UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte HARRY J. BUNCKE

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Appeal No. 2006-1376
Application No. 09/596,806

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ON BRIEF

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Before OWENS, CRAWFORD, and FETTING, *Administrative Patent Judges.*

OWENS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal is from a rejection of claims 1-11, which are all of the pending claims.

THE INVENTION

The appellant claims a device and method for applying non-penetrating clips to wound sites or tissue separation sites.

Claim 1, which claims the device, is illustrative:

1. A device for applying non-penetrating clips to small blood vessels or other wound sites or tissue separation sites where suturing or other wound closure techniques would be impossible or undesirable, comprising:
a hand-held clip applier, including:
a handle suitable for gripping in the hand of a surgeon,
a clip storing and dispensing stem extending from a forward end of the handle, the stem having a tip at a remote end, the tip including means for dispensing and serially applying metal clips in non-penetrating engaging configuration against sections of tissue on either side of a wound or tissue separation to clamp the two sections of tissue together, upon the receipt of mechanical force to a clip-applying component of the stem,
a movable member within the handle which, when caused to move by a force applied from outside the handle, is effective to cause movement of the clip-applying component in the stem so as to cause dispensing and application of a clip, and
linkage means engaged with the movable member within the handle and extending to a position in the handle capable of receiving a pushing force from the exterior of the handle, and
a flexible cable release device comprising a cable sheath, and an internal cable capable of delivering a compressive pushing force through the sheath, a hand operable actuator at a remote hand-grippable end of the cable release, remote from the clip applier, for applying a pushing force to slide the cable through sheath so as to cause extension of a pusher tailpiece out of a proximal end of the cable sheath when the hand operable actuator is engaged, the sheath at the proximal end having means for connection to the handle of the hand-held clip applier in a position to apply force to the linkage means in the handle by motion of the pusher tailpiece, thus advancing the linkage means and movable member within the handle, and thus advancing the clip-applying component to dispense and apply a clip when the thumb button on the flexible cable release device is pushed, the cable sheath and internal cable being sufficiently flexible as to

avoid movement of the tip when the hand operable actuator is moved to apply said pushing force,

whereby with the cable release device connected to the clip applier the hand-held clip applier can be held very steadily in one hand with its tip under the microscope while the force to apply a clip is supplied at the remote end of the cable release device, avoiding any movement of the tip at the instant of clip application.

THE REFERENCE

Swiggett	4,485,817	Dec. 4, 1984

THE REJECTION

Claims 1-11 stand rejected under 35 U.S.C. § 103 as being unpatentable over the admitted prior art (figures 1-4) in view of Swiggett.

OPINION

We reverse the aforementioned rejection. We need to address only the independent claims, i.e., claims 1, 3 and 9. Claim 1 requires a hand-held clip applier that includes a cable sheath and an internal cable that are sufficiently flexible to avoid movement of the tip of the clip applier's clip storing and dispensing stem when a remote hand operable actuator is moved to apply, via the internal cable, a pushing force to the handle of the hand-held clip applier. Claim 3 requires a hand-held clip applier that includes a tubular sheath and an internal movable medium that are sufficiently flexible to avoid movement of the tip of a clip storing and dispensing stem when a remote actuator

is engaged and moved to apply, via the moveable medium, a force to the handle of the clip applier. Claim 9 requires a method for applying non-penetrating surgical clips using a hand-held clip applier wherein the engaging of a remote actuator of a flexible remote force-transmitting device connected to the handle of the clip applier is not performed by the hand holding the handle of the clip applier.

The admitted prior art is a hand-held clip applier having on its handle a pair of thumb/finger wings (18) that are squeezed together by a surgeon when the tip (12) of the stem (14) of the clip applier's clip applying component (36) has been correctly placed and a clip is to be applied (specification, page 8, lines 17-19; figure 1).

Swiggett discloses a surgical stapler having an applicator (16) that is inserted into the lumen of an organ to be stapled (col. 3, lines 47-49 and 55-56). The stapler's actuator (12) is connected to the applicator by a flexible shaft (14) that is longitudinally flexible in any direction but retains a shape into which it is bent (col. 2, lines 20-22; col. 3, lines 49-56). "The transmission of the actuation force by the flexible shaft is effected in such a manner that it has no significant tendency to straighten the shaft" (col. 2,

lines 26-29). "Preferably, a stiffer, but still flexible, second tube or sleeve containing the small-diameter tube gives the shaft the relatively slight degree of rigidity necessary to enable the flexible shaft to maintain a desired shape into which the shaft has been bent" (col. 2, lines 41-45).

Regarding claims 1 and 3 the examiner argues that "appellant has not defined sufficiently flexible in the current application specification such that it would preclude that of Swiggett to be considered 'sufficiently flexible.' 'Sufficiently flexible' is a relative term and a base for comparison has not been established" (answer, page 5). The degree of flexibility required by claims 1 and 3 is sufficient flexibility to avoid movement of the tip of a clip storing and dispensing stem when a hand operable actuator is moved (claim 1) or a remote actuator is engaged (claim 3). The examiner has not established that Swiggett's shaft has that degree of flexibility, or explained how Swiggett would have fairly suggested, to one of ordinary skill in the art, a shaft having that degree of flexibility. The examiner argues that Swiggett' shaft "would necessarily yield isolation movement via the surgeon's hand" (answer, page 4), but the examiner does not provide supporting evidence or reasoning.

Regarding claim 9 the examiner argues that Swiggett's handle surely is suitable for gripping (answer, page 3), and that the appellant's claimed method would be "inherently obvious" (answer, page 7). As argued by the examiner, Swiggett's applicator, when not in use, can be held in a person's hand. However, the appellant's claim 16 requires that in use, the engaging of the actuator at the remote end of the flexible device is not performed by the hand holding the handle of the clip applier. Swiggett's disclosure that the applicator is inserted into the lumen of an organ to be stabled (col. 3, lines 55-56) indicates that, in use, the applicator is not held by a hand. Also, Swiggett's disclosure that the stiffness of the flexible shaft sufficient to avoid significant straightening during staple application (col. 1, lines 59-68; col. 2, lines 20-29 and 41-45) indicates that it is the stiffness of the shaft, not a hand, that holds the applicator in place. The examiner has not explained why, in light of these disclosures by Swiggett, one of ordinary skill in the art would have been led by the applied prior art to not engage a hand-held clip applier's remote actuator using the hand holding the clip applier's handle.

For the above reasons we conclude that the examiner has not established a prima facie case of obviousness of the appellant's claimed invention.

DECISION

The rejection of claims 1-11 under 35 U.S.C. § 103 over the admitted prior art (figures 1-4) in view of Swiggett is reversed.

REVERSED

TERRY J. OWENS Administrative Patent Judge	)	
MURRIEL E. CRAWFORD Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
ANTON W. FETTING Administrative Patent Judge	)	

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