EXHIBIT 2

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Vanderbilt University v. ICOS Corporation, No. 05-506 SLR
Vanderbilt's Statement of Issues of Fact and Law that Remain to be Litigated

1. The Vanderbilt Scientists made independent conceptual contributions to one or more claims of the Patents-at-Issue.

A. Legal Standard for Joint-Inventorship.

In order to be an "inventor" of a patent, the individual must have made independent conceptual contributions to any element of any claim on the patent. *Burroughs Wellcome Co. v. Barr Labs., Inc.,* 40 F.3d 1223, 1228 (Fed. Cir. 1994) (holding "[c]onception is the touchstone of inventorship, the completion of the mental part of the invention"). Conception occurs when a person has a definite idea of a complete and operable invention. *Id.* at 1229. The legal standard of conception can be considered the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention." *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (quoting 1 Robinson on Patents 532 (1890)).

In order for conception to be complete, the inventor must only have a definite idea of how to carry out the invention. It is not required that the inventor know how it will work. The test for conception is whether the inventor had an idea that was definite and permanent enough that one skilled in the art could carry out the invention. *Burroughs*, at 1228. Discovery that the invention actually works is part of the reduction to practice and is not conception. *Id.*

One is not precluded from being a joint inventor simply because the contribution to a collaborative effort is experimental. *See Burroughs*, 40 F.3d at 1229. Further, if the conception supplements and complements the other person's conception, then there may be an invention and joint-inventorship. *See William R. Thropp & Sons Co. v. DeLaski & Thropp Circular Woven*

Tire Co., 226 F.941, 949 (3d Cir. 1915) ("If the conceptions of one supplement and complement the conceptions of the other, the result might be invention and therefore joint invention."). Persons may be co-inventors even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent. *Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1997). All that is required of a co-inventor is that he or she (1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art. *Id.*

Inventorship is a question of law that rests on factual underpinnings. *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998); *Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 981 (Fed. Cir. 1997) ("[W]hether particular suggestions and contributions of third persons amount to co-inventorship turns on the facts of the particular case."). There is a presumption that inventors named on an issued patent are correct and misjoinder or nonjoinder of inventors must be proven by clear and convincing evidence. *Fina Oil and Chemical Co. v. Ewen*, 123 F.3d 146, 1472 (Fed. Cir. 1997). This standard "applies without regard to the circumstances of a particular case." *Hess*, 106 F.3d at 980. Notwithstanding the general principles regarding the burden of proof discussed in these cases, Vanderbilt maintains that, for the reasons expressed by Judge Lourie in his concurring opinion in *Eli Lilly and Co. v. Aradigm*, 376 F.3d 1352 (Fed. Cir. 2004), and asserted by Eli Lilly in that case, the appropriate burden of proof under the facts and circumstances of this case is the preponderance of the evidence.

Evidence of invention must be independently corroborated. *Fina Oil*, 123 F.3d at 1474 ("Of course, every putative inventor must nonetheless provide corroborating evidence of any asserted contributions to the conceptions of the invention. Like conception of the entire invention, a contribution to conception is a mental act which cannot be accurately verified without corroboration."). Whether the inventor's testimony has been sufficiently corroborated is evaluated under a "rule of reason" analysis, in which an evaluation of all pertinent evidence is made so that a sound determination of the credibility of the alleged co-inventor's story may be reached. *Ethicon*, 135 F.3d at 1460. Corroborating evidence may take many forms, including documents prepared by a putative inventor. *Id.* Circumstantial evidence about the inventive process and/or oral testimony of someone other than the alleged inventor may also serve as corroborating evidence. *Id.*

If the patentees and assignees agree, correction of inventorship can be had by application to the Commissioner. However, if the parties do not agree, judicial resolution of co-inventorship contests is explicitly authorized by 35 U.S.C. § 256.

B. The Vanderbilt Scientist's Made Significant Conceptual Contributions to the Patents-at-Issue.

Vanderbilt is the successor and assignee of the rights of the Vanderbilt Scientists as co-inventors of the Patents-at-Issue. The Vanderbilt Scientists conceived that a PDE-5 inhibitor resulting from their suggestions would be effective in treating male impotence and communicated that information to Glaxo. Glaxo employed the results of the Vanderbilt team's research in the conception of Tadalafil, and, in using recombinant human PDE-5 to test the inhibitor, taking advantage of the amino acid sequence that Vanderbilt's scientists had discovered and used to clone recombinant bovine PDE-5.

Through their extensive research of the chemistry and biology of cGMP, its dependent protein kinase, the family of phosphodiesterases and their respective interactions, the Vanderbilt Scientists conceived of novel ways to modify cGMP to increase its inhibitory activity vis-à-vis PDE-5. Vanderbilt Scientists made conceptual contributions to the inventions described in claims 1-8, 10 and 12-13 of Patent 5,859,006 as follows:

i. The Vanderbilt Scientists were the first to discover that, notwithstanding the nature or structure of any particular or specific PDE5-inhibiting molecule, that molecule must satisfy certain "rules" of physical and chemical structure.

a. The Vanderbilt Scientists applied the design concepts that they learned through the synthesis and testing of the PDE-5 inhibitory cGMP analogs to the design and synthesis of other PDE-5 inhibitors and discovered that the attachment of bulky, hydrophobic and electron-donating substituents to PDE 5 inhibitors at a position thereon analogous to the 8 position of cGMP would significantly increase the potency of the inhibitor. They theorized that the reason for the increase in potency was that such substituents at the critical location in the inhibitor molecule mimicked the function of the ribose phosphate component of cGMP in binding to PDE 5. Thus with the attachment of the bulky substituent at the position analogous to the 8 position of cGMP, the inhibitor more closely resembled the entire cGMP molecule in chemical and biological function.

b. The Vanderbilt Scientists communicated to Glaxo in their January 1992 research proposal their novel concept that PDE-5 inhibitors enhanced by the attachment of bulky, hydrophobic and electron donating substituents at a position analogous to the 8 position on the cGMP molecule would be effective in treating male impotence, now more commonly referred to as male erectile dysfunction or "ED." They were the first to recognize that a key substituent on the molecule must also be "hydrophobic" in order to add potency and successfully restrict the

specificity thereof to PDE-5. They were also the first to recognize that the spatial orientation of the appended hydrophobic groups is critical for potency of the inhibitor. Further, the Vanderbilt Scientists specifically suggested several candidate hydrophobic substituents that should be used. One such substituent that Vanderbilt suggested (phenyl) is present in Tadalafil and another (methoxy) closely related to the methylenedioxy which is present in Tadalafil; and

c. The Vanderbilt Scientists were the first to suggest that the presence of electron-donating groups on the phenyl ring of successful candidate PDE-5 inhibitors increased potency and that the presence of electron-withdrawing groups decreased potency.

Using all three of these "rules," the Vanderbilt Scientists' conception of the compounds claimed in the Patents-at-Issue is reflected in the "R2" substituent described in Claim 1 of each patent and the resulting structural relationship between that substituent and the beta carboline molecule. In addition, the Vanderbilt Scientists' contribution to the conception of the compounds claimed in the Patents-at-Issue as reflected in the "R2" substituent described in Claim 1 of each patent and the resulting structural relationship between that substituent and the beta carboline molecule was significant to the claimed compounds as a whole as it is responsible for much of the potency of the compounds as PDE-5 inhibitors.

ii. Glaxo Used Vanderbilt's conceptions to arrive at the patented compounds.

In the article The Discovery of Tadalafil, A Novel and Highly Selective PDE5 Inhibitor.1:5,6,11,11a-Tetrahydro-1*H*-imidazo[1'5':1,6]pyrido[3,4-*b*]indole-1,3(2*H*)-dione Analogues, 46 J. MED. CHEM. 4525 (Alain Daugan *et al.* 2003) (hereinafter, "Article I"), the French Glaxo team modified the C-5 position with either heterocyclic or aromatic groups; the 3-thienyl modification yielding the most active compound. Instead of using this modification in the next generation of drugs described in article The Discovery of Tadalafil, A Novel and Highly

Selective PDE5 Inhibitor.2:2,3,6,7,12,12a-hexahydropyrazino[1',2':1,6]pyrido[3,4-*b*]indole-1,4-dione Analogues, 46 J. MED. CHEM. 4533 (Alain Daugan *et al.* 2003) (hereinafter, "Article II"), the French Glaxo team used a phenyl group with various substituents as Vanderbilt had suggested. All of the active compounds the Vanderbilt Scientists sent to the French Glaxo team during this time contained phenyl groups with various substituents. Glaxo changed the direction of its research based on the Vanderbilt conceptions.

iii. The Vanderbilt scientists were the first to identify the critical amino acid sequence of PDE5 and the bovine DNA sequence that encodes for PDE-5 that was eventually used to clone human PDE-5.

In using recombinant human cGMP to test the inhibitor, taking advantage of the amino acid sequence that Vanderbilt's scientists had discovered and used to clone recombinant human PDE-5.

The contribution of the Vanderbilt Scientists to the conception of the compounds claimed in the Patents-at-Issue is further reflected in the claimed application of the use of PDE-5 inhibitors for the treatment of impotence of male mammals.

2. The Vanderbilt Scientists communicated their novel concepts for PDE-5 inhibitors to Glaxo.

To be a joint inventor a person must "have some quantum of collaboration or connection with the other person(s)." *Kimberly Clark Corp. v. Proctor and Gamble Dist. Co., Inc.*, 973 F.2d 911 (Fed. Cir. 1992). Joint inventorship requires communication between the inventors. Chisum § 2.02[2]. A joint invention occurs when two or more persons, collaborating together, each contribute to the conception of the solution to a problem that constitutes the invention. *Id.* However, it is not necessary for the inventors to physically work together, for the ideas to have occurred to both inventors at the same time, for each inventor to have conceived the same part

of the ultimate invention or made the same type of contribution, or for the inventive contributions to be of equal importance. *Id.* Independent, conceptual contributions are identified without regard to their relative scientific or commercial importance to the total invention. *Id.* The patent system does not attempt to evaluate or rank the relative contributions of individual co-inventors. *Id.* Each co-inventor is considered to have the same legal interest in a joint invention as any other co-inventor. *Id.*

The Vanderbilt Scientists' independent conceptual contributions to the discovery of the Patents-at-Issue discussed above were communicated to Glaxo at various times, including the following:

First, through the course of their work under the 1989 Glaxo Grant Agreement, Vanderbilt reached the conclusion that in order for a PDE-5 inhibitor to be potent; its structure must closely mimic the structure of the cGMP molecule. That theory was expressed to Glaxo when (i) Dr. Corbin visited Glaxo on November 1, 1991, (ii) he spoke via telephone to Dr. Ross of Glaxo during the last week of December 1991, and (iii) Dr. Corbin wrote to Dr. Ross on January 3, 1992 to outline his research proposal. With respect to developing new phosphodiesterase inhibitors, Dr. Corbin stated:

> We will design phosphodiesterase inhibitors based on the theory that the potencies of existing inhibitors, . . . could be enhanced by appending groups that would allow the inhibitors to more **closely resemble the entire Cyclic GMP molecule**

(Emphasis supplied).

The same information was discussed by the Vanderbilt scientists with Dr. Ross when he visited Vanderbilt on February 2nd and 3rd, 1992, and was contained in the Vanderbilt research proposal Dr. Ross received on February 24, 1992. Dr. Ross then shared that proposal with key members of the Glaxo UK and French Labs on April 8, 1992 and they discussed the proposal on

April 9, 1992. The same information was conveyed again in the 1992 Research Agreement. It was discussed again by Dr. Corbin with Dr. Hyafil, the head of Glaxo's French lab, during his meeting with the Vanderbilt Scientists at Vanderbilt on September 30, 1992.

Vanderbilt's efforts to design cGMP analogs/PDE5 inhibitors that closely resembled the cGMP molecule were also reflected in the structures of analogs/inhibitors that the Vanderbilt Lab developed and tested. Many of those compounds were described in Dr. Corbin's January 3, 1992 letter and the 1992 Agreement. Vanderbilt sent samples of those compounds to Glaxo's G.M. Drew in August 1992 for study at Glaxo's UK lab. The UK lab reported on its testing of the compounds on October 21, 1992. On November 18, 1992 Glaxo asked for more samples, which Vanderbilt sent the next day. While meeting with him at Vanderbilt on September 30, 1992, the Vanderbilt scientists gave samples to Dr. Hyafil for testing at Glaxo's French lab. The samples were then tested by Dr. Hyafil's Glaxo colleague, Dr. Pascal Grondin. On December 11, 1992, Grondin wrote to Corbin with the results of those tests, some of which had been performed by Dr. Anne-Charlotte de Gouville, another scientist in Glaxo's French Lab. Vanderbilt sent more compounds to Glaxo's French Lab in February 1993. Nearly all of the compounds send by Vanderbilt to Glaxo from August through November 1992 closely mimicked the structure of the cGMP molecule in the following ways:

1. Compared to the Zaprinast-based molecules upon which Glaxo was focusing, the orientation of the key substituents are to the right side of the molecule as depicted in conventional structural formulae.

2. Their molecular structures embody a six-member phenyl ring.

Many of these compounds were also reflected in slides that Dr. Corbin presented to Glaxo representatives.

Further, during the course of the 1989 Research Agreement Vanderbilt research demonstrated that appending electron-donating groups to the molecule's phenyl ring resulted in increased potency with respect to activating PKG. This discovery was conveyed to Glaxo at the latest in November 1990. It was repeated in an article written by members of the Vanderbilt Lab that was submitted to Glaxo on April 18, 1991, publication of which was approved by Glaxo on June 24, 1991.

Also, the Vanderbilt Lab was the first to recognize that a key substituent on an effective PDE5 inhibitor molecule must also be "hydrophobic" in order to add potency and that the spatial orientation of the appended hydrophobic groups is critical for potency of the inhibitor. Tests performed by Glaxo in collaboration with Vanderbilt on Vanderbilt's cGMP analogs further showed that such hydrophobicity also contributed significantly to improved specificity of the potent inhibitors' activity to PDE5. The Vanderbilt Lab specifically suggested several candidate hydrophobic substituents, including phenyl and another substituent appended to the phenyl, i.e., a methoxy group. All of the active compounds the Vanderbilt Lab sent to the French Glaxo team in 1992 and 1993 contained phenyl groups with various substituents, including methoxy. In addition, Vanderbilt discussed the importance of hydrophobicity (i) with Dr. Ross when he visited Vanderbilt in February 1992 and (ii) with Dr. Hyafil when he visited in September 1992.

In addition to the above, Dr. Corbin discussed each of these rules with the Glaxo scientists that he met with during his visit to Glaxo's French lab in June 1993.

In these same communications, Vanderbilt communicated to Glaxo its novel concept that PDE-5 inhibitors could be used to treat male impotence.

3. Alain Daugan was not the sole inventor of the Patents-at-Issue.

To be a sole inventor, a person must be responsible for the conception of the invention as described in all the patent claims. *Burroughs,* 40 F.3d at 1228. Remarkably, the patents identify one Glaxo scientist, Alain Daugan, as the sole inventor of Tadalafil. It is impossible that Dr. Daugan invented Tadalafil by himself in light of the number of complex scientific disciplines necessarily involved in the discovery of Tadalafil. In addition, Dr. Daugan has admitted that he did not conceive of the use of Tadalafil for the treatment of male impotence or ED.

4. *American Bioscience* supports Vanderbilt's claims to Joint-Inventorship.

ICOS relies heavily on the Federal Circuit's decision in *Bd. of Educ. v. American Bioscience, Inc.*, 333 F.3d 1330 (Fed. Cir. 2003) in its defense to Vanderbilt's claims of joint-inventorship of the Patents-at-Issue. That reliance is misplaced. *American Bioscience* does not change the legal standard of joint-inventorship, and the Federal Circuit's application of existing law to the facts of that case actually supports Vanderbilt's claims here.

A. The Vanderbilt's Scientists' contributions are the same as those of the American Bioscience scientists.

In *American Bioscience*, Florida State University had brought an action to correct the inventorship on a patent of an anti-cancer drug. The District Court, *inter alia*, credited Florida State's position and changed the inventorship of the patent. On appeal, the Federal Circuit reversed the District Court and reinstated the original inventors on the patent. Although it would be an easy mistake to equate Vanderbilt's claims here with those being made by Florida State in *American Bioscience*, the only similarity is the fact that both entities are universities. Vanderbilt's claims to inventorship are instead similar to, if not identical to, the claims of the American Bioscience scientists whose inventive contributions were validated by the Federal Circuit.

Florida State challenged the sufficiency of the inventive contributions of American Bioscience scientists Soon-Shiong, Desai and Tao. The District Court removed Soon-Shiong and Desai as inventors. In reinstating Soon-Shiong and Desai, the Federal Circuit stated:

> Contrary to the district court's conclusions and FSU's assertions, the record indicates that it was the VivoRx[1] scientists who had the idea of making compounds having both a 10-hydroxy group and a nitro group. ***Because there is no evidence that the idea of making taxol analogs having both a 10-hydroxy group (i.e., taxoteres) and a nitro functional group came from anyone other than Soon-Shiong and Desai, we conclude that FSU did not meet its burden.***

American Bioscience, at 1339 (emphasis added).

Soon-Shiong and Desai were thus held to be joint inventors based upon their conception of adding certain substituent groups to the taxotere scaffold, even though they did not conceive of the entire compound.

Similarly, a third American Bioscience scientist, Tao, was also held to be a joint inventor despite the fact that the Federal Circuit had already found that there was no evidence that he had anything to do with conceiving the idea of a compound having both a 10-hydroxy group and a nitro functional group, which the Court credited exclusively to Soon-Shiong and Desai. Nevertheless, Tao was "correctly retained" as a joint inventor:

> Tao also contributed to the conception of the claimed invention. The record reflects that ***Tao introduced the idea of incorporating tert-butoxycarbonyl, isobutoxycarbonyl, and isopropoxycarbonyl groups, and chose the attachment point for the nitro group.*** The district court correctly retained Tao as a coinventor and that issue is not before us.

Id. (emphasis added).

Like Soon-Shiong and Desai, Tao did not conceive of the entire compound. He conceived of certain substituents in addition to the ones that Soon-Shiong and Desai had thought

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[1] VivoRx was the prior name of American Bioscience, Inc.

of and also conceived of the proper location for the attachment of the nitro group that Soon-Shiong and Desai had suggested. None of the three American Bioscience scientists conceived of the entire compound. Each contributed separate and distinct components of the compound and, on that basis, each was held to be a joint inventor.

The Federal Circuit made it abundantly clear that it is unnecessary to conceive of the entire compound in order to be a joint inventor in its discussion of a fourth claimed inventor, Nadizadeh, who conceived of *none* of the claimed compound, but conceived of a method of making the taxol derivatives. The Court acknowledged that under certain circumstances he nevertheless could also have been a joint inventor:

> If Tao, Soon-Shiong, and Desai had conceived the structures of the claimed compounds, but were then unable to make them without Nadizadeh's help, Nadizadeh might have been a coinventor.

American Bioscience, at p. 1342.

Although Nadizadeh was held not to be a joint inventor under the facts in *American Bioscience*, the Federal Circuit clearly stated that one does not need to conceive of *any part* of the compound, much less the *entire* compound, in order to be considered to be a joint inventor.

The contributions that the Vanderbilt scientists made to the Patents-at-Issue are indistinguishable from those of Soon-Shiong, Desai and Tao in *American Bioscience.* Like the three American Bioscience scientists, Corbin, Francis and Konjeti also identified substituents to be added to the scaffold and like Tao, they identified the attachment point for the substituents. Like the scientists in *American Bioscience*, the Vanderbilt scientists should be added as joint inventors of the Patents-at-Issue.

B. *American Bioscience* did not change the Legal Standard of Joint-Inventorship.

ICOS focuses on *American Bioscience* as if it were a landmark case, pioneering new law in the field of joint inventorship. It is not. It merely restates the existing law in the context of the invention of a chemical compound.

ICOS' own expert witness, Michael Sofocleous, a patent lawyer and former patent examiner at the Patent and Trademark Office, acknowledged that *American Bioscience* contains nothing new about inventorship generally, or joint inventorship specifically:

> Q. Is it your opinion that the American Bioscience case changed the law of inventorship with respect to chemical compounds?
> A. No.
> Q. Did it merely restate what was the existing law of inventorship with respect to chemical compounds?
> A. It basically restates existing law, and it applies the facts of that case to that law to come up with this conclusion.
> Q. In your opinion, did the American Bioscience case introduce any new concepts, novel concepts if you will, to the law of inventorship with respect to chemical compounds?
> A. I think American Bioscience has correctly stated the law that it indicates and it applies the particular facts to that law.
> Q. Was the law the same before the case as it was after the case with respect to inventorship?
> A. I believe it was, yes.
> Q. Was the law the same before the case as after the case with respect to co-inventorship or joint inventorship?
> A. Yes, I believe it was. It's consistent with the law.

Deposition of Michael Sofocleous, ("Sofocleous Deposition") August 14, 2007, pp. 33-34. Indeed, Mr. Sofocleous acknowledged that it was not he who identified *American Bioscience* as being "dispositive" (as Mr. Sofocleous refers to it in his report) admitting that the opinion was brought to his attention by one of ICOS' attorneys in this case, Elliot Mendelson.[2] Whatever the source, it is undisputed that *American Bioscience* is no more authoritative than the long series of inventorship cases upon whose precedent it is based. In a rare agreement with Mr. Sofocleous,

[2] Mr. Sofocleous further admitted that Mr. Mendelson worked on the draft report with Mr. Sofocleous and even acknowledged that some of the language in Mr. Sofocleous' report was provided by Mr. Mendelson. Sofocleous Deposition, pp. 8-9.

Vanderbilt's expert, Commissioner Gerald J. Mossinghoff [3] ("Commissioner Mossinghoff"), likewise opined that *American Bioscience* is not a "leading case." Deposition of Commissioner Mossinghoff, August 14, 2007, at p. 70.

The cases decided after the *American Bioscience* decision likewise do not cite the case as controlling authority on joint inventorship but rather continue to quote the truly landmark decisions on the issue such as the decision in *Fina Oil and Chem. Co.v. Ewen*, 123 F3d 1466 (Fed. Cir. 1997), a case relied upon by *both* Commissioner Mossinghoff and Mr. Sofocleous in their respective reports. *Fina Oil* stated the law as follows:

> The issue of joint inventorship is governed by 35 U.S.C. § 116, which states, in relevant part:
>
> > When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.
>
> ***This provision sets no explicit lower limit on the quantum or quality of inventive contribution required for a person to qualify as a joint inventor.*** Rather, a joint invention is simply the product of a collaboration between two or more persons working together to solve the problem addressed. *Burroughs Wellcome*, 40 F.3d at 1227, 32 USPQ2d at 1919. The determination of whether a person is a joint inventor is fact specific, and no bright-line standard will suffice in every case.

Fina Oil, at p. 1473 (emphasis added).

In his deposition, Mr. Sofocleous was asked about this quoted portion of *Fina Oil* and agreed that it was a correct statement of the law. Sofocleous Deposition at pp. 53-54.

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[3] Mr. Mossinghoff is, *inter alia*, a professor of Patent Law at George Washington University Law School, former President of the Pharmaceutical Research Manufacturers of America, former Commissioner of Patents and Trademarks and an Assistant Secretary of Commerce and U.S. Ambassador to the Diplomatic Conference on the revision of the Paris Convention. Mr. Sofocleous called Commissioner Mossinghoff "an excellent patent administrator" and acknowledged that Commissioner Mossinghoff was "my boss at the Patent Office." Sofocleous Deposition at p. 18.

Other post-*American Bioscience* cases have likewise ignored *American Bioscience* and continued to rely on older, precedential cases on joint inventorship, such as *Monsanto v. Kamp*, 269 F.Supp. 818 (D.D.C. 1967). For example, in *Ultra-Precision Mfg. v. Ford Motor Co.*, 2004 WL 3507671 (E.D. Mich. 2004), the Court discussed joint inventorship as follows:

> The court in *Monsanto v. Kamp*, 269 F.Supp. 818, 824 (D.D.C.1967), stated the pertinent principles as follows:
>
> A joint invention is the product of collaboration of the inventive endeavors of two or more persons working toward the same end and producing an invention by their aggregate efforts. To constitute a joint invention, it is necessary that each of the inventors work on the same subject matter and make some contribution to the inventive thought and to the final result. Each needs to perform but a part of the task if an invention emerges from all of the steps taken together. ***It is not necessary that the entire inventive concept should occur to each of the joint inventors, or that the two should physically work on the project together.*** One may take a step at one time, the other an approach at different times. One may do more of the experimental work while the other makes suggestions from time to time. ***The fact that each of the inventors plays a different role and that the contribution of one may not be as great as that of another does not detract from the fact that the invention is joint if each makes some original contribution, though partial, to the final solution of the problem.***

(Emphasis added).

This is consistent with the long line of cases discussing the quantum of the contribution that is necessary for joint inventorship. In *Rodgard Corp. v. Miner Enterprises, Inc.* 12 U.S.P.Q.2D 1353, 1989 WL 41727 (W.D.N.Y. 1989) the Court stated the rule in similar fashion, again citing *Monsanto v. Kamp:*

> One may conceive a general or imperfect outline of an entirely novel thing, which, without the conception of another developing it and giving it body, might never amount to invention; ***but if the conceptions of one supplement complement the conceptions of the other, the result might be invention and therefore joint invention.*** *Monsanto Company v. Kamp*, 269 F.Supp. 818, 824

> (D.D.C.1967) (quoting from *DeLaski and Thropp C.W.T. Co. v. Wm. R. Thropp & Sons Co.*, 226 Fed. 941 (3rd Cir.1915).

(Emphasis added.)

It has always been clear that it is unnecessary to joint inventorship that the joint inventor conceive of the entire invention as long as the contribution is a significant part of the invention. This was succinctly stated in *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998):

> Because it is undisputed that the invention was conceived while Link and Pannu were engaged in a collaborative enterprise and it is furthermore undisputed that Pannu conceived *significant aspects of the invention*, Pannu is certainly a least a co-inventor. (emphasis added)

Nowhere in *American Bioscience* does the Federal Circuit state that it intended to depart from these long established and settled principles.

C. ICOS' argument takes isolated language from *American Bioscience* out of its context.

The thrust of ICOS' argument is based upon a single passage lifted from the *American Bioscience* decision and removed from the remaining context of the opinion. ICOS would have the Court focus on the following statements:

> Having in mind specific portions of a claimed compound is not the same as conceiving the compound with all its components. One must have a conception of the specific compounds being claimed, with all of their component subsitituents…

American Bioscience at p. 1340.

From that quote, ICOS extrapolates that to be a *joint* inventor of a chemical compound, an *individual person* must conceive of the entire compound.[4] There is no support in the opinion for such a reading. Indeed, as Commissioner Mossinghoff pointed out in his deposition, such a

[4] Ironically, if ICOS' interpretation of American Biosciences was a correct statement of the law, Alain Daugan, the named inventor on the subject patents, would not be an inventor or a joint inventor because, by his own testimony, he did not conceive of the entire structure of the patented compounds, but only of the addition of certain substituents to the compounds.

reading would be inconsistent with the ultimate holding of *American Bioscience* (discussed above) that Soon-Siong, Desai and Tao were joint inventors, even though none of the three conceived of the entire compound. Commissioner Mossinghoff explained that Judge Lourie, who wrote the opinion, used "one" as an indefinite pronoun to refer to one inventive entity, including all collaborators, *not* one individual:

> So you have to read this, if he says "one must", and Judge Allen Lourie uses that phrase throughout here, meaning one must take account of this, one must take account—he's not saying two can't do it, it's just one must.
>
> If you read this as one inventive entity must have a conception of the specific compounds, it makes sense. If you don't read it that way, what you say is that this decision is totally and completely internally in conflict because we know Tao had nothing to do with what he said was an important part of this, namely a taxol analog having both a 10-hydroxy group and a nitro functional group because they didn't come from Tao, they came only from Soon and Desai, and yet the final punch line of the Court is Tao is a joint inventor.

Deposition of Commissioner Mossinghoff, August 14, 2007, at p. 56.

Commissioner Mossinghoff went on to further highlight the absurdity of ICOS reading of this part of *American Bioscience* by pointing out that such a construction would mean that there could never be joint inventors of patents that claimed only one chemical compound:

> So the idea that any one person has to have all of this together is not a fair reading of *American Bioscience*, and it's not a fair reading of the cases that follow it.
>
> Indeed, if that were true, that one person had to have a definite and permanent conception of the molecule itself and all of its components, if that were true, I would submit you would never have joint inventors of U.S. patents that claim only one compound.
>
> And I've already mentioned the Astrazeneca case, very recent case, July of 2007.

Deposition of Commissioner Mossinghoff, August 14, 2007, at p. 60.

The *Astrazeneca* case to which Commissioner Mossinghoff referred is now reported as *In re Metoprolol Succinate Patent Litigation (AstraZeneca et al. v. KVPharmaceutical Company)*, 494 F.3d 1011 (Fed. Cir. 2007). The *Astrazeneca* case, while not involving issues of inventorship, involved a patent for a single compound with multiple inventors, and was decided long after ICOS' reading of *American Bioscience* would supposedly have made that an impossibility.

In perhaps the only reported decision on inventorship that came after the *American Bioscience* decision, and cites to it, the United States District Court for the Eastern District of Michigan in *Regents of the University of Michigan v. Bristol-Myers, Squibb Co.*, 301 F.Supp.2d. 633 (E.D. Mich. 2003) adopted reasoning antithetical to ICOS' reading of the case and consistent with Vanderbilt's. In discussing joint inventorship, (and having just discussed *American Bioscience* in the prior section) the court stated,

> To make a case for joint inventorship, the inventor must show that he made a "contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and [did] more than merely explain to the real inventors well-known concepts and/or the current state of the art." *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998). Each inventor must work on the "same subject matter and make a contribution to the inventive thought and to the final result." *Monsanto Co. v. Kamp*, 269 F.Supp. 818, 824 (D.D.C. 1967). The contribution of each inventor, however, need not be the same type or amount, and a joint inventor must make such a contribution only to one claim of a patent. *Id.* at 824. ***A joint inventor need not have had the definite and permanent conception of the full invention--otherwise he would be the sole inventor.***

Id. at 642 (emphasis added).

Even ICOS own expert, Mr. Sofocleous, refused to adhere to ICOS' reading of this passage of *American Bioscience*. At first, Mr. Sofocleous attempted to toe the ICOS line, resulting in an obviously untenable position:

> Q. Is it possible for individuals to be joint inventors of a single compound?
> A. It is possible for individuals to be joint inventors of a single compound.
> ...
> Q. So unless two people came to the same idea at the same time and announced it at the same time, they couldn't be co-inventors of a single compound is that correct?
> A. That is possible.

Sofocleous Deposition at pp. 25 and 26.

Mr. Sofocleous soon abandoned that strained reading of *American Bioscience* and adopted a more reasoned, and reasonable, construction:

> Q. Take that same hypothetical I gave you based on your original hypothetical of two chemists sitting in a conference room discussing changes to make to a prior art based compound.
> One of the scientists suggests adding a hydroxy or hydroxyl group, the other scientist suggests adding a nitro group. As it turns out, they do both, they add both of those things to the compound. Are they co-inventors of that compound?
> A. I believe so, yes.
> Q. And that is despite the fact that one of them conceived one part of the molecule and the other one conceived a different part of the molecule; is that correct?
> A. Because you have a joint collaboration, a going back and forth between them trying to perfect and trying to improve and make a new molecule.

Sofocleous Deposition at pp. 27-28.

Given this hypothetical, ICOS' own expert conceded that joint inventor status could be based upon individuals making separate, and different, contributions to a single compound. Even Mr. Sofocleous does not read *American Bioscience* the way the ICOS urges this Court to do.

ICOS's fallback position is that *American Bioscience* requires that each joint inventor be "aware of" the final invention in order to obtain joint inventorship status. Once again, ICOS' own expert, Mr. Sofocleous, refused to adopt that construction:

Q. Let's go back to our hypothetical of the two chemists in the room. They have a prior art based compound. A says I think you ought to add a hydroxyl group to it. B says nothing. A leaves the room, B says I'm not telling him that I think we should add a nitro group to it also, takes the idea from A, adds the hydroxyl group, adds the nitro group that he thought of without telling A, and produces the compound, which is ultimately patented. Is A not a co-inventor because B didn't tell him his idea?
A. I have to think about that question. I can't make a quick decision on it.
Q. Take as much time as you need.
A. Why don't we just take a break. Time for a break?
Q. Sure.
A. OK
...
[Recess taken.]
A. We're back on the record?
Q. Yes.
A. In trying to answer your question, I would think they were both joint inventors.
Q. Even though B never told A what he intended to do with the compound with A's idea?
A. I would think under those circumstances, if there—you know, I would say that most judges—there could be a majority would say that they're co-inventors because A made a contribution to the invention, and B used that novel, provided that his suggestion was novel and not known in the prior art, and then adding his feature to it, knowing the contribution of A that it would be joint inventors.
That would be the—I think that would be the better likelihood of the law.

Sofocleous Deposition at pp. 47-48.

In discussing the same hypothetical later in his deposition, Mr. Sofocleous further emphasized that "awareness" of the complete compound was not necessary for joint inventorship:

Q. In the hypothetical we discussed before the last break, scientist A wouldn't have been aware of the chemical structure of the compound that was ultimately patented either, would he?
A. Well, the hypothetical we talked about. But there in that hypothetical, inventor A had communicated his idea of a novel compound to inventor B.
...
Q. Okay. But he wasn't aware of the improvement.

> A. A was not aware of the improvement, but that was his contribution to that compound.
> Q. So that in the hypothetical, it didn't matter to his ability to be a co-inventor that he was not aware of the final compound; isn't that correct?
> A. Under the facts of that case where we had a direct communication of a novel compound to B, and B improved on it and ran off when it was supposed to be a joint collaboration, yes.

Sofocleous Deposition at pp.55-56.

This last hypothetical discussed with Mr. Sofocleous mirrors what the evidence will show occurred in this case. Vanderbilt is inventor A. Glaxo was inventor B. Glaxo ran off with Vanderbilt's idea when there was supposed to have been a joint collaboration. Under those facts, as ICOS' own expert concedes, there is nothing in *American Bioscience* that creates any impediment to Vanderbilt being a joint inventor.