

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>ALZHEIMER'S INSTITUTE OF AMERICA, INC.</b>	:	<b>CIVIL ACTION</b>
	:	
<b>v.</b>	:	
	:	
<b>AVID RADIOPHARMACEUTICALS, et al.</b>	:	<b>NO. 10-6908</b>
	:	

**MEMORANDUM OPINION**

**Savage, J.**

**July 1, 2013**

In its post-trial motion seeking judgment as a matter of law or a new trial, plaintiff Alzheimer's Institute of America ("AIA") challenges the jury verdict finding that Michael Mullan was not the sole inventor and that John Hardy, at least, was a co-inventor of the Swedish mutation inventions that are the patents-in-suit, and that the University of South Florida ("USF") did not waive its rights to the inventions.<sup>1</sup> With the exception of its sufficiency of the evidence argument, AIA's grounds for judgment as a matter of law are the same as those it made at the summary judgment stage.<sup>2</sup> Nothing occurred at trial or since our ruling on the summary judgment motions that has any effect on our interpretation of the law and its application to this case. For the same reasons given in our summary

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<sup>1</sup> The factual background of the case and the historical details of how the invention, the Swedish mutation, was conceived and developed are recited in our summary judgment memorandum opinion ruling on Avid Radiopharmaceuticals ("Avid") and The Trustees of the University of Pennsylvania's ("Penn") motion challenging AIA's standing to bring this infringement action. *Alzheimer's Inst. of Am., Inc. v. Avid Radiopharmaceuticals.*, No. 10-6908, 2011 WL 3875341 (E.D. Pa. Aug. 31, 2011). Because the parties are familiar with those facts and the history, we shall not reiterate them.

<sup>2</sup> AIA's counsel conceded that "the bulk of the legal arguments that we are making on motion for judgment as a matter of law and the waiver issue are the same" as those made on summary judgment. See transcript of oral argument on post-trial motions, 4/16/13 Tr. at 3:22-4:22.

judgment opinion,<sup>3</sup> we reject AIA's renewed arguments that the Florida regulation<sup>4</sup> is preempted by federal law, USF's failure to comply with certain of the regulation's requirements voided any ownership rights it may have had in the Swedish mutation invention, and the only manner in which USF could obtain legal title to the patents is via a written assignment pursuant to 35 U.S.C. § 261.

As to the sufficiency of the evidence, any reasonable jury could have concluded from the evidence that Hardy was a co-inventor of the patented invention. Likewise, there is ample evidence to support the jury's finding that USF had not waived its ownership rights in the inventions. Therefore, we shall deny AIA's motion for judgment as a matter of law.

The motion for new trial attacks jury instructions on inventorship and waiver, and evidentiary rulings excluding certain documents. The complaints about the jury instructions are derivative of those made in the motion for judgment as a matter of law, that is, AIA complains that the instructions were consistent with our rulings which AIA contend were legally incorrect. Because the jury instructions correctly stated the law and the precluded evidence was properly excluded, the motion for new trial will also be denied.

### **Co-Inventorship**

AIA contends that there was a lack of "substantial evidence" upon which the jury could find that Hardy had made a "significant contribution to the conception" of the invention, qualifying him as a co-inventor.<sup>5</sup> Relying on *Amgen, Inc. v. Chugai*

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<sup>3</sup> The rationale for our rulings on summary judgment is explained in our memorandum opinion, which is incorporated in this Memorandum Opinion. See *Alzheimer's Inst. of Am.*, 2011 WL 3875341.

<sup>4</sup> Fla. Admin. Code R. 6C4-10.012 (1992).

<sup>5</sup> AIA Br. at 3 (Doc. No. 315).

*Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991), AIA argues that there was no evidence that Hardy contributed to the “discovery of the location, structure, or physical properties of the Swedish mutation, as required for conception of a DNA invention under *Amgen*.”<sup>6</sup> As a corollary argument, AIA challenges the jury instruction on conception, claiming it failed to inform the jury that Hardy could only have been a co-inventor “if he contributed significantly to identification of the location and structure of the mutation.”<sup>7</sup> (emphasis in original).

We start with the analysis of what constitutes a significant contribution to the conception of the Swedish mutation. Must it be as specific as AIA contends? Stated differently, to qualify as an inventor, did Hardy have to discover the precise “location, structure, or physical properties” of the Swedish mutation?<sup>8</sup>

AIA confuses contribution and conception. Its argument overlooks the fundamental difference between the two concepts. Two or more persons may work together, not necessarily in time and place, to reach the point of conception, but not all may be actively involved at the precise moment of conception. Each one of them is an inventor so long as he or she made a significant contribution to the conception. Hence, a qualifying significant contribution may precede conception.

AIA’s reading and interpretation of *Amgen* ignores the warning in *Fina Oil and Chemical Co. v. Ewen*, 123 F.3d 1466, 1474 (Fed. Cir. 1997), that the doctrine of simultaneous conception and reduction to practice “cannot be used . . . to show that

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<sup>6</sup> *Id.*

<sup>7</sup> *Id.* at 27.

<sup>8</sup>*Id.* at 3.

because the first person did not conceive or reduce to practice the entire claim of the invention, he or she did not at least contribute in some significant way to the ultimate conception.” Instead, AIA seeks to impose a stricter standard for joint inventorship than the law requires. Applying AIA’s proffered standard would eliminate joint inventors and denigrate their significant contributions to an invention.

Joint inventorship is governed by the patent statute itself. 35 U.S.C. § 116. Two or more persons may be deemed joint inventors even though they did not physically work together on the invention or at the same time or make the same type or amount of contribution to every claim of the patent. *Id.* “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.” *Fina Oil*, 123 F.3d at 1473 (citing *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1227 (Fed. Cir. 1994)). Nevertheless, not all participation in the developmental or experimental process constitutes contribution for purposes of joint inventorship status. To qualify as a joint inventor, one must make a significant contribution to the conception of the invention. See *Fina Oil*, 123 F.3d at 1473. In other words, a joint inventor must make a significant contribution on the road to and not necessarily at reaching conception.

Viewing the evidence in the light most favorable to the defendants as the verdict winners,<sup>9</sup> we conclude that there was sufficient evidence to support the jury’s determination

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<sup>9</sup> In determining whether a jury’s verdict is supported by a sufficient evidentiary basis, all reasonable inferences are drawn in favor of the verdict winner. See *Reeves v. Sanderson Plumbing Prod., Inc.*, 530 U.S. 133, 150 (2000) (citation omitted). A court may not substitute its judgment of the facts and its own credibility determinations for that of the jury. *Id.*; *Acumed LLC v. Advanced Surgical Servs., Inc.*, 561 F.3d 199, 211 (3d Cir. 2009) (quoting *Lightning Lube, Inc. v. Witco. Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993)); *Fineman v.*

that Hardy was a co-inventor. To get there, the jury had to find that Hardy had made a significant contribution to the invention. Indeed, a reasonable jury could have concluded that both Mullan and Hardy had collaborated to discover the Swedish mutation. That Hardy was not present at the time and place when the identity and location of the mutation was confirmed does not mean he was not a co-inventor. There was abundant evidence that he and Mullan had been working together on the project to identify the Swedish mutation before and at the time of conception.

Evidence supporting the jury's finding that Hardy was a co-inventor was provided by not only Hardy, but by others involved in the process. Hardy's testimony was also corroborated by contemporaneous documents.

Hardy, after obtaining the DNA and pedigrees for families 139 and 144 from Dr. Lannfelt,<sup>10</sup> decided to conduct molecular genetic studies on those families.<sup>11</sup> He instructed Houlden to do a GT12 analysis on families 139 and 144.<sup>12</sup> After evaluating the results of that testing, Hardy concluded that because they suggested a mutation, exons 16 and 17 of that suspected gene should be sequenced.<sup>13</sup> Consistent with the plan to have the discovery occur in Florida instead of the United Kingdom, Hardy had the DNA samples

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*Armstrong World Indus., Inc.*, 980 F.2d 171, 190 (3d Cir. 1992).

<sup>10</sup> 4/17/12 Tr. at 65:2-66:24 (Hardy); 4/18/12 Tr. at 156:6-12 (Goate).

<sup>11</sup> 4/17/12 Tr. at 66:25-67:15 (Hardy).

<sup>12</sup> 4/17/12 Tr. at 68:10-18 (Hardy); 4/18/12 Tr. at 12:25-14:9 (Houlden); 4/18/12 Tr. at 156:13-25 (Goate).

<sup>13</sup> 4/17/12 Tr. at 70:9-18, 74:23-75:6 (Hardy); 4/18/12 Tr. at 19:9-24, 110:12-19 (Houlden).

sent to Mullan for sequencing.<sup>14</sup>

Hardy's testimony was corroborated by Drs. Houlden and Duff. Additionally, his testimony was substantiated by laboratory notebooks and other documents created contemporaneously with the discovery of the Swedish mutation.

Dr. Houlden testified that Hardy had concluded that the GT12 data suggested a mutation on the APP gene of affected members of families 139 and 144. He stated that Hardy had told him to send DNA from those families to Mullan to be sequenced in Florida.<sup>15</sup>

Houlden knew that Mullan and Hardy jointly wanted the new mutations discovered in Florida rather than in London.<sup>16</sup> Dr. Duff also corroborated Dr. Hardy's testimony. She testified that although Drs. Hardy and Mullan knew there was a genetic abnormality in the Swedish families when they were in London, they deliberately held off on formally identifying the sequence mutations until they got to Florida.<sup>17</sup>

Having the sequencing done in Florida rather than in London could have been seen by the jury as nothing more than a step in furtherance of the conspiracy to avoid the inventions becoming the property of Imperial College or Athena. In that context, Hardy and Mullan were working together on the project. They could have been considered by the jury as both attempting to deceive Imperial College and USF by having the sequencing done in Florida. So it follows that the jury could have concluded that omitting Hardy as a co-

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<sup>14</sup> 4/17/12 Tr. at 79:17-23, 97:3-5 (Hardy); 4/18/12 Tr. at 21:5-13 (Houlden); 4/18/12 Tr. at 159:16-20 (Goate).

<sup>15</sup> 4/17/12 Tr. at 79:17-23, 97:3-5 (Hardy); 4/18/12 Tr. at 21:5-13, 32:21-23, 100:5-6 (Houlden).

<sup>16</sup> 4/18/12 Tr. at 32:21-23, 100:5-6 (Houlden).

<sup>17</sup> 4/18/12 Tr. at 206:16-207:6, 224:9-19 (Duff).

inventor on the patent application was part of the ploy to defraud Imperial College and Athena.

The jury also had circumstantial evidence corroborating Dr. Hardy's testimony. There were documents, prepared prior to the discovery of the Swedish mutation, that reveal Hardy's proposed plan and process to discover the Swedish DNA. In his March 6, 1991 letter to Dr. Lieberburg,<sup>18</sup> Hardy wrote, "we intend to screen all the families we have for APP mutations by sequencing and also by linkage (we need to check whether there are families in which we can definitively rule out APP[)]." (emphasis in original). The letter, as a jury could reasonably conclude, proves that Hardy was involved in and directing the process to discover the mutation.

Hardy's draft letter to Dr. Lieberburg dated April 30, 1991<sup>19</sup> further corroborates his testimony that he developed and directed the strategy to "assess whether affected individuals share a single copy of the APP gene [using the GT12 marker]."<sup>20</sup> He advised that if the affected individuals in a family share a single copy of APP, then "exons 16 and 17 [will be] sequenced." Exons 16 and 17 were sequenced in all of the early-onset families collected at Hardy's laboratory at Imperial.<sup>21</sup>

The '169 patent application itself, which was submitted by Mullan alone, provides what the jury could have found to be corroborating evidence of Hardy's role. It recites that

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<sup>18</sup> DTX 92.

<sup>19</sup> DTX 98.

<sup>20</sup> DTX 98 at ELAN 023396.

<sup>21</sup> 4/17/12 Tr. at 27:20-28:6 (Hardy); 4/18/12 Tr. at 130:1-23 (Goate); PTX-96 (Crawford Ph.D. thesis) at FC000102.

“We tested F144 for linkage between AD and GT12.”<sup>22</sup> (emphasis added). The evidence revealed that this step was done at Hardy’s laboratory at Imperial by Houlden at Hardy’s direction. The application further describes that the sequencing was jointly done and was the next step built on the previous one. “We therefore sequenced exons 16 and 17 of the APP gene . . . .”<sup>23</sup>

Hardy arranged to have the DNA sent to Mullan in Florida for the purpose of sequencing exons 16 and 17. He was not a mere messenger or deliveryman. This evidence – Hardy’s testimony, the corroborating testimony of Houlden, Duff and Goate, and the contemporaneous documents – was sufficient to permit the jury to find, clearly and convincingly, that Hardy was directing the process and substantially contributed to the invention. Thus, there is no basis for granting AIA judgment as a matter of law.

### **Waiver**

AIA argues that there is an insufficient evidentiary basis for the jury’s finding that under either the Florida regulation or Florida common law, USF did not waive its rights in all inventions made by Mullan. It contends that, to the contrary, the evidence is “unequivocal” that USF intended to waive its rights to any inventions Mullan made prior to August 15, 1992.

The “unequivocal evidence” relied upon by AIA includes two letters: the May 4, 1992 letter, prepared by Clyde & Co. on April 29, 1992, and signed by George Newkome,

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<sup>22</sup> DTX 265.

<sup>23</sup> DTX 265 (emphasis added).

USF's Vice President of Research, on May 4, 1992;<sup>24</sup> and Newkome's November 20, 1992 letter to Anthony Reading, USF's then head of the Department of Psychiatry.<sup>25</sup> AIA selectively quotes a portion of one sentence in the May 4, 1992 letter – “[A]ll ownership of rights in any work carried out by [Hardy and Mullan] and inventions made by them before August 15, 1992 belong exclusively to Hardy and Mullan”<sup>26</sup> – as “unequivocally establish[ing]” Newkome's intent to release all of USF's rights in Mullan's inventions conceived before the start of the new academic year. The November 20, 1992 letter, according to AIA, confirms USF's intention to waive its rights to any inventions Mullan [and Hardy] made prior to August 15, 1992. AIA quotes the following language from the November 1992 letter:

[N]ow that Drs. Hardy and Mullan have signed their contracts for this academic year, all University of South Florida policies and procedures apply to them. This includes the inventions and works policies. It should be noted that all rights for intellectual property developed after August 15, 1992, under the auspices of Drs. Hardy and/or Mullan belong to the University of South Florida. Copies of the applicable USF policies and rules previously have been given to Drs. Hardy and Mullan, and an additional copy is attached hereto.<sup>27</sup>

AIA argues that this language reflects Newkome's recognition that USF's policies applied to Hardy and Mullan only after August 15, 1992, which was what it characterizes as the “key date” set forth in the May 4, 1992 letter. It claims the language also supports

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<sup>24</sup> PTX 34. This letter was prepared by Clyde & Co. Throughout the trial, AIA characterized this letter as evidence of USF's “broad waiver” of all rights in all inventions discovered by Hardy and Mullan before August 15, 1992.

<sup>25</sup> PTX 42.

<sup>26</sup> PTX 34 at 2.

<sup>27</sup> PTX 42.

AIA's contention that USF agreed to a "broad waiver" of its rights to any inventions made by Mullan prior to August 15, 1992.

There is ample evidence from which a reasonable jury could have found that Newkome did not intend to waive USF's rights to the Swedish mutation invention.

There is evidence that when Newkome signed the May 4, 1992 letter, he did not intend to waive USF's ownership rights to Hardy and Mullan's inventions, but rather intended to draw a bright line between the work done by Hardy and Mullan on the London mutations at Imperial College and any new work that they would do later at USF. As characterized by Newkome, the May 4, 1992 letter referred to the disputes among Imperial College, Hardy and Mullan over ownership rights to the London mutations. Indeed, the letter's language seemed to create that impression. Clyde & Co., who were Mullan and Hardy's solicitors in the United Kingdom, wrote:

We act on behalf of Drs Hardy and Mullan in relation to certain matters in the UK. . . .

As you know Drs Hardy and Mullan have been involved in important developments in Alzheimer's disease prior to and at St Mary's Hospital in London, and we understand that you are already aware that the question of ownership and exploitation of inventions made by Hardy and Mullan and how they should be exploited have given rise to some difficulties here. . . .

We would like to avoid further complications at this stage in relation to Hardy and Mullan's rights and in particular to avoid any further arguments about ownership or rights to exploit which might impede exploitation. . . .<sup>28</sup>

Newkome's testimony provided the context for his signing the May 4, 1992 letter. It supplied a basis for the jury's finding that he did not intend to waive USF's rights to the

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<sup>28</sup> PTX 34.

Swedish mutation.<sup>29</sup> Newkome testified that when he signed the letter, he was aware that Hardy and Mullan had discovered the London mutations while working at Imperial College and they had a dispute with Imperial College concerning ownership of those inventions.<sup>30</sup> In January of 1992, Mullan and Hardy had asked him and USF to intervene on their behalf with respect to their dispute with Imperial College. In light of that request, USF retained patent counsel for advice regarding the feasibility of applying for a patent in the United States related to the “inventions that they had patented in England,” including “the two gene mutations discovered by them.”<sup>31</sup>

Mullan agreed that the language in the May 4, 1992 letter focused on the London mutations. He acknowledged that the language explicitly referring to Hardy and Mullan’s “involve[ment] in important developments in Alzheimer’s disease prior to and at St. Mary’s Hospital in London,”<sup>32</sup> and the express desire “to avoid further complications at this stage in relation to Hardy and Mullan’s rights and in particular to avoid any further arguments about ownership or rights to exploit which might impede exploitation”<sup>33</sup> referred to the London mutations. Mullan also admitted that he believed that Newkome signed the letter because Newkome understood the work Mullan was doing was “in some way a follow

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<sup>29</sup> See PTX 34 (“*We understand that you are already aware that the question of ownership and exploitation of inventions made by Hardy and Mullan and how they should be exploited have given rise to some difficulties here.*”) (emphasis added).

<sup>30</sup> 4/13/12 Tr. at 115:4-11, 137:4-10, 139:20-24, 141:8-142:16 (Newkome).

<sup>31</sup> 4/13/12 Tr. at 137:11-19, 138:8-149:7 (Newkome); USF trial exs. 13, 17.

<sup>32</sup> 4/16/12 Tr. at 10:23-11:13 (Mullan).

<sup>33</sup> 4/16/12 Tr. at 11:14-19, 13:1-13 (Mullan).

through [of the work he] had been doing in Europe.”<sup>34</sup>

Mullan’s testimony regarding the letter could easily have been considered by the jury as consistent with Newkome’s testimony. According to Newkome, he signed the May 4, 1992 letter in order to “separate the intellectual property that was previously created at Imperial College in England by Hardy and Mullan. . . . [so] that anything that was created in England would belong to [Hardy and Mullan] or Imperial College.”<sup>35</sup> He stated that USF was “trying to make a distinct break,”<sup>36</sup> and “really wanted to make sure that there was a distinct dividing line between the intellectual property invented in Imperial College versus that which would be invented at the University of South Florida.”<sup>37</sup> He explained that when he inserted the August 15, 1992 date in the letter, he “was trying to put a time frame on things that were being completed by them from Imperial College versus the new things that would be started at the University of South Florida.”<sup>38</sup> He gave Hardy and Mullan “their rights to things that were created under [Imperial College]” to allow Hardy and Mullan to “deal with Imperial College.”<sup>39</sup> In short, his testimony was that he wanted to avoid an intercollegiate battle with Imperial College over ownership rights to inventions that were created in London.

Newkome explained that he chose August 15, 1992 as the cut-off date for Mullan

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<sup>34</sup> 4/16/12 Tr. at 13:18-14:4 (Mullan).

<sup>35</sup> 4/13/12 Tr. at 134:8-23 (Newkome).

<sup>36</sup> 4/13/12 Tr. at 178:20-24 (Newkome).

<sup>37</sup> 4/13/12 Tr. at 142:5-8 (Newkome).

<sup>38</sup> 4/13/12 Tr. at 147:12-15(Newkome).

<sup>39</sup> 4/13/12 Tr. at 134:13-135:4 (Newkome).

and Hardy to wrap up any issues surrounding their London mutation inventions while at Imperial College because it was the start of the new semester at USF.<sup>40</sup> He testified that he

signed [the May 4, 1992 letter] in such a way that it would end the very first part of the fall semester, the first fall semester they were there. So it started in August some date, 1992. So there was a demarcation. I expected them to complete all of the necessary stuff, to complete the publications, the extra stuff for patents and copyrights that belonged to Imperial College, because that is where they did the work originally. But they needed to clean things up. So I did that. And then what occurred is, is that on the first day, which is August 15th, 1992, they would be no longer accountable for anything at Imperial College. From then on, I expected them to have cleaned up all their loose ends in the summer and in the spring of 1992.<sup>41</sup>

There is ample evidence to support a finding that at the time he signed the May 4, 1992 letter, Newkome had no knowledge of the discovery of the Swedish mutation invention and consequently could not have known that it had been discovered while Mullan was employed at USF. Newkome testified that when he signed the letter on May 4, 1992, he believed that Mullan and Hardy had not yet begun any new research at USF. Prior to that time, neither Mullan nor Hardy had disclosed that they had done work or made any discoveries while at USF.<sup>42</sup> Nor did Mullan, Hardy or Sexton reveal anything about any such work at the meeting where he signed the letter. Mullan told Newkome at the meeting that he had been unable to do any new work because the laboratories were not ready.<sup>43</sup>

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<sup>40</sup> 4/13/12 Tr. at 135:20-21 (Newkome).

<sup>41</sup> 4/13/12 Tr. at 135:5-19 (Newkome).

<sup>42</sup> 4/13/12 Tr. at 142:24-143:15 (Newkome).

<sup>43</sup> 4/13/12 Tr. at 143:16-144:6, 149:5-17, 150:6-10 (Newkome).

Newkome testified "I could not see how any type of new significant research could be done if, in fact, there were no laboratories."<sup>44</sup> Mullan and Hardy told him that after that meeting, they were planning to clean, stock and make the lab "workable."<sup>45</sup> The message conveyed, whether intentionally or not, was that work at USF had not yet started.

The language in the May 4, 1992 letter supports Newkome's testimony. There is no explicit reference to any work, discovery or invention that had been made by Mullan or Hardy at USF. It certainly does not identify any discovery of a new mutation, let alone the Swedish mutation.<sup>46</sup> On the contrary, the language, as well as Mullan's interpretation of it, could reasonably be construed by a jury to refer to the work on the London mutation at Imperial College.

The November 20, 1992 letter from Newkome to Reading does not support AIA's argument. It does not establish Newkome's intent to waive USF's rights in any invention made by Mullan prior to August 15, 1992. In this letter, written more than six months after Newkome had signed the May 4, 1992 letter, he wrote that all USF policies and procedures apply to Mullan and Hardy "now that [they] have signed their contracts for this academic year," and that "all rights for intellectual property developed after August 15, 1992, under the auspices of Drs. Hardy and/or Mullan belong to [USF]."<sup>47</sup>

At trial, Newcome explicitly rejected AIA's interpretation of the letter as a broad waiver. His testimony was as follows:

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<sup>44</sup> 4/13/12 Tr. at 145:6-10 (Newkome).

<sup>45</sup> 4/13/12 Tr. at 148:20-149:4 (Newkome).

<sup>46</sup> 4/13/12 Tr. at 142:24-143:2 (Newkome).

<sup>47</sup> PTX 42.

Q: So isn't that saying that until they signed their contracts for the academic year, that the South Florida policies and procedures did not apply to them?

A: No, it does not.

Q: Then why is it written that way?

A: It's written this way saying that no longer are there any obligations to Imperial College, which there was in place up to that date.<sup>48</sup>

Newkome further testified that he had no intention of waiving any of USF's rights to inventions made by Mullan and Hardy while they were at USF, even if made before August 15, 1992. "I did not waive anything from the University of South Florida at all, ever. We were simply trying to figure out how do you leave things from previous owners and leave them be accountable of which then the University itself would be free."<sup>49</sup>

It was up to the jury to determine from this conflicting testimony whether USF knowingly and intentionally waived its ownership rights in the Swedish mutation invention. There was evidence from which the jury could have reasonably concluded that Newkome did not know about the Swedish mutation invention and that he believed USF was only waiving ownership rights to inventions made by Mullan and Hardy that related to their work at Imperial College. Therefore, the jury reasonably found that he had not intended to waive USF's rights to *any undisclosed* inventions resulting from new work done by Mullan and Hardy prior to August 15, 1992.

AIA further argues that even if the May 4, 1992 letter itself did not clearly prove USF's knowledge of its ownership rights in *all* of Mullan's inventions, disclosed or

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<sup>48</sup> 4/13/12 Tr. at 208:15-209:2 (Newkome).

<sup>49</sup> 4/13/12 Tr. at 135:22-136:10 (Newkome).

undisclosed, there was other evidence that established Newkome's knowledge of the Swedish mutation discovery when he signed the letter on May 4, 1992. AIA cites three documents, which were created well after Newkome had signed the May 4, 1992 letter.

In the first document, the "Burgess Memo,"<sup>50</sup> AIA points to the following language as demonstrating Newkome's knowledge of the Swedish mutation invention:

Hardy sent sets of the Swedish and English samples to Dr. Mullan at USF for the purpose of Mullan conducting computer analysis to locate the gene mutation in the DNA. Dr. Mullan utilized his USF space/computer for this work, and also utilized the facilities of the Tampa Bay Research Center in Clearwater, Florida for the "sequencing" studies of Swedish samples.<sup>51</sup>

Additionally, AIA notes Newkome's testimony that at the time he received the Burgess memo in June of 1993, he knew that USF "potentially had an ownership interest in the [Swedish mutation patents]."<sup>52</sup> The second document is a letter Hardy sent to Newkome on October 25, 1993. In that letter, there is mention of "samples from a Swedish family" in which "[Mullan] found a third amyloid mutation . . . and wrote it up" and for which he submitted a patent application.<sup>53</sup> The third document, an email string exchanged between Newkome and Hardy in July of 1997, references the "Swedish patent," and that "[Mullan

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<sup>50</sup> PTX 44. This is an internal memorandum dated June 15, 1993 from Bryan Burgess, Associate Vice President for Health Sciences, Legal/Institutional Affairs, to Newkome, documenting the events preceding and following a dispute between Drs. Hardy and Mullan that occurred in May, 1993 regarding Hardy's attempted shipment of DNA samples from USF to England. Burgess's involvement in the dispute arose when Dean Marvin Dunn of the Medical School requested that he travel to the UPS facility in Kentucky to retrieve the DNA samples being held there. Burgess obtained the background information in the memo from speaking with Mullan, Hardy and Newkome. 4/19/12 Tr. at 6:10-7:2, 19:20-28:13, 44:13-50:24 (Burgess); 4/13/12 Tr. at 156:23-163:13, 224:23-232:11 (Newkome).

<sup>51</sup> PTX 44 at 3.

<sup>52</sup> 4/13/12 Tr. at 231:1-9 (Newkome).

<sup>53</sup> PTX 48 at 1; 4/13/12 Tr. at 236:16-237:24.

and Crawford] knew about the mutation when you [Newkome] signed [the letter].”<sup>54</sup>

According to AIA, these three documents prove that at the time Newkome signed the May 4, 1992 “waiver letter,” USF knew that the Swedish mutation had been invented by Mullan and knowingly waived its rights to that invention. AIA contends that USF’s failure to assert its ownership rights to the Swedish mutation invention during the twenty years following its discovery confirms that USF intended to relinquish any ownership rights in Mullan’s inventions created before August 15, 1992. AIA asserts that “[a]lthough the issue of USF’s ownership interest in Dr. Mullan’s inventions was raised time and time again, USF did not assert any claim,” and made “repeated representations” that it had no such ownership interest.<sup>55</sup> AIA argues that the Burgess memo proves that Mullan and Hardy disclosed to Newkome “the specific project and conditions” of the Swedish mutation discovery at least prior to June of 1993, the date of the memo.<sup>56</sup> AIA states that “[a]lthough Dr. Mullan’s inventions were repeatedly disclosed, USF never made any attempt to comply” with the requirement of the Florida regulation that it inform Mullan of its intent to assert an interest in the Swedish mutation invention within 120 days of disclosure.<sup>57</sup>

Contrary to AIA’s assertion, the evidence at trial did not “unequivocally establish” that USF had knowledge of the Swedish mutation invention by the time Newkome signed the May 4, 1992 letter, or more than a year later when the Burgess memo was written. As we have already detailed, there is ample evidence supporting Newkome’s testimony to the

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<sup>54</sup> PTX 56 at 3; 4/13/12 Tr. at 190:20-205:1 (Newkome).

<sup>55</sup> AIA Br. at 21-22.

<sup>56</sup> *Id.* at 20.

<sup>57</sup> *Id.* at 22.

contrary. Regarding the evidence of his knowledge of the Swedish mutation invention after May 4, 1992, Newkome specifically testified that nothing in the post-1992 documents – the Burgess memo, which was created in June of 1993; Hardy’s October 25, 1993 letter to Newkome; and Hardy’s emails sent to him in 1997 – alerted him that Mullan had made any inventions at USF prior to August 15, 1992 that were unrelated to the work Mullan and Hardy had done at Imperial College. At most, these later documents led him to believe that USF “*potentially* had an ownership interest” in the Swedish mutation invention.<sup>58</sup> Newkome explained that he believed that the references in the October 1993 letter related to a patent unrelated to the Swedish mutation. He could make no other determination because he never received a disclosure describing the work Mullan had done prior to August 15, 1992 at USF.<sup>59</sup> He perceived Hardy’s emails as Hardy pursuing a vendetta against Mullan with whom he had a falling out four years earlier. Still never having received a disclosure describing the work Mullan did at USF prior to August 15, 1992, Newkome testified, he had no new information about the Swedish mutation.<sup>60</sup>

These documents do not “unequivocally” prove what Newkome knew when he signed the May 4, 1992 letter. They were created sixteen or more months later. Even assuming they informed Newkome of the Swedish mutation discovery at the time he saw them, this is hardly “unequivocal” evidence of his having had that knowledge when he signed the May 4, 1992 letter more than a year earlier. Of course, this evidence had a bearing on what Newkome’s intent was when he signed the May 4, 1992 letter. It could

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<sup>58</sup> 4/13/12 Tr. at 231:1-9, 237:8-24 (Newkome); PTX 44.

<sup>59</sup> PTX 48; 4/13/12 Tr. at 238:1-239:17 (Newkome).

<sup>60</sup> PTX 56; 4/13/12 Tr. at 193:12-194:13, 197:4-200:7, 200:21-201:22 (Newkome).

have been considered corroborating evidence of his intent to waive all rights USF may have had. After hearing and seeing this evidence, the jury rejected that interpretation. It was not unreasonable for the jury to conclude that the post-May 4, 1992 communications did not prove USF's intent to relinquish any ownership rights in the Swedish mutation invention or any other new work performed by Mullan at USF prior to August 15, 1992.

As we stated in our summary judgment memorandum opinion, “[w]hat Mullan, Hardy and USF understood and intended by the [May 4, 1992 letter] is not clear. The letter is susceptible to more than one meaning.”<sup>61</sup> At trial, all parties presented evidence about what and when USF knew about the Swedish mutation invention. The jury's determination that USF did not knowingly and intentionally waive its rights because Newkome lacked sufficient knowledge to waive a known right was amply supported by the evidence.

The jury was free to accept or reject the testimony of the witnesses who gave conflicting versions of events surrounding the creation and meaning of the May 4, 1992 letter. AIA is asking us to substitute our findings of the facts and our assessment of credibility for those of the jury. We cannot and will not do so. Drawing all reasonable inferences in favor of the verdict winners, as we must, we conclude that the jury's finding that USF did not knowingly and intentionally waive its ownership rights in the Swedish mutation invention is supported by sufficient evidence. Thus, we cannot disturb it.

### **Avid and Penn's Standing to Contest AIA's Standing**

AIA argues that Avid and Penn lack standing to assert USF's potential ownership interest in the patents because USF holds no more than an equitable interest in the

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<sup>61</sup> *Alzheimer's Inst. of Am., Inc.*, 2011 WL 3875341, at \*12.

patents-in-suit. Drawing a distinction between rights in the invention and rights in the patents, AIA asserts that even if the Florida regulation vests legal title to an invention made by an employee in USF, rights in an *invention* do not confer the same benefits as do rights in a *patent*. Citing *Arachnid, Inc. v. Merit Industries, Inc.*, 939 F.2d 1574 (Fed. Cir. 1991), AIA contends that because Mullan never executed a written assignment pursuant to 35 U.S.C. § 261 transferring patent rights to USF, USF has, at most, an equitable claim to the patents-in-suit.

Avid and Penn counter that in challenging AIA's standing to bring this infringement action, they do not assert any equitable right of USF. Rather, they contend that AIA lacks legal title to the patents in suit.

Avid and Penn are correct. Lacking legal title to the patent, a plaintiff does not have standing to pursue an infringement action. *Abraxis Bioscience, Inc. v. Navinta LLC*, 625 F.3d 1359, 1364 (Fed. Cir. 2010) (citing *Paradise Creations, Inc. v. UV Sales, Inc.*, 315 F.3d 1304, 1309-10 (Fed. Cir. 2003)). When the rights to an invention are transferred or vested in another by contract or by operation of law, a subsequent purported assignee of the inventor lacks legal title in any ensuing patent because the inventor had nothing to assign at the time of the purported assignment. See *FilmTec Corp. v. Hydranautics*, 982 F.2d 1546, 1550, 1553-54 (Fed. Cir. 1992); *FilmTec Corp. v. Allied-Signal Inc.*, 939 F.2d 1568, 1572-73 (Fed. Cir. 1991); *Picture Patents, LLC v. Aeropostale, Inc.*, 788 F.Supp. 2d 127, 131, 136-37 (S.D.N.Y. 2011); *Imatec, Ltd. v. Apple Computer, Inc.*, 81 F.Supp. 2d 471, 481 (S.D.N.Y. 2000).

Avid and Penn did not assert any rights USF may have. They challenged AIA's standing to bring an action for infringement of the patents, contending AIA did not validly

own them. They did not assert any other person or entity's ownership of the patents. Instead, they claimed only that AIA did not have valid rights to the patents. It was AIA's burden to prove otherwise.

### **Equitable Estoppel**

AIA argues that USF is estopped from asserting an ownership claim in the Swedish mutation invention based on its conduct and silence over twenty years. It contends that it should have been permitted to prove that USF's failure to assert an interest in the invention during the twenty years after May 4, 1992 prevents USF from now asserting that it did not waive ownership rights in it.

Equitable estoppel against USF is not relevant to the issue of AIA's standing to bring this infringement action against Avid and Penn. As we stated at the charging conference, the issue of equitable estoppel

may be relevant to any claims that USF may have against AIA, but that is not what we are trying in this case. It's whether AIA can bring an action against Avid and Penn for infringement. That is all we are trying in this case. You might have that argument [of equitable estoppel] somewhere down the line. .

<sup>62</sup>

In other words, the defense of equitable estoppel may be available in a later action brought against AIA by USF.

AIA's standing to bring this infringement action against Avid and Penn does not turn on USF's ability to claim an ownership interest in the patents. Therefore, the question of AIA's standing is independent of any issue of equitable estoppel.

Even if equitable estoppel were a relevant issue, AIA did not establish reliance, an

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<sup>62</sup> 4/18/12 Tr. at 339:18-19, 349:5-12.

essential element of the defense. Equitable estoppel requires reliance on a representation as to a material fact that is contrary to a position asserted later. See *A.C. Aukerman Co. V. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1041 (Fed. Cir. 1992) (citation omitted). In support of its argument that USF is estopped from asserting an ownership interest in the invention, AIA points to several exhibits, some admitted into evidence, and some excluded from evidence.<sup>63</sup> Each exhibit is a letter or email string between USF and someone other than Mullan or Sexton. There is no evidence that Mullan or Sexton ever saw these documents. Therefore, AIA could not have relied on them. As we ruled at the charging conference,

[t]here's absolutely no evidence that USF ever made a representation [to AIA] that is contrary to the position that it now finds itself in. Internal memos that were not communicated to AIA do not constitute evidence of reliance, inducement. . . . [A]ll of the evidence that [was] produced on the estoppel issue are all a failure to act. . . . AIA was aware of the facts.<sup>64</sup>

### **Jury Instructions**

AIA challenges the jury instructions on joint inventorship and waiver. It also complains that we improperly rejected its requests for instructions on equitable estoppel and on the applicability of two provisions of the Florida regulation covering inventions discovered by USF employees.

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<sup>63</sup> PTX 42, 48 and 56 were admitted into evidence; PTX 47 and 52 were not.

<sup>64</sup> 4/18/12 Tr. at 348:16-344:4.

The jury instructions on joint inventorship correctly stated the law.<sup>65</sup> The instruction was as follows:

To qualify as an inventor, one must make a significant contribution to the conception of at least one or more of the claims of the patent. The claims are the numbered paragraphs at the end of the patent which define the scope of the invention.

Conception occurs when the inventor forms in his mind a definite and permanent idea of the complete and operative invention as it is to be applied in practice. An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue.

Conception of an invention is complete when the inventor has formed the idea of how to make and use every aspect of the invention. All that is required is that it be made without the need for any further inventive effort.

If one only explains to the actual inventors well-known concepts or the current state of the art, he is not an inventor. Merely helping with experiments by carrying out the inventor's instructions does not make someone an inventor. What is required is some significant contribution to the idea claimed.

Whether the contribution is significant is measured against the scope of the full invention. A person may be an inventor even if he does not make the same type or amount of contribution, and even if he does not contribute to the subject matter of each claim in the patent. A person may be a co-inventor even though he does not physically work together with another as

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<sup>65</sup> Where a party claims a jury charge stated an incorrect legal standard, the charge is taken as a whole and viewed in light of the evidence to determine if it fairly and adequately submitted the issues in the case. *Cooper Distrib. Co. v. Amana Refrigeration, Inc.*, 63 F.3d 262, 275 (3d Cir. 1995) (quoting *Limbach Co. v. Sheet Metal Workers Int'l Ass'n*, 949 F.2d 1241, 1259 n. 15 (3d Cir. 1991)). In other words, we must consider "the totality of the instructions and not a particular sentence or paragraph in isolation." *Cooper*, 63 F.3d at 275 (citation omitted). Only if the instruction was confusing and misleading will a new trial be granted. See *Pryer v. C.O. 3 Slavic*, 251 F.3d 448, 454 (3d Cir. 2001) (quotation omitted). If the instruction was erroneous, a new trial is not warranted if the error was harmless. *Cf. Murray v. United of Omaha Life Ins. Co.*, 145 F.3d 143, 156-57 (3d Cir. 1998) (where "the findings necessarily implicit in the verdict of the jury compel the conclusion that the jury would have reached the same result had it been instructed according to the correct legal standard," the error was harmless).

long as he has some open line of communication during or at approximately the time of his inventive effort.

A person's contribution must be proved by more than his own testimony. In other words, his testimony alone is insufficient to meet the clear and convincing evidence standard. There must be corroborating evidence. Corroborating evidence can be found in documentary or physical evidence made contemporaneously with the inventive process, or the oral testimony from someone other than the person claiming to be a co-inventor.

If you are clearly convinced that John Hardy made a significant contribution to the Swedish mutation invention, then you must find that Hardy is a co-inventor of the Swedish mutation patents. On the other hand, if you are not clearly convinced that Hardy made a significant contribution to the Swedish mutation invention, you must find that Hardy is not a co-inventor of the Swedish mutation invention.<sup>66</sup>

These instructions informed the jurors that they had to find that one claiming to be an inventor had to have made a significant contribution to the conception of the invention. They pointed out the distinction between a general goal or research plan on the one hand and a specific, settled idea or solution on the other hand. They made clear that what was required, by clear and convincing evidence, was that the person had to have made a "significant contribution." Thus, the instruction on co-inventorship was legally correct.

AIA argues that the instruction on the second element of waiver was improper because it limited the time, scope and manner of actual or constructive knowledge of USF's ownership rights.

The instruction was as follows:

The second element AIA must prove by a preponderance of the evidence is that USF had actual or constructive knowledge of the right. . . . There can be no waiver if the party against

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<sup>66</sup> 4/20/12 Tr. at 14:2-15:23.

whom the waiver is invoked did not know all of the material facts or was misled about the material facts. If you find that AIA has not proven by a preponderance of the evidence that Dr. George Newkome was in possession of all of the material facts regarding the Swedish mutation invention prior to signing the May 4th Letter, there was no waiver.

Florida law, which governs the procedure for USF's waiver of rights in inventions owned by it, requires that an employee fully and completely disclose all inventions to the University's President or Vice President for Research.<sup>67</sup>

First, AIA contends that it was error to instruct the jury that actual or constructive knowledge could only be found where disclosure was made in the manner prescribed by the Florida regulation. AIA contends that the part of the instruction stating that Florida law requires "an employee [to] fully and completely disclose all inventions to the University's President or Vice President for Research"<sup>68</sup> only arises under the regulation. See Fla. Admin. Code Ann. r. 6C4-10.012(3)(a)(1) (1992). According to AIA, because the regulation does not provide the exclusive mechanism for waiving rights to an invention, USF could have waived its rights under Florida common law. Thus, AIA argues that the instruction erroneously tied waiver to the Florida regulation.

AIA is mistaken. In addition to instructing on the knowledge and disclosure requirement of the Florida regulation, we also charged the jury that AIA must prove by a preponderance of the evidence that USF had actual or constructive knowledge of the right. It was accurate that the Florida regulation required that employees must "fully and completely disclose" all inventions to the University's President or Vice President for

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<sup>67</sup> 4/20/12 Tr. at 17:18-18:11.

<sup>68</sup> 4/20/12 Tr. at 18:9-11.

Research. See Fla. Admin. Code Ann. r. 6C4-10.012(3)(a)(1).

The instruction did not direct the jury to find that there could be no waiver unless there had been compliance with the regulation. Non-compliance was only a factor in the knowledge analysis. Contrary to AIA's contention, the jury was not instructed that "actual or constructive knowledge" could only be found where disclosure was made in the *manner* prescribed by the Florida regulation (*i.e.*, the invention disclosure form). Therefore, the instruction on waiver was not improperly tied to the Florida regulation.

Second, AIA also argues that the waiver instruction incorrectly tied the knowledge requirement to the May 4, 1992 letter by requiring Newkome to have had actual or constructive knowledge of USF's rights "prior to signing the May 4th letter. . . ." <sup>69</sup> AIA insists that because proof of waiver "may be express, or implied from conduct or acts that lead a party to believe a right has been waived," and can be based "upon conduct demonstrating an intent to relinquish a known right," USF's failure to assert ownership after the Burgess memo purportedly fully disclosed the circumstances of the Swedish mutation invention establishes that USF intended to relinquish a known right. It posits that the court's instruction on waiver should not have been limited to Newkome's knowledge preceding execution of the May 4, 1992 letter, <sup>70</sup> even though AIA consistently throughout the trial premised its waiver theory on that letter.

AIA had to prove that Newkome had been in possession of all of the material facts regarding the Swedish mutation invention prior to signing the May 4, 1992 letter, which AIA

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<sup>69</sup> 4/20/12 Tr. at 18:2-6.

<sup>70</sup> AIA Br. at 29.

characterizes as an “unequivocal” waiver. It had to demonstrate actual or constructive knowledge of the existence of the right alleged to have been waived to establish waiver. See *Bristol W. Ins. Co. v. Albertson*, 41 So.3d 378, 381 (Fla. Dist. Ct. App. 2010); *Winans v. Weber*, 979 So.2d 269, 274 (Fla. Dist. Ct. App. 2007). The only possible documented source of such a waiver was the May 4, 1992 letter. AIA produced no other evidence bearing on USF’s knowledge and intent at the time of the purported waiver. Indeed, its trial strategy and arguments to the jury were that the May 4, 1992 letter was a “broad waiver” of all of USF’s rights to the Swedish mutation. Therefore, the only conduct after May 4, 1992 that could be relevant to USF’s intent is evidence that is probative of Newkome’s knowledge and intent at the time he signed the May 4, 1992 letter.

Contrary to AIA’s argument, the instruction that unless AIA proved that “Newkome was in possession of all of the material facts *regarding the Swedish mutation invention* prior to signing the May 4th Letter, there was no waiver” was correct.<sup>71</sup> Using the same argument that the May 4, 1992 letter was a broad waiver expressly disclaiming *all* rights USF might otherwise have had in Mullan’s inventions made before August 15, 1992, AIA argues that no basis exists for limiting the scope of USF’s alleged waiver to the Swedish mutation inventions.

Because the issue of waiver related only to the ownership rights to the Swedish mutation invention, the instruction was appropriate. Additionally, we repeat that before one can waive a right, he must have knowledge of the existence of the right alleged to have been waived, which includes knowledge of all of the material facts.

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<sup>71</sup> 4/20/12 Tr. at 18:3-6 (emphasis added).

Whether work on the Swedish mutation was done at USF and whether it was new and distinct from the work done at Imperial College were material facts. Finally, even if the instruction had not limited the scope of USF's alleged waiver to the Swedish mutation invention, there was, as we said earlier, ample evidence for the jury to have found that USF did not knowingly and intentionally give Mullan and Hardy a broad waiver of its rights to all inventions made by them prior to August 15, 1992.

AIA sought an instruction that required the jury to find that USF relinquished any ownership rights in the Swedish mutation patents if it determined that USF had not complied with two provisions of the regulation. The first provision states that "If the University wishes to assert its interest in the invention, the President or Vice President of Research shall inform the employee within 120 days of the employee's disclosure to the President or Vice President of Research." Fla. Admin. Code Ann. r. 6C4-10.012(3)(a)(2) (1992).

The other provision requires the "University and the employee [to] sign an agreement recognizing the terms of" the regulation. Fla. Admin. Code Ann. r. 6C4-10.012(4) (1992). AIA requested an instruction that if the Swedish mutation invention was disclosed and USF did not assert an interest within 120 days of disclosure, or USF and Mullan did not sign an agreement acknowledging the terms of the regulation, USF did not own rights in the Swedish mutation patents.

AIA also argues that the failure to instruct the jury on these provisions precluded it from relying on additional grounds to establish USF's waiver. It contends that there was evidence at trial that USF failed to timely assert its interest and that Mullan signed his employment contract, which was the only written agreement between him and USF,

months after the discovery of the Swedish mutation inventions. Accordingly, so AIA contends, the jury should have been instructed that it could consider these additional grounds in evaluating whether USF had waived its rights in the Swedish mutation inventions.

Because these provisions do not constitute prerequisites for application of the regulation vesting property rights in USF, AIA's proffered instruction was not a correct statement of the law. As we stated at the charging conference, the applicability of the Florida regulation is not conditioned upon USF "asserting an interest" in its employees' inventions within 120 days of disclosure of the inventions to the President or Vice President for Research. USF was not required to take action to perfect its title. Similarly, in our summary judgment ruling, we had already rejected AIA's contention that the applicability of the Florida regulation is conditioned upon the employee signing an agreement recognizing its terms. Because AIA mischaracterized the Florida regulation and its applicability in its proposed instructions, we properly refused to give them.

AIA argues that the jury should have been instructed on equitable estoppel. As we already stated, equitable estoppel is not available because it is not relevant to the issue of AIA's standing. Additionally, even if equitable estoppel were relevant, AIA failed to establish the reliance element of equitable estoppel at trial. Therefore, we properly refused AIA's proposed jury instructions on equitable estoppel.

### **Evidentiary Rulings**

AIA asserts that it is entitled to a new trial because the court erroneously excluded evidence and argument pertaining to: (1) USF's post-May 4, 1992 conduct; (2) the applicability of the Florida regulation and the USF Policy on Inventions and Works; and (3)

the conclusions of law previously determined in the summary judgment memorandum opinion, including contesting USF's ownership of the Swedish mutation invention by operation of law.

*Evidence of USF's Post-May 4, 1992 Conduct*

AIA challenges the rulings precluding it from introducing into evidence four documents that it contends prove that USF knew that Mullan had discovered the Swedish mutation while employed at USF and failed to assert any rights in the inventions. These documents, according to AIA, were relevant to both waiver and equitable estoppel.

Avid, Penn and USF counter that the proffered evidence of documents created long after May 4, 1992 is irrelevant as to Newkome's intent to waive USF's rights in the Swedish mutation and is impermissible hearsay.

As we have ruled, equitable estoppel was not an issue. Consequently, any evidence proffered to establish an equitable estoppel defense was properly excluded as irrelevant. Thus, we shall consider AIA's evidentiary arguments as they relate to waiver.

USF Health Science News<sup>72</sup>

AIA proffered the August 13, 1992 USF publication "USF Health Sciences News," which describes the discovery of the Swedish mutation invention, to show that USF was on notice of the inventions, not for the truth. AIA posits that because the newsletter was published by the University, it is "akin to a press release."<sup>73</sup> Consequently, USF and Newkome cannot claim they had no knowledge of this document or of its contents.

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<sup>72</sup> PTX 238.

<sup>73</sup> AIA Br. at 32; 4/3/12 Tr. at 246:1-24.

Avid, Penn and USF argue that the August 13, 1992 “USF Health Sciences” newsletter was properly excluded because it was not written or read by Newkome, and it was not published until several months after the May 4, 1992 letter. Therefore, according to the defendants, it could not have had a bearing on Newkome’s knowledge or intent at the time he signed the letter.<sup>74</sup>

The defendants are correct. Additionally, AIA does not dispute that there was no evidence that Newkome had seen the article prior to his 2011 deposition. The article was not written by and does not quote Newkome or anyone else who had authority to waive USF’s rights in inventions. Indeed, the only person quoted as a source was Mullan.

The newsletter was properly excluded. A publication that does not bear Newkome’s imprimatur was not probative of his intent three months earlier. Additionally, the article does not establish that USF was on notice as of the date the article was written that Mullan had discovered the invention while at USF. The article does not state where or when the Swedish mutation invention was discovered. Nor did the author of the article have authority to speak or act on behalf of USF. In short, AIA failed to lay a foundation for admission of the newsletter which, under the circumstances, was capable of misleading and confusing the jury.

#### The Reading Letters<sup>75</sup>

AIA proffered two letters from USF’s head of the Department of Psychiatry, Dr. Reading, dated September 14, 1993 and July 26, 1995, to show that when Newkome

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<sup>74</sup> 4/3/12 Tr. at 214:14-215:9, 216:9-15, 238:24-240:2, 247:1-10, 248:23-249:3.

<sup>75</sup> PTX 47; PTX 52.

signed the May 4, 1992 letter he had intended it to constitute “a broad waiver of all rights prior to August 15th.”<sup>76</sup> In the 1993 letter, Reading wrote to Bengt Winblad of the Karolinska Institute that “the University of South Florida is not in any way involved in the patent that Dr. Mullan has applied for with regard to the APP 670/671 mutation that he reported”<sup>77</sup> – a statement that was literally true. In the 1995 letter, addressed “To Whom it May Concern,” Reading wrote that “the University was not involved in the development of the invention which Dr. Mullan is seeking to patent with regard to the APP 670/671 (Swedish) mutation” and “to the degree that the University might normally have any rights in this patent, these rights were waived because the work leading to the invention was completed before August 15, 1992.”<sup>78</sup>

AIA argues that Reading would not have made these representations without first conferring with Newkome and to show that AIA eventually received the letters. It contends that the Reading letters are not hearsay because they were offered to show USF’s understanding of its ownership rights to the inventions, not for the truth of the matter asserted. It also argues that the letters should not have been excluded just because Newkome did not author them. According to AIA, Reading would have testified that he would only have made the representations in the letter that USF’s rights had been waived after receiving confirmation of this from Newkome.

Avid, Penn and USF argue that the letters written by Reading were properly excluded because they have no bearing on Newkome’s intent when he signed the May 4,

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<sup>76</sup> 4/3/12 Tr. at 219:19-220:3.

<sup>77</sup> PTX 47.

<sup>78</sup> PTX 52.

1992, letter. They point to the fact that Reading had no authority to waive USF's rights in inventions and had no recollection of having talked to Newkome or Preston concerning those letters. Additionally, they point to Newkome's denial of having had any discussions with Reading about waiving rights to the inventions, and to Preston's lack of recollection of having had any discussions with Reading about this topic. Finally, they point to the fact that the 1993 letter itself indicates that Reading spoke with Mullan, who was the source of his knowledge.<sup>79</sup>

The letters were not excluded as hearsay. Reading did not deny having written the letters. The 1993 letter was excluded because it lacked any indicia of reliability as to the source of the language that Reading used in the letter. It is undisputed that Reading had no authority to waive USF's rights in inventions. Only the President or Vice President for Research (Newkome) had that authority. Despite AIA's assertion that Reading would not have written the letter without consulting with either of those two authorities, it conceded that he had no recollection of having talked to either Newkome or Preston concerning the 1993 letter. At best, he speculated that it was his "belief" that he would have talked to "Newkome's right-hand man," Preston, before writing the letter.<sup>80</sup> The letter itself reveals the source was Mullan. AIA did not offer any reliable evidence that Newkome knew of or authorized the letter. Without evidence connecting the contents of the Reading letter to Newkome, it had no relevance as to Newkome's intent when he signed the May 4, 1992, letter.

The July 26, 1995 letter from Reading, addressed "To Whom it May Concern,"

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<sup>79</sup> 4/3/12 Tr. at 253:9-14, 254:8-20, 260:1-6, 263:21-265:3, 274:24-275:5, 278:2-279:14.

<sup>80</sup> 4/3/12 Tr. at 220:15-20.

lacked a sufficient foundation establishing its reliability. Reading could not remember why it was written or to whom it was addressed. Mullan had “instigated it but for what purpose I don’t know.”<sup>81</sup> AIA concedes Reading did not consult with Newkome or Preston about it.<sup>82</sup> Under these circumstances, the letter was irrelevant to Newkome’s intent in signing the May 4, 1992 letter.

June 2000 *Nature* Article<sup>83</sup>

When making its proffer for admission of a 2000 article published in the scientific journal *Nature*, AIA’s counsel conceded it was hearsay within hearsay. But, he sought its admission as a business record.<sup>84</sup> The article reports that Preston acknowledged that USF’s intellectual property procedures did not apply to Dr. Mullan: “Kenneth Preston, the University of South Florida’s director of patents and licensing, acknowledges that initially ‘there was an agreement not to apply rules and procedures regarding intellectual property’ to Mullan” and “as a result, a discovery that would normally have been owned by the university ended up in private hands.”<sup>85</sup> AIA contends that it proffered testimony from Preston that he did not deny making this statement and would not have made such a statement without confirming it with Newkome. Additionally, AIA points out that the article itself was attached to the Declaration of John Normanton as a business record.

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<sup>81</sup> 4/3/12 Tr. at 278:22-24.

<sup>82</sup> 4/3/12 Tr. at 276:15-17.

<sup>83</sup> PTX 237.

<sup>84</sup> 4/3/12 Tr. at 244:16-21.

<sup>85</sup> PTX 237 at 8.

AIA argues that these documents are not inadmissible hearsay. They contend they are statements of intent. Statements probative of the declarant's intent are admissible only when made at the time of the state of mind. Specifically, the rule excepts statements of "the declarant's then-existing state of mind (such as . . . intent . . .)." Fed. R. Evid. 803(3). The exception does not include a "statement of memory or belief to prove the fact remembered or believed . . . ." *Id.* Thus, statements made post-May 4, 1992 are not admissible to prove what Newkome's intent was on May 4, 1992.

Undoubtedly, AIA sought to offer the article to prove the truth of what Preston had reportedly said. It wanted to show that USF had waived its rights to the Swedish mutation invention. Again, we reiterate that Preston had no authority to waive USF's rights. Furthermore, there was no evidence providing a basis for those statements. There was no opportunity to cross-examine him.

The article was properly excluded as hearsay. AIA did not offer any evidence that Preston adopted the author's quoting him. In fact, Preston did not recall making such a statement.<sup>86</sup> AIA did not show that Preston was an employee authorized to make any statement on behalf of USF regarding any waiver of USF's rights in inventions. Thus, the statement did not qualify under Rule 801(d)(2)(c) or any other rule of the Federal Rules of Evidence.

*Applicability of the Florida Regulation  
and the USF Policy on Inventions and Works*

AIA complains that it was precluded from introducing evidence and argument regarding application of the Florida regulation and USF's Policy on Inventions and Works.

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<sup>86</sup> 4/3/12 Tr. at 240:17-241:3, 244:24-245:3.

It contends that while Avid, Penn and USF were permitted to present evidence that the regulation and the policy have the force of law, objections to AIA's cross-examination on this issue were unfairly sustained.

Specifically, it points to Burgess being permitted to testify on direct examination about implementation of the regulation and policy, how the regulation and policy are applied in practice, and under what circumstances rights in an employee's invention may be waived. Then, it was denied the opportunity to cross-examine Burgess on nearly identical topics made relevant by direct examination. For example, the court sustained objections to AIA's questions regarding USF's compliance with the regulation, language included in and late execution of employment contracts, and the circumstances under which a Disclosure of Invention Form may not be required. AIA was also precluded from arguing in closing that the policy did not apply because Mullan had not yet signed an employment contract. AIA argues that it should have been allowed this cross-examination and argument referring to the language of the regulation and Mullan's employment contracts to establish that neither the regulation nor USF's policy applied to vest rights to the inventions in USF.<sup>87</sup>

The cross-examination of Burgess regarding whether Mullan had signed an agreement recognizing the terms of the Florida regulation was properly precluded because the applicability of the regulation is not conditioned upon the employee signing an agreement recognizing the regulation's terms. Additionally, the argument that the USF policies did not apply to Mullan because he had not signed his employment agreement was

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<sup>87</sup> 4/19/12 Tr. at 10-11, 12-17, 41-42, 44, 61-63.

an improper attempt to argue a legal conclusion.

Even if these rulings were erroneous, they did not affect AIA's substantial rights and were harmless. Fed. R. Civ. P. 61; *Hirst v. Inverness Hotel Corp.*, 544 F.3d 221, 228 (3d Cir. 2008). Furthermore, the rulings did not affect the outcome of the case.

#### *Granting Motions in Limine Regarding Law of the Case*

AIA argues that we should have reconsidered our ruling made on summary judgment that the Florida regulation vested legal title to Mullan's inventions in USF. It contends the extensive discovery conducted after the court's initial ruling makes the "law of the case" doctrine inapplicable. Given the earlier ruling, it was precluded from presenting the evidence discussed regarding the regulation or USF's Policy on Inventions and Works.

We properly rejected AIA's attempt to relitigate the summary judgment ruling that the Florida regulation vested ownership of Mullan's inventions in USF. Only "extraordinary circumstances" warrant a court's reconsideration of an issue decided earlier in the course of litigation, including: (1) the availability of new evidence; (2) the announcement of supervening new law; or (3) the earlier decision was clearly erroneous and would create manifest injustice. *Pub. Interest Research Grp. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 116-17 (3d Cir. 1997). None of these extraordinary circumstances applies in this case.

#### **Conclusion**

For the reasons stated, we shall deny AIA's motion for judgment as a matter of law and its motion for a new trial.