

United States District Court,  
S.D. California.

**QUIDEL CORPORATION,**  
Plaintiff.

v.

**INVERNESS MEDICAL INNOVATIONS, INC.; Inverness Medical Switzerland GmbH; Applied Biotech, Inc.; and Armkel, LLC,**  
Defendants.

**Inverness Medical Innovations, Inc.; Inverness Medical Switzerland GmbH; Applied Biotech, Inc.; and Armkel, LLC,**  
Counter-Claimants.

v.

**Quidel Corporation,**  
Counter-Defendants.

Civil Nos. 04CV0378-B(LSP), 04CV0489-B(LSP)

**June 29, 2004.**

Morgan Chu, Irell and Manella, Los Angeles, CA, for Plaintiff/Counter-Defendants.

J. Anthony Downs, Anastasia M. Fernands, Lana S. Shiferman, Roland H. Schwillinski, U. Gwyn Williams, Goodwin Procter, Boston, MA, Sean C. Cunningham, DLA Piper US, San Diego, CA, for Defendants/Counter-Claimants.

**ORDER CONSTRUING DISPUTED CLAIMS FOR UNITED STATES PATENT NUMBER 6,485,982**

**RUDI M. BREWSTER, District Judge.**

Before the Court is the matter of claims construction for United States Patent Number 6,485,982 ("the Charlton '982 patent") in the above titled cases for patent infringement. FN1 Pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996), the Court conducted a Markman hearing regarding construction of the disputed claim terms for the Charlton '982 patent on May 17-19, 2004.

Plaintiff/Counter-Defendant Quidel Corporation ("Quidel") was represented by the law firm of Irell & Manella LLP, Defendant/Counter-Plaintiff Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH, Applied Biotech, Inc., and Wampole Laboratories (collectively "Inverness") were represented by Goodwin Procter LLP and Gray, Cary, Ware & Freidenrich LLP, and Defendant Armkel LLC ("Armkel") was represented by the law firm of Proskauer Rose LLP.

FN1. On February 20, 2004, Quidel filed suit against Inverness alleging infringement of, *inter alia*, United States Patent Number 4,943,522 in case number 04CV378. On March 9, 2004, Inverness filed its answer and counterclaim in the 04CV378 case. In its counterclaim, Inverness asserted that Quidel is infringing,

*inter alia*, the Charlton '982 patent which is the subject of the instant claims construction order.

Also on March 9, 2004, Inverness filed its complaint in case number 04CV489 alleging Quidel is infringing United States Patent Number 6,534,320. Quidel filed its answer and counterclaim in the 04CV489 case on May 6, 2004.

The purpose of the Markman hearing was for the Court, with the assistance of the parties, to prepare jury instructions interpreting the pertinent claims for the claim terms at issue in the Charlton '982 patent. Additionally, the Court and the parties prepared a "case glossary" for terms found in the claims and the specification for the Charlton '982 patent, considered to be technical in nature and which a jury of laypersons would not understand clearly without specific definition. As the case advances, the parties may request additional terms to be added to the glossary as to further facilitate the jury's understanding of the disputed claims.

After careful consideration of the parties' arguments and the applicable statutes and case law, the Court **HEREBY CONSTRUES** the claim terms in dispute in the Charlton '982 patent and **ISSUES** the relevant jury instructions as written in Exhibit A, attached hereto. Further, the Court **HEREBY DEFINES** all pertinent technical terms as written in Exhibit B, attached hereto.

**IT IS SO ORDERED**

***EXHIBIT A-CHARLTON '982 PATENT CLAIM CHART***

<b>VERBATIM CLAIM LANGUAGE</b>	<b>COURT'S CLAIM CONSTRUCTION</b>
<b>Claim 5</b>	
A test device comprising a conjugate and a test strip;	A test device <b>comprising</b> [including but not limited to] a <b>conjugate</b> [substances that are joined] and a <b>test strip</b> [strip-shaped object that is used to perform a test];
the conjugate comprising a first binder for a ligand and a colored particle bound thereto, the conjugate forming a complex with the ligand when present together in liquid;	the conjugate comprising a <b>first binder for a ligand</b> [a substance that binds to the target substance] and a <b>colored particle</b> [a small colored object, greater than molecular size, that is not soluble in the liquid sample being tested] <b>bound</b> [held in chemical or physical combination] thereto, the conjugate forming a complex with the ligand when present together in liquid;
the test strip comprising a sorbent material defining a flow path extending from a sample application site to at least a test site, the flow path guiding there along transport of the conjugate and a liquid suspected to contain a ligand;	the test strip comprising a <b>sorbent</b> [absorbent (taking in or drawing in) and/or adsorbent (accumulating on the surfaces) ] material defining a flow path extending from a sample application site to at least a test site, the flow path guiding there along transport of the conjugate and a liquid suspected to contain a ligand
a second binder for capturing the ligand or the complex, the second binder being immobilized at the test site;	a second binder for capturing the ligand or the complex, the second binder being <b>immobilized</b> [fixed in place or position] at the test site;
whereby accumulation of colored particles at the test site produces a color visible to the unaided eye indicative of the presence of the ligand in the liquid.	whereby accumulation of colored particles at the test site produces a color visible to the unaided eye indicative of the presence of the ligand in the liquid.
<b>Claim 6</b>	

The test device of claim 5 wherein the conjugate is disposed in the flow path upstream of the test site and is mobilizable along the flow path with passing liquid.	The test device of claim 5 wherein the conjugate is <b>disposed</b> [placed] in the flow path upstream of the test site and is <b>mobilizable</b> [capable of being put into movement] along the flow path with passing liquid.
<b>Claim 7</b>	
The test device of claim 6 wherein the conjugate is in dry form.	The test device of claim 6 wherein the conjugate <i>disposed in the flow path</i> is in dry form.
<b>Claim 18</b>	
A method of detecting a ligand in a liquid sample, the method comprising the steps of:	A method of detecting a ligand in a liquid sample, the method comprising the steps of:
(a) providing a test device comprising a conjugate and a test strip,	(a) providing a test device comprising a conjugate and a test strip,
the conjugate comprising a first binder for a ligand and a colored particle bound thereto,	the conjugate comprising a first binder for a ligand and a colored particle bound thereto,
the test strip comprising a sorbent material defining a flow path extending from a sample application site to at least a test site,	the test strip comprising a sorbent material defining a flow path extending from a sample application site to at least a test site,
a second binder for capturing the ligand or the complex, the second binder being immobilized at the test site;	a second binder for capturing the ligand or the complex, the second binder being immobilized at the test site;
(b) applying a liquid sample to the device upstream of the test site so that	(b) applying a liquid sample to the device upstream of the test site so that
the sample and the conjugate are transported to the test site by liquid wicking or wetting along the flow path, and the conjugate forms a complex with the ligand when present together in the liquid; and	the sample and the conjugate are transported to the test site by liquid wicking or wetting along the flow path, and the conjugate forms a complex with the ligand when present together in the liquid; and
(c) observing visually the test result at the test site wherein the accumulation of colored particles produces a color indicative of the presence of the ligand in the liquid.	(c) observing visually the test result at the test site wherein the accumulation of colored particles produces a color indicative of the presence of the ligand in the liquid.
<b>Claim 19</b>	
The method of claim 18, wherein the conjugate is dried in the flow path upstream of the test site, the liquid sample is applied upstream of the dried conjugate, and the conjugate is mobilized along the flow path by passing liquid.	The method of claim 18, wherein the conjugate is dried in the flow path upstream of the test site, the liquid sample is applied upstream of the dried conjugate, and the conjugate is mobilized along the flow path by passing liquid.

## EXHIBIT B-CHARLTON '982 PATENT GLOSSARY

***Comprising***-including but not limited to

***Conjugate***-substances that are joined

***Test Strip***-strip-shaped object that is used to perform a test

***Colored Particle***-a small colored object, greater than molecular size, that is not soluble in the liquid sample being tested

***Bound***-held in chemical or physical combination

***Sorbent***-absorbent (taking in or drawing in) and/or adsorbent (accumulating on the surfaces)

***Immobilized***-fixed in place or position

***Disposed***-placed

***Mobilizable***-capable of being put into movement

S.D.Cal.,2004.

Quidel Corp. v. Inverness Medical Innovations, Inc.

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