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Subject: U.S. TRADEMARK APPLICATION NO. 85645727 - ZYMO PHARMA - 1311US - Request for
Reconsideration Denied - Return to TTAB - Message 1 of 3

Attachment Information:

Count: 13

Files: 8-1-2014 10-01-31 AM.jpg, TP2-1.jpg, TP2-2.jpg, TP3.jpg, TP4.jpg, TP5-1.jpg, TP5-2.jpg, TP6-1.jpg,
TP6-2.jpg, TP7-1.jpg, TP7-2.jpg, TP8.jpg, 85645727.doc

**UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)
OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION**

U.S. APPLICATION SERIAL NO. 85645727

MARK: ZYMO PHARMA



CORRESPONDENT ADDRESS:

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ZYMO RESEARCH CORP

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GENERAL TRADEMARK INFORMATION:

<http://www.uspto.gov/trademarks/index.jsp>

APPLICANT: Zymo Research Corp.

CORRESPONDENT'S REFERENCE/DOCKET NO:

1311US

CORRESPONDENT E-MAIL ADDRESS:

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REQUEST FOR RECONSIDERATION DENIED

ISSUE/MAILING DATE: 8/1/2014

The trademark examining attorney has carefully reviewed applicant's request for reconsideration and is denying the request for the reasons stated below. See 37 C.F.R. §2.64(b); TMEP §§715.03(a)(2)(B), (a)(2)(E), 715.04(a). The requirement(s) and/or refusal(s) made final in the Office action dated January 9, 2014, are maintained and continue to be final. See TMEP §§715.03(a)(2)(B), (a)(2)(E), 715.04(a).

In the present case, applicant's request has not resolved all the outstanding issue(s), nor does it raise a new issue or provide any new or compelling evidence with regard to the outstanding issue(s) in the final Office action. In addition, applicant's analysis and arguments are not persuasive nor do they shed new light on the issues. Accordingly, the request is denied.

Applicant argues that the consumers of the goods and services are highly sophisticated. However, the fact that purchasers are sophisticated or knowledgeable in a particular field does not necessarily mean that they are sophisticated or knowledgeable in the field of trademarks or immune from source confusion. TMEP §1207.01(d)(vii); see, e.g., *Stone Lion Capital Partners, LP v. Lion Capital LLP*, ___ F.3d. ___, ___, 110 USPQ2d 1157, 1163 (Fed. Cir. 2014); *Top Tobacco LP v. N. Atl. Operating Co.*, 101 USPQ2d 1163, 1170 (TTAB 2011). In other words, just because someone has a Masters or Doctorate degree does not mean that they are immune from being trademark confusion.

Additionally, when the relevant consumer includes both professionals and the general public, the standard of care for purchasing the goods is that of the least sophisticated potential purchaser. *Stone Lion Capital Partners, LP v. Lion Capital LLP*, ___ F.3d. ___, ___, 110 USPQ2d 1157, 1163 (Fed. Cir. 2014) (quoting *Gen. Mills, Inc. v. Fage Dairy Processing Indus. SA*, 100 USPQ2d 1584, 1600 (TTAB 2011)); *Alfacell Corp. v. Anticancer, Inc.*, 71 USPQ2d 1301, 1306 (TTAB 2004). Thus, members of the general public who may read about or be familiar with the registrant's goods and services may easily be confused into thinking that the goods and services are related as the same sources that produce pharmaceuticals very frequently also provide related scientific and research services. See attached Internet evidence showing other third parties who provide pharmaceuticals and related scientific and research services.

The trademark examining attorney has attached evidence from the USPTO's X-Search database consisting of a number of third-party marks registered for use in connection with the same or similar goods and/or services as those of both applicant and registrant in this case. This evidence shows that the goods and/or services listed therein, namely pharmaceuticals and related scientific, research or medical services, are of a kind that may emanate from a single source under a single mark. See *In re Anderson*, 101 USPQ2d 1912, 1919 (TTAB 2012); *In re Albert Trostel & Sons Co.*, 29 USPQ2d 1783, 1785-

86 (TTAB 1993); *In re Mucky Duck Mustard Co.*, 6 USPQ2d 1467, 1470 n.6 (TTAB 1988); TMEP §1207.01(d)(iii).

The filing of a request for reconsideration does not extend the time for filing a proper response to a final Office action or an appeal with the Trademark Trial and Appeal Board (Board), which runs from the date the final Office action was issued/mailed. *See* 37 C.F.R. §2.64(b); TMEP §715.03, (a)(2)(B), (a)(2)(E), (c).

If time remains in the six-month response period to the final Office action, applicant has the remainder of the response period to comply with and/or overcome any outstanding final requirement(s) and/or refusal(s) and/or to file an appeal with the Board. TMEP §715.03(a)(2)(B), (c). However, if applicant has already filed a timely notice of appeal with the Board, the Board will be notified to resume the appeal. *See* TMEP §715.04(a).

/Marcie R. Frum Milone/

Trademark Examining Attorney

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(email for informal communications only)



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Sutro Biopharma, Inc. has the only scalable biochemical protein synthesis platform.

Sutro Biopharma, located in South San Francisco, is developing a new generation of multi-functional antibody drug conjugate combination therapeutics and bifunctional antibody-based therapeutics for targeted cancer therapies. These therapeutics will significantly extend the clinical impact of current oncology therapeutic approaches, and are beyond what can be envisioned with current (cell-based) expression technologies. Sutro's biochemical synthesis technology, which underpins these therapeutics, allows the rapid and systematic exploration of many protein drug variants to research, discover and develop drug candidates. Our market cycle for hundreds of protein variants, including those incorporating non-natural amino acids, takes approximately ten weeks. Once identified, production of these protein drug candidates can be rapidly and predictably manufactured at commercial scales. In addition to developing its own drug pipeline, Sutro Biopharma is collaborating with select pharmaceutical and biotech companies in the research, discovery, development, and manufacture of novel protein therapeutics.

NEWS

3/24/2014 - Sutro Biopharma to Present at 21st Annual Future Leaders in the Biotech Industry Conference
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1/7/2014 - Sutro Biopharma to Collaborate with Memorial Sloan-Kettering Cancer Center to Produce Bisppecific Antibodies for the Treatment of Neuroblastoma
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12/11/2013 - Sutro Biopharma Closes \$26 Million Financing, Expands Development of Novel Immuno-Oncology Products
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TECHNOLOGY



Sutro Biopharma has the capability to apply medicinal chemistry principles and approaches to the methodical design and development of novel protein therapeutics.

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Sutro Biopharma's Scalable Biochemical Protein Synthesis Platform

Designing and Manufacturing a New Generation of Biotherapeutics

Conventional methods for expressing proteins utilize cell lines originating from bacteria, yeast, insects, plants, or mammals. Because these methods require intact, functioning cells, the biochemical and biophysical parameters under which proteins are produced using these methods are inherently limited, often failing to produce many proteins and biologics. Using cell-free expression systems to produce protein variants is also a cumbersome way to enable selection of the best therapeutic candidates.

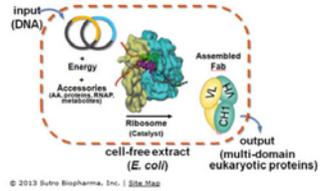
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Sutro Biopharma's technology platform is made possible by the separation, into an extract, of the cellular components required to produce proteins from the process of protein generation itself. The extract includes all the necessary biochemical components for energy production, transcription and translation and can be used to support cell-free biochemical protein synthesis by the addition of the specific DNA sequence for the desired protein. The process produces single proteins at g/L yields in 8-10 hours at any scale.

A wide variety of protein products have been produced using Sutro's platform. These range from small peptides to multimers complex mammalian proteins such as monoclonal antibodies.

Uniquely, production of proteins in our cell free system can be scaled rapidly from sub-1mL scale to manufacturing scale; the platform is effectively a liquid handling solution to protein synthesis. The advantages of such a flexible platform over conventional cell-based expression systems are enormous:

- Proteins can be rapidly engineered and optimized by producing many variants in parallel in 96-well plates from DNA libraries
- Producing large quantities of a particular protein can be accomplished days from first DNA synthesis, allowing large animal pharmacology and safety assessments to be performed during the design and discovery phase of development
- Linearly scalable candidate production is assured with predictable performance from batch to batch production
- A single master cell bank used for extract generation is capable of providing the manufacturing format for many different proteins, leading to accelerated development times
- Extract stockpiling provides a means for flexible and fast deployment of surge protein production in the event of unexpected demand for product
- The synthesis of many novel therapeutic proteins and families of proteins that are challenging by cell-based expression systems is now feasible, for example:
 - Difficult-to-fold proteins
 - Cytotoxic molecules
 - Non-natural amino-acid containing proteins





Antibody-Drug Conjugate:

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Sutro's cell-free expression technology provides a rapid and powerful platform for the discovery and development of next generation antibody-drug conjugates (ADCs). Current ADCs in development have immense promise, but they are limited by the fact that they are structurally heterogeneous populations in which the position and number of conjugated linkers and warheads vary significantly. Such heterogeneity prevents the definition of structure-activity relationships (SARs). Consequently, using traditional ADC technologies prevents researchers from discovering and developing candidates with optimal therapeutic indices and can result in products with unpredictable and sub-optimal pharmacokinetic properties, stability and efficacy.

Sutro can incorporate non-natural amino acids (nNAAs) at any site in an antibody structure, thereby allowing for single-species ADCs with site-specific conjugation of linker and warhead. Of vital importance in this process is Sutro's ability to perform rapid and parallel synthesis of numerous variants taking advantage of a substantial number of different sites, enabling analyses early in discovery to define SARs and locate the best positions for nNAA incorporation based on:

- Protein expression levels
- Efficiency of incorporation of the nNAA
- Linker / warhead conjugation efficiency
- Target binding efficiency
- Cell killing efficiency
- Internalization characteristics

It has been well documented that the cell-killing effects of ADCs are highly dependent on the location of the warhead as well as the drug to antibody ratio. Sutro can control both of these variables with exquisite specificity, resulting in truly optimized product candidates.

Sutro has also addressed the challenge of manufacturing nNAAs-containing ADCs by engineering additional versions of cell-free extract that achieve high rates of incorporation of nNAAs and by developing chemistries that allow for efficient conjugation of linkers and warheads to antibodies.

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Sutro Biopharma has the capability to apply medicinal chemistry principles and approaches to the methodical design and development of novel protein therapeutics.



Bispecific Antibodies



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Sutro's cell-free expression technology provides a rapid and powerful platform for the discovery and development of antibodies that bind simultaneously to two separate antigens (bispecific antibodies). Bispecific antibodies can be designed to achieve different purposes:

- To bring an antigen-expressing cell in close proximity to a killing cell, e.g. bispecifics that comprise a tumor cell antigen-binding site and a T-cell or NK cell antigen-binding domain
- To increase the apparent affinity of binding to an antigen, using avidity, e.g. by binding two separate proteins or two epitopes of a single protein on a cell's surface
- To increase the relative selectivity of binding of an antibody to a particular antigen on disease tissue over normal tissue by using a similar avidity approach, e.g. two antigens expressed on the same diseased cell
- To increase the internalization rates of particular antigens on a cell's surface by cross-linking two cell surface proteins or by binding to two different epitopes on a given antigen. This emerging approach could also be used to more efficiently deliver warhead payloads to tumor cells using a bispecific antibody-drug conjugate

While many different bispecific antibody formats have been exemplified using cell-based expression systems, and some have been successful enough to show promise as new classes of therapeutics, the precise geometry and spatial orientation of binding domains, linkers and functional domains can be a challenge to optimize.

Additionally, the use of cell-based systems has revealed immense difficulties in their expression efficiency, particular at larger scale, often resulting in poorly folded and aggregated material. Consequently, using traditional cell-based technologies prevents researchers from discovering and developing bispecific candidates with optimal therapeutic indices and can result in products with unpredictable pharmacokinetic properties, stability and efficacy.

Sutro's technology has the ability to perform rapid expression and characterization of many variants early in discovery to define structure-activity relationships and thereby optimize:

- Binding efficiency to each target
- Spatial orientation and linker design
- Target killing efficiency
- Protein expression and folding efficiency
- Stability

Sutro can optimize rapidly for all of these variables with exquisite specificity, resulting in optimized product candidates.

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Sutro Biopharma has the capability to apply medicinal chemistry principles and approaches to the methodical design and development of novel protein therapeutics.



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Sutro Biopharma to Collaborate With Memorial Sloan-Kettering Cancer Center to Produce Bispecific Antibodies for the Treatment of Neuroblastoma

SAN FRANCISCO, Jan. 07, 2014 - Sutro Biopharma, a biopharmaceutical company developing a new generation of protein therapeutics, including next-generation antibody drug conjugates and bispecific antibodies, today announced that it has entered into a collaboration agreement with Memorial Sloan-Kettering Cancer Center to use Sutro's proprietary cell-free protein synthesis technology to produce bispecific antibodies that were discovered by Memorial Sloan-Kettering for the treatment of neuroblastoma in children.

"Neuroblastoma is the most common extra-cranial solid tumor in children, and long-term survival for children with advanced disease diagnosed after 18 months of age is unsatisfactory despite aggressive chemotherapy," said Trevor Hallam, Ph.D., chief scientific officer of Sutro. "Sutro's technology allows the generation, and importantly, the rapid screening of a large number of variations of bispecific antibodies. This will enable us to take bispecific antibodies with the desired characteristics faster into the clinic and potentially provide pediatric neuroblastoma patients with a much needed effective treatment option to combat this disease."

Under the collaborative agreement Sutro will use its cell free protein synthesis technology to produce four different bispecific antibodies discovered by Memorial Sloan-Kettering. These antibodies will be directed against CD3 on T-cells and, as the second target, against the ganglioside GD2, which is expressed on the surface of human neuroblastoma cells, as well as in melanoma and osteosarcoma. Hai-Kong V. Cheung, M.D., Ph.D., head of Memorial Sloan-Kettering's Neuroblastoma program, will use preclinical models to test the bispecific antibodies manufactured by Sutro.

Dr. Cheung added, "We and others have previously shown that the use of an anti-

Dr. Ueung azoo. "We and others have previously shown that the use of an anti-CD3 and anti-CD2 bispecific antibody has a strong scientific rationale, and anti-CD2 monoclonal antibodies targeting the ganglioside GD2 have demonstrated efficacy in clinical trials in pediatric neuroblastoma. We hope that the use of Sutro's technology will facilitate a more rapid, high-throughput optimization of these bispecific antibodies in the future, and allow us to investigate novel variants of these molecules quickly before bringing the winner to the clinic."

About Sutro Biopharma

Sutro Biopharma, located in South San Francisco, is developing a new generation of antibody drug conjugate therapeutics and bifunctional antibody-based therapeutics for targeted cancer therapies. These therapeutics will significantly extend the clinical impact of current oncology therapeutic approaches and are beyond what can be envisioned with current, cell-based expression technologies. Sutro's biochemical synthesis technology, which underpins these therapeutics, allows the rapid and systematic exploration of many protein drug variants to identify drug candidates. Those the potential candidates are identified, production can be rapidly and powerfully scaled up to commercial levels. Sutro has established a Good Manufacturing Practice (cGMP) facility for the production of clinical supplies of materials using its biochemical protein synthesis platform. Sutro has formed multiple partnerships with biopharma companies utilizing its technology, including a collaboration with Celgene Corporation to design and develop novel antibody drug conjugates and bispecific antibodies as well as to manufacture a proprietary Celgene antibody.

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Sutro Biopharma

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Sutro Biopharma is a private biopharmaceutical company headquartered in South San Francisco that develops antibody-based therapeutics, including antibody-drug conjugates and bispecific antibodies for cancer therapies and other diseases. Founded in 2003 under the name Fundamental Applied Biology, the company became Sutro Biopharma in 2009. The current CEO, William Newell, joined Sutro in January 2009. Newell has over 15 years of senior management experience in the biotechnology industry, and has worked for companies such as Aerovance, QLT, Inc., and Ayxs Pharmaceuticals, Inc. Sutro's CFO, Edward Albini, previously worked at Iteco Biopharmaceuticals, Novacea, and Lynx Therapeutics. Jeremy Bender, CBO, has worked at Allos Therapeutics and the Boston Consulting Group in the past. The CSO, Trevor Hallam, formerly worked at Palatin Technologies, AstraZeneca, Glaxo Group Research, and Roche Research Centre. The company received \$26M in Series D funding in December 2013.^[1] The company's investors include Alta Partners, Skyline Ventures, SV Life Sciences, Lilly Ventures, Amgen Ventures and Celgene.

Sutro's Xpress CF™ and Xpress CF+™ technologies are based on Stanford Professor James R. Swartz's patented Open Cell-Free Synthesis (OCFS) technology.^[2] The platform allows the parallel expression of hundreds of protein variants, including those incorporating non-natural amino acids, in as little as two weeks.^[3] The company has established a Good Manufacturing Practice (cGMP) facility for the production of clinical supplies of materials using its biochemical protein synthesis platform.^[4]

Sutro Biopharma



Type	Private
Industry	Biotechnology
Headquarters	South San Francisco
Website	sutrobio.com@

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In 2012 Sutro formed a collaboration with Celgene worth over \$500 million if all programs are successful to design and develop ADCs and bispecific antibodies for two undisclosed targets as well as manufacture a proprietary Celgene antibody using the company's technology platform.^[2] The company has also formed a collaboration with Sanofi Pasteur for the development of undisclosed vaccine candidates.^[3] and a multi-year collaboration with Pfizer for the research, development and commercialization of peptide-based therapeutics.^[4] In 2014 Sutro entered into a collaboration with Memorial Sloan-Kettering Cancer Center to produce four different bispecific antibodies that are discovered by MSKCC for the treatment of neuroblastoma in children using Sutro's technology. The bispecific monoclonal antibodies will be directed against CD3 on T-cells and, as the second target, against the ganglioside GD2, which is expressed on the surface of human neuroblastoma cells, as well as in melanoma and osteosarcoma.^[5] In May 2014, Sutro signed a License and Agreement with EnWave Corporation. The company licensed EnWave's Radiant Energy Vacuum technology to dehydrate cell-free extracts, which will facilitate both storage and shipping of extract for use in development and commercialization of Sutro products.^[6]

References

- ^[1] http://www.fiercebiotech.com/story/big-biopharmas-help-flush-20m-round-sutros-antibody-rd-work/2013-12-11/
- ^[2] "Microscale to Manufacturing Scale-up of Cell-Free Cytokine Production—A New Approach for Shortening Protein Production Development Timelines."
- ^[3] "Microscale to Manufacturing Scale-up of Cell-Free Cytokine Production—A New Approach for Shortening Protein Production Development Timelines."
- ^[4] "Sutro-Celgene partnership a strategic fit."
- ^[5] "Celgene wraps \$500M deal to partner with Sutro on next-gen ADCs."
- ^[6] "Sanofi Pasteur, Sutro team up on vaccine candidates."
- ^[7] "Sutro Strikes Deal With Pfizer."
- ^[8] "Memorial Sloan-Kettering to Use Sutro Technology for Neuroblastoma Research."
- ^[9] http://www.4-traders.com/ENWAVE-CORP-12455067/news/EnWave-Inks-Commercial-License-Deal-with-Sutro-Biopharma-for-powderREV-Technology-16528702/

Categories: Pharmaceutical companies of the United States | Biotechnology companies of the United States

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Transforming the Lives of Patients

WITH SEVERE GENETIC AND ORPHAN DISEASES

We are developing next generation products based on the transformative potential of gene therapy to treat patients with severe genetic and orphan diseases. We have two clinical stage products in development for childhood cerebral adrenoleukodystrophy and beta-thalassemia/sickle cell disease, a preclinical oncology program in partnership with Celgene, a world-class team and a broadly applicable gene therapy platform [READ MORE >>](#)



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- Scientist, Drug Product Process Development

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Our Gene Therapy Platform

Gene Therapy

Gene therapy has been an evolving field for the last 20 years that has been characterized by great hope and potential. Gene therapy represents a unique opportunity to change the way patients with severe genetic and orphan diseases are treated by addressing the underlying cause of their disease, rather than offering solutions that focus only on their symptoms. By correcting the underlying genetic defect, we believe gene therapy can provide transformative disease modifying effects—potentially with life-long clinical benefits based on a single therapeutic administration.

Clinical proof of concept has been reported in peer-reviewed and industry journals across numerous important diseases, including:

- Beta-thalassemia
- Adrenoleukodystrophy
- Retinal disease
- Chronic lymphocytic leukemia
- Acute lymphocytic leukemia
- Hemophilia B

A growing body of gene therapy-based clinical data, the establishment of regulatory guidelines to govern the development and approval of gene therapy products and increased investment from the biopharmaceutical industry suggest that the time is now for gene therapy to emerge as an important new therapeutic modality for patients with significant unmet medical need. Encouraged by these developments, we believe we are particularly well-positioned to drive the continued advancement of gene therapy technology in treating severe genetic and orphan diseases.



Nick Leschly, chief scientist
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bluebird bio CEO Nick Leschly presents at TEDx Boston
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