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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

BIO-RAD LABORATORIES, INC.,

Plaintiff,

v.

APPLERA CORPORATION - APPLIED BIOSYSTEMS, INC.,

Defendant.

Case No. C02-5946 JW

APPLERA'S NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT ON WHETHER BIO-RAD CAN ASSERT THE DOCTRINE OF EQUIVALENTS TO EXTEND CLAIM 16'S MARKUSH GROUP TO REACH POLYACRYLAMIDE

Date: October 25, 2004
Time: 9:00 a.m.
Dept.: Courtroom 8, 4th Floor
Judge: Hon. James Ware

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I. Notice of motion and motion.

To Bio-Rad Laboratories, Inc. ("Bio-Rad"), and its counsel of record: Please take notice that on October 25, 2004, at 9 a.m. or as soon thereafter as the matter may be heard, at the United States District Court for the Northern District of California, 280 South 1st Street, San Jose, CA 95113, defendants, Applera Corporation and Applied Biosystems (collectively "Applera"), will and hereby do move this Court for an Order that for the purposes of the doctrine of equivalents, polyacrylamide is ***not*** within the scope of "a substantially linear polymer selected from the group ***consisting of*** [1] methyl cellulose, [2] hydroxypropyl methyl cellulose, [3] hydroxyethyl methyl cellulose, and [4] hydroxybutyl methyl cellulose," which is one of the limitations of Claim 16 of U.S. Patent No. 5,089,111 – the patent-in-suit.

This motion will be and is based on applicable law, all of the papers, admissible evidence, and argument submitted to the Court in connection with the Court's resolution of this motion, the complete files and records of this action, and all matters of which the Court must or may take judicial notice. As explained more fully in the following Memorandum of Points and Authorities (beginning with § 3, below), the material facts regarding this motion are undisputed: they consist almost exclusively of the file history of the patent-in-suit, which by law is publicly available. The issues that this motion presents are questions of law for the Court to resolve.

II. Nature of relief sought.

Claim 16 of the '111 patent contains the limitation "a substantially linear polymer selected the group ***consisting of*** [1] methyl cellulose, [2] hydroxypropyl methyl cellulose, [3] hydroxyethyl methyl cellulose, and [4] hydroxybutyl methyl cellulose." The four specified chemicals are what the patent law calls a "Markush group." In its Final Infringement Contentions, Bio-Rad does not assert that polyacrylamide was within the literal scope of Claim 16's Markush group. In other words, Bio-Rad acknowledges that polyacrylamide is ***not*** [1] methyl cellulose, [2] hydroxypropyl methyl cellulose, [3] hydroxyethyl methyl cellulose, or [4] hydroxybutyl methyl cellulose. Instead, Bio-Rad asserts that the doctrine of equivalents extends the scope of Claim 16's Markush group to include polyacrylamide.

This motion is directed to that assertion. Pursuant to Rule 56 of the Federal Rules of Civil Procedure, the applicable statutory and case law, and this Court's Local Rules, Applera seeks an Order that Claim 16's Markush group does ***not*** for purposes of the doctrine of equivalents include polyacrylamide.

Dated: September 20, 2004

Respectfully submitted,

Weil, Gotshal & Manges LLP

By: /s/
Alice Garber
Attorneys for Defendant,
Applera Corporation -
Applied Biosystems

III. Memorandum of points and authorities.

In this patent case, the plaintiff, Bio-Rad Laboratories, Inc., alleges that Applera Corporation infringes a patent that Bio-Rad obtained 12 years ago and applied for 15 years ago. Bio-Rad's Final Infringement Contentions allege that Applera's asserted use of its POP polymers to perform molecular sieving infringe Claim 16 of the patent-in-suit under the doctrine of equivalents. This motion is directed at Bio-Rad's doctrine of equivalents assertion.

In particular, this motion presents two issues, both of which are issues of law for the Court to resolve:

1. Under *Festo,*[1] when a patentee narrows requested patent coverage because of the PTO's prior art rejection, he is presumed to have surrendered the rejected coverage for purposes of the doctrine of equivalents. In a claim directed to a method of separating a mixture of sample ions in a sample, Bio-Rad requested patent coverage for the use of a "a substantially linear polymer" in that method. The PTO rejected Bio-Rad's requested patent coverage because a prior artist had "successfully performed molecular sieving experiments using non-crosslinked linear ***polyacrylamide***." Bio-Rad did not object or appeal; instead, it narrowed the claim to avoid that prior art. Now Bio-Rad asserts that under the doctrine of equivalents, its patent coverage of "a substantially linear polymer" extends to the use of polyacrylamide for molecular sieving. Can Bio-Rad now recapture what it is presumed to have surrendered?

2. Under *Johnston & Johnston,*[2] "when a patent drafter discloses but declines to claim subject matter, [he] dedicates that unclaimed subject matter to the public." Before the PTO, Bio-Rad initially took the position that the patent-in-suit's coverage of "a substantially linear polymer" discloses the use of polyacrylamide in the claimed methods of molecular sieving. Claim 16 lists four chemical groups, but not polyacrylamide, and Bio-Rad has conceded that polyacrylamide is ***not*** literally within the scope of those four groups. However, Bio-Rad now argues that under the doctrine of equivalents, Claim 16 extends the reach of "a substantially linear

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[1] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722 (2002).

[2] *Johnson & Johnston Associates, Inc. v. R.E. Services Co., Inc.*, 285 F.3d 1046 (Fed. Cir. 2002) (en banc).

polymer" to covers polyacrylamide. Can Bio-Rad now recapture what it agrees it did not claim?

IV. Undisputed material facts and additional background.

Although there are two independent bases for this motion, the material facts underlying each basis overlaps. The following facts are undisputed.

A. In the first application in the file history of the patent-in-suit, Bio-Rad sought patent coverage for the use of "a substantially linear polymer" as a molecular sieving polymer.

On January 27, 1989, Bio-Rad, as the assignee of named inventors Ming Zhu, Jeng-Chyn Chen, and Stellan Hjerten (Bio-Rad and the named inventors are collectively "Applicants" or "Bio-Rad"), filed U.S. Patent Application No. 07/303,174 ("the '174 Application") with the United States Patent and Trademark Office.[3] The '174 Application was entitled "Electrophoretic Sieving in Gel-Free Media with Dissolved Polymers."[4]

As initially filed, the '174 Application contained 27 claims, Claims 1 and 27 of which were independent, with Claims 2-26 depending from claim 1.[5] In the specification, Applicants described their invention: "It has now been discovered that sample ions, and particularly biomolecules, may be separated from each other on the basis of molecular size by electrophoresis through an aqueous solution of a ***non-crosslinked polymer*** of a selected molecular weight (or molecular weight range) and concentration. . . . [¶] The present invention resides in the discovery that ***dissolved linear polymers*** in general produce a molecular sieving effect when used in certain amounts."[6]

There are two claims most relevant to the prosecution history estoppel issues in this motion – initially filed claim 1 and initially filed claim 27. In initially filed Claim 1,

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[3] Declaration of Alice Garber In Support Of Applera's Motion On Whether Bio-Rad Can Assert The Doctrine Of Equivalents To Extend Claim 16's Markush Group To Reach Polyacrylamide, ("Garber Decl."), Exh. 1 at ABBR 065850-871 ['111 Patent File History, Application No. 07/303,174 as filed ("'174 Application")].

[4] *Id.* Exh. 1 at ABBR 065846 [PTO cover sheet with title], 065850 ['174 Application, page 1 (title page)].

[5] *Id.* Exh. 1 at ABBR 065864-868 ['174 Application pages 15-19 (originally-filed claims)].

[6] *Id.* Exh. 1 at ABBR 065851 ['174 Application, page 2 at lines 6-11, 34-37].

Applicants requested patent coverage for a "substantially linear [unspecified] polymer":

> A method of separating a mixture of sample ions of varying molecular weights in a simple into components, said method comprising electrophoretically passing said sample through a separation column containing a gel-free aqueous solution of a substantially linear polymer having a molecular weight of about 10,000 to about 2,000,000, said molecular weight being within a range of about 0.1 to about 200 times the average molecular weight of said macromolecular species in said mixture, the concentration of said polymer in said solution being sufficient to retard the flow of said species through said molecular separation column to degrees which vary with the molecular weights of said species.[7]

And in initially filed Claim 27, Applicants requested patent coverage for a specified linear polymer – one selected from four identified chemical groups:

> A method of separating a mixture of polynucleotide chains in a sample, said polynucleotide chains each containing from about 10 to about 10,000 base pairs, said method comprising electrophoretically passing said sample through a capillary column containing a gel-free aqueous solution of a substantially linear polymer selected from the group consisting of [1] methyl cellulose, [2] hydroxypropyl methyl cellulose, [3] hydroxyethyl methyl cellulose, and [4] hydroxybutyl methyl cellulose, said polymer characterized in terms of the viscosity of a 2% aqueous solution thereof being within a range of about 1,000 centipoise to about 10,000 centipoise at 25.degree. C., and the concentration of said polymer in said solution is from about 0.1% to about 0.5% by weight.[8]

The referenced group of four chemicals (methyl cellulose, hydroxypropyl methyl cellulose, hydroxyethyl methyl cellulose, and hydroxybutyl methyl cellulose) are what the patent law calls a "Markush group." A Markush group "is a listing of specified alternatives of a group in a patent claim, typically expressed in the form: a member selected from the group consisting of A, B, and C. . . . '[A] Markush group, incorporated in a claim, should be 'closed,' i.e. it must be characterized with the transition phrase 'consisting of,' rather than 'comprising' or 'including.' Thus, 'members of the Markush group are used singly.'"[9]

Applicants submitted to the PTO the following references, in each case explaining

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[7] *Id.* Exh. 1 at ABBR 065864 ['174 Application, page 15 (originally-filed claim 1)].

[8] *Id.* Exh. 1 at ABBR 065868 ['174 Application, page 19 (originally-filed claim 27)] (emphasis and brackets supplied).

[9] *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc.*, 334 F.3d 1274, 1280-81 (Fed. Cir. 2003).

"the relevance of each reference":

- Tietz, Dietmar, et al., "Electrophoresis in Uncrosslinked ***Polyacrylamide***: ***Molecular Sieving*** and Its Potential Applications," Electrophoresis 7, 217-220 (1986) (hereafter "Tietz et al."), which, according to Bio-Rad, was "relevant for its disclosure of molecular sieving in a solution of uncrosslinked polymer";

- Bode, "The Use of Liquid ***Polyacrylamide*** in ***Electrophoresis***," 204-210,[10] which, according to Bio-Rad, was "relevant for its discussion of the inclusion of uncrosslinked polymer in a molecular sieving medium"; and

- Bode, "The Use of Liquid ***Polyacrylamide*** in ***Electrophoresis***," 83 Analytical Biochemistry, 364-371 (1977), which, according to Bio-Rad, was "relevant for its discussion of the influence of uncrosslinked polymer in a molecular sieving medium."[11]

As we next explain, the PTO rejected the coverage that Applicants sought, because it was obvious from the prior art.

B. The PTO rejected Applicants' requested patent coverage because a reference in the prior art regarding the use of polyacrylamide as a molecular sieving polymer made the requested patent coverage unpatentable.

The PTO rejected the coverage that Applicants sought – a molecular sieving claim directed to the use of a "substantially linear polymer" – on multiple grounds. For present purposes, however, the important rejection was the PTO's rejection under 35 U.S.C. § 103 of the coverage that Applicants sought because that coverage was "unapatentable over Tietz et al."[12] Under § 103, if a patent claim would have been obvious to one of ordinary skill based on a piece of prior art or some combination of prior art, the patent must not issue – and, if it does, it is invalid.[13] In particular, the PTO concluded that "Tietz et al. report that they successfully performed molecular sieving experiments using non-crosslinked linear ***polyacrylamide*** in the concentration range of 5-20% wt/v. . . . [T]he ***polyacrylamide*** must inherently have had the

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[10] Applicants omitted the journal title and date for this reference in the statement submitted to the PTO.

[11] *Id.* Exh. 1 at ABBR 065872-4 [January 27, 1989 Disclosure Statement] (emphasis supplied).

[12] *Id.* Exh. 1 at ABBR 065889 [May 29, 1990 Office Action, page 3].

[13] *See Graham v. John Deere Co.*, 383 U.S. 1, 15 (1966) (If difference between prior art and subject matter for which the applicant seeks a patent is such that subject matter as a whole would have been obvious at the time to a person skilled in the art, then subject matter cannot be patented.)

characteristics recited in the claims, e.g., a molecular weight of about 10,000 to about 2,000,000."[14] In other words, the PTO thought that the application disclosed and claimed the use of polyacrylamide for molecular sieving, and rejected Applicants' attempt to claim such use.

Although the PTO reached that conclusion and made the appropriate rejection based on it, the PTO did not reject initial Claim 27, which (like rejected Claim 1) was directed to a method of molecular sieving and sought coverage for "a substantially linear polymer." But Applicants drew this limitation much more narrowly – it added the qualification that the "substantially linear polymer" had to be "selected from the group consisting of [1] methyl cellulose, [2] hydroxypropyl methyl cellulose, [3] hydroxyethyl methyl cellulose, and [4] hydroxybutyl methyl cellulose." As Bio-Rad does not assert that polyacrylamide is within the literal scope of issued Claim 16's Markush group, and thus concedes that polyacrylamide is not literally within the four specified chemical types in that Markush group.[15] That concession squares with the conclusion that the PTO did not regard initial Claim 27 (which became issued Claim 16) as covering polyacrylamide. We discuss this more below.

The PTO's rejection of patent coverage for "a substantially linear polymer" was a rejection related to patentability – specifically, an obviousness rejection because of prior art. Applicants did not challenge the PTO's conclusion that the requested coverage was obvious in light of the prior art.[16] Applicants did not, for example (as one often sees in file histories) argue that the examiner was wrong in concluding that the claimed invention was invalid in light of the prior art. Alternatively, they could have appealed to the Board of Patent and Trademark

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[14] Garber Decl. Exh. 1 at ABBR 065889 [May 29, 1990 Office Action, page 3].

[15] *Id.* Exh. 2 [Bio-Rad's April 22, 2004 Local Rule 2-6(a) Final Infringement Contentions – cover page ("Claim 16 has been amended to indicate that the solutions containing POP in the capillaries infringe the claim under the doctrine of equivalents" and "claim 1 has been amended to remove POP"), page 3 (claim 1 not asserted against Applied Biosystems' polyacrylamide-containing "POP" polymers) and page 10 (only claim 16 is asserted against Applied Biosystems' polyacrylamide-containing "POP" polymers, and then only under "Doctrine of Equivalents" as to the Markush group).

[16] *Id.* Exh. 1 at ABBR 065894-898 [Applicants' July 16, 1990 Response to the May 29, 1990 Office Action (no challenge to the Examiner's rejection of claim 1 over the Tietz polyacrylamide paper; claim 1 amended to recite "substantially linear <u>water-soluble cellulose derivative</u> polymer") (underlining in original)].

Appeals.[17] But they didn't do that, either. Instead, Applicants narrowed the scope of the patent coverage they sought. In particular, they limited the scope of "a substantially linear polymer" to make clear that they did not seek coverage for the use of polyacrylamide as a molecular sieving agent.

C. Bio-Rad did not appeal. Instead, Bio-Rad amended its requested patent coverage to avoid the prior art reference that disclosed the use of polyacrylamide as a molecular sieving polymer.

In a mailing on July 13, 1990, "in response to Office Action of May 29, 1990" (that is, in response to the PTO's rejection of original Claim 1 of the '174 Application), Applicants narrowed the patent coverage they sought. In particular, they amended the limitation in question here – "a substantially linear polymer" – to disclaim the use of polyacrylamide[18]

On July 20, 1990, after Applicants had made that amendment to disclaim the rejected patent coverage, the PTO mailed Applicants a Notice of Allowance and Issue Fee Due," advising that "[t]he application identified above has been examined and is allowed for issuance as a patent. Prosecution on the merits is closed."[19] However, on December 26, 1990 (twelve years to the day before Bio-Rad filed this lawsuit), the PTO mailed a "Notice of Abandonment" of the '174 Application because of Applicants' failure to pay the required issue fee within three months after the Notice of Allowance.[20]

On September 27, 1990, Applicants filed U.S. Patent Application No. 07/589,915 ("the '195 Application") with the PTO, asserting that the '915 Application was a continuation-in-part of the '174 Application.[21] ("A continuation-in-part is an application filed during the lifetime of an earlier nonprovisional application . . . , repeating some substantial portion or all of the

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[17] 35 U.S.C. § 134 (statutory basis for right to appeal); Garber Decl., Exh. 1 at ABBR 065846-926 ['174 Application file history (no appeal taken)].

[18] *Id.* Exh. 1 at ABBR 065895 [Applicants' July 16, 19990 Response to the May 29, 1990 Office Action (no challenge to the Examiner's rejection of claim 1 over the Tietz polyacrylamide paper; claim 1 amended to recite "substantially linear water-soluble cellulose derivative polymer") (underlining in original)].

[19] *Id.* Exh. 1 at ABBR 065900 [July 20, 1990 Notice of Allowability].

[20] *Id.* Exh. 1 at ABBR 065904 [December 26, 1990 Notice of Abandonment].

[21] *Id.* Exh. 3 at ABBR 065932-956 ['111 Patent File History – Application No. 07/589,915 as filed ("'915 Application")].

earlier nonprovisional application and adding matter not disclosed in the said earlier nonprovisional application."[22]) The '915 Application's title was identical to the '174 Application's title ("Electrophoretic Sieving in Gel-Free Media with Dissolved Polymers"), and so was its abstract.[23]

In Claim 16 of the '915 Application, Applicants sought patent coverage for a specified substantially linear polymer – a polymer from four specified chemical groups:

> A method of separating a mixture of polynucleotide chains in a sample, said polynucleotide chains each containing from about 10 to about 10,000 base pairs, said method comprising electrophoretically passing said sample through a capillary column containing a gel-free aqueous solution of a substantially linear polymer selected from the group consisting of [1] methyl cellulose, [2] hydroxypropyl methyl cellulose, [3] hydroxyethyl methyl cellulose, and [4] hydroxybutyl methyl cellulose, said polymer characterized in terms of the viscosity of a 2% aqueous solution thereof being within a range of about 1,000 centipoise to about 10,000 centipoise at 25.degree. C., and the concentration of said polymer in said solution is from about 0.1% to about 0.5% by weight.[24]

On September 20, 1991, the PTO issued a Notice of Allowance and Issue Fee Due, together with the "Examiner's Statement of Reasons for Allowance" ("Statement of Reasons"). The PTO includes a Statement of Reasons in the file histories of certain patents (such statements are not required) in order "to improve the quality and reliability of issued patents by providing a complete file history which should clearly reflect, as much as is reasonably possible, the reasons why the application was allowed. Such information facilitates evaluation of the ***scope*** and strength of a patent by the patentee and the public and may help avoid or ***simplify litigation of a patent***."[25]

In the Statement of Reasons, the PTO emphasized the reasons why it allowed Claim 16, which claims the use of "substantially linear polymer" as a molecular sieving agent, despite its earlier rejection (in light of Tietz *et al*. and other references) of requested coverage for

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[22] Garber Decl., Exh. 4 [MPEP 5th Ed. (Rev. 13, Nov. 1989) Section § 201.08].

[23] *Id.* Exh. 3 at ABBR 065933 ['915 Application, page 1 (title page)] and 065954 ['915 Application, page 22 (abstract)].

[24] *Id.* Exh. 3 at ABBR 065952 ['915 Application, page 20 (claim 16)].

[25] Garber Decl., Exh. 5 [MPEP 5th Ed. (Rev. 13, Nov. 1989) Section § 1302.14]; *see also* 37 C.F.R. § 1.109 (1989) ("If the examiner believes that the record of the prosecution as a whole does not clear that his or her reasons for allowing a claim or claims, the examiner may set forth such reasoning") (C.F.R. section since superseded).

the use of "substantially linear polymer" as a molecular sieving agent. The PTO wanted to make clear that the fact that because Applicants had ***limited*** the claim to four specific Markush groups, it avoided the prior art that taught the use of a polyacrylamide as a molecular sieving polymer. In particular, the PTO's Statement of Reasons explained – with emphasis in original – that its "search of the prior art failed to reveal any reference(s) which . . . teach explicitly or fairly suggest a method of separating a mixture of polynucleotide chains in a sample . . ., said method comprising electrophoretically passing said sample through a capillary column containing a gel-free aqueous solution of a substantially linear polymer selected ***from the group consisting of [1] methyl cellulose, [2] hydroxypropyl methyl cellulose, [3] hydroxyethyl methyl cellulose, and [4] hydroxybutyl methyl cellulose***, . . ."[26]

The PTO invited comments from Applicants on the PTO's Statement of Reasons, but Applicants failed to submit any.[27] The PTO issued the '915 Application as U.S. Patent No. 5,089,111 – the patent in this lawsuit, which Bio-Rad filed the day after Christmas 2002.[28]

D. Now Bio-Rad asserts that under the doctrine of equivalents, the reach of "a substantially linear polymer" extends to include polyacrylamide – the PTO's rejections notwithstanding.

Bio-Rad's infringement contentions have been something of a moving target in this case. Its Final Infringement Contentions were its fourth iteration of its position. In those Final Infringement Contentions, Bio-Rad does ***not*** assert that the asserted use of Applera's POP polymers literally infringe Claim 16's patent coverage for "a substantially linear polymer selected from the group consisting of [1] methyl cellulose, [2] hydroxypropyl methyl cellulose, [3] hydroxyethyl methyl cellulose, and [4] hydroxybutyl methyl cellulose." In other words, Bio-Rad's Final Infringement Contentions concede that polyacrylamide is ***not*** literally "a substantially linear polymer selected from the group consisting of [1] methyl cellulose, [2] hydroxypropyl

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[26] Garber Decl., Exh. 3 at ABBR 065974-975 [Examiner's September 20, 1991 Statement of Reasons for Allowance](emphasis in original as double underlines; brackets supplied).

[27] *Id.* Exh. 3 at ABBR 065975 [Examiner's September 20, 1991 Statement of Reasons for Allowance ("any comments considered necessary by the applicant must be submitted no later than the payment of the Issue Fee") and ABBR 065978-986 [issue fee transmittal documents (no comments submitted regarding Examiner's Statement of Reasons for Allowance)].

[28] *Id.* Exh. 6 [U.S. Patent No. 5,089,111 (with issue date of February 18, 1992)].

methyl cellulose, [3] hydroxyethyl methyl cellulose, and [4] hydroxybutyl methyl cellulose." Instead, Bio-Rad contends only that the doctrine of equivalents extends Claim 16's reach to cover polyacrylamide.[29]

This motion is directed to that assertion, and to it we now turn.

V. Discussion.

In this lawsuit, Bio-Rad has attempted to expand the reach of Claim 16 beyond the Markush group that it claimed. Bio-Rad now wants polyacrylamide included in that Markush group – not literally, but under the doctrine of equivalents. There are two independent but related reasons why Claim 16's reach does not extend so far: prosecution history estoppel (discussed in § V(A), below) bars expansion under the doctrine of equivalents. So does the disclosure-dedication (discussed in § V(B), below).

A. Prosecution history estoppel bars expansion, under the doctrine of equivalents, of the patent coverage that the PTO allowed.

1. The purpose, general rules, presumptions, and burdens in assessing prosecution history estoppel issues.

As the Supreme Court explained in *Festo*, patent rights are property rights, and "like any property right, its boundaries should be clear. This clarity is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not. For this reason, the patent laws require inventors to describe their work in 'full, clear, concise, and exact terms,' . . ."[30] The Supreme Court also explained in *Festo* that "[u]nfortunately, the nature of language makes it impossible to capture the essence of a thing in a patent application."[31] Hence the doctrine of equivalents: the doctrine that "[t]he scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described."[32]

But the "doctrine of equivalents exists in some tension with other core tenets of the

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[29] *See* note 13, *supra*.

[30] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 730-31 (2002).

[31] *Festo*, 535 U.S. at 731.

[32] *Festo*, 535 U.S. at 732.

patent law, perhaps most notably the requirement that the patentee 'particularly point[] out and distinctly claim [] the subject matter which the applicant regards as his invention,' and the function of patent claims to provide notice to competitors regarding the scope of the patent grant."[33] So the law imposes restraints on the range of permissible "equivalents" in assessing a patentee's efforts to expand a claim's reach beyond the scope of what the PTO actually issued.

For example, a patentee cannot claim, through the doctrine of equivalents, subject matter existing in the prior art.[34] The doctrine of equivalents can extend the reach of the patent claim only to those differences that are 'not insubstantial'; "the question which thus emerges is whether . . . under the circumstances the change was so insubstantial that the . . . invocation of the doctrine of equivalents [is] justified"[35] The " doctrine of equivalents cannot be used to vitiate an element from the claim in its entirety."[36] And, immediately relevant here, "prosecution history estoppel will exclude from the doctrine of equivalents any subject matter that was, by amendment or argument during prosecution, relinquished."

Based on the undisputed facts of record contained in the file history that Bio-Rad created before the PTO, the focus here is amendment-based prosecution history estoppel. "Estoppel arises when an amendment is made to secure the patent and the amendment narrows the patent's scope."[37] "A patentee who narrows a claim as a condition for obtaining a patent disavows his claim to the broader subject matter."[38] In particular, "[a] rejection indicates that the patent examiner does not believe the original claim could be patented. While the patentee has the right to appeal, his decision to forgo an appeal and submit an amended claim is taken as a concession that the invention as patented does not reach as far as the original claim."[39]

The various legal limitations on the application of the doctrine of equivalents are

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[33] *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1366 (Fed. Cir. 1999).

[34] *K-2 Corp.*, 191 F.3d at 1367.

[35] *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 399 U.S. 605, 610 (1950).

[36] *K-2 Corp.*, 191 F.3d at 1367.

[37] *Festo*, 535 U.S. at 736.

[38] *Festo*, 535 U.S. at 737.

[39] *Festo*, 535 U.S. at 734.

to be determined by the court as a matter of law.[40] "The standard for determining whether particular subject matter was relinquished is an objective one that depends on what a competitor reasonably would conclude from the patent's prosecution history."[41] "The application of prosecution history estoppel is a question of law."[42] As a question of law, it is appropriately resolved on summary adjudication.[43] Moreover, it is not Applera's burden to show that the estoppel applies. Instead, the Supreme Court and the Federal Circuit have both instructed that ***the patentee (here, Bio-Rad) must show that the estoppel does <u>not</u> apply***: "the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question."[44]

As explained below, Bio-Rad cannot meet its burden here.

2. Bio-Rad is presumed to have disclaimed the territory between "a substantially linear polymer" (the rejected limitation) and "a substantially linear polymer consisting of" the Markush group.

When Bio-Rad filed the application to which it claims priority for the '111 Patent, it tried to obtain coverage for "a substantially linear polymer." The PTO rejected the coverage that Applicants sought, concluding that in light of prior art, that claim would have been obvious to one of ordinary skill in the art. Applicants had a number of options in light of that rejection. If, for example, they believed that the PTO was wrong, they could have responded to that objection (or "traversed" it, as patent prosecutors would say) in writing, given reasons why they thought that the claimed invention was not obvious in light of the prior art that the PTO cited.[45]

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[40] *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997).

[41] *Mark I Marketing Corp. v. RR. Donnelley & Sons Co.*, 66 F.3d 285, 291 (Fed. Cir. 1995).

[42] *Mark I*, 66 F.3d at 291.

[43] *See Texas Instruments v. United States ITC*, 988 F.2d 1165, 1173 (Fed. Cir., 1993) ("Prosecution history estoppel is a policy oriented limitation to the range of equivalents available to the patentee, a limitation that we review as a question of law.").

[44] *Festo*, 535 U.S. at 740; *see also, Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 347 F.3d 1355, 1359 (Fed. Cir., 2003) (Patentee must rebut the presumption of surrender from a narrowing amendment during prosecution.).

[45] Garber Decl., Exh. 7 [MPEP 5th Ed. (Rev. 6, Oct. 1987) Section 714.02 (citing and quoting 37 C.F.R Section 1.111) ("after the office action, if adverse in any respect, the applicant . . ., if he or she persists in his or her application for a patent . . . , must reply thereto and may request reconsideration or further examination, with or without amendment")].

Or, if for any reason they thought they could not change the examiner's conclusion, they could have appealed the rejection to the Board of Patent and Trademark Appeals.[46] But Applicants didn't try either route. Instead, they narrowed the patent coverage they sought, changing the "a substantially linear polymer" limitation, thereby effectively agreeing with the PTO that the coverage they sought was not patentable.

More than effectively agreed, actually; as a matter of law Applicants are ***presumed*** to have agreed. The Supreme Court emphasized in *Festo* that an applicant's "decision to forgo an appeal and submit an amended claim is taken as a concession that the invention as patented does not reach as far as the original claim."[47]

We turn, then, to what apparently are Bio-Rad's rationale (thus far they have not provided one) for its assertion that although (a) they conceded to the PTO that their request for patent coverage for "a substantially linear [unspecified] polymer" was invalid in light of prior art that disclosed the use of polyacrylamide, and (b) they subsequently narrowed that coverage to avoid that prior art, they are still free, in this litigation filed some twelve years after they obtained the patent, to argue that their patent coverage for "a substantially linear polymer selected from the group consisting of" four chemicals (which Bio-Rad concedes are not literally polyacrylamide) nonetheless includes polyacrylamide.

3. Bio-Rad will be unable to rebut the presumption that it disclaimed the patent coverage between "a substantially linear polymer" and "substantially linear polymer consisting of" the Markush group.

It is important to understand that as the patentee Bio-Rad, ***not Applera***, bears the burden regarding whether Bio-Rad's choices before the PTO bar Bio-Rad's attempt to use the doctrine of equivalents.[48] Bio-Rad will not be able to meet that burden.

Bio-Rad may, for example, argue that because the patent coverage it requested got

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[46] *Id.* Exh. 8 [MPEP 5th Ed. (Rev. 13, Nov. 1989) Sections 1201, 1205 (citing and quoting 35 U.S.C. Section 134 and 37 C.F.R. Section 1.191 ("An applicant . . . dissatisfied with the primary examiner's decision in the second or final rejection of his or her claim may appeal to the Board for review of the examiner's rejection")].

[47] *Festo*, 535 U.S. at 734.

[48] *Festo*, 535 U.S. at 740 ("we hold here that the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question").

narrowed in a parent application that it abandoned, Claim 16 is somehow exempt because it issued from is a continuation-in-part. That argument would be wrong. Prosecution history estoppel cannot be avoided by filing a continuation or continuation-in-part, as the Federal Circuit has noted in *Mark I* and other cases.[49] Indeed, *Mark I* is instructive on prosecution history estoppel issues in this case, so we briefly turn to it.

There, the patentee plaintiff submitted a "broadly claimed a process for reproducing color images by printing with two printing plates and two inks."[50] But the PTO rejected those claims because of prior art that suggested replicating a color image using two printing plates and two inks. Instead of responding to the rejection, Mark I filed a continuation-in-part application with new claims, narrowing the initial claims to require that the first printing plate be made by sequentially interposing filters.[51] After further interaction with the PTO, the plaintiff filed another continuation-in-part, requiring that both plates be made by sequentially interposing colored filters.[52] The latter continuation issued and became the patent-in-suit. The defendant argued that the prosecution history, and in particular the narrowing amendments made to the predecessor applications, "shows that Mark I surrendered claim coverage for a process not involving sequential interposition of colored filters."[53] The patentee argued that the fact that the narrowing amendments occurred in a predecessor application precluded the doctrine of equivalents.

The Federal Circuit disagreed, holding that "[t]he fact that the claims of the '659 application were not themselves rejected by the Patent Office or amended by Mark I does not call for a different result. . . . [A]n estoppel is not avoided by failing to respond to a rejection and instead meeting the substance of the rejection by filing a narrower continuing application."[54]

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[49] *Mark I*, 66 F.3d at 291-92; *see also Desper Products, Inc. v. Osound Labs, Inc.*, 157 F.3d 1325, 1338 (Fed. Cir. 1998).

[50] *Mark I*, 66 F.3d at 291.

[51] *Id.*

[52] *Id.* at 291-92.

[53] *Id.* at 292.

[54] *Id.*

So, too, of this case. The PTO rejected the claim coverage that Bio-Rad initially sought because prior art rendered the claimed coverage – "a substantially linear polymer" – obvious in light of prior art that disclosed a method of molecular sieving using polyacrylamide. In response, Bio-Rad amended that requested coverage, adding additional language and thereby narrowing it. (Both the Supreme Court and the Federal Circuit have held that by adding additional language, an applicant narrows the limitation in question and thus raises the *Festo* presumption of surrender as a matter of law; indeed, the Federal Circuit has observed that "[t]hat the addition of a claim limitation constitutes a narrowing amendment is manifest in the language of [the Supreme Court decisions in] both *Warner-Jenkinson* and *Festo*.[55]) By conceding that patent coverage for "a substantially linear polymer" did not include polyacrylamide, Bio-Rad is presumed to have surrendered patent coverage for that limitation.

Bio-Rad may also argue that because issued Claim 16 was not amended during prosecution, prosecution history estoppel cannot apply to it – in other words, that the fact that issued Claim 16 was not amended insulates it from prosecution history estoppel. In the post-*Festo* case of *Glaxo Wellcome, Inc. v. Impax Laboratories, Inc.*, this Court (Patel, J.) rejected this very kind of argument.[56] That case involved a patent on sustained-release tablets; as this Court emphasized, "[n]otably, the '798 patent is titled 'Controlled Sustained Release Tablets Containing Bupropion.' Sustained release is the clear focus of the invention."[57] There, in claim 18, the patentee initially tried to claim patent coverage for

> A sustained release tablet containing a mixture of (a) 100 mg of bupropion hydrochloride and (b) means for releasing between about 25 and 45% of bupropion hydrochloride in one hour, between 60 and 85% in 4 hours and not less than 80% in eight hours in distilled water.[58]

The PTO, however, "rejected [this claim] under 35 U.S.C. § 112 as being non-enabled" – in other words, for a reason related to patentability.[59] In response, the patentee added a limitation (in

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[55] *Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1140-41 (Fed. Cir. 2004); *Warner-Jenkinson*, 520 U.S. at 33-34 ("introduc[ing] a new element" to the claims at issue raises presumption of surrender); *Festo*, 535 U.S. at 741.

[56] 220 F.Supp.2d 1089 (N.D. Cal. 2002).

[57] *Id*. at 1096.

[58] *Id.* at 1091.

[59] *Id*. at 1094.

italics as follows) specifying that the means would be HPMC:

> A sustained release tablet containing a mixture of (a) 100 mg of bupropion hydrochloride and (b) means for releasing between about 25 and 45% of bupropion hydrochloride in one hour, between 60 and 85% in 4 hours and not less than 80% in eight hours in distilled water *said means comprising hydroxypropyl methylcellulose [HPMC]*.[60]

Both at the time of filing and at the time of the amendment, claim 1 mentioned HPMC:

> A controlled sustained release tablet comprising 25 to 500 mg of bupropion hydrochloride and hydroxypropyl methylcellulose [HPMC], the amount of hydroxypropyl methylcellulose to one part of bupropion hydrochloride being 0.19 to 1.1 and said tablet having a surface to volume ratio of 3:1 to 25:1 cm -1 and said tablet having a shelf life of at least one year at 59 degrees to 77 F. and 35 to 60% relative humidity[.], *said tablet releasing between about 20 and 60 percent of bupropion hydrochloride in water in 1 hour, between about 50 and 90 percent in 4 hours and not less than about 75 percent in 8 hours*.[61]

The patentee then sued Impax, alleging that a chemical known as "HPC" was the equivalent of HPMC and that Impax infringed claim 1 (and others) under the doctrine of equivalents.[62] This Court rejected that assertion as follows.

> As an initial matter, the patentee argued that "Claim 1 is distinct from the other challenged claims because it mentioned HPMC from the inception. For this reason, plaintiff summarily contends: 'NO AMENDMENT, NO ESTOPPEL.'"[63] This Court noted that such an argument is wrong, and exalts form over substance: "Barring estoppel because a patentee never amended a particular claim, however, 'exalts form over substance.' Contrary to plaintiff's assertion, estoppel may apply to unamended [claim] terms."[64] This Court concluded that the patentee was ***not*** entitled to claim equivalents of HPMC for purposes of claim 1, even though the HPMC limitation of claim 1 was never amended during prosecution:

> Plaintiff is estopped from claiming infringement by equivalents of claim 1 because of amendments to claims 14, 15, 18 and 19. Although HPMC was not added to claim 1 during prosecution, it was added to these other

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[60] *Glaxo*, 220 F. Supp at 1091 (brackets supplied).

[61] *Id*. at 1091 (italics represent the amendment); *id*. at 1096 ("Claim 1 . . . mentioned HPMC from the inception").

[62] *Id*. at 1092 ("Plaintiff does not contend that HPMC is literally present in the IMPAX product. Instead, plaintiff alleges infringement under the doctrine of equivalents").

[63] *Id*. at 1096.

[64] *Id*. (internal citations omitted).

> claims. Prosecution history estoppel extends to unamended claims where the challenged element was amended elsewhere in the patent.[65]

In particular, in reasoning that resonates given the issues in this case, this Court reasoned that:

> Plaintiff added HPMC to claims 18 and 19 during prosecution to avoid a section 112 enablement rejection. As originally drafted, these claims arguably included every sustained-release formulation. By replacing the general means-function language with a more-specific claim limitation, plaintiff surrendered all equivalents. The amendments indisputably narrowed the patent with respect to sustained release. Plaintiff must accept the consequences of these amendments.[66]

Glaxo governs the prosecution history estoppel issues here. In *Glaxo*, the patentee did not amend the claim at issue: "[a] controlled sustained release tablet comprising 25 to 500 mg of bupropion hydrochloride and hydroxypropyl methylcellulose [HPMC]." Nor did Bio-Rad: Claim 16, which claims "a substantially linear polymer selected the group ***consisting of*** [1] methyl cellulose, [2] hydroxypropyl methyl cellulose, [3] hydroxyethyl methyl cellulose, and [4] hydroxybutyl methyl cellulose," issued without amendment. In *Glaxo*, the patentee had in a different claim tried to obtain broad coverage with general language: claim 18, which sought to obtain coverage for "[a] sustained release tablet containing a mixture of (a) 100 mg of bupropion hydrochloride and (b) means for releasing . . . ." So did Bio-Rad: initial claim 1, which had the broad language "a substantially linear polymer." In *Glaxo*, that broad language "arguably included every sustained-release formulation"[67]; here, Applicants' broad language in initial claim 1 arguably included every substantially linear polymer. In *Glaxo*, the PTO rejected the requested broad coverage for a reason related to patentability.[68] So did the PTO here: it concluded that a prior art reference entitled "Electrophoresis in Uncrosslinked ***Polyacrylamide***: Molecular Sieving and Its Potential Applications" made the requested coverage obvious.

All of this led this Court to conclude in *Glaxo* that "[b]y replacing the general [claim] language with a more-specific claim limitation, plaintiff surrendered all equivalents. The

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[65] *Id*. at 1096-7.

[66] *Id*. at 1094 (internal citations omitted).

[67] *Glaxo*, 220 F.Supp.2d at 1094.

[68] *Id*. at 1094 ("[t]he PTO originally rejected claims 18 and 19 under 35 U.S.C. section 112 as being non-enabled").

amendments indisputably narrowed the patent with respect to sustained release. Plaintiff must accept the consequences of these amendments."[69] This Court must reach that same conclusion here. Bio-Rad replaced a general claim limitation with a more-specific claim limitation. It thereby surrendered all equivalents with respect to electrophoretic sieving in gel-free media with dissolved polymers.

The Federal Circuit's decision in *Builders Concrete*, upon which this Court relied in *Glaxo*, confirms the above analysis.[70] There, Builders Concrete had added a "passage" limitation to independent claim 1 during the review process. Claim 10, which included the passage limitation from the inception, was 'allowable as is' – just like initial Claim 27 (which is textually identical to issued Claim 16) of Bio-Rad's patent. After the patent issued, Builders Concrete brought an infringement action against a competing marine float, arguing that the competing product infringed claim 10 under the doctrine of equivalents. But, as this Court noted in *Glaxo*, "the Federal Circuit rejected this argument, applying prosecution history estoppel to the passage limitation in claim 10 because of amendments made to claim 1 during prosecution."[71] The Federal Circuit "encouraged consideration of the prosecution history of all claims when assessing the 'fair scope' of the claim in suit."[72]

Which brings up an additional pointer: "the prosecution history of all claims when assessing the 'fair scope' of the claim in suit." As noted above, in certain – by no means all – file histories the PTO includes a Statement of Reasons in order "to improve the quality and reliability of issued patents by providing a complete file history which should clearly reflect, as much as is reasonably possible, the reasons why the application was allowed. Such information facilitates evaluation of the ***scope*** and strength of a patent by the patentee and the public and may help avoid or ***simplify litigation of a patent***."[73] In the Statement of Reasons of the file history in this case,

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[69] *Glaxo*, 220 F.Supp.2d at 1094.

[70] *Builders Concrete, Inc. v. Bremerton Concrete Products Co*., 757 F.2d 255 (Fed. Cir. 1985).

[71] *Glaxo*, 220 F.Supp.2d at 1097 (citing *Builders Concrete*, 757 F.2d at 260).

[72] *Id*. (citing *Builders Concrete*, 757 F.2d at 260).

[73] Garber Decl., Exh. 5 [MPEP 5th Ed. (Rev. 13, Nov. 1989) Section § 1302.14]; *see also* 37 C.F.R. § 1.109 (1989) ("If the examiner believes that the record of the prosecution as a whole does not clear that his or her reasons for allowing a claim or claims, the examiner may set forth

the PTO specifically commented on Claim 16, emphasized that it was allowing Claim 16 in light of the Markush group.[74] The best reading of the file history is that the PTO included that statement of reasons because of its rejection of initial Claim 1 (which included the limitation "substantially linear polymer") based on the reference that taught the use of polyacrylamide but its allowance of initial Claim 27 (which included the limitation "substantial linear polymer consisting of" the Markush group). As the MPEP and applicable regulations require it to, the PTO wanted to ensure that the public understood that the PTO did not consider polyacrylamide to be within the scope of the Markush group – that is the reason why the PTO allowed initial Claim 16. Indeed, Bio-Rad has not provided any other plausible explanation as to why the PTO emphasized the Markush group in its Statement of Reasons. The above explanation is the only one that is consistent with the file history.

And even if it were not, there is another reason that prevents Claim 16's reach from being extended beyond what Bio-Rad claimed and what the PTO allowed: the disclosure-dedication rule confirmed in *Johnson & Johnston* and its progeny. To that we now turn.

B. The dedication-disclosure rule confirmed in Johnson & Johnston and its progeny bars expansion of Claim 16 beyond what Bio-Rad claimed and what the PTO allowed.

It is a "well-established rule that 'subject matter disclosed but not claimed in a patent application is dedicated to the public.'"[75] This rule applies here, because during prosecution Bio-Rad behaved as if the use of polyacrylamide was disclosed.

In the specification, Bio-Rad described its invention as encompassing a wide range of potential polymers:

> It has now been discovered that sample ions, and particularly biomolecules, may be separated from each other on the basis of molecular size by electrophoresis through an aqueous solution of a non-crosslinked polymer of a selected molecular weight (or molecular weight range) and concentration. . . . The polymers used herein are generally non-

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such reasoning") (C.F.R. section since superseded).

[74] *See* note 24, *supra*.

[75] *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1106 (Fed. Cir. 1996); *see also Johnson & Johnston Associates, Inc. v. R.E. Services Co., Inc.*, 285 F.3d 1046, 1051 (Fed. Cir. 2002) (en banc); *PSC Computer Products, Inc. v. Foxconn International, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004) (citations omitted).

> crosslinked polymers. Branched or linear polymers may be used, linear polymers being preferred for many applications. In addition, the polymers may be neutral or charged, neutral being preferred in applications where charge interaction between the sample ions and the polymer is sought to be avoided. . . . [¶] Within these parameters, the particular type of polymer may vary widely. . . . [¶] Specific examples of water-soluble cellulose derivatives useful in this invention are . . . [1] methyl cellulose, hydroxypropyl methyl cellulose, [2] hydroxyethyl methyl cellulose, [3] hydroxybutyl methyl cellulose, and [4] hydroxyethyl ethyl cellulose. . . . Methyl cellulose is particularly preferred. . . . With this in mind, and depending on the size of the sample ions sought to be separated, the cellulose derivative may vary widely in terms of this viscosity characterization.[76]

When the PTO concluded that Bio-Rad was not entitled to patent coverage for a claim to "a substantially linear [unspecified] polymer" because an article in the prior art entitled "Electrophoresis in Uncrosslinked ***Polyacrylamide***: Molecular Sieving and Its Potential Applications," Bio-Rad did not respond, in words or substance, that polyacrylamide was outside the scope of "a substantially linear [unspecified] polymer." To the contrary, Bio-Rad responded by narrowing the scope of the patent coverage that it requested. Hence Bio-Rad behaved as if it had claimed polyacrylamide (and thus necessarily described it) but needed to, and did, disclaim such coverage in order to avoid prior art.

As the Federal Circuit explained in *Johnson & Johnston*, "a patentee cannot narrowly claim an invention to avoid prosecution scrutiny by the PTO, and then, after patent issuance, use the doctrine of equivalents to establish infringement because the specification discloses equivalents."[77] *Johnston & Johnston* and its progeny prohibit the extension of Claim 16 to reach polyacrylamide.

There are strong policy reasons for the dedication-disclosure rule, and those policy reasons also prohibit the result sought by the patentee here. Most fundamentally, the dedication-disclosure rule ensures that patents are not given broader coverage than was actually allowed by the PTO: "[b]y enforcing [that] rule, the courts avoid the problem of extending the coverage of an exclusive right to encompass more than that properly examined by the PTO."[78] As explained

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[76] Garber Decl., Exh. 1 at ABBR 065934, 065936 ['174 Application, page 2, lines 11-15 and 25-30, and page 4, lines 13-14, 20-26, 29, and 32-35].

[77] *Johnston & Johnston*, 285 F.3d at 1054.

[78] *Johnston & Johnston*, 285 F.3d at 1055.

above, the only fair reading of the prosecution history in this case is that the PTO did not consider polyacrylamide to be within the scope of Claim 16's coverage for "a substantially linear polymer selected from the group consisting of" the Markush group. In addition, "[t]he patentee, as the author of the claim language, may be expected to draft claims encompassing readily known equivalents."[79] If, as Bio-Rad now claims, polyacrylamide is an equivalent of the Markush group in Claim 16, it was surely within Applicants' power to try to claim it: after all, the file history's prior art references all concern the use of polyacrylamide in molecular sieving.

Moreover, the dedication-disclosure rule serves the public notice function that patents provide, because "[w]ere the patentee allowed to reclaim some specifically-disclosed-but-unclaimed matter under the doctrine of equivalents, the public would have no way of knowing which disclosed matter infringed and which did not."[80] Here the file history shows that the PTO did not consider polyacrylamide to be within the patentable scope of a claim directed to "a substantially linear polymer," and it would turn the public notice function on its head now to conclude that polyacrylamide is, after all, within that scope.

Finally, not to have the dedication-disclosure rule "would merely encourage a patent applicant to present a broad disclosure in the specification of the application and file narrow claims, avoiding examination of broader claims that the applicant could have filed consistent with the specification.'"[81] Which is precisely what the patentee here seeks to achieve: avoid examination of the broader claim – a claim in which polyacrylamide is within the scope of "a substantially linear polymer selected from the group consisting of" the Markush group.

And in the context of this case, there is a much stronger reason for this rule. "Every day that passes after the issue of the patent adds to the strength of [the public's right to use unclaimed matter], and increases the barrier against subsequent expansion of the claim by reissue under a pretense of inadvertence and mistake."[82] The patent-in-suit issued some ***twelve years***

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[79] *Festo*, 535 U.S. at 740-1; *see also PSC Computer Products*, 355 F.3d at 1360-61.

[80] *PSC Computer Products*, 355 F.3d at 1360.

[81] *Johnston & Johnston*, 285 F.3d at 1054-55.

[82] *PSC Computer Products*, 355 F.3d at 1361 (citation omitted; brackets in original).

before Bio-Rad brought this suit. Insofar as Bio-Rad has disclosed in discovery, Bio-Rad has ***never*** asserted against any company at any time in those twelve years that polyacrylamide is within Claim 16's scope. It is far too late in the day for Bio-Rad now to seek the expansion of the claim that it seeks from this Court.

VI. Conclusion.

Bio-Rad has the burden on this motion. It must show that, despite the file history created by those who appeared of record in the prosecution of the patent (its General Counsel, its outside patent counsel, and its inventors), polyacrylamide is within the reach of Claim 16's "substantially linear polymer selected from the group consisting of" limitation. But the file history points, and points hard, to the opposite conclusion. The PTO concluded that a claim directed to a "substantially linear polymer" did not include polyacrylamide – and ***could not*** include polyacrylamide, because the prior art rendered such a claim unpatentable. When the PTO allowed issued Claim 16, it took extra care to emphasize that it was doing so because of the Markush group – emphasis that makes sense only in light of the prior rejection of the "substantially linear polymer" limitation. As this Court's decision in *Glaxo* confirms, Bio-Rad's choice to narrow the coverage it sought does not allow it, now and some twelve years later, to recapture what it surrendered. Finally, to the extent that Bio-Rad now takes the position that the specification discloses the use of polyacrylamide, *Johnson & Johnston* and its progeny prohibit Bio-Rad from recapturing what it dedicated to the public.

For all of these reasons, Applera respectfully asks that the Court grant summary adjudication that Claim 16 of the patent-in-suit does not extend, for purposes of the doctrine of equivalents, to polyacrylamide. Applera has submitted a proposed Order herewith, and asks that the Court issue it.

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Respectfully submitted,
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