Ethicon Endo-Surgery, Inc. v. Covidien LP (Fed. Cir. January 13, 2016)

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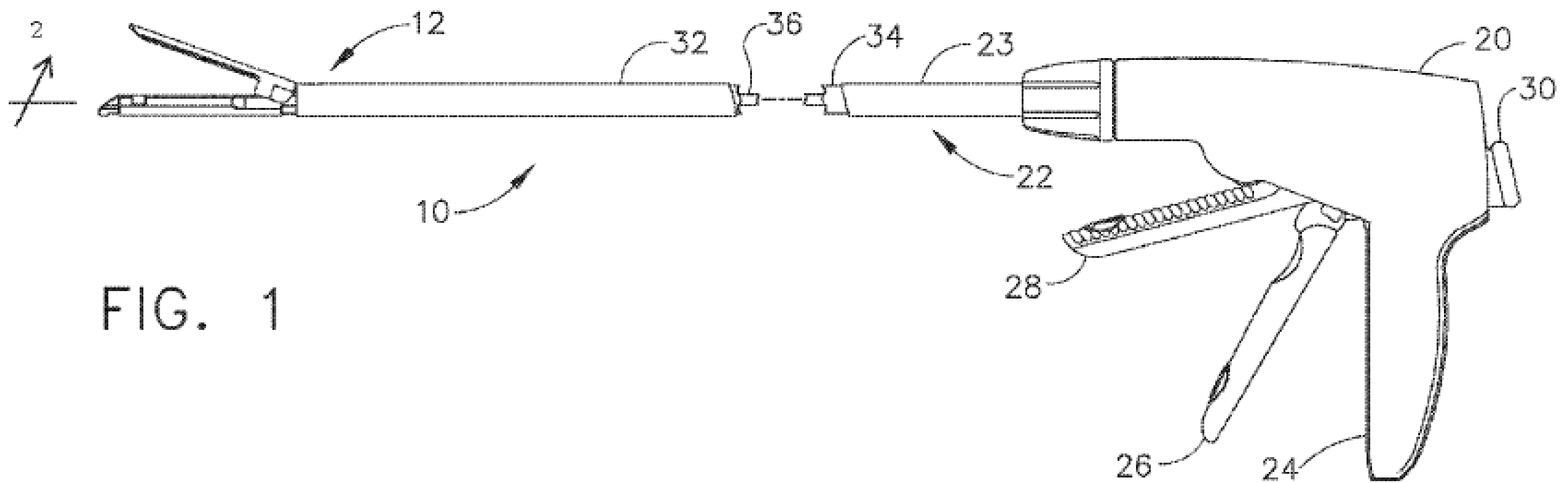
March 2, 2016

Background

- Ethicon owns U.S. Patent No. 8,317,070 directed to surgical stapling devices that produce formed stapes having different lengths



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Claim 1 of the '070 Patent

A surgical stapling device comprising an end effector that comprises:

a circular anvil having a staple forming surface;

a plurality of staples facing the staple forming surface of the anvil, each staple comprising a main portion and two prongs, wherein the two prongs each comprise a first end and a second end, wherein the first ends are connected to opposite ends of the main portion, and wherein the *two prongs extend non-parallelly from the main portion*; and…

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Claim 1 of the ‘070 Patent

…a staple driver assembly comprising a plurality of staple drivers, wherein each staple driver supports one of the plurality of staples and is configured such that, when the staple driver assembly is actuated, each staple driver drives the staple into the staple forming surface of the anvil, wherein a *first quantity of the staples have a first pre-deformation height*, measured from a lower surface of the main portion to the second end of the first prong, and *a second quantity of the staples have a second pre-deformation height*, measured from a lower surface of the main portion to the second end of the first prong, *wherein the first height is less than the second height*, such that when the staple driver assembly is actuated, the first quantity of staples have a different formed staple length than the second quantity of staples.

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The ‘070 Patent

- “Surgical staples have been used in the prior art to simultaneously make a longitudinal incision in tissue and apply lines of staples on opposing sides of the incision” (col 1, lines 45-47).
- Asserted point of novelty – combination of:
  - The use of staples of different heights before and after stapling and
  - The use of staples with non-parallel legs

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The '070 Patent

- The use of different sized staples allows the surgical stapling device to be used on a broader range of tissue thicknesses.
- It is undisputed that these staples were first disclosed 25 years ago.

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The ‘070 Patent

- The use of staples with non-parallel legs allow the staple legs to press against the side of the staple cartridge and stay in the cartridge without falling out.
- It is undisputed that these staples were first disclosed in US 3,494,533 from 1970.
- Ethicon’s expert testified that he used nonparallel staples 50-75% of the time in his practice.

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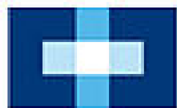
Background

- In 2010, Covidien began selling surgical staplers that allegedly embody the claimed invention of the ‘070 Patent.
- A Covidien brochure for this stapler mentions “progressive staple heights.”
- The staplers achieved over $1 billion in product sales in their first 3 years.



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Background

- On March 25, 2013, Covidien petitioned the USPTO for *inter partes* review of all claims (claims 1-14) of the ‘070 Patent on the ground that the claims would have been obvious over the prior art.
- On August 26, 2013, the PTAB granted the petition.
- On June 9, 2014, the same panel of the PTAB found all claims of the ‘070 Patent to be obvious.

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Background

- Ethicon admitted that all of the recited elements of the patent claims were found in the prior art.
- The Board concluded that one of ordinary skill in the art would have been motivated to combine the prior art staplers disclosing staples of varying heights with staples of non-parallel legs to securely hold the staples in the cartridge because the benefits of both were well known at the time of the invention.

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Background

- *KSR* Rationale: combining prior art elements according to known methods to yield predictable results

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Background

- Ethicon appeals, arguing that the final decision of the PTAB should be set aside because it was made by the same panel that made the decision to institute the IPR.

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35 U.S.C. § 314(a)

- The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

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37 CFR 42.4(a)

- The Board institutes the trial on behalf of the Director.

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Discussion

- The PTO has determined that the decision to institute and the final decision should be made by the same Board panel in the interest of efficiency.
- Ethicon argues that this combination of functions is improper because the statute requires that the decision to institute the IPR not be made by the same panel of the PTAB that makes the ultimate decision in the IPR.

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Does the Federal Circuit even have jurisdiction?

- The PTO argues that 35 U.S.C. § 314(d) bars the Federal Circuit from considering this issue on appeal because it is an issue concerning the institution of an IPR.
- 35 U.S.C. § 314(d) states, “The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.”

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Does the Federal Circuit even have jurisdiction?

- However, 35 U.S.C. § 319 states, “A party dissatisfied with the final written decision of the Patent Trial and Appeal Board under section 318(a) may appeal the decision….”
- The Federal Circuit determined that Ethicon is not challenging the institution decision but rather alleges a defect in the final decision.

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Due Process

- Ethicon argues that having the same panel make the decision to institute the IPR and then later decide the merits of the IPR raises serious due process concerns.
- The panel of the Board is first exposed to a limited record consisting of the petition and the patent holder's preliminary response, so the panel may prejudge the case before seeing a full record.
- Thus, the panel is not an impartial decision maker.

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Due Process

- As such, the AIA should be construed to preclude the Director from delegating the decision to institute to the same panel of the Board that makes the final decision.
- The Federal Circuit disagrees with Ethicon.
- After reviewing several Supreme Court cases, the Federal Circuit concluded that the Supreme Court has never held a system of combined functions to be a violation of due process.

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Due Process

- Both the decision to institute and the final decision are adjudicatory decisions and do not involve combining investigative and/or prosecutorial functions with an adjudicatory function.
- The IPR procedure is directly analogous to a district court determining whether there is a likelihood of success on the merits and then later deciding the merits of a case.

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Due Process

- Ethicon also argues that the panel's exposure to a limited record in the decision to institute the IPR improperly biases the panel so as to disqualify the panel from making the final decision on the merits.
- To rise to the level of presenting actual bias, the challenger must show that an adjudicator is exposed to unofficial, extrajudicial sources of information.

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Can the Director delegate the power to institute IPR to the PTAB?

- Ethicon argues that:
  - Congress specifically gave the Director the power to institute IPR (35 U.S.C. § 314(a)).
  - Congress did not explicitly give the Director authority to delegate the institution decision to the Board.
  - Congress gave the Board the power to make the final determination.
  - As such, Congress intended to keep the functions of institution and final decision separate.

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Can the Director delegate the power to institute IPR to the PTAB?

- Federal Circuit states that the statute or legislative history does not indicate a concern with separating the functions of initiation and final decision.
- Agency heads have implied authority to delegate to officials within the agency, even without explicit statutory authority.
- There is nothing in the Constitution or the statute that precludes the same Board panel from making the decision to institute the IPR and then rendering the final decision.

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Merits of the Case

- Ethicon does not challenge the Board's finding that all of the claim elements are found in the prior art.
- Ethicon does not challenge the Board's finding that one of ordinary skill in the art would have been motivated to combine the prior art elements to arrive at the invention in the '070 Patent.
- Ethicon only argues that the Board did not properly consider the secondary considerations of non-obviousness.

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Secondary Considerations

- Ethicon argues that the Board did not consider the commercial success of the allegedly infringing Covidien device.
- The Board determined that Ethicon did not show a nexus between the commercial success of the allegedly infringing product and the patented features.

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Secondary Considerations

- The Covidien products included numerous unclaimed features.
  - Staple line strength
  - Superior leak resistance
  - Ergonomic design
  - Precise articulation
- The Board also had substantial evidence that the commercial success of the Covidien products was due to the single feature of varying staple heights rather than the combination of varied staple heights and non-parallel staple legs.

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Decision

- PTAB is affirmed.
- But there was a dissent…

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Dissent by Judge Newman

- The AIA established a threshold step called "institution" by the Director of the PTO followed by trial and adjudication by a new adjudicatory body established by the PTO.
- As a safeguard of administrative objectivity, Congress divided the functions of institution and trial into separate bodies within the PTO.

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Dissent by Judge Newman

- At the first stage, the Director determines whether the review is to be instituted.
  - The Director may designate an examiner or solicitor to conduct this initial review.
- If instituted by the Director, the Board then conducts a trial on the merits.

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Dissent by Judge Newman

- The bifurcated design of post-grant review is clear from the language of § 314(a) and § 316(c).

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35 U.S.C. § 314(a)

- The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

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35 U.S.C. § 316(c)

- The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each inter partes review instituted under this chapter.

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Dissent by Judge Newman

- Congress unambiguously placed these separate determinations in different decision-makers, applying different criteria.
- The majority's endorsement of the PTO's statutory violation departs not only from the statute, but also from the due process guarantee of a "fair and impartial decision-maker."

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Dissent by Judge Newman

- Permitting the same decision-maker to review its own prior decision may not always provide the constitutionally required impartial decision maker.

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Analogy

- Ethicon wants a bifurcated system.

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Lawyers Have Heart

- 10K Race and 5K Run & Walk
- June 11, 2016
- Free Shirt!

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 2    41:22    270 Stephen Leon         M
 3    43:16    274 Chad Rink            M
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 6 (1:01:01)   271 Paul Lewis           M
 7 (1:27:02)   275 Viengxay Saengchanh  F
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Questions?

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