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#### *AURIS HEALTH, INC. V. INTUITIVE SURGICAL OPERATIONS*: A NEW "RIGID RULE" FOR PATENT OBVIOUSNESS

Auris Health, Inc. v. Intuitive Surgical Operations, Inc., 32 F.4th 1154 (Fed. Cir. 2022)\*

The Federal Circuit potentially just announced a new "inflexible and rigid rule" for the obviousness analysis of patent validity. In *Auris Health, Inc. v. Intuitive Surgical Operations, Inc.*, the Federal Circuit held that evidence of generic industry skepticism, standing alone, cannot preclude a finding of motivation to combine.<sup>1</sup>

Intuitive Surgical Operations, Inc. ("Intuitive") is the assignee and owner of U.S. Patent No. 8,142,447 ("the '447 patent"),<sup>2</sup> which relates to robotically-assisted surgery systems.<sup>3</sup> Auris Health, Inc. ("Auris") petitioned for inter partes review of all five claims of the '447 patent, arguing they are obvious in light of the prior art.<sup>4</sup> The Board determined that Auris's asserted prior art combination—Smith and Faraz—disclosed each limitation of the challenged claims, and the only question was whether or not a skilled artisan would have been motivated to combine Smith and Faraz.<sup>5</sup>

The Board ultimately concluded that a skilled artisan would not be motivated to combine Smith and Faraz because there was generic industry skepticism "for using robotic systems during surgery in the first place."<sup>6</sup> On appeal, Auris challenged the Board's reliance on the general industry skepticism to find a lack of motivation to combine.<sup>7</sup> Thus, the court was tasked with determining to what extent generic industry skepticism plays in the motivation-to-combine inquiry.

<sup>\*</sup> By Jake Moawad, J.D. Candidate, Santa Clara University School of Law, 2023.

<sup>&</sup>lt;sup>1</sup> See 32 F.4th 1154 (Fed. Cir. 2022).

<sup>&</sup>lt;sup>2</sup> See U.S. Patent No. 8,142,447 (issued Mar. 27, 2012).

<sup>&</sup>lt;sup>3</sup> *Id.* at col. 1 ll. 37–41.

<sup>&</sup>lt;sup>4</sup> See Auris Health, Inc. v. Intuitive Surgical Operations, Inc., No. IPR2019-01533, 2021 WL 826396 (P.T.A.B. Mar. 3, 2021) [hereinafter "*PTAB Decision*"].

<sup>&</sup>lt;sup>5</sup> Auris Health, Inc., 32 F.4th at 1156; see also U.S. Patent No. 5,624,398 (issued Apr. 29, 1997) [hereinafter "Smith"]; U.S. Patent No. 5,824,007 (issued Oct. 20, 1998) [hereinafter "Faraz"].

<sup>&</sup>lt;sup>6</sup> See PTAB Decision, 2021 WL 826396 at \*8–9.

<sup>&</sup>lt;sup>7</sup> Auris Health, Inc., 32 F.4th at 1158.

#### I. BACKGROUND FACTS & THE '447 PATENT

In robotically-assisted surgery, a variety of surgical instruments will be remotely controlled by a master control.<sup>8</sup> This master controller will typically include input devices, such as a joystick, coupled with servo mechanisms that connect to and control the surgical instruments.<sup>9</sup> By manipulating the input device, the surgeon is able to direct the surgical instruments<sup>10</sup>—like a RC drone. However, surgery often requires a variety of tools and surgical instruments, for example, scissors, scalpels, clamps, towels, etc., and the surgery team must swap out instruments as they move from one task to the next.<sup>11</sup> Not surprisingly, the number of independent surgical controllers can be limited due to space constraints and costs.<sup>12</sup>

Things are further complicated in minimally invasive procedures. In minimally invasive procedures, the number of entry points into a patient is generally limited by space constraints.<sup>13</sup> Because surgeons want to avoid unnecessary incisions into a patient, a number of different surgical instruments will be introduced through the same trocar sleeve into the patient<sup>14</sup>; i.e., the more that can be fit into the same trocar sleeve means the less incisions that are needed—and the better off the patient will be.<sup>15</sup> This means that instrument swapping can be more challenging in robotically-assisted surgery systems due to space constraints, different ranges of motion that must be calibrated for different surgical instruments, and the time needed to swap out those instruments.<sup>16</sup>

The invention embodied by the '447 patent attempts to address the difficulties described above.<sup>17</sup> The invention uses a robotic system with a servo-pulley mechanism, which allows a surgeon to more quickly swap out surgical instruments.<sup>18</sup> The invention also uses tools with memory structures that perform a few functions when attached to the tool manipulator.<sup>19</sup> The memory can provide a signal verifying that the tool is compatible with the particular system, identify what type of

<sup>10</sup> Id.

<sup>&</sup>lt;sup>8</sup> '447 patent at col. 1 ll. 42–44.

<sup>&</sup>lt;sup>9</sup> *Id.* at col. 1 ll. 49–55.

<sup>&</sup>lt;sup>11</sup> See PTAB Decision, 2021 WL 826396 at \*1.

<sup>&</sup>lt;sup>12</sup> '447 patent at col. 1–2 ll. 62–2.

<sup>&</sup>lt;sup>13</sup> See *id.* at col. 2 ll. 2–5.

<sup>&</sup>lt;sup>14</sup> See id. at col. 2 ll. 6–8.

<sup>&</sup>lt;sup>15</sup> See id.

<sup>&</sup>lt;sup>16</sup> See id. at col. 2 ll. 9–15.

<sup>&</sup>lt;sup>17</sup> *Id.* at col. 1 ll. 37–41.

<sup>&</sup>lt;sup>18</sup> '447 patent at col. 2 ll. 50–57.

<sup>&</sup>lt;sup>19</sup> *Id.* at col. 2 ll. 63–67.

tool is attached to the system and reconfigure its programming for that tool, and indicate tool-specific information—for example, calibration data, tool life data, etc.<sup>20</sup>

#### II. PROCEDURAL BACKGROUND

On June 12, 2019, Auris filed a petition requesting an inter partes review of all five claims of the '447 patent.<sup>21</sup> Auris argued that the claims of the '447 patent were unpatentable because they failed the nonobvious requirement of patentability.<sup>22</sup> More specifically, Auris argued that two pieces of prior art—Smith and Faraz—disclosed each and every limitation of the challenged claims and that a skilled artisan would have been motivated to combine Smith and Faraz.<sup>23</sup>

In defining a skilled artisan, Auris asserted that a person having ordinary skill in the art at the time of the invention would include "someone with a good working knowledge of robotics and medical devices," or include "someone having an undergraduate education in electrical engineering, mechanical engineering, robotics, biomedical engineering, or a related field of study, along with about two years of experience in academia or industry studying or developing robotics or medical devices such as robotic surgical systems."<sup>24</sup> Because Intuitive did not contest Auris's definition, and because it was consistent with the '447 patent and prior art record, the Board adopted Auris's definition.<sup>25</sup>

In the Federal Circuit's analysis, the court noted that "Smith discloses a robotic surgical system that uses an exoskeleton controller, worn by a clinician, to remotely manipulate a pair of robotic arms, each of which holds a surgical instrument."<sup>26</sup> Smith teaches using a servopulley system to allow the surgeon to control the robotic arms.<sup>27</sup> However, Smith also provides that an assistant may relocate and move the robotic arms as necessary.<sup>28</sup> Figure 1A of Smith is provided below<sup>29</sup>:

<sup>&</sup>lt;sup>20</sup> *Id.* at col. 3 ll. 1–28.

<sup>&</sup>lt;sup>21</sup> See PTAB Decision, 2021 WL 826396 at \*1.

<sup>&</sup>lt;sup>22</sup> See id. at \*3.

<sup>&</sup>lt;sup>23</sup> Id.

<sup>&</sup>lt;sup>24</sup> Id.

<sup>&</sup>lt;sup>25</sup> *Id.* at \*3.

<sup>&</sup>lt;sup>26</sup> See Auris Health, Inc., 32 F.4th at 1156; see also PTAB Decision, 2021 WL 826396 at \*4.

<sup>&</sup>lt;sup>27</sup> Smith at col. 6. ll. 46–67.

<sup>&</sup>lt;sup>28</sup> *Id.* at col. 8. ll. 48–51.

<sup>&</sup>lt;sup>29</sup> Id. at Fig. 1A.



The Federal Circuit also noted that "Faraz discloses an adjustable stand that holds surgical instruments."<sup>30</sup> The stand can be adjusted manually or robotically,<sup>31</sup> and the stand can allow a surgeon to perform surgery with fewer assistants, as it can support multiple surgical instruments while they are being moved.<sup>32</sup> Figure 1 of Faraz is provided below<sup>33</sup>:

 $<sup>^{30}</sup>$  See Auris Health, Inc., 32 F.4th at 1157; see also PTAB Decision, 2021 WL 826396 at \*5.

<sup>&</sup>lt;sup>31</sup> Faraz at col. 6. ll. 23–29.

<sup>&</sup>lt;sup>32</sup> *Id.* at col. 6 ll. 30–43.

<sup>&</sup>lt;sup>33</sup> Id at Fig. 1.



FIG. I

Before the Board, Auris argued that claims 1–5 of the '447 patent were unpatentable as obvious over Smith and Faraz.<sup>34</sup> Auris argued that Smith disclosed each limitation of claim 1 except "moving a robotic manipulator arm supporting the instrument in at least one degree of freedom."<sup>35</sup> Auris suggested that, although Smith does not expressly teach this limitation, Smith renders the limitation obvious in light of Faraz.<sup>36</sup> Aruis further argued that, consequently, "a skilled artisan would be motivated to combine Smith and Faraz to decrease the number of assistants needed during surgery by robotizing some of their tasks," and therefore, the claims of the '447 patent would be unpatentable.<sup>37</sup>

Intuitive countered Auris's arguments, suggesting that Auris failed to establish a sufficient motivation to modify Smith in view of Faraz.<sup>38</sup> Intuitive argued that the ordinary artisan would not have been motivated to use a robotically surgical stand.<sup>39</sup> Intuitive based its argument on the fact that "surgeons were skeptical about performing

<sup>&</sup>lt;sup>34</sup> *PTAB Decision*, 2021 WL 826396 at \*4.

<sup>&</sup>lt;sup>35</sup> *Id.* at \*6.

<sup>&</sup>lt;sup>36</sup> Id.

<sup>&</sup>lt;sup>37</sup> Auris Health, Inc., 32 F.4th at 1158; see also PTAB Decision, 2021 WL 826396 at \*6.

<sup>&</sup>lt;sup>38</sup> *PTAB Decision*, 2021 WL 826396 at \*7.

<sup>&</sup>lt;sup>39</sup> Id.

robotic surgery in the first place, [so] there would have been no reason to further complicate Smith's already complex robotic surgical system with [Faraz's] roboticized surgical stand."<sup>40</sup> Intuitive supported its argument with expert testimony that, at the time of the invention, there was great industry skepticism with respect to robotic surgery.<sup>41</sup>

The Board agreed with Intuitive.<sup>42</sup> The Board concluded that "the evidence … supports the position [that] there is no motivation to complicate Smith's system when there is skepticism at the time of the invention for using robotic systems during surgery in the first place."<sup>43</sup> Accordingly, the Board concluded that claims of the '447 patent were not unpatentable.<sup>44</sup>

#### III. FEDERAL CIRCUIT'S REVIEW

Auris appealed the Board's conclusion, challenging the Board's reliance on the general skepticism about the field of robotic surgery to find a lack of motivation to combine.<sup>45</sup> On review, the Federal Circuit considered the question of whether generic industry skepticism—on its own—can preclude a finding of motivation to combine.<sup>46</sup> The majority of the panel, Judge Dyk and Judge Prost, concluded "that generic industry skepticism cannot, standing alone, preclude a finding of motivation to combine."<sup>47</sup>

The majority noted that "evidence of industry skepticism may play a role in an obviousness inquiry—but as a secondary consideration in a significantly different context."<sup>48</sup> In *WBIP*, *LLC v. Kohler Co.*, the court explained that skepticism of industry participants or skilled artisans regarding how a problem could be solved or the workability of the claimed solution favors nonobviousness.<sup>49</sup> The *WBIP* court also noted that "[d]oubt or disbelief by skilled artisans regarding the likely success of a combination or solution weighs against the notion that one would combine elements in references to achieve the claimed

<sup>46</sup> See id. at 1158–59.

<sup>48</sup> See id. (citing WBIP, LLC v. Kohler Co., 829 F.3d 1317, 1335–36 (Fed. Cir. 2016)).

<sup>49</sup> 829 F.3d at 1333.

 $<sup>^{40}</sup>$  Id. at \*7–8.

<sup>&</sup>lt;sup>41</sup> Id.

<sup>&</sup>lt;sup>42</sup> See id. at \*9.

<sup>&</sup>lt;sup>43</sup> See id.

<sup>&</sup>lt;sup>44</sup> See PTAB Decision, 2021 WL 826396 at \*10.

<sup>&</sup>lt;sup>45</sup> *Auris Health, Inc.*, 32 F.4th at 1158.

<sup>&</sup>lt;sup>47</sup> See id. at 1159.

invention."<sup>50</sup> However, a major caveat is that "the evidence of skepticism must be specific to the invention, not generic to the field."<sup>51</sup>

The panel noted that Intuitive provided no caselaw to suggest that the Board may rely on generic industry skepticism to find a lack of motivation to combine.<sup>52</sup> The panel further explained that the Board almost exclusively relied on "evidence of general skepticism about the field of robotic surgery to find a lack of motivation to combine Smith and Faraz," and that this was "insufficient."<sup>53</sup> The panel declined to weigh the parties' remaining evidence because it would have been inappropriate to do so in the first instance on appeal.<sup>54</sup> The panel therefore remanded the case to the Board to "examine the sufficiency of the record evidence to establish that there was a motivation to combine utilizing the correct criteria."<sup>55</sup>

## IV. JUDGE REYNA'S DISSENT AND CRACKS IN THE MAJORITY'S OPINION

Judge Reyna filed a dissenting opinion.<sup>56</sup> In his dissent, Judge Reyna found that "the Board's determination that Auris failed to show a motivation to combine is adequately supported by substantial evidence and was not contrary to [the] law on obviousness."<sup>57</sup> Judge Reyna had no issue with the majority's conclusion that skilled artisans' general skepticism toward robotic surgery, by itself, *could be* insufficient to negate a motivation to combine; however, he disagreed that it could "*never* support a finding of no motivation to combine."<sup>58</sup> Judge Reyna started by noting four reasons the Board gave for why Auris's proffered motivation to combine was inadequate.<sup>59</sup>

Judge Reyna first noted that the Board credited Dr. Choset's testimony that "there was great skepticism for performing telesurgery, and *because of this skepticism* one of ordinary skill in the art at the time

<sup>&</sup>lt;sup>50</sup> *Id.* at 1333–34.

<sup>&</sup>lt;sup>51</sup> Auris Health, Inc., 32 F.4th at 1159 (citing WBIP, LLC, 829 F.3d at 1335–36).

<sup>&</sup>lt;sup>52</sup> See id.

<sup>&</sup>lt;sup>53</sup> See id. (citing PTAB Decision, 2021 WL 826396 at \*8).

<sup>&</sup>lt;sup>54</sup> See id. (Auris argued that combining Smith and Faraz would reduce the number of assistants, while Intuitive argued that such a combination would come at the expense of precision required for surgery).

<sup>&</sup>lt;sup>55</sup> See id.

<sup>&</sup>lt;sup>56</sup> See id. at 1159-61 (Reyna, J., dissenting).

<sup>&</sup>lt;sup>57</sup> See Auris Health, Inc., 32 F.4th at 1159 (Reyna, J., dissenting).

<sup>&</sup>lt;sup>58</sup> See id. at 1160 (Reyna, J., dissenting) (emphasis added).

<sup>&</sup>lt;sup>59</sup> See id.

of the invention *would not have been compelled to complicate Smith's system further* by including a robotic surgical stand."<sup>60</sup> He went on to state that this is *specific* evidence of industry skepticism related to a *specific* combination of references that the majority declined to consider.<sup>61</sup> Second, Judge Reyna noted that "the Board found that the petitioner failed to 'articulate how one would have combined Smith and Faraz to achieve the stated goal of reducing the number of assistants."<sup>62</sup> Third, Judge Reyna observed that "the Board credited Dr. Choset's testimony that the combination would be unacceptable because it 'would have limited a physician's ability to manipulate Smith's servo-pulley tray and related components."<sup>63</sup> And finally, Judge Reyna noted that the Board credited Dr. Choset's testimony that the combination would be unacceptable because it that the amount of precision that is required for surgery.<sup>64</sup>

More interestingly, Judge Reyna expressed concern "that the majority opinion may reasonably be understood to announce an inflexible and rigid rule, namely that it is 'impermissible' for the Board to consider evidence of artisans' skepticism toward robotic surgery in determining motivation to combine."<sup>65</sup> Judge Reyna noted that there is no authority supporting this proposition, and it appears to be at tension with the central thrust of the Supreme Court's decision in *KSR International Co. v. Teleflex Inc.*<sup>66</sup> Prior to *KSR*, the Federal Circuit employed a "teaching, suggestion, or motivation" ("TSM") test.<sup>67</sup> Under the TSM test, a patent claim was proved obvious only if "the prior art, the problem's nature, or the knowledge of a person having ordinary skill in the art reveal[ed] some motivation or suggestion to combine the prior art teachings."<sup>68</sup> In *KSR*, the Supreme Court quickly "reject[ed] the rigid approach of the Court of Appeals," and reaffirmed an "expansive and flexible approach" of determining obviousness.<sup>69</sup>

<sup>65</sup> See id.

<sup>&</sup>lt;sup>60</sup> See id. (emphasis in original) (citing *PTAB Decision*, 2021 WL 826396 at \*8).

<sup>&</sup>lt;sup>61</sup> See id. at 1159 (Reyna, J., dissenting).

<sup>&</sup>lt;sup>62</sup> See id. at 1160 (Reyna, J., dissenting) (citing *PTAB Decision*, 2021 WL 826396 at \*9).

<sup>&</sup>lt;sup>63</sup> See Auris Health, Inc., 32 F.4th at 1160 (citing *PTAB Decision*, 2021 WL 826396 at \*9).

<sup>&</sup>lt;sup>64</sup> See id. (citing PTAB Decision, 2021 WL 826396 at \*9).

<sup>&</sup>lt;sup>66</sup> See id. (referring to KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 415 (2007)).

<sup>&</sup>lt;sup>67</sup> See KSR, 550 U.S. at 399.

<sup>&</sup>lt;sup>68</sup> Id.

<sup>69</sup> Id. at 415.

Judge Reyna correctly takes issue with the potentially new rigid rule that skilled artisans' general skepticism toward robotic surgery could "never support a finding of no motivation to combine."<sup>70</sup> The majority's rigid proposition appears to take a step back to the inflexible TSM regime. Judge Reyna additionally noted that, in past cases, the Federal Circuit "accounted for the attitudes of medical professionals toward certain types of procedures when determining whether a motivation to combine has been adequately demonstrated."<sup>71</sup>

In addition, Judge Reyna expresses concern over the majority's conclusion that "industry skepticism may play a role in an obviousness inquiry—but as a secondary consideration in a significantly different context."<sup>72</sup> Judge Reyna observes that "this assertion suggests, to some extent, that objective indicia [the fourth *Graham* factor] are less important or less probative of obviousness or non-obviousness than the other *Graham* factors."<sup>73</sup>

In *Graham v. John Deere*, the Supreme Court established the four factors to be considered when making an obviousness determination: (1) the scope and content of the prior art; (2) the level of skill of a person of ordinary skill in the art; (3) the differences between the claimed invention and the teachings of the prior art; and (4) the extent of any objective indicia of non-obviousness.<sup>74</sup> Although the secondary considerations might not always play a role in an obviousness determination, there is no authority stating that they are "less probative of obviousness or non-obviousness than the other Graham factors."<sup>75</sup> Judge Reyna noted how the majority's proposition appears inconsistent with a number of the Federal Circuit's opinions.<sup>76</sup>

<sup>73</sup> See id.

<sup>&</sup>lt;sup>70</sup> See Auris Health, Inc., 32 F.4th at 1160 (Reyna, J., dissenting).

<sup>&</sup>lt;sup>71</sup> See id. at 1160–61 (Reyna, J., dissenting) (citing examples).

<sup>&</sup>lt;sup>72</sup> See id. at 1161 (Reyna, J., dissenting) (citing id. at 1159).

<sup>&</sup>lt;sup>74</sup> 383 U.S. 1, 17–18 (1966).

<sup>&</sup>lt;sup>75</sup> Auris Health, Inc., 32 F.4th at 1160 (Reyna, J., dissenting).

<sup>&</sup>lt;sup>76</sup> See id. (citing Apple Inc. v. Samsung Elecs. Co., 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc) ("A determination of whether a patent claim is requires consideration invalid as obvious under § 103 of all four Graham factors, and it is error to reach a conclusion of obviousness until all those factors are considered."); Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573 (Fed. Cir. 1996) ("It is the secondary considerations that are often most probative and determinative of the ultimate conclusion of obviousness or nonobviousness. The district court did not provide reasons for apparently discounting Pro-Mold's evidence of secondary considerations; that was error as a matter of law."); Mintz v. Dietz & Watson, Inc., 679 F.3d 1372, 1378 (Fed. Cir. 2012) ("These objective guideposts are

In conclusion, *Auris Health, Inc. v. Intuitive Surgical Operations, Inc.* appears to introduce a new rigid rule that generic industry skepticism cannot, standing alone, preclude a finding of motivation to combine.<sup>77</sup> Furthermore, it appears to suggest that the objective indicia of industry skepticism may play a role in an obviousness inquiry *only* as a secondary consideration.<sup>78</sup> Moving forward, litigators would be wise to ensure evidence of skepticism is not generic to the field but rather *specific* of industry skepticism related to a *specific* combination of references.

powerful tools for courts faced with the difficult task of avoiding subconscious reliance on hindsight.")).

<sup>&</sup>lt;sup>77</sup> See Auris Health, Inc., 32 F.4th at 1154.

<sup>&</sup>lt;sup>78</sup> See id.