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Review of Developments in Intellectual Property Law

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Obviousness of Pharmaceuticals - Patentability Over Known, Structurally Similar Compounds

Ethyl, methyl, butyl…futile – the running joke in grad school. Just try a different substituent until you find an active compound – or not. But while tweaking an alkyl substituent might seem "obvious" in the lab, when it comes to patent protection of small molecules, is it necessarily obvious? When examining a patent application with claims directed to novel chemical compounds, an examiner may reject those claims under 35 U.S.C. § 103 as obvious over structurally similar compounds in the prior art. Likewise, an accused infringer will often allege that the asserted claims to chemical compounds are "obvious" when challenging the validity of a patent. Successfully overcoming a charge of obviousness can be critical where the compound(s) in question are clinical candidates or are already highly successful commercial therapeutics. So how can you defeat those assertions?

Obviousness Before *KSR*

While the concept of obviousness seems intuitive, it is not easily defined. Fortunately, the Supreme Court provided some guidance in the form of a framework that can be used when considering the obviousness of a claim. The seminal case of *Graham v. John Deere Co. of Kansas City*[1] counsels that the following factors be considered in any obvious analysis: 1) the scope and content of the prior art, 2) the differences between the claimed subject matter and the prior art, 3) the level of ordinary skill in the art, and 4) any secondary considerations such as commercial success,

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Post-Issuance Options: The Benefits and Risks of Reexamination and Reissue

Congratulations, your patent has issued. Using the time you no longer spend chatting with your patent attorney, you decide to catch up on old (as in, before your filing date) issues of your favorite technical magazine. You come across an article that seems quite similar to your invention, and you begin to wonder: are my claims too broad/narrow?

Overbroad or overly narrow claims are examples of aspects of an issued patent that may be modified through either reexamination or reissue. In each of reexamination and reissue, prosecution of an issued patent is reopened to address areas of concern in the issued patent. However, reexamination and reissue are not interchangeable – each offers its own benefits and its own risks. Before requesting one of reexamination or reissue of your patent, it is important to be aware of what is required of you, what is required of your patent, and what effects the reexamination or reissue could have in the future.

Reexamination

Reexamination offers an opportunity for patent owners (and patent challengers) to reopen prosecution of an issued patent within the period of enforceability of the patent.[1] Reexamination will only be granted in light of *a substantial new question of patentability*.[2] Which begs the question: what qualifies as a "substantial new question of patentability?" The answer is twofold.

First, the substantial new question of patentability must arise out of one or more patents or

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long-felt but unresolved need, failure of others, etc.

Based on the teachings of *Graham v. John Deere* and other Supreme Court decisions, the Court of Customs and Patent Appeals ("CCPA"), the predecessor to the Federal Circuit, developed its own jurisprudence on the meaning of obviousness. A key test developed by the CCPA was the Teaching, Suggestion or Motivation test ("TSM") for ascertaining whether a combination of known elements was obvious. Under this test, a claim is obvious if there is a teaching, suggestion, or motivation that would cause a person of ordinary skill in the art to combine known elements, or modify a known item in a particular way.

When the Federal Circuit was formed and thereby replaced the CCPA, the Federal Circuit adopted the CCPA's precedents, including the TSM test. But over time, the Federal Circuit's obviousness analysis and application of the TSM test became rigid, drifting away from considering the level of skill in the art and toward focusing on what was explicitly taught or suggested in the cited prior art references. That changed, however, in the wake of the Supreme Court's opinion in *KSR Int'l Co. v. Teleflex Inc.*[2]

KSR Framework

The patent-in-suit in *KSR*, licensed to Teleflex, was directed towards a position adjustable pedal assembly with an electronic sensor attached to the assembly for use in cars and light trucks. When Teleflex sued KSR for infringement by KSR's adjustable pedal assembly, KSR countered with an attack on the validity of the patent-in-suit, including an argument that the asserted claim of the patent-in-suit was obvious. Applying the teachings of *Graham v. John Deere* and the TSM test, the district court found the asserted claim invalid as obvious and granted summary judgment in favor of KSR. Teleflex appealed, and the Federal Circuit, applying the TSM test, reversed. The Federal Circuit found that the district court had failed to make specific findings as to the understanding or principle that would have led a skilled person to combine the teachings of the cited references and prepare the claimed pedal assembly and, as such, had not been strict enough in applying the TSM test. In response to KSR's argument to the contrary, the Federal Circuit reiterated its standard that obvious to try is not obvious.

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The general consensus is that it is easier to establish obviousness post-*KSR* than it was pre-*KSR*.

KSR then appealed and the Supreme Court reversed the Federal Circuit. In its decision, the Supreme Court took the Federal Circuit to task for applying a rigid obviousness analysis that failed to fully comport with *Graham v. John Deere* and other Supreme Court case law. In particular, the Supreme Court made clear that an obviousness analysis needs to be expansive and flexible, and that such an approach is inconsistent with the Federal Circuit's practice of rigidly applying the TSM test. However, the Supreme Court did not completely reject the TSM test; rather, it made clear that "there is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis."[3] Thus, the TSM test is still a viable test, but it is not to be rigidly applied. Following *KSR*, the TSM analysis no longer requires an express teaching or suggestion in the cited prior art. Instead, the analysis must consider whether a person of ordinary skill could have been motivated by any need or problem and might use familiar items in ways beyond their primary purpose.

In *KSR*, the Supreme Court also made clear that an approach that is obvious to try may, in fact, be obvious. More specifically, where there is a need to solve a problem and there are a "finite number of identified, predictable solutions,"[4] pursuing those known options may indeed be obvious, because common sense would dictate that those options be tried. Indeed, the Supreme Court advised that, as a general principle, rigid rules that deny factfinders the use of common sense are improper and inconsistent with the law.

The general consensus is that it is easier to establish obviousness post-*KSR* than it was pre-*KSR*. But how has *KSR*, which was concerned with a rather simple mechanical device, affected the obviousness analysis for chemical inventions? Fortunately, in the approximately four years since the *KSR* case was decided, the Federal Circuit has issued several obviousness opinions, a few of which are discussed below, that provide guidance on conducting an obviousness inquiry in the chemical arts, and that provide insight into defending against an assertion of obviousness.

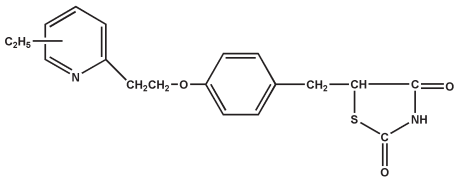
Structural Obviousness of Pharmaceuticals After *KSR*: Example Federal Circuit Opinions

Takeda v. Alphapharm

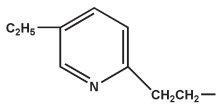
Following on the heels of *KSR*, the Federal Circuit had an opportunity to address structural obviousness in *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*[5] Alphapharm was sued by Takeda for infringement of U.S. Patent No. 4,687,777 (the "'777 patent") following Alphapharm's Paragraph IV certifi-

cation in conjunction with its filing of an ANDA to manufacture a generic version of Takeda's Actos® ("pioglitazone"), used to treat Type 2 diabetes. Pioglitazone is a member of a class of drugs for the treatment of diabetes known as thiazolidinediones ("TZDs"), a technology area in which Takeda had been active for decades. In asserting invalidity of the '777 patent, Alphapharm alleged that the claims were obvious in view of "compound b," a prior art TZD compound disclosed in the '777 patent and in earlier Takeda patent applications.

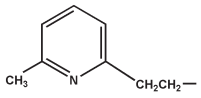
Claim 1 of the '777 patent is directed to a compound of the formula:



The portion of the claimed structure that was at issue is the ethyl-substituted pyridyl ring at the left of the molecule. The ethyl substituent is in the 5-position in pioglitazone:



Compound b, the prior art compound asserted by Alphapharm, contains the same core structure as the claimed formula, but has a methyl at the 6-position of the pyridyl ring:



The district court concluded that there was no motivation in the prior art to select compound b as a lead compound for diabetes therapeutics and that the prior art taught away from its use. Thus, the district court found that Alphapharm had failed to make a *prima facie* case of obviousness. The district court further concluded that even if Alphapharm had established a *prima facie* case of obviousness, it was rebutted by pioglitazone's unexpected nontoxicity. The Federal Circuit affirmed those findings.

On appeal, Alphapharm argued, *inter alia*, that the district court's decision was erroneous on the basis that it had misapplied the law on obviousness, particularly with regard to structurally similar chemical compounds. The Federal Circuit found no error, and noted that even in view of the pronouncement in *KSR* that the TSM test was not to be rigidly or mandatorily applied, "in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound."[6]

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Since *KSR*, the Federal Circuit has issued several obviousness opinions that provide guidance on conducting an obviousness inquiry in the chemical arts, and that provide insight into defending against an assertion of obviousness.

In its analysis, the Federal Circuit noted the *Graham v. John Deere* factors endorsed in *KSR*, but focused primarily on the first factor: the scope and content of the prior art. More specifically, the Federal Circuit first addressed the matter of selection of compound b as the lead compound,[7] and then turned to the choice of the claimed compounds in the '777 patent.

With respect to the lead compound issue, Alphapharm had argued that the prior art (including a statement in the prosecution history of an earlier Takeda application noting that compound b was of particular importance) would have led one of skill in the art to select compound b as a lead compound – and then one of skill in the art would make two obvious types of modifications: homologation (replacing the methyl of compound b with ethyl) and "ring walking" (moving the substituent to each position on the ring). The Federal Circuit agreed with the district court's finding that Alphapharm's assertions were unfounded.

More specifically, the Federal Circuit agreed that while compound b was disclosed in the prior art, and efficacy data provided, it was but one of *many* disclosed compounds, and there was nothing in the prior art to suggest that of the many compounds (most of which lacked data that would permit an assessment of efficacy and safety), compound b was one of the best performing compounds and therefore could be a candidate as a lead compound. Moreover, there was a prior art journal article that singled out compound b as having negative effects, making it an unattractive candidate as a lead compound to one of skill in the art. Those negative effects were, in fact, particularly problematic to those suffering from diabetes. Thus, the Federal Circuit agreed that the journal article taught away from the use of pyridyl compounds, including compound b, in the treatment of diabetes.

The Federal Circuit, having affirmed that Alphapharm had failed to establish a *prima facie* case of obvious, nevertheless addressed

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the issue of the choice of the claimed compounds in the '777 patent, and concluded that this served as a second basis on which Alphapharm's obviousness argument failed. The Federal Circuit concluded that there was nothing in the prior art that suggested the specific modifications necessary to arrive at the claimed compound of the '777 patent from compound b. In particular, the evidence showed that while homologation and "ring-walking" were routine, one of skill in the art would consider various different substituents, including, for example, halides, in modifying the pyridyl ring. Additionally, prior work with related compounds suggested that homologation would have no tendency to decrease the unwanted side effects, leading one of skill in the art in a different direction. And finally, the journal article found to teach away from the claimed invention also showed unpredictability in the biological activity of various substituents within the TZD class of compounds.

Alphapharm argued, based on prior case law, that there was an expectation that structurally similar compounds would have similar properties, and that expectation had to be rebutted in order to avoid an obviousness determination. The Federal Circuit concluded that Takeda had indeed rebutted that presumption: experimental results showed that pioglitazone exhibited superior properties over compound b, as it was non-toxic, and there was no reasonable expectation that pioglitazone would possess non-toxicity, especially in view of the toxicity of compound b.

Procter & Gamble v. Teva

The Federal Circuit opined on the obviousness of isomers in *Procter & Gamble Co. v. Teva Pharm., Inc.*[8] Teva Pharmaceuticals ("Teva"), looking to sell a generic version of Procter and Gamble's ("P&G") osteoporosis drug, Actonel® ("risedronate"), filed a Paragraph IV certification that included an allegation that the claims of P&G's patent, U.S. Patent No. 5,583,122 (the "'122 patent"), were obvious in light of the disclosure contained in P&G's expired U.S. Patent No. 4,761,406 (the "'406 patent"). P&G then sued Teva for infringement.

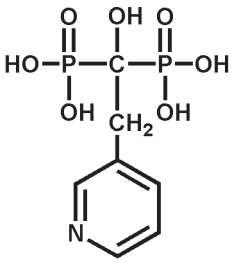
In support of its contention that the asserted claims of the '122 patent were invalid, Teva argued that the structural similarity between the prior art compound 2-pyr EHDP (disclosed in the '406 patent) and risedronate rendered the claims of the '122 patent invalid. (The structures of risedronate and 2-pyr EHDP are shown on this page.)

The district court rejected Teva's argument. In finding the claims to risedronate to be non-obvious, the court determined that the '406 patent would not have led a person of ordinary skill in the art to use 2-pyr EHDP as the lead compound. The court also relied on 1) the extremely unpredictable nature of bisphosphonates at the time of the invention, and 2) there being no motivation for a person of ordinary skill in the art to perform the modifications necessary to make risedronate from 2-pyr EHDP. Finally, the court found that secondary considerations of non-obviousness supported its conclusions.

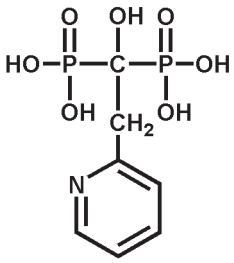
On appeal, the Federal Circuit affirmed. The Federal Circuit started with an identification of the applicable legal standards, noting that the TSM test provided useful insights, so long as it wasn't rigidly applied, and acknowledging *KSR* and its prior decision in *Takeda*. The court further stated that post-*KSR*, an obviousness analysis for a chemical compound generally begins with the reasoned identification of a lead compound. It was noted, however, that a patent owner can refute a *prima facie* case of obviousness by demonstrating a property of the compound that a person of ordinary skill in the art would find surprising or unexpected.

snippets

Even in view of the pronouncement in *KSR* that the TSM test was not to be rigidly or mandatorily applied, "in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound."



Risedronate



Prior Art Compound 2-pyr EHDP

The Federal Circuit began its analysis by noting that even if 2-pyr EHDP was the lead compound (a review the Federal Circuit did not undertake), there was no evidence that a person of ordinary skill would have modified it to make risedronate. The Federal Circuit noted that risedronate and 2-pyr EHDP were isomers, and that structurally similar compounds often have similar properties, which could lead to the requisite motivation to modify the prior art compound. But, there was evidence that each bisphosphonate compound exhibited its own properties and activities and should be considered on its own, and that inferring characteristics and activities from one bisphosphonate to another was dangerous and could be misleading. There was also evidence that P&G prepared and tested the 2-pyr and 4-pyr EHDP isomers along with risedronate and reported that the 4-pyr EHDP was not active in inhibiting bone resorption. Since the bisphosphonate art was unpredictable, as the chemical arts often are, the Court stated that "*KSR*'s focus on [ ] 'identified, predictable solutions' may present a difficult hurdle because potential solutions are less likely to be genuinely predictable."[9] The Court, however, agreed with the district court's conclusion that Teva had failed to establish the requisite motivation for a person of ordinary skill in the art to synthesize and test risedronate.

The Federal Circuit also found that there was insufficient evidence showing a person of ordinary skill in the art would have had a "reasonable expectation of success" in synthesizing and testing risedronate.[10] The Federal Circuit analyzed the issue by focusing on whether a particular molecular modification would be carried out as a part of routine testing, *i.e.* where "a person of ordinary skill is faced with a 'finite number of identified, predictable solutions' to a problem and pursues 'the known options within his or her technical grasp.'"[11] As the Federal Circuit noted, non-routine testing would be where one of skill in the art could only vary all parameters or try numerous possible choices until the desired result is achieved, because the prior art provides no indication of which parameters are key or which choices are likely to be successful.[12] Teva's evidence on this issue was deemed not persuasive, as it failed to establish that the bisphosphonate art was predictable, that the necessary structural modification was routine, or that there was a reasonable expectation of success. Thus, the Federal Circuit held that the district court did not err in finding that Teva had failed to establish a *prima facie* case of obviousness.

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Post-*KSR*, an obviousness analysis for a compound generally begins with the reasoned identification of a lead compound.

Finally, the Federal Circuit addressed secondary considerations of non-obviousness. Actonel® was characterized as "an undisputed commercial success" with aggregate domestic sales of $2.7 billion. The Federal Circuit further considered whether Actonel® satisfied a long-felt but unmet need and agreed that when the application that matured into the '122 patent was filed, the existing treatments for osteoporosis were inadequate. Thus, the Federal Circuit found that it was not clear error for the district court to have found that secondary considerations supported the non-obviousness of the claims.

Sanofi-Synthelabo v. Apotex, Inc.

The Federal Circuit addressed the patentability of an enantiomer in light of the prior disclosure of the racemic compound in *Sanofi-Synthelabo v. Apotex, Inc.*[13] U.S. Patent No. 4,847,265 (the "'265 patent"), assigned to Sanofi-Synthelabo ("Sanofi"), covers the platelet aggregation inhibitor clopidogrel bisulfate (Plavix®). Clopidogrel bisulfate is the dextrorotatory enantiomer of methyl alpha-5(4,5,6,7-tetrahydro(3,2-c)thienopyridyl)(2-chlorophenyl)-acetate and it is used to treat heart attacks and strokes. Apotex, Inc. ("Apotex") filed an ANDA seeking approval for generic Plavix®, and in its Paragraph IV certification alleged that the '265 patent was invalid as obvious because racemic methyl alpha-5(4,5,6,7-tetrahydro(3,2-c)thienopyridyl)(2-chlorophenyl)-acetate was described in two prior art patents owned by Sanofi, U.S. Patent No. 4,529,596 and Canadian Patent No. 1,194,875.

The district court found the '265 patent to be non-obvious. The district court presumed that Apotex had established a *prima facie* case of obviousness based on the prior disclosure of the racemate, statements made in the prior art patents regarding enantiomers, and general knowledge in the art that enantiomers may be separated and may have different biological activities. But, based on the unpredictable and unusual properties of the claimed dextrorotatory enantiomer, the district court found the presumption of obviousness to have been overcome. Specifically, evidence showed that the enantiomers of methyl alpha-5(4,5,6,7-tetrahydro(3,2-c)thienopyridyl)(2-chlorophenyl)-acetate had the rare characteristic of "absolute stereoselectivity," where the dextrorotatory enantiomer provided all of the favorable antiplatelet activity but no significant neurotoxicity, while the levorotatory enantiomer produced no antiplatelet activity but virtually all of the

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neurotoxicity. Additionally, experts for both Sanofi and Apotex agreed that it while it was known that enantiomers could have different properties, "absolute stereoselectivity" was impossible to predict.

On appeal, Apotex argued that the recognition in the prior art that methyl alpha-5(4,5,6,7-tetrahydro(3,2-c)thienopyridyl)(2-chlorophenyl)-acetate existed as an enantiomeric mixture outweighed any unexpected properties of the separate dextrorotatory enantiomer. Apotex contended that since Sanofi had been developing racemic methyl alpha-5(4,5,6,7-tetrahydro(3,2-c)thienopyridyl)(2-chlorophenyl)-acetate as a drug, it was natural to use it as a lead compound for further research. Moreover, Apotex argued, it was known that enantiomers may have different properties and that the separation of enantiomers could be achieved through well-known chemical techniques. Thus, Apotex reasoned a person of ordinary skill in the art would have had motivation to separate the enantiomers and a reasonable expectation of success in separating and evaluating the individual enantiomers. However, evidence adduced at trial (including an admission by Apotex's expert) showed that while differing biological properties would be expected for different enantiomers, it was not possible predict the extent or nature of those differences. Thus, the Federal Circuit found there was no clear error in the district court's conclusion of non-obviousness, particularly in view of the evidence that one of skill in the art would not have reasonably predicted that the dextrorotatory enantiomer would provide all of the therapeutically beneficial activity and none of the adverse side effects.

The Federal Circuit also found no clear error in the district court's decision to dismiss Apotex's argument that techniques for separating enantiomers were well known in the art and as such, separated enantiomers were obvious as a matter of law. Before the district court, the evidence indicated that Sanofi had suffered several failures as it tried to separate the enantiomers and that the method Sanofi ultimately used to separate the enantiomers of methyl alpha-5(4,5,6,7-tetrahydro(3,2-c)thienopyridyl)(2-chlorophenyl)-acetate, *i.e.*, diastereomeric salt formation, had previously failed when Sanofi attempted to separate the enantiomers of a compound related to methyl alpha-5(4,5,6,7-tetrahydro(3,2-c)thienopyridyl)(2-chlorophenyl)-acetate. Thus, the Federal Circuit endorsed the district court's conclusion that enantiomeric separation in this particular instance was difficult and unpredictable.

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A patentee can refute a *prima facie* case of obviousness by demonstrating a property of the compound that one of ordinary skill in the art would find surprising or unexpected.

Finally, the Federal Circuit dismissed Apotex's argument that the district court did not adequately follow the Supreme Court's holding in *KSR* that the "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."[14] Apotex contended that Sanofi simply separated the isomers and identified their properties, and that the properties were those of the racemate, just allocated between the isomers. The Federal Circuit was unpersuaded by this argument, particularly in view of the evidence supporting the district court's finding that the result of the separation of the enantiomers was unpredictable.

Conclusion

Taken together, these cases provide some clear guidance to an applicant or patentee faced with an assertion that its pending or asserted claims are obvious in view of a structurally similar compound in the prior art, which can be summarized as follows:

- Claims directed to homologs, isomers, and enantiomers of, or compounds having structural similarity to, known compounds are not *ipso facto* obvious. However, the presumption that structurally similar compounds would have similar properties must be rebutted.
- In order to establish a *prima facie* case of obviousness of a new compound, a reason must be identified as to why one of skill in the art would have been led to modify a known compound in the particular manner necessary to arrive at the new compound. More specifically, there must also be a basis for selecting a particular compound – from among other known compounds – as a lead compound to be modified.
- In order to establish a *prima facie* case of obviousness, there must be a reasonable expectation of success in synthesizing and testing the claimed compound; modifications that involve non-routine testing (such as varying all parameters where there is no indication as to which parameters are key or which choices might lead to success) are not considered to have a reasonable expectation of success.
- Prior art that reveals negative properties of a lead compound, or teaches away from the claimed compounds, can prevent a patent examiner or patent challenger from being able to establish

a *prima facie* case of obviousness.

- An assertion of obviousness may be negated where there is nothing in the prior art to suggest the specific modifications made to the lead compound to arrive at the claimed compound.
- A showing of unpredictability among a particular class of compounds can support a non-obviousness argument; the greater the unpredictability, the more likely it is that a new compound will be found non-obvious.
- Even if a *prima facie* case of obviousness can be established, experimental results demonstrating superior, unpredictable, or unusual properties of a claimed compound over the lead compound can rebut a presumption that structurally similar compounds have similar properties and are therefore obvious.
- Secondary considerations, such as commercial success and failure of others, may be helpful in leading to a finding of non-obviousness.

Endnotes

1. 383 U.S. 1 (1966).
2. 550 U.S. 398 (2007).
3. *Id.* at 1741.
4. *Id.* at 1732.
5. 492 F.3d 1350 (Fed. Cir. 2007).
6. *Id.* at 1357
7. "Lead compound" was – and continues to be – used to refer to "a compound in the prior art that would be most promising to modify in order to improve upon its [] activity and obtain a compound with better activity." *Id.* at 1357.
8. *Procter & Gamble Co. v. Teva Pharm., Inc.* 566 F.3d 989 (Fed. Cir. 2009).
9. *Id.* at 996 (quoting *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008)).
10. *Id.*
11. *Id.* (quoting *KSR*, 550 U.S. at 421).
12. *Id.* at 996-997.
13. 550 F.3d 1075 (Fed. Cir. 2008).
14. *KSR v. Teleflex*, 550 U.S. at 416.

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printed publications.[3] Other types of prior art (*e.g.*, prior sale or public knowledge) cannot be used as a basis for requesting reexamination. The substantial new question of patentability may arise out of patents or publications already considered during prosecution if presented in a new light in the reexamination request, or out of newly-discovered patents or publications.[4] Second, the substantial new question of patentability must be *truly new*, meaning it cannot solely be based on a rejection already considered during prosecution.[5]

In order to initiate a reexamination, a request must be made to the Patent and Trademark Office ("PTO") that identifies the patents and/or publications, the substantial new question of patentability, and each claim for which reexamination is requested; it must also provide a detailed explanation of the pertinence and manner of applying the patents and/or publications to every claim for which reexamination is requested.[6] If the request is initiated by a patent owner, the request may additionally include (a) an explanation of how the claims to be reexamined are distinguishable from the identified patents and/or publications, and (b) proposed amendments to one or more of the claims to be reexamined.[7]

For a patent challenger, reexamination comes in two forms: *ex parte* and *inter partes*. In an *ex parte* reexamination, a patent challenger cannot take any action beyond the filing of a request for reexamination.[8] In contrast, *inter partes* reexamination allows a patent challenger to participate in the reexamination proceedings beyond the filing of the request.[9] On its face, *inter partes* reexamination seems to be a preferable course of action for most patent challengers, but in fact, *ex parte* reexamination is significantly more popular.[10] There are three main reasons for this.[11] First, *ex parte* reexamination allows a patent challenger to remain anonymous, thereby avoiding retaliatory action by the patent owner.[12] Second, *ex parte* reexamination is less expensive than *inter partes* reexamination based on the reduced request fee (currently $2,520.00 for *ex parte* reexamination versus $8,800 for *inter partes* reexamination) and the ability to avoid the fees associated with ongoing participation in an *inter partes* reexamination.[13] Third, a patent challenger whose request for an *inter partes* reexamination results in an order for reexamination is estopped from asserting at a later time, in any civil action, the invalidity of a claim finally determined to be valid and patentable on any ground that the third-party requester raised or *could have raised* during the *inter partes* reexamination proceedings.[14]

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Before requesting either reexamination or reissue of your patent, it is important to be aware of what is required of you, what is required of your patent, and what effects the reexamination or reissue could have in the future.

Once a request for reexamination is granted, the patent is examined in a manner similar to that of normal prosecution, with the exceptions that (a) requests for extension of time must be supported by a showing of sufficient cause[15] and (b) requests for continued examination are not available.[16] The reexamination is handled by an Examiner in a special Central Reexamination Unit at the PTO instead of the original Examiner.[17] Following reexamination, a reexamination certificate is issued by the PTO that notes any cancellations or amendments to the claims of the issued patent.[18]

Reissue

Reissue offers an opportunity for patent owners to reopen prosecution of an issued patent any time before the expiration date of the patent. Reissue will only be granted to correct errors that occurred without deceptive intent and that cause the patent to be wholly or partly inoperative or invalid.[19]

Examples of errors that may cause a patent to be deemed wholly or partly inoperative or invalid include claims that are too narrow, claims that are too broad, inaccuracies in the specification or drawings, a missing or incorrect claim for foreign priority, and a missing or incorrect reference to a prior copending applications.[20] Examples of errors that generally will not cause the patent to be deemed wholly or partly inoperative or invalid include typographical or clerical errors.[21]

Unlike reexamination, reissue may allow for broadening of one or more claims of a patent, provided that the reissue is requested within two years of the grant of the patent.[22] A reissue that broadens one or more claims of a patent is referred to as a broadening reissue.[23] However, such broadening is not without limit. Not surprisingly, reissue precludes the incorporation of new matter into any portion of the patent, including the claims.[24]

Further, reissue precludes the "recapture" of any subject matter surrendered during prosecution of the patent.[25] Recapture refers to an attempt to remove from a claim a limitation that was added during prosecution to overcome a rejection.[26] Typically, if a limitation that was added during prosecu-

tion to overcome a rejection is completely removed from the claim in a broadening reissue, there is recapture.[27] Recently, though, the United States Court of Appeals for the Federal Circuit noted that while a limitation introduced to overcome a rejection may not be completely removed due to the recapture doctrine, "[t]he limitation may be modified . . . so long as it continues to materially narrow the claim scope relative to the surrendered subject matter such that the surrendered subject matter is not entirely or substantially recaptured."[28]

To request reissue, a patent owner must file a reissue oath or declaration that includes a statement that the patent owner believes the original patent to be "wholly or partly inoperative or invalid."[29] The patent owner must further specify the error that caused the patent to be wholly or partly inoperative or invalid.[30] One must recognize the importance of the reissue oath – the patent owner's statement that the patent, as issued, is *wholly or partly inoperative or invalid* may create significant estoppel for the patent owner. This estoppel may have two notable effects: intervening rights and claim construction issues.

Intervening rights refers to the rights of a competitor to rely on the claims of the issued patent until the patent reissues.[31] In some cases, intervening rights will be granted to a competitor who, "prior to the grant of a reissue, made, purchased, offered to sell, or used within the United States, or imported into the United States, anything patented by the reissue patent," thereby freeing the competitor of past damages for actions that would have infringed the reissued patent, but not the original patent (absolute intervening rights).[32] Further, when "substantial preparation was made before the grant of the reissue," the court may allow for the continued manufacture or sale of the product that infringes the reissue patent (equitable intervening rights).[33]

Claim construction issues can also arise when a reissued patent is asserted in litigation because statements made in a reissue oath may affect the construction of the claims in the reissued patent. For example, in *Lucky Litter, LLC v. International Trade Commission*, the asserted patent included a claim that recited that a "comb moves toward the discharge position [of a litter chamber] automatically upon the occurrence of a predetermined event."[34] In an effort to preserve the validity of the patent over a particular reference raised in litigation, the appellee asserted that the "predetermined

Problem	Reexamination or Reissue?	Who can request?
Failure under § 112 (Enablement, Best Mode)	Reissue	Patent Owner
Failure under § 101 Patentable Subject Matter)	Reissue	Patent Owner
Missing or Incorrect Claim for Foreign Priority	Reissue	Patent Owner
Missing or Incorrect Reference to Prior Copending Application	Reissue	Patent Owner
Typographical Error	Neither (Certificate of Correction)	Patent Owner
Inventorship	Reissue (or Certificate of Correction)	Patent Owner
Claims Too Narrow	Reissue	Patent Owner
Claims Too Broad	Reissue or Reexamination	Patent Owner or Third Party
Failure to Cite a Pertinent Reference that Raises a Substantial New Question of Patentability	Reissue or Reexamination	Patent Owner or Third Party
Substantive Error in Specification	Reissue	Patent Owner
Substantive Error in Drawings	Reissue	Patent Owner
Failure to Include One or More Dependent Claims	Reissue[39]	Patent Owner

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Post-Issuance Options: The Benefits and Risks of Reexamination and Reissue

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event" had to be understood, in light of the specification, to be only a "cat exit."[35] In response, the appellant pointed to a reissue oath filed in a request for broadening reissue of the asserted patent, which identified as an error in the issued patent claims that were too narrow as a result of being limited to a cat exit.[36] The court determined that the statement in the reissue oath required the term "predetermined event" to be construed according to its plain meaning as opposed to the appellee's proposed construction.[37]

Reexamination vs. Reissue

Reexamination and reissue each offer their own benefits and risks. There are a number of issues to consider before launching into either process. First, consider the purpose of your request. For example, if you wish to broaden your claims, reissue is your only option. If you are a patent owner and wish to pass a reference through the PTO, reexamination is likely your best option, and is your only option if you do not believe your claims need to be amended. If you are a third party that would like to invalidate the claims of a competitor, reexamination is your only option. In addition, if your patent has expired, but is still within the remaining period of enforceability, only reexamination can be used.[38]

Second, consider the consequences of each. Before requesting a reexamination, be sure to remember that your claims may be confirmed but could also be narrowed. Also, remember that continued prosecution is not permitted in reexamination proceedings. And before requesting a reissue, put careful consideration into your reissue oath to avoid creating unwanted estoppel. In addition, you must be aware of the possibility of intervening rights in both reissue and reexamination.

Finally, if you have a chain of pendency back to the issued patent, consider filing a continuation application rather than applying for reexamination or reissue. In some cases, a continuation application may offer a solution without the risks involved in reexamination and reissue.

Endnotes

1. 37 C.F.R. § 1.510(a) (2010). Infringement occurring during the lifetime of a patent may be enforced for up to six years following the expiration date of the patent. 35 U.S.C. § 286.
2. 35 U.S.C. § 303(a) (2006).
3. 37 C.F.R. § 1.510(b)(1) (2010).
4. M.P.E.P. § 2216 (8th ed. Rev. 7, Jul. 2010).
5. *Id.*
6. 37 C.F.R. § 1.510 (b)(1)-(2) (2010).
7. 37 C.F.R. § 1.510 (b)(2), (e) (2010).
8. There is one exception: if a patent owner submits a statement in response to the request for *ex parte* reexamination, the patent challenger may submit a reply to the patent owner's statement. 37 C.F.R. §§ 1.530(c), 1.535 (2010).
9. 37 C.F.R. § 1.947 (2010).
10. In 2010, 780 *ex parte* reexamination requests were filed, as compared with only 281 *inter partes* reexamination requests. U.S. Patent and Trademark Office, *Ex Parte Reexamination Filing Data*, Mar. 31, 2011; U.S. Patent and Trademark Office, *Inter Partes Reexamination Filing Data*, Mar. 31, 2011.
11. W. Todd Baker, *Ex Parte Patent Reexamination & Patent Reissue – Opportunities and Pitfalls*, Intell. Prop. Course Handbook Series, Jan.-Feb. 2011, at 4.
12. *Id.*; M.P.E.P. § 2213.
13. 37 C.F.R. § 1.20 (a)-(b) (2010); Baker, *supra* note 11, at 4.
14. 35 U.S.C. § 315(c) (2010).
15. 37 C.F.R. § 1.550(c) (2006).
16. M.P.E.P. § 2271.
17. M.P.E.P. § 2236 (I).
18. 35 U.S.C. § 307(a) (2006).
19. 35 U.S.C. § 251 (2006).
20. M.P.E.P. § 1402.
21. Typically, these errors may be corrected via a certificate of correction, as described in M.P.E.P. § 1481.
22. 35 U.S.C. § 251 (2006).
23. M.P.E.P. § 1412.03.
24. M.P.E.P. § 1411.02.
25. M.P.E.P. § 1412.02.
26. For a more comprehensive discussion of recapture, *see* M.P.E.P. § 1412.02.
27. M.P.E.P. § 1412.02(I)(C).
28. *In re Mostafazadeh*, No. 2010-1260, 2011 WL 1642830, at *4 (Fed. Cir. May 3, 2011). Notably, the Federal Circuit made this statement in a decision affirming the PTO's Board of Patent Appeals and Interferences rejection of the claims of a reissue application on the basis of recapture.
29. 37 C.F.R. § 1.175(a)(1) (2010).
30. *Id.*
31. 35 U.S.C. § 252 (2006); M.P.E.P. § 1460. Intervening rights resulting from reexamination proceedings parallels the intervening rights resulting from reissue patents. 35 U.S.C. §§ 307(b), 316(b).
32. 35 U.S.C. § 252 (2006).
33. *Id.* Intervening rights may be granted following a reexamination as well. M.P.E.P. §§ 2293, 2693.
34. *Lucky Litter LLC v. Int'l Trade Comm'n*, 403 Fed. Appx. 490, 493 (Fed. Cir. 2010).
35. *Id.* at 494.
36. *Id.* at 493 (noting that "recitations regarding a cat exit sensor and a delay means . . . are too limiting of the invention.").
37. *Id.* at 494.
38. *See* 37 C.F.R. 1.150(a) (2010).
39. *See In re Tanaka*, No. 2010-1262, 2011 WL 1437887, at *5 (Fed. Cir. Apr. 15, 2011).

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Stanford v. Roche, the Bayh-Dole Act, and the Possibility of Unintended Consequences

Introduction

Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems et al. involves a question of whether the Bayh-Dole Act prevents an employee of a university from assigning rights in an invention that arose, at least in part, from federally-funded research.[1] The Federal Circuit held that it does not and, applying standard contract principles, found that the Roche defendants had acquired equitable title to inventions arising from federally-funded research as a result of a Stanford employee's unilateral assignment of the inventions to a Roche predecessor. Stanford petitioned for *certiorari*, and the Supreme Court granted the petition. Oral argument was held on February 28, 2011, and a decision is expected shortly.

This may be a case of "be careful what you ask for" for Stanford. That is to say, there is a risk that—if Stanford succeeds—its own freedom to contract with respect to federally-funded research could be substantially restricted. Though perhaps counterintuitive, such a result may provide a good example of the law of unintended consequences, *i.e.*, that an intervention in a complex system (*e.g.*, that of the allocation of intellectual property rights arising from federally-funded research) always creates unanticipated and often undesirable outcomes. For better or worse, the Bayh-Dole Act put in place a system that has governed interactions between the Federal Government, contractors, and their inventors for the last thirty years. Stanford's attempt to overturn the Federal Circuit's opinion, while potentially beneficial for Stanford in the instant case, may also serve to inject uncertainty into an otherwise relatively stable system with relatively established expectations.

More specifically, in future situations where Stanford may desire to assign rights associated with federally-funded research, such as in the sale of a business or the settlement of an infringement or interference dispute, Stanford may find that uncertainty in the allocation of the rights at issue may make such an assignment agreement difficult to come by. In short, if Stanford is successful, the fact that Bayh-Dole Act may trump the university's own contractual rights may make industry less confident about entering into agreements with universities and researchers.

The Facts of *Stanford v. Roche*

The relevant facts in *Stanford* are fairly straightforward. A Stanford employee conducting federally-funded research used polymerase chain reaction ("PCR") materials from Cetus, a Roche predecessor, and received technical advice and other information from Cetus scientists, to develop methods for quantifying Human Immunodeficiency Virus ("HIV") in human blood samples. When a patent issued from the researcher's work, Stanford sued Roche, and, in response, Roche claimed title to the patent based on a prior agreement between the researcher and Cetus.[2]

Three types of agreements govern the respective rights in the patents-in-suit:

1. An employment agreement, including a "Copyright and Patent Agreement" ("CPA") between the researcher and Stanford, under which the researcher "agree[d] to assign or confirm in writing to Stanford and/or Sponsors that right, title and interest in . . . such inventions as required by Contracts or Grants."
2. A "Visitor's Confidentiality Agreement" ("VCA") that states that the researcher "will assign and do[es] hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements" that the researcher may devise "as a consequence of" work at Cetus.
3. Multiple "Materials Transfer Agreements" that permitted Stanford to use the PCR-related materials and information supplied by Cetus. These agreements provided Cetus with licenses to technology that Stanford created as a result of access to Cetus's materials.

Also of note was Stanford's invention rights policy which stated: "[u]nlike industry and many other universities, Stanford's invention rights policy allows all rights to remain with the inventor if possible."[3]

The Federal Circuit Opinion

The Federal Circuit held that the researcher's CPA with Stanford was only a promise to assign rights to any future inventions and, at best, gave the promisee, *i.e.* Stanford, equitable rights.[4] The Federal Circuit had previously held that such an agreement to assign is not an actual assignment and requires a subsequent written instrument to complete the assignment.[5] Indeed, it would appear that any other interpretation of Stanford's CPA would be inconsistent with Stanford's invention rights policy, which expressly allowed "all rights to remain with the inventor if possible."

By contrast, the VCA with Cetus, signed by the inventor/researcher, contained an unambiguous, actual, assignment.[6] Cetus gained equitable title with the execution of the VCA, and legal title vested with the filing of the parent application.[7] As such, the researcher's later attempt to assign rights to Stanford failed.

Stanford argued that it was a *bona fide* purchaser under 35 U.S.C. § 261 because Cetus/Roche did not record its assignment within three months after the subsequent assignment to Stanford.[8] But actual or constructive notice precludes a *bona fide* purchase, and the Federal Circuit found that Stanford was on notice of the assignment via its agent/employee (*i.e.*, the researcher).[9]

The Federal Circuit also rejected Stanford's

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argument that the Bayh-Dole Act negated the researcher's assignment and allowed Stanford a "right of second refusal" to the patents after the Government refrained from exercising its rights.[10] The Federal Circuit found that, at most, the Government had a discretionary option to the researcher's rights and could claw back any rights assigned to Roche.[11] The Court found that the Bayh-Dole statutory scheme did not automatically void the rights that Cetus received from the researcher.[12] Notably, however, the Federal Circuit "express[ed] no opinion as to whether [the researcher's] execution of the VCA violated any provisions of the Bayh-Dole Act, or whether the Act provides the Government or Stanford some other legal recourse to recover [the researcher's] rights."[13]

Finally, Federal Circuit rejected Stanford's argument that the VCA unlawfully restrained the researcher from "engaging in a lawful profession, trade or business" and was void under the California Business and Professions Code § 16600.[14] The Federal Circuit noted that the California provision applies to "employment restrictions on departing employees, not to patent assignments."[15]

Arguments Submitted to the Supreme Court

Stanford sought *certiorari* on the Federal Circuit's decision under the Bayh-Dole Act. The Government filed an amicus brief asserting that the Bayh-Dole Act requires that all rights to any federally-funded inventions are either vested in the Government or retained by the contractor (*e.g.*, Stanford).[16] To make this argument, the Government had to ignore the various references to the "inventor" throughout the Bayh-Dole Act. Instead of using the "inventor" language from the Bayh-Dole Act, the Government suggested that Act refers to a "recipient of federal funds under a funding agreement."[17]

The Government further asserted that the researcher possessed only a contingent interest in obtaining title to the invention if (a) Stanford waived or failed to exercise its rights under the Act and (b) the Government then authorized the researcher to retain title.[18] Because Stanford "elected to retain title and complied with the statutory requirements for doing so," the Government reasoned that the contingent interest was "of no practical value."[19] According to the Government, the researcher "could not assign to Cetus any higher priority in the federally funded inventions than [the researcher] himself would have possessed," which in this case was none.[20]

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As noted in arguments before the Supreme Court, Stanford's interpretation of the Bayh-Dole Act, in at least some significant respects, appears inconsistent with settled practice of the last thirty years.

From a policy stand-point, the Government made the argument that the commercialization of government-funded projects may be jeopardized if rights to such projects could be lost due to an inventor's prior, unilateral, assignment.[21] The Government also asserted that, if patent rights *do not* automatically vest with contractors, a substantial increase in due diligence costs may result[22] and the security of existing and pending patents may be at risk.[23]

Additional amicus briefs were filed. The American Intellectual Property Law Association ("AIPLA") argued that such fears are unjustified.[24] The AIPLA emphasized that, while due diligence may be costly, universities are currently able to adequately protect non-federally funded research.[25]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") emphasized what is, perhaps, the most challenging aspect of Stanford and the Government's position: the widespread practice of requiring individual inventors to execute documents in which they assign their existing and prospective intentions to their employers.[26] PhRMA's brief details these practices and the extent to which agencies have consistently required such assignments.[27]

Intel Corporation warned that if patent rights *do* automatically vest with contractors, universities could simply provide small amounts of government funding for any project and, as a result, legally own all rights to any invention produced therefrom.[28] Intel suggested that this would "damage . . . industrial-academic collaborations."[29]

However, the nonprofit BayhDole25[30] argued that the Bayh-Dole Act does not allow government rights to federally-funded inventions to be defeated by the "whims of individual inventors who, according to the Federal Circuit opinion, have the unfettered right to assign their federally funded inventions without regard to Bayh-Dole's statutory provisions."[31] The American Association of University Professors made the counterpoint that professors are not "for-hire" inventors.[32] Further, the University Professors noted that if the Bayh-Dole Act made the process of assignment unnecessary, as suggested by Stanford, universities would not have been conducting "the very process—acknowledging faculty ownership of inventions born from scholarly research and effectuating technology transfer of that ownership" for the past thirty years.[33]

Oral Argument Before the Supreme Court

At oral argument, a number of justices raised questions that generally seemed to suggest favor for Roche's position. Justice Ginsburg noted that the problem here seemed to be Stanford's employment agreement, which did not automatically assign its employees' rights to the university: [34]

> The whole thing that was wrong here is that Stanford, instead of drafting the agreement "I agree to assign," should have said "I hereby assign" and then there would be no case.

Justice Kagan echoed Justice Ginsburg's point when she asked: [35]

> [I]s this a Stanford-specific problem or is it a more general problem? In other words, are there many universities that have agreements like Stanford's that would be subject to the Federal Circuit's ruling? Or is this just an example of one university that unfortunately has a bad agreement?

Justice Kagan also asked the Government:[36]

> So why doesn't the Federal Government just require assignments from employees to the university?

Either an improved agreement according to Justice Ginsburg, or a federally mandated assignment according to Justice Kagan, would avoid the problems Stanford faces in this case.

Justice Alito noted that there are two facts that "seem to me to cut pretty strongly against" Stanford's argument: (1) "that it has long been the rule that inventors have title to their patents initially, even if they make those inventions while working for somebody else" and (2) the Bayh-Dole Act says that the contractor can "elect to retain title, which means hold onto a title that the—organization already has. 'Retain' does not mean obtain."[37] In other words, where a contractor has failed to take proper steps to assure that it obtains rights to its employees' inventions in the first place, the contractor may not be said to have rights to "retain."

Justice Sotomayor also questioned:[38]

> Does the—as a practical matter, when a university is seeking a patent, doesn't it have to identify the inventors and get their—proof of their assignment before it can claim ownership of the patent?

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At issue is not just the rights of industry vis-à-vis researchers, universities and the Government, but also the rights of universities and researchers vis-à-vis the Government.

Justice Scalia concurred with Justice Sotomayor's sentiment:[39]

> If—if the government was going to make such a huge change from normal patent law where the inventor owns his invention until he assigns it to his employer, why wasn't that set forth clearly?

Justice Kennedy, in turn stated:[40]

> What you're asking for, based on submissions to us of amici, of amicus briefs, means a very great change in how—how—how patents are held.

Justice Breyer, on the other hand, noted case law cited by the amicus brief submitted by the Association of American Universities and the Advancement For Science and the Council on Education, held that third-party assignments in an analogous situation—a government employee who has an obligation to assign an invention to the government—were void as against public policy.[41] Chief Justice Roberts also noted that relying on funding agreements to require the contractor to get assignments from the inventors may yield the patchwork of arrangements across government agencies that the Bayh-Dole Act was intended to avoid.[42]

Thoughts as We Await the Supreme Court's Decision

At issue, of course, is not just the rights of industry vis-à-vis researchers, universities and the Government, but also the rights of universities and researchers vis-à-vis the Government. The interpretation of the Bayh-Dole Act proposed by Stanford may well come back to haunt Stanford's own future attempts at administration of its own intellectual property. As noted in the various arguments before the Supreme Court, Stanford's interpretation of the Bayh-Dole Act, in at least some significant respects, appears inconsistent with settled practice of the last thirty years. As a result of disturbing the somewhat established system of allocation of intellectual property rights under thirty years of the Bayh-Dole Act, Stanford may, as an unintended consequence, increase industry reluctance to enter into agreements with Stanford and other similarly situated universities and researchers. The outcome Stanford seeks may well also stifle interchange of information between industry and researchers such as Cetus' and the Stanford employee's activities here.

Contrary to the Government's position, the Federal Circuit's decision does not appear to affect a substantial number of colleges or universities or other federally-funded institutions. As Justice Ginsburg and Justice Kagan noted at oral argument, the real problem with Stanford's position was the clearly problematic language of its employment agreement. A simple rewording of the

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employment agreement would have avoided the problem altogether. Accordingly, the issues raised in this case do not appear to be significant, systematic, problems that require a new interpretation of the Bayh-Dole Act and a substantial revision of the expectations regarding who owns the rights to inventions.[43]

Endnotes

1. 583 F.3d 832 (Fed. Cir. 2009).
2. For a more thorough discussion of the agreements relevant to this case, *see id.* at 837-838.
3. *Id.* at 841.
4. *Id.* at 841-842. The Federal Circuit commented that, "[w]hile Stanford might have gained certain equitable rights against [the researcher], Stanford did not immediately gain title to [the researcher]'s inventions as a result of the CPA, nor at the time the inventions were created." *Id.*
5. *See IpVenture, Inc. v. Prostar Computer, Inc.*, 503 F.3d 1324, 1327 (Fed. Cir. 2007).
6. *Stanford*, 583 F.3d at 842. The Federal Circuit noted that, "Paragraph 3 of the VCA recites: 'I will assign and do hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements.' In contrast to the CPA, the VCA's language of 'do hereby assign' effected a present assignment of [the researcher]'s future inventions to Cetus." *Id.* (internal citations omitted).
7. *Id.* As the Federal Circuit explained, upon execution of the VCA "CETUS immediately gained equitable title to [the researcher]'s inventions . . . Cetus's equitable title converted to legal title no later than the parent application's filing date." *Id.*
8. *Id.* at 842-843.
9. *Id.* at 843. The Federal Circuit noted that although "Stanford contends…that Stanford received no notice of [the researcher]'s countervailing assignment to CETUS . . . Stanford's argument fails because there can be no genuine dispute that Stanford had at least constructive or inquiry notice of the VCA." *Id.*
10. *Id.* at 844-845.
11. *Id.* at 844.
12. *Id.*
13. *Id.* at 844 n.1, citing *Cf. Cent. Admixture*, 482 F.3d at 1353.
14. *Id.* at 845-846.
15. *Id.* at 846.
16. *See* Brief for the United States as Amicus Curiae in Support of Petitioner on Writ of Certiorari at 6. The Government urged that "[t]he Act creates a presumption that title to federally funded inventions will vest in the contractor, as opposed to the government or the inventor . . . The government 'may receive title to any subject invention' when the contractor does not timely disclose the invention, elect to retain the invention, elect to retain title, or seek patent protection for the invention. 35 U.S.C. 202(c)(1)-(3)." *Id.*
17. *Id.* at 5.
18. *Id.* at 18.
19. *See* Brief for the United States as Amicus Curiae on Petition for a Writ of Certiorari at 13-14.
20. *Id.* at 14.
21. *See* Brief for the United States as Amicus Curiae in Support of Petitioner on Petition for a Writ of Certiorari at 30-31.
22. Stanford made a similar argument: It is no answer to suggest that a contractor like Stanford can alleviate such uncertainties by combing through the files of each faculty member, graduate student, or employee who may be an inventor and seeking documents from all of the third parties with whom those people may have interacted. Even such due diligence cannot prove a negative. Absolute assurance that a contrary assignment does not exist is impossible. Brief of Petitioner at 47.
23. *See* Brief for the United States as Amicus Curiae in Support of Petitioner on Petition for a Writ of Certiorari at 30-31 (emphasis added); s*ee also* Brief of Amici Curiae Association of American Universities, *et al.* at 36.
24. *See* Brief of Amicus Curiae American Intellectual Property Law Association in Support of Neither Party at 28–32.
25. *See id.* at 28.
26. *See* Brief for the Pharmaceutical Research and Manufacturers of America as Amicus Curiae Supporting Respondent at 13-18.
27. *See id.*
28. *See* Brief of Intel Corporation, et al., as Amici Curiae in Support of Respondents at 18-19.
29. *See id.* at 19.
30. "BayhDole25 is a not-for-profit educational and research organization created to study the U.S. Bayh-Dole Act of 1980, as well as similar U.S. and international technology transfer legislation and related issues. BayhDole25 performs independent, non-partisan research projects and provides educational materials relating to technology transfer legislation and its role in the successful commercialization of science and technology through public-private partnership." About BayhDole25, http://www.bayhdole25.org/about (last visited May 31, 2010).
31. *See* Brief of Amicus Curiae Bayhdole25, Inc. in Support of Petitioner at 9.
32. *See* Brief of Amici Curiae American Association of University Professors, *et al.* in Support of Affirmance at 11.
33. *Id.* at 19.
34. Transcript of Oral Argument at 36.
35. *Id.* at 24.
36. *Id.* at 18.
37. *Id.* at 14-15.
38. *Id.* at 20.
39. *Id.* at 15.
40. *Id.* at 23.
41. *Id.* at 28-30. Justice Breyer referred to *Li v. Montgomery*, No. 99-5106, 2000 WL 815992 (D.C. Cir. May 15, 2000), an unpublished decision of the D.C. Circuit.
42. *See id.* at 35.
43. As Justice Kennedy remarked at oral argument, "why can't we resolve this case in a simple way . . . If we can resolve this case on a simple contract basis, why not do it?" *Id.* at 23.

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- ☐ Electrical Practice
- ☐ Mechanical Practice
- ☐ Litigation Practice
- ☐ Prosecution Practice
- ☐ Other

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