

PRESENTATION:

**PATENT VALIDITY LITIGATION
IN THE COURTS**

Mark Janis*

The first question I want to ask – and I want to raise a series of questions – is should we be talking about this topic at all? Here is why I ask the question, which is in part serious. I think, at least in its first decade, the Federal Circuit seemed to take the establishment of uniform standards of patent validity as its core mission, its true focus. If you think about their approach to the presumption of validity, if you think about the cases on obviousness, this is evident. However, in its second decade and up to the present, the Federal Circuit seems to me to have shifted focus; it's now focusing on doctrines of infringement and doctrines of enforceable scope.

Perhaps you might ask the question, “Why talk about validity now?” Similarly, it seems to me that in its first decade, the Federal Circuit was still dealing with traditional technological areas, primarily mechanical arts. Starting in the second decade and certainly continuing through today, the Federal Circuit increasingly has been dealing with non-traditional technical areas: software, biotechnology, etc. As a result, many patent law issues, particularly validity, have become much more complicated and perhaps even impenetrable to generalists in some cases.

This change in emphasis might raise the question of what this means for the future of patent validity litigation as we do it now, starting out in generalist District Courts. Does it mean, for example (I am throwing this out without necessarily meaning to suggest an answer), that validity defenses in patent litigation will really become, or have become, merely and primarily a set-up for a non-infringement case? For example, by way of an argument that would state, “Judge, if you construe the claims this way the patent is invalid; therefore, you should construe it this other way and the patent would not be infringed.” This is a very common, age-old argument, but is the direction we are going with validity defenses in infringement. There are many questions flowing from this – certainly the question of what this means for jury participation and patent validity issues. Thus, I wanted to begin with those questions.

I want to cover two or three items here. First, I will begin by looking at results from empirical studies to give an overview of what scholars have said about the numbers on patent validity litigation. Second, I will discuss recent developments in “on-sale bar,”

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* Professor of Law, University of Iowa School of Law.

§102(g), and the law of inventorship. I will discuss the “on-sale bar” because it is a commonly asserted defense, with a number of new cases fleshing out the Supreme Court decision in the *Pfaff* case.¹ I also selected a less common, obscure set of cases in which the Federal Circuit fills in gaps in the law of §102(g), prior invention, and in the law of inventorship. I will discuss those subjects and if I have time, I have a few other comments.

First of all, the empirical studies, on which I’d like to make two points. One study done in 1998, by Lemley and Allison, studied 300 reported Federal Circuit and District Court decisions between 1989 and 1996.² The study found that in 54% of the court decisions patent claims sustained a validity challenge, thus 46% found patent invalidity. This type of study, to me at least, would tend to refute the proposition that validity defenses are a dead letter, just a set-up, or could not refute the proposition. There are many arguments one could make. I found those numbers surprising.

If you look further, there are additional empirical studies on success rates for particular types of invalidity assertions, including assertions of the statutory bar and of obviousness. Here, the numbers are a little more like what I expected. For example, the success rate is relatively high for the assertion of statutory bars, consistent with patent lawyer wisdom. If you have a statutory bar, you really have a chance at prevailing on a statutory bar leading to anticipation. Thus, according to the study, there was a 60% success rate in the cases asserting the above, and a 36% success rate in cases asserting obviousness. One way to construe the result is that it is difficult to win on an obviousness argument. I usually took the position, when litigating an obviousness argument, that it was nearly impossible to win. It is attempted, but you really would not expect to prevail – which is, possibly, what this statistic bears out.

The Allison Lemley study, done in 1998, included a relatively limited sample. Another, more recent study, done by Kimberly Moore was published in the *Michigan Law Review* in late 2000.³ She collected cases from 1983-1999, including both reported and unreported decisions. The sample included 1,151 cases involving validity issues during trial or decisions of validity issues. The results slightly differ from Allison Lemley. The Moore study found that in 67% of the sample cases patent claims were sustained against validity challenge. This number is closer to my opening proposition that validity claims are difficult to win. Interestingly, the study also broke down the cases by jury and judge, finding that juries sustained validity in 71% of the cases. I am not sure exactly what that means and exactly what decisions the jury made. However, in bench trial cases, only 64% of the claims

¹ *Pfaff v. Wells Electronics, Inc.*, 119 S.Ct. 304, 48 U.S.P.Q. 2d 1641 (1998).

² John R. Allison and Mark Lemley, *How Federal Circuit Judges Vote in Patent Validity Cases*, 27 FLA ST. L. REV. 745 (2000) (absence of correlation between Federal Circuit panel composition and outcomes of appeals on validity issues).

John R. Allison and Mark Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AM. INTEL. PROP. L. ASS’N Q.J. 185 (1998) (validity of litigated patents upheld in 54% of cases in study sample).

³ Kimberly A. Moore, *Judges, Juries, and Patent Cases – An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365 (2000) (validity of litigated patents upheld in 67% of cases in study sample – 64% of bench trials; 71% of jury trials).

were sustained against validity. Thus, Moore makes the point that juries are a little friendlier to the patentee regarding validity than judges.

It is hard to draw broad conclusions from these empirical studies, but it would be very interesting, a few years from now, to do a study looking at trends. For example, what is it going to look like in 2005, what does it look like today, and what did it look like in 1990? It might be interesting to see if there is some sort of a shift. That is an overview of the empirical picture, to at least give you some notion of what the numbers represent.

I want to turn from there to specific doctrines; the first is the “on-sale bar.” The history of the “on-sale bar” is probably well known and does not have to be recounted in much detail. The “on-sale bar” doctrine, as I view it, reduces to two basic variables. One, what was the nature of the offer? What kind of requirements should be imposed to find that an offer existed? The second, how complete must the offered subject matter be? These seem to be the two dominating issues, particularly the latter question, and are the subject of much litigation.

A capsule of the “on-sale bar” history, probably familiar to most of you here, begins with the *Timely Products* case, Second Circuit, 1975.⁴ The court discarded the requirement that the offered subject matter be on hand, in favor of a requirement that the offered subject matter be reduced to practice. The next case is *UMC*, Federal Circuit, 1987.⁵ The Federal Circuit discarded the requirement that the offered subject matter must be reduced to practice, in favor of a totality of the circumstances approach. In this approach, the court looks to see whether the subject matter was developed somewhere beyond the level of a conception, but not all the way to a reduction to practice – somewhere in the middle.

After the *UMC* case, because the Federal Circuit incorporated the totality of the circumstances approach, the Federal Circuit was free to do pretty much as it wished. Thus, in the argument it is difficult to determine exactly what the court did. Some would argue that the court was creeping back toward a reduction to practice requirement. It is not quite there, but there were tests showing that the invention had to be sufficiently complete. The *Microchemical* case,⁶ for example, is getting close to some requirement for reduction to practice, or at least moving in that direction, in any event.

Finally, at the end of this trail of cases is the Supreme Court’s decision in *Pfaff*.⁷ In that case, the Supreme Court criticized the use of the totality of the circumstances test on the ground that it lacked certainty. The Court criticized the substantially complete formulation of the Federal Circuit on similar grounds. Then the Supreme Court installed a new test containing two elements. One goes to the variable about whether there is an offer, making one part of the test that the product must be the subject of a commercial offer for sale, and the other part that the subject matter must be ready for patenting. The Court explained that either it is reduced to practice or – and this is really the important part – it is

⁴ *Timely Products Corp. v. Aaron*, 523 F.2d 288 (2d Cir. 1975).

⁵ *UMC Electronics Co. v. United States*, 816 F.2d 647, 2 USPQ2d 1465 (Fed. Cir. 1987).

⁶ *MicroChem. Inc. v. Great Plains Chem. Co.*, 900 F.Supp.1386 (D.Colo.1995).

⁷ *Supra*, note 1.

described in sufficient detail to enable a person “skilled in the art” to practice the invention.

Recent Federal Circuit cases interpreted the Supreme Court’s decision. What is a commercial offer for sale? What does it mean for something to be ready for patenting? A few cases are worth calling to your attention.

One set of cases goes to the question of whether there exists a commercial offer in the meaning of the *Pfaff* case. In one interesting case from summer 2001, *Group One v. Hallmark*,⁸ the Federal Circuit held that in order for an offer to be considered a commercial offer in the §102(b) sense, it must be a formal contract offer. The Federal Circuit said to look to the UCC to determine the question.

A few comments are important here. First, as the Federal Circuit acknowledged in the above case, the holding is contrary to prior statements, probably *dicta*, in the Federal Circuit’s *RCA*⁹ decision. There the Federal Circuit said a formal contract offer was not necessary. The *Hallmark* case is an interesting departure. Second, the Federal Circuit said it was arriving at this result because the Supreme Court in *Pfaff* instructed the Federal Circuit to impart greater certainty to the “on-sale bar”. “Certainty” is the rationale here. It seems that this rule is only as certain as contract law; I remember that being a difficult subject in law school. If Dean Knight, a contracts professor, were here, I would ask him to illuminate us about that. However, it is only as certain as that, and maybe that is the best you can do. Third, it seems that this gives patentees an argument that they are certainly likely to press: “these were discussions not offers;” “this was not a formal contract offer.” My instinct is that patentees are going to argue this often, but are most often going to lose because it is easy to make an offer in a contract sense. Maybe it will turn out that the Federal Circuit will spend a lot of time distinguishing the facts of this case. In any event, it will be interesting to see the results stemming from the increased litigation that will result, I believe, around that point.

Another case I will mention is the *Brasseler* case.¹⁰ Without going into detail here, the Court talks about the nature of the offer and refuses to recognize a joint developer exception to the notion of the existence of an offer.

Those cases attempt to add a gloss to the notion of what is a commercial offer for sale.

Several other cases speak to the “ready for patenting” standard. One that I think is particularly interesting is the Federal Circuit decision this Spring in *Robotic Vision Systems v. View Engineering*.¹¹ Here the Federal Circuit makes a point of saying that *Pfaff* really changed the rules and case outcomes. The claimed invention was a scanning method. There were several pre-critical data activities, one of which was contact between a patentee

⁸ *Group One Ltd. V. Hallmark Cards, Inc.*, 254 F.3d 1041, 59 USPQ2d 1121 (Fed. Cir. 2001) (discussions and correspondence between parties did not rise to the level of a commercial offer).

⁹ *RCA Corp. v. Data General Corp.*, 887 F.2d 1056, 12 U.S.P.Q.2d 1449 (Fed. Cir. 1989).

¹⁰ *Brasseler USA v. Stryker Sales Corp.*, 182 F.3d 888 (Fed. Cir. 1999) (transaction between alleged joint developers constituted an offer for sale).

¹¹ *Robotic Vision Systems, Inc. v. View Eng., Inc.*, 249 F.3d 1307 (Fed. Cir. 2001) (complete conception satisfies “ready for patenting” standard even where inventor lacks “complete confidence that his invention will work for its intended purposes”).

and a customer. The contacts were later determined to rise to the level of a commercial offer. Later, but still before the critical date, one of the co-inventors explained to a fellow employee the scanning method and asked the fellow employee to create software that, I gather, would control the scanning method. Apparently, there was evidence showing skepticism about whether the software could be written and if it would work, prior to the critical date. The Federal Circuit, reviewing those facts on appeal, held that the explanation from the patentee to the fellow employee was given in sufficient detail to evidence a conception, to evidence an enabling disclosure. Therefore, as of that time, the subject matter was ready for patenting and satisfied the second alternative prong of the ready for patenting test.

I have a few comments on the result in the *Robotic Vision* case. It strikes me as an important case, particularly for software issues and perhaps beyond. First, the Federal Circuit makes a big deal about the fact that it is applying new standards since the *Pfaff* case changed things. The Federal Circuit previously ruled that under the old standards applied before *Pfaff*, if the software had not been completed prior to the critical date, no “on-sale bar” would be triggered. The Federal Circuit said that *Pfaff* now requires the court to hold that as long as there is a complete conception – a conception giving an enabling disclosure – the “on-sale bar” is triggered, showing that the subject matter is ready for patenting. The case highlights the Federal Circuit perception of the difference in standards.

Second, I wondered (and I am not a software person), about the impact of that decision in the software industry. It struck me that the Federal Circuit has never established a very rigorous §112 enabling disclosure requirement in software cases, at least not as compared to chemical and biotech cases. That might seem like a welcome feature of the case law if you were operating in the computer software industry; however, this may change now, because the low-level §112 enablement might also translate into a low-level of disclosure required for triggering the “on-sale bar.” It will be interesting to see how this pans out for software inventions, particularly in an industry that is very aggressive and characterized by entrepreneurial zeal and a willingness to disclose early.

A number of other cases over the last couple of years have spoken to the question of what is “ready for patenting.” Many of these are cases where there was a reduction to practice. In the *STX*¹² case there was a prototype reduced to practice according to the construed claims. The *Abbott*¹³ and *Scaltech*¹⁴ cases, both Federal Circuit 1999 decisions, talk about subject matter reduced to practice. The cases indicate that as long as the subject matter

¹² *STX, L.L.C. v. Brine, Inc.*, 211 F.3d 588 (Fed. Cir. 2000) (operative prototype satisfies “ready for patenting” standard even where prototype did not necessarily exhibit performance qualities recited in claim preamble).

¹³ *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 182 F.3d 1315 (Fed. Cir. 1999) (product satisfies “ready for patenting” standard even where product “inherently possesses each of the limitations of the claims...whether or not the parties to the transaction recognize that the product possesses the claimed characteristics”).

¹⁴ *Scaltech Inc. v. Retec/Tetra, L.L.C.*, 178 F.3d 1378 (Fed. Cir. 1999) (process satisfies “ready for patenting” standard where process “inherently possessed each of the claim limitations...whether or not the seller recognized that his process possessed the claimed characteristics”).

inherently satisfies the claim limitations it does not really matter if the parties to the sales transactions were not aware of it at the time. As long as the subject matter is reduced to practice, this inherently satisfies the limitation to claim that it is going to be reduced to practice, and is therefore ready for patenting – thus triggering the “on-sale bar.”

I want to make a summary comment or two on those cases; perhaps we can follow up with the panel. There is no question that those cases add many layers of gloss to an already reasonably complicated area. I think we ought to be asking: is this progress, is this just more doctrine, and does this give greater certainty? We have to ask these questions because it is the rationale underlying *Pfaff*. Do we end up with greater certainty or not? This is very important in seeking patent protection and in trying to protect investments.

Lastly, and to me as an academic, most importantly, what about the policy vision here? In the days when the Federal Circuit applied a totality of the circumstances test, it had a litany of policies it would often recite. Were those policies just related to the totality of the circumstances approach? What is the policy objective for the “on-sale bar” under this new regime? Are they the same or different policies? I do not know the answer to that question, but I think it is worth asking, especially as we go further and further down the road, adding layers of doctrine in this area. There are a number of recent works of scholarship on these cases concerning the “on-sale bar.”¹⁵ Some have good explanations of law.

Let me turn briefly to a few cases on invention and inventorship. Here I am lumping together discreet issues. They sound more alike than perhaps they really are. First, the issue of inventorship: Who is a proper inventor? Second, priority of invention: When did the invention occur? The first issue implicates §§102(f) and 256 of the patent statute; the second implicates primarily §102(g). There are a few recent cases on this topic, which is unusual – one of the reasons that I chose this area. It is rare to see so many cases on this topic in such a short period. Here they are in summary.

One case of great interest in the Academy is a decision of several days ago entitled, *Chou v. University of Chicago*.¹⁶ Here the Federal Circuit held that a former post-doc student had standing to sue for correction of inventorship, even though it was deemed that she had assigned rights to the invention to the University by way of the University blanket assignment policy. The court concluded that an expectation of ownership is not a standing prerequisite for a suit to correct inventorship under §256. I should mention that the student

¹⁵ William C. Rooklidge, Russell B. Hill, *The Law of Unintended Consequences: The On Sale Bar After Pfaff v. Wells Electronics*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 163 (2000).

Timothy R. Holbrook, *The More Things Change, the More They Stay the Same: Implications of Pfaff v. Wells Electronics, Inc. and the Quest for Predictability in the On-Sale Bar*, 15 BERKELEY TECH. L.J. 933 (2000).

Michael Colaianni, *Reduction to Practice and the “On-Sale” Bar: It’s Time to Return to Timely Products*, 18 NO. 4 INTELL. PROP. L. NEWSL. 16 (Summer 2000).

Isabelle R. McAndrews, *The On-Sale Bar After Pfaff v. Wells Electronics: Toward a Bright-Line Rule*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 155 (1999).

Imron T. Aly, *Seller Beware: The Scope of the On Sale Bar After Pfaff v. Wells*, 7 TEX. INTELL. PROP. L.J. 403 (1999).

¹⁶ *Chou v. University of Chicago*, 254 F.3d 1347 (Fed. Cir. 2001) (standing to sue for correction of inventorship).

had a financial interest by virtue of the assignment policy. She was entitled, if she was an inventor, to a fraction of 25% (or some percentage) of the royalties. This was the reason that convinced the Federal Circuit that she had a potential injury and therefore had standing.

Interestingly, the Federal Circuit raised, but did not resolve, a question about whether injury to reputational interest is sufficient to confer standing. The alleged injury would be, “I was left off of this patent and it would have enhanced my reputation to be on this patent.” (I suppose that if it were a bad patent you would probably not want to be on it.) Does that sort of reputational interest confer standing? This will have to be resolved in a future case. I do not know if that will come up much in the Academy, because I think most folks do have a financial interest by virtue of the policies I have seen. I certainly do not know, but wonder if it might come up in the private sector, where, I think, you could have many employees who give blanket assignments, but who do not necessarily have any discreet financial interest in royalty proceeds. It is an interesting question and we will see if it comes up in a future case.

A second interesting co-inventorship case is *Acromed v. Sofamor Danek Group*,¹⁷ out of the orthopedic arts. The court articulates standards; I do not know if the court simply restates the question or adds anything, but it is certainly worth knowing. This case applies the principle that an alleged co-inventor must show not only evidence of contribution to the conception of at least one claim and corroboration of that, but must also show that the contribution was significant. The court says, “[S]ignificant in quality and not merely an explanation of well-known concepts.” If you just have an explanation of well-known concepts, you do not have any conception, you do not have an invention. The court relied on the word “significant” to say that the explanations given were merely explanations of one of ordinary skill in the art and didn’t rise to the level of invention. I think that allows significant room for argument, and it will be interesting to see if anything is made of that.

Another case I will mention briefly is *Solomon v. Kimberly-Clark*,¹⁸ a Federal Circuit 2000 decision. Here the inventor’s deposition testimony raised a question about whether the inventor was really the inventor at all of the claimed invention or the sole inventor of the claimed invention – something we always worry about in practice. The court faced two issues. One regarding §112, second paragraph, the invention argument. The court said you could not use inventor testimony, as a matter of law, to adjudicate that. In the second issue, the court said that you can use inventor testimony in connection with the §102(f) argument, but the court seemed to suggest that it would only be in rare circumstances, because that kind of testimony supports a conclusion of derivation under §102(f). Thus, both these arguments were slapped down by slightly different means – which was interesting because that was something I had not seen in the doctrine before.

¹⁷ *Acromed Corp. v. Sofamor Danek Group, Inc.*, 253 F.3d 1371, 59 USPQ2d 1130, 1135 (Fed. Cir. 2001) (difference between inventive contribution and mere exercise of ordinary skill).

¹⁸ *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372 (Fed. Cir. 2000) (clear and convincing standard for proving 102(f) invalidity).

Lastly, I will mention a couple of other cases. The *Perseptive Biosystems*¹⁹ case is interesting for the proposition that if you intentionally fail to disclose information relevant to an inventorship issue, you could be socked with inequitable conduct. I will not say anything more about that because one of our panelists knows much more about the facts of the case than I do, having been a District Court judge who decided the case.

Another case in my outline – I do not have time to go into in detail – is *Apotex v. Merck*,²⁰ a June 2001 decision of the Federal Circuit. This case filled in gaps about the law of §102(g), suppression and concealment, the burdens of production, and about whether there are geographic limitations applicable to proof of suppression or concealment. The court says that disclosure anywhere in the world can negate an argument of suppression or concealment. Again, here the Federal Circuit is doing what it has done very well over the course of its tenure, filling in small gaps in the doctrine and seeming to do it in a reasonable fashion.

There are many other cases to discuss [on allocation of decisionmaking authority on validity issues, and harmonization issues bearing on validity²¹], but I do not have time. I will stop here. Thank you.

¹⁹ *Perseptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315 (Fed. Cir. 2000) (inequitable conduct for intentional omission of information relevant to inventorship).

²⁰ *Apotex USA, Inc. v. Merck & Co., Inc.*, 254 F.3d 1031 (Fed. Cir. 2001) (102(g) “abandoned, suppressed, or concealed” standard: burdens; absence of geographic limitation).

²¹ [Ed.: Mr. Janis notes in his outline several other recent cases pertinent to 35 U.S.C. §102(g): Existence of Prior Invention, but did not have time to discuss them. They are: *Mycogen Plant Science, Inc v. Monsanto Co.*, 234 F.3d 1316, 58 USPQ2d 1030 (Fed. Cir. 2001) (102(g) diligence standard); *Mycogen Plant Science, Inc v. Monsanto Co.*, 243 F.3d 1316 (Fed. Cir. 2001) (simultaneous conception and reduction to practice of process invention); *Environ Prods., Inc. v. Furon Co.*, 215 F.3d 1261 (Fed. Cir. 2000) (preponderance of the evidence standard for priority between interfering patents).]