with a chimeric gene construct. Although the notes had been circulated among company officials and employees, the company had not submitted the notes to the patent examiner.

An accurate identification of inventors is vital to the health of a US patent. While the patent office allows patent applicants to correct honest mistakes about inventorship, courts view a deliberate misrepresentation of inventorship to constitute inequitable conduct. PerSeptive Biosystems, Inc. lost patents when a court decided that its inventors – with deceptive intent – had failed to name research collaborators from another company as co-inventors.

The Danger of Misleading Statements

Patent applications may include “working examples” that describe performed experiments, as well as “prophetic examples” that predict various aspects of the invention. By convention, the past tense signals to the patent examiner that the inventors had performed the described work. Inventors must not write a prophetic example in the past tense. An incorrect verb tense transforms the example into a time bomb.

An inappropriate use of the past tense has detonated several biotech patents. A battle over *Taq* enzyme patent rights revealed that Cetus Corporation inventors had written as a prophetic example in the past tense a detailed enzyme purification protocol. Later, the applicant used that information to distinguish the claimed enzyme from the prior art. Inequitable conduct, a district court judge decided. Another court found that Novo Nordisk engaged in inequitable conduct when its inventors supported the patentability of a claimed biosynthetic growth hormone with “data” from a prophetic example written in the past tense.

Misleading statements may also arise during patent prosecution when inventors file an affidavit called a Rule 132 Declaration to support patentability. While fighting a rejection of patent claims to a glaucoma treatment, a Pharmacia inventor filed a declaration asserting that a certain dose of a prior art compound does not significantly decrease intraocular pressure. The inventor had co-authored an article that contradicted the assertion. The declaration also reported a result from an experiment that had not been performed. The Federal Circuit's finding of inequitable conduct terminated patent rights.

In *Aventis v. Amphastar*, the Federal Circuit affirmed a finding of inequitable conduct during the prosecution of a patent to a composition of low molecular weight heparins, a drug marketed as Lovenox® in the United States. The case focused on declarations written by a scientist on behalf of Aventis that distinguished claimed formulations from prior art formulations by their properties. The court found that the scientist had failed to inform the patent examiner that comparisons had been performed with different dosages of the claimed and prior art compounds.

Inequitable Conduct Rulings Incite Judicial Dissent

Judge Rader highlights the traditional view of inequitable conduct in his dissent of the *Aventis* decision:

“Without doubt, candor and truthful cooperation are essential to an ex parte examination system. With burgeoning application rates, the USPTO must rely on applicant submissions to narrow the prior art search. And, of course, those submissions must be reliable. The threat of inequitable conduct, with its ‘atomic bomb’ remedy of unenforceability, ensures that candor and truthfulness.”

Perhaps, courts are too willing to deploy this bomb. The facts of the *Aventis* patent, Rader says, support a good faith mistake, not deceptive intent. Rader cautions that the Federal Circuit has relaxed the standards for proclaiming inequitable conduct. His warning echoes Judge Newman's dissent of the *McKesson* decision: “This court returns to the ‘plague’ of encouraging unwarranted charges of inequitable conduct, spawning the opportunistic litigation that here succeeded despite consistently contrary precedent.”

One day, courts may demand more evidence of deceptive intent before pronouncing inequitable conduct. Until then, inventors should exercise scrupulous vigilance in their dealings with the patent office.

Sources

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