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# A Labeling Methodology for Identifying Business Product Innovation in Pharmaceutical Articles

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#### **Abstract**

In collaboration with the National Center for Science and Engineering Statistics (NCSES), this effort stems from a larger effort aimed at identifying business product innovations across various economic sectors. Specifically, the purpose of this effort was to create a human-labeled data set for identifying business and product innovation using articles covering the pharmaceutical sector. The human-labeled data is intended to help train supervised machine learning algorithms like BERT (Bidirectional Encoder Representations from Transformers) to enable greater accuracy for the automation of detecting business product innovations.

# A Labeling Methodology for Identifying Business Product Innovation in Pharmaceutical Articles

Nathaniel J. Ratcliff and Neil Kattampallil

#### INTRODUCTION:

Innovation is traditionally measured through surveys of selected companies such as the National Science Foundation's Annual Business Survey (ABS), and the previously conducted Business R&D and Innovation Survey (NSF, 2020). Our project focuses on business product innovation, defined in OECD's Oslo Manual (2018) as "a new or improved product or process (or combination thereof) that differs significantly from the unit's previous products or processes and that has been made available to potential users (product) or brought into use by the unit (process)."

The primary goal of this project is to use news articles and natural language processing (NLP) methods while leveraging Google's BERT (Devlin et al., 2018) to measure business innovation, particularly within the pharmaceutical industry due to its high rate of innovation. To achieve this goal, three main tasks are needed including: (a) text classification to identify news articles that mention innovation; (b) named-entity recognition (NER); and (c) question answering (QA) to extract company names from these articles to identify the innovators.

The short guide reported below outlines the basic methodology used by our project to identify innovation in articles by human labelers. The purpose of this effort was to create a human-labeled data set for identifying business and product innovation using articles covering the pharmaceutical sector. The human-labeled data set will be used to further train machine learning algorithms for better accuracy and optimization.

#### **DATA SOURCE:**

The primary data source was 300 public online articles covering the pharmaceutical sector that had previously been identified as containing information related to business/product innovation by a previously-trained version of the transformer-based machine learning technique for natural language processing known as BERT (Bidirectional Encoder Representations from Transformers).

#### WORKING DEFINITION OF BUSINESS/PRODUCT INNOVATION:

Definition of innovation: "An innovation is a new or improved product or process (or combination thereof) that differs significantly from the unit's previous products or processes and that has been made available to potential users (product) or brought into use by the unit (process)" (Oslo Manual, 2018, p. 20).

Definition of product innovation: "A product innovation is a new or improved good or service that differs significantly from the firm's previous goods or services and that has been introduced on the market" (Oslo Manual, 2018, p. 21).

Basic criteria for determining business product innovation:

- a) Must be a new product for the company;
- b) Product is currently available on the market;
- c) Product is new and available to the U.S. market.

#### INNOVATION LABELING WORKSHEET:

The Excel worksheet embedded below documents the labeling of 300 pharmaceutical articles.



BINN\_Labeling\_Work sheet.xlsx

#### **COLUMNS CONTINED WITHIN WORKSHEET:**

Headings in blue represent the various columns contained within the Excel worksheet embedded above.

an – (alphanumeric): Article identifier code.

**full\_text** – (text): Full text of article.

**publisher** name – (text): Name of publisher for the article.

**BERT** company – (text): BERT-identified name of company from the article.

**BERT** product – (text): BERT-identified name of the product from the article.

Is this article about a new medical innovation available in the market? – (dichotomous): 'Y' = Yes, article was about a new innovation; 'N' = No, article was not about a new innovation.

If not about a launch, is this article about FDA submission approval review process of a drug or medical device? – (dichotomous): 'Y' = Yes, article was about an FDA approval of a product (or some point in the approval process); 'N' = No, article not about FDA approval.

**Is this article an aggregate of several news stories?** – (dichotomous): 'Y' = Yes, article contained multiple descriptions of innovative companies and/or products; 'N' = No, article did not contain multiple descriptions of innovative companies and/or products.

What is the innovative companys name? – (text): Identified name of the company by human labeler.

What is the product name? – (text): Identified name of the product by human labeler.

Edge Cases – (text): Comments by labeler to identify edge cases.

**company\_match** – (categorical): 'Y' = Yes, match between BERT-identified company and human labeler identified company; 'N' = No match; 'NA' = not applicable due to missing information or no innovation.

**product\_match** – (categorical): 'Y' = Yes, match between BERT-identified product and human labeler identified product; 'N' = No match; 'NA' = not applicable due to missing information or no innovation.

#### **CASE EXAMPLES:**

In this section, case examples are presented with the full article text for the various labeling of business/product innovation as well as example edge cases that were observed.

The following case examples are presented:

- Business/Product Innovation
- Business/Product Innovation with FDA Approval
- FDA Approval (no clear indication of market availability)
- FDA Clinical Trial
- Research & Development
- Patent Application or Approval
- Aggregate or Summary of Multiple Companies

The highlighting contained within the original text of pharmaceutical articles represents different aspects of the articles which was consider for determining the company name (yellow), product name (green), whether the article contained text describing an FDA approval process (turquoise), whether the article contained text referring to research & development (purple), and/or information pertaining to the application or issuance of a patent (gray).

Company Name Highlight Color

Product Name Highlight Color

FDA Process Highlight Color

Research Highlight Color

Patent Highlight Color

#### Business/Product Innovation

Clear cut cases of an article describing an innovative firm and product.

#### Case # ID: BWR0000020170308ed38000ed

Article: At INTERPHEX NYC, Adents and Microsoft to Jointly Present Adents in Volume Cloud Serialization and Traceability SolutionSpecial conference with experts and executives of Microsoft Team scheduled for Wednesday, March 22 at 3:00pm

EAST WINDSOR, N.J.--(BUSINESS WIRE)--March 08, 2017-- Adents, a leading provider of versatile and easily deployable serialization and track-and-trace software solutions, in collaboration with Microsoft, will arrounce to the U.S. market Adents Product a new Cloud scription and mecability solution. Adents Product enters the market as the only Level 4 traceability solution that can centrally manage regulatory requirements mandated in the pharmaceutical industry, as well as allow pharmaceutical companies and CMOs to take advantage of the massive amounts of data generated during the serialization and track & trace process.

This Smart News Release features multimedia. View the full release here: http://www.businesswire.com/news/home/20170308006238/en/

In addition to allowing for compliance with incrementally complex regulations, recently opens up new horizons beyond regulatory compliance in terms of data analysis (including Microsoft Power BI), machine learning tools or additionnal capabilities through third party solutions such as OEE Tracker and Supplier portal developed by Supply Chain Wizard.

The jointly developed solution will be showcased at INTERPHEX NYC, March 21-23, during a special conference with experts and executives of the Microsoft Team scheduled for Wednesday, March 22 at 3:00pm.

Adents is also utilizing its presence at INTERPHEX to showcase Adents Seriza, a fully configurable, standardized serialization software solution. A unique centralized configuration tool at the site level, Adents Seriza offers unprecedented levels of flexibility and scalability for pharmaceutical manufacturers and packagers; two of its additional benefits, speed to deployment and ease of integration, are key factors considering the looming November 27, 2017 serialization regulatory deadline in the United States. By that date, per 2013's Drug Supply Chain Security Act, pharmaceutical manufacturers are required to print a unique product identification code on all Rx units of sale and homogenous cases distributed domestically.

At INTERPHEX, Adents Foodia and Adents Seriza will be demonstrated live throughout the show at Adents Booth #3773. Adents Seriza will be shown on two separate machines, including an LSI Model 1400 Print & Apply Case Labeler as well as modular from prominent labelling equipment manufacturer HERMA, reinforcing Adents position as a turnkey solution combining premium-performance software, a large choice of hardware and access to a global network of certified solution partners.

Innovative Company: Adents Innovative Product: Adents Prodigi

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#### Case # ID: BIOELSE020170412ed4600016

Article: Jaguar and Napo Pharmaceuticals Inc issue commercial updates. Jaguar Animal Health Inc, an animal health company focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals, foals, and high value horses, and Napo Pharmaceuticals Inc, a human health company developing and commercializing novel gastrointestinal prescription products from plants used traditionally in rainforest areas, announced on 6 Apr 2017 the following commercial updates. As announced 28 Feb 2017, Napo has signed an agreement with Alamo Pharma Services Inc for the establishment and management of a national sales team for wives. Wivest townsheld to support the company by the US FDA for the symptomatic relief of noninfectious diarrhoea in adults with HIV/AIDS on antiretroviral therapy. Alamo is providing a team of shared sales representatives to supplement the dedicated Napo representatives to promote and sample wivest in the symptomic trees throughout the company for the dedicated Napo representatives to promote and sample wivest in the symptomic trees throughout the company is the symptomic trees throughout the company for the sales and forecast that the symptomic trees throughout the company for the sales for the indication of CID in dogs to be the company's first drug product candidate available commercially. Pending FDA approval of Canalevia for CID, Jaguar expects Canalevia for the indication of CID in dogs to be the company's first drug product candidate available commercially. Pending FDA approval of Canalevia for CID, Jaguar expects to conduct the commercial launch of Canalevia for this indication in 2018. Jaguar's lead drug product candidate, under investigation for various types of diarrhoea in dogs, Canalevia is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the Croton lechleri tree, which is sustainably harvested. Original Source: BioSpace.com, 2017. From website: http://www.biospace.com.

Innovative Company: Jaguar Animal Health Inc; Napo Pharmaceuticals Inc Innovative Product: Mytesi

#### Business/Product Innovation with FDA Approval

Cases in which business/product innovation is described alongside FDA approvals.

#### Case # ID: ALGPS00020171202edc2000dx

Article: Dr.Reddy's gets USFDA nod for mineral creamgh its wholly owned subsidiary Promius Pharm, LLC, has announced its fifth consecutive, first cycle NDA approval for Proprietary Product Group.

of age or older. Psoriasis is a serious medical condition affecting ~7.5 million people in the United States. Imports, formally referred to as DFD-06, had been recently licensed to Encore Dermatology Inc. for the commercialization of the production lie production in United States.

The most common side effects of the cream includes discoloration of the treated site.

Dr Reddys Laboratories is Indias second largest pharmaceutical company in terms of revenue. The company started its business as a bulk-drugs player and then rapidly moved up the value chain to become a major genericformulations company with global operations.

The companys product portfolio spans a number of therapeutic categories, among them gastric ulcer medicines, antibiotics, pain relievers, antidepressants and cardiovascular drugs. DRL markets its products in more than 100 countries; production than 100 countries; production than 100 countries; product in the LEX Europe, incline and Russia.

Innovative Company: Dr. Reddy's Laboratories

Innovative Product: Imopyz (Clobetasol Propionate) cream

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#### Case # ID: BWR0000020170727ed7r0006c

Article: Cogstate Receives Positive FDA Notification Regarding Medical Device Regulatory SubmissionCompany to Launch COGNIG AND Digital Cognitive Testing Tool in U.S. Healthcare Market

BOSTON--(BUSINESS WIRE)--July 27, 2017-- The cognitive science company, Cogstate today announced that its healthcare division has received notification from the U.S. Food and Drug Administration (FDA) that the Company's 510(k) submission (K171658) for the COGNIGNAW (IM) cognitive assessment system has been reviewed by the Center for Devices and Radiological Health and found to meet the requirements of regulations 21 CFR 882.1470; Class II Exempt Medical Device. This political particular allows the company to market the neither device for company to market the neither device.

The CONTORAMITY system is a digital cognitive assessment tool with self-administered assessment that can be completed both in-clinic and at-home. It is for prescription use, and is intended to aid healthcare professionals with an objective measurement of cognition for use in individuals aged 6 - 99 years old. The system can be used to assess cognition on a single occasion or cognitive change over periodic assessments. Performance on the system is unaffected by language, education, cultural background, or practice.

"After more than fifteen years of intense efforts in supporting academic research and pharmaceutical clinical trials around the world, Cogstate is excited to enter the U.S. market for cognitive assessment on the front lines of clinical practice," commented Frank Cheng, President of Cogstate Healthcare. "We look forward to bringing the proven and widely-published technology into the healthcare ecosystem to benefit an exponentially larger pool of patients."

Factors that may affect an individual's cognition include the presence of mild cognitive impairment (MCI), Alzheimer's disease, concussion, head injury, major depressive disorder, HIV related dementia, schizophrenia, attention deficit hyperactivity disorder (ADHD), multiple sclerosis, Parkinson's disease, the effects of medication or surgery, as well as a variety of psychological states (e.g. stress, fatigue).

Cogstate

**Innovative Company: Cogstate** 

Innovative Product: COGNIGRAM(TM)

#### FDA Approval (no clear indication of market availability for product)

> Cases in which FDA approval is described but not enough information to determine if product made it to a U.S. market to become available.

#### Case # ID: RTNSIN0020171102edb20006m

Article: Zydus' Nesher gets USFDA final approval Nesher Pharmaccuticals, a subsidiary of Zydus Pharmaccuticals USA, has received the final approval from the USFOOd and Drug Administration to market Device and Autobic and Autobic arms Sollies, tablets.

Tablets are available in strengths of 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 20 mg and 30 mg, the company said in a filing to the Bombay Stock Exchange. The drug is used in the treatment of attention deficit hyperactivity disorder and narcolepsy.

The drug will be produced at Nesher's manufacturing facility located at St. Louis, MO, USA.

The group has now more than 165 approvals and has so far filed over 300 ANDAs since the commencement of the filing process in FY 2003-04.

Meanwhile, shares of the company were trading at Rs 507.90 apiece, up 2.05 per cent from the previous close at 13:04 hours on BSE.

**Innovative Company**: Nesher Pharmaceuticals; Zydus Pharmaceuticals USA **Innovative Product**: Dextroamphetamine Sulfate, Amphetamine Sulfate

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#### Case # ID: CLMBSTGM20170223ed2g0000t

Article: FDA Approves Injectable Psoriasis Drug for Tough CasesTHURSDAY, Feb. 16, 2017 (HealthDay News) -- A new drug to treat tough cases of the skir condition psoriasis has won approval from the U.S. Food and Drug Administration.

Valeant Pharmaceuticals' injectable drug with threatments was approved for adults with moderate-to-severe psoriasis that isn't responding to other recommended treatments. However, the drug carries a warning about increased risk for suicidal behavior. Psoriasis is characterized by raised patches of red skin and flaking. The condition usually begins between ages 15 and 35 and is thought to be an autoimmune disorder, meaning the body mistakenly attacks healthy cells.

"Moderate-to-severe plaque psoriasis can cause significant skin irritation and discomfort for patients, and today's approval provides patients with another treatment option for their psoriasis," said the FDA's Dr. Julie Beitz.

Beitz is director of the Office of Drug Evaluation III in the FDA's Center for Drug Evaluation and Research

The drug is intended for patients who are candidates for systemic therapy -- treatment with pills or injectable drugs that travel through the bloodstream -- or phototherapy (ultraviolet light treatment), and have failed to respond or stopped responding to past therapies, the FDA said.

The drug works by inhibiting the inflammatory response that contributes to development of plaque psoriasis, the most common form of the skin disease, the FDA said.

approval was based on three clinical trials that included more than 4,300 patients. Compared to those who took a placebo, more of those participants who took the drug had skin that was clear or almost clear, the agency said.

However, the drug carries a "boxed warning" about the risk of suicidal thoughts and attempts and it's only available through a suicide risk evaluation program, the FDA

Among patients who took the those with a history of suicide attempts or depression had greater risk of suicidal thoughts and attempts compared to others, according to trial results. However, a direct cause-and-effect relationship wasn't established.

"Patients and their health care providers should discuss the benefits and risks of before considering treatment," Beitz said in an agency news release.

Because state affects the immune system, patients also may have a greater risk of getting an infection, or an allergic or autoimmune condition, the FDA said.

The most common side effects reported in the trials included joint and muscle pain, headache, fatigue, nausea or diarrhea, low white blood cell count and fungal infections.

More information

The American Academy of Family Physicians has more on psoriasis.

Innovative Company: Valeant Pharmaceuticals
Innovative Product: Siliq (brodalumab)

#### FDA Clinical Trial

Cases in which an FDA clinical trial is being described at various stages but not reaching FDA approval or availability on the market.

#### Case # ID: CHPR000020170301ed2m0000c

Article: BioVie submits additional information to FDA for BioVie clinical trial in ascites patients. BioVie Inc, a development-stage company focused on the discovery, development, and commercialization of innovative drug therapies for liver disease, announced on 22 Feb 2017 that it has submitted a complete response to the US Food and Drug Administration (FDA) addressing the issues identified in the Investigational New Drug Application (IND) clinical hold letter received by BioVie last month. If notified by the FDA that the trial may proceed, BioVie plans to commence a mid-stage (Phase Ib) clinical trial of BioVie in patients with refractory ascites due to advanced liver cirrhosis. BioVie plans to commence a mid-stage (Phase Ib) clinical trial of BioVie in patients with refractory ascites due to advanced liver cirrhosis. BioVie Inc, 2017. Found on website: http://www.marketwired.com.

Innovative Company: BioVie Inc Innovative Product: BIV201

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#### Case # ID: ATPHAM0020170211ed29000dz

Article: TRACON Pharmaceuticals Announces Top-line Results from NCI-Sponsored Phase 2 Trial of Recurrent GlioblastomaFeb. 9 -- TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration and fibrotic diseases, today reported top-line results from a randomized Phase 2 clinical trial of Recurrent glioblastoma (GBM) funded and conducted by the Clinical Therapy Evaluation Program (CTEP) of the National Cancer Institute (NCI). In the trial, Results combined with Avastin (bevacizumab) was compared to single agent Avastin in a total of 101 patients with recurrent GBM following chemoradiation. The trial was designed to detect a three-month improvement in progression free survival (PFS), the primary endpoint, from the expected value of 3.45 months with single agent Avastin. Top-line data indicate that the combination of Recurrent GBM patients, although the combination was associated with a non-significant increase in overall survival. Detailed data and the associated correlative analyses are expected to be presented at an oncology conference later this year.

"Glioblastoma is a very challenging indication for drug development," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "We are grateful to the National Cancer Institute for sponsoring the trial and to the patients and providers who participated, and look forward to the detailed survival analysis from this trial, as well as data from multiple company-sponsored trials of TRACON in other indications later this year."

Source: TRACON Pharmaceuticals

**Innovative Company: TRACON Pharmaceuticals** 

Innovative Product: TRC105

#### Case # ID: ENPNEW0020171229edct0005p

Article: GW Pharmaceuticals Announces Acceptance of NDA Filing for Equito ox in the treatment of Lennox-Gastaut syndrome and Dravet syndromeRelease date - 28122017

LONDON and CARLSBAD - GW Pharmaceuticals plc (Nasdaq: GWPH) ('GW' or 'the Company'), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing with Priority Review its recently submitted New Drug Application (NDA) for confidence (Cannabacies) of CBD, an investigational treatment for seizures associated with Lennox-Gastaut syndrome (LGS) and Dravet syndrome, two rare and difficult to treat conditions of childhood-onset epilepsy. The PDUFA (Prescription Drug User Fee Act) goal date for completion of the FDA review of the confidence of the product of the

Priority Review status is designated for drugs that may offer major advances in treatment or provide a treatment where no adequate therapies exist. The granting of Priority Review for the application compared to a standard review.

In its acceptance letter, the FDA has stated that it is currently planning to hold an advisory committee meeting to discuss this application.

'We are pleased with the FDA's acceptance of our NDA filing with Priority Review, an action that underscores the unmet need in the LGS and Dravet syndrome populations,' said Justin Gover, GW's Chief Executive Officer. 'We look forward to working with the FDA during the review process to support the case for approval of priorities of a much needed new treatment option for patients that suffer from these highly treatment-resistant conditions of childhood-onset epilepsy.'

Innovative Company: GW Pharmaceuticals plc

**Innovative Product:** Epidiolex

#### Research & Development

> Cases in which a research study is being described but not yet reaching FDA clinical trial or approval stages.

#### Case # ID: INDFED0020140913ea9b001bi

Article: BAYER HEALTHCARE DESIGNER LAUNCHES COMPANY-SPONSORED RESEARCH PROJECT LAWRENCE, Kan., Sept. 11 -- The University of Kansas issued the following news release:

Two industrial designers for Bayer Healthcare, Raymond Yao and Lauren Bock, have met with Center for Design Research students to launch a new sponsored-tesearch project. It is Bayer-CDR's third collaboration in as many years. Bock is no stranger to the CDR, having studied there with Gregory Thomas, professor of design and director of the CDR. She received a BFA in industrial design from KU in 2013. After graduation, she interned at Bayer and now works as one of the company's user-experience designers.

The students are enrolled in the Department of Design's ADS 560 advanced Design Research Topics class. In it students work on design problems that have been proposed by a sponsor company, in this case Bayer. After the student has successfully addressed a comprehensive set of issues presented by the problem statement, the result will be an innovative new product design.

"The benefit for a company such as Bayer is that the students take a fresh look at everything involved in the design of a new product, with no preconceptions," Thomas said.

He and Robert Hurtz, the head of Bayer Diabetes Care Product Engineering, developed the problem statement last semester ahead of the meeting earlier this month.

"This problem is called 'Design for Diabetes Disabilities: Exploration in Mechanical and Mobile Applications," Thomas said. "The students are focusing on the design of what we hope will be a new generation of products and services geared toward diabetics with disabilities."

Bock added, "The Center for Design Research has worked with Bayer Diabetes Care over the past several years to conceptualize care and maintenance products and services to enable diabetics to better manage their health. In this project the students will develop new products and services that will aid and enhance the mobility and lifestyle of disabled diabetic patients

"We want to create devices that will help provide these patients with a higher level of self-reliance than they currently have," she said.

The brief is challenging, requiring that the students understand diabetes and the many complications its patients might develop, as well as developing problem-solving skills.

"What we're looking for are easy-to-use devices that can address the problems that arise from any of a number of disabilities a diabetes patient might develop," Yao said. He is the head user-experience designer for Bayer Healthcare Diabetes Care.

"These devices must be user-friendly and clearly present information to people who may have glaucoma, hearing loss or other disabilities," he said. "Also, today's users can draw from a broad range of devices such as smartphones, tablets, wearables and more."

The class will present their projects to Bayer representatives in December.

Bayer Diabetes Care was the first corporate sponsor when the projects offer real possibilities for problem solving that are very important to our students," Thomas said.

Bayer's support of the base important over the last several years. In addition to sponsored-research projects that have helped fund the center, it initiated offering internships for two students each summer, which has lead to permanent employment.

Bock is not the only former the student to find employment with Bayer. Kent DiasAbeygunawardena, a 2014 BFA graduate from the design department's industrial design program, interned there and now works for Bayer Radiology & Interventional in Pittsburgh, Pennsylvania.

**Innovative Company: Bayer Healthcare** 

**Innovative Product: NA** 

#### Case # ID: ASMAREN020170315ed3e0008e

Article: United States: Elite Pharmaceuticals, Inc. Initiates Pivotal Biogenivalence Fed Study

For Reformulated Sequestry Elite Pharmaceuticals, Inc., announced today that it has initiated pharmacokinetic testing of its reformulated sequesters. The reformulated product is expected to have a shorter Tmax under fed conditions.

Elite is conducting a bioequivalence study which is a pivotal, open and it is a pivotal, open and its reformulation of sequestry and bioequivalence of the modified formulation of sequestry to the original formulation of sequestry and to a comparator product under fed conditions. The study has enrolled forty-five healthy volunteers and the first subjects have been dosed.

equestOs is Elite's investigational immediate-release oxycodone with sequestered naltrexone abuse-deterrent opioid product for the management of moderate to severe acute pain where the use of an opioid analgesic is appropriate."We are pleased to have this bioequivalence study underway for sequestors," commented Nasrat Hakim, President and CEO of Elite. "We are expecting results for this study by the middle of May and re-submitting the NDA prior to the end of the year."

Innovative Company: Elite Pharmaceuticals, Inc.

Innovative Product: SequestOx

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### Patent Application or Approval

> Cases in which a patent has been applied for or approval by a patent office but no indication of market availability.

#### Case # ID: ATPHAM0020170404ed3n000b6

Article: Egalet Announces Issuance of New U.S. and International Patents for Guardian Techno March 23 -- Egalet Corporation (Nasdaq: EGLT) ("Egalet"), a fully integrated specialty pharmaceutical company focused on developing, manufacturing and marketing innovative treatments for pain and other conditions, today announced the issuance of new U.S. and international patents for Egalet's proprietary The United States Patent and Trademark Office (USPTO) has issued patent number 9,549,899 covering extended-release tablets for . It is the second U.S. patent covering ARYMO ER. The patent offers protection through oral use only -CII developed using Egalet's 2033 and is listed in the Orange Book. European patent number 2393487 has been issued to Egalet and offers protection of products developed using . Also issued is Australian patent number 2015200243. It is the third in a patent family. Both the European and Australian patents offer protection through Canadian patent number 2,751,667 also was issued and covers One 's immediate-release system designed to slow the release of the active pharmaceutical ingredient in the presence of alcohol. The patent offers protection through 2030. "The newly issued patents further strengthen our ability to grow our business through the development of immediate- and extended-release products using our ," said Mark Strobeck, Ph.D., executive vice president and chief operating officer at Egalet. Egalet has been granted a total of 18 U.S. patents and 95 patents outside of the U.S. that cover Sugnation I submotions and its product candidates.

**Innovative Company:** Egalet Corporation

Innovative Product: Guardian Technology, ARYMO ER

#### Case # ID: CHPR000020170307ed2s0001h

Article: US patent grants for IMP321 in cancer. Prima BioMed Ltd announces the granting of patent number 9,579,382 entitled "Use of Recombinant LAG-3 or the Derivatives thereof for Eliciting Monocyte Immune Response" by the US Patent Office. The method of use claims granted for this patent will provide protection for the treatment of cancer where a plurality of doses of IMP321 is used to generate a monocyte mediated response. Broad claims covering dosage and route of administration have also been granted. As part of the company's intellectual property strategy, further applications have been filed in the US seeking additional protection for the IMP321 product itself and for use in combination with other reagents. Patent expiry is expected to be 6 Jul 2029 after a patent term adjustment of 276 days. (Full text). Original Source: Prima BioMed Ltd, 2017. Found on website: http://www.marketwired.com.

MarketwiredWebsite: http://www.marketwired.com

Innovative Company: Prima BioMed Ltd

**Innovative Product**: IMP321

#### Aggregate or Summary of Multiple Companies

> Cases in which multiple companies or products are described in a summary article but not clear indication of innovation.

#### Case # ID: HAMW000020140516ea5n000zu

**Article**: Research and Markets; Cancer Vaccines Drug Pipeline Update 20142014 MAY 23 (NewsRx) -- By a News Reporter-Staff News Editor at Health & Medicine Week -- Research and Markets (http://www.researchandmarkets.com/research/k6ft29/cancer\_vaccines) has announced the addition of the "Cancer Vaccines Drug Pipeline Update 2014" report to their offering.

Cancer vaccines offer an attractive therapeutic addition, delivering treatment of high specificity, low toxicity and prolonged activity. However, despite years of R&D, a reproducible survival benefit has proved elusive, leaving the market wide open. There are today 233 companies plus partners developing 275 cancer vaccine drugs in 600 developmental projects in cancer. In addition, there are 7 suspended drugs and the accumulated number of ceased drugs over the last years amounts to another 181 drugs. Cancer Vaccines Drug Pipeline Update lists all drugs and gives you a progress analysis on each one of them. Identified drugs are linked to 161 different targets. All included targets have been cross-referenced for the presence of mutations associated with human cancer. To date 137 out of the 140 studied drug targets so far have been recorded with somatic mutations.

The software application lets you narrow in on these mutations and links out to the mutational analysis for each of the drug targets for detailed information. All drug targets are further categorized in the software application by 44 classifications of molecular function and with pathway referrals to BioCarta, KEGG, NCI-Nature and NetPath. Drug Pipeline Update at a Glance Investigators Includes more than 233 principal companies plus their collaborators. There is direct access from inside the application to web pages of all principal companies. Drug name & Synonyms Lists commercial, generic and code names for drugs. Developmental stage This Drug Pipeline Update contains 275 cancer vaccine drugs in development, which have a total of 600 developmental projects in cancer. In addition there are suspended and ceased drugs. Pipeline Breakdown According to Number of Drugs Marketed # 12

Registered #1

Pre-registration # 2

Phase III # 31

Phase II # 105

Phase I # 82

Preclinical # 142

No Data # 2

Suspended #7

Ceased # 181 For more information visit http://www.researchandmarkets.com/research/k6ft29/cancer\_vaccines.

Keywords for this news article include: Genetics, Oncology, Software, Therapeutics, Cancer Vaccines, Biological Products, Research and Markets.

Our reports deliver fact-based news of research and discoveries from around the world. Copyright 2014, NewsRx LLC

Innovative Company: NA Innovative Product: NA

#### Case # ID: MFGCLU0020131215e9cf0001x

Article: Research and Markets Offers Report: Triple Analysis: Colorectal Cancer, Melanoma and Prostate CancerResearch and Markets has announced the addition of the "Triple Analysis: Colorectal Cancer, Melanoma and Prostate Cancer" report to its offerings.

In a release, Research and Markets noted that report highlights include: The report focuses on cancer drug development strategies in Colorectal Cancer, Melanoma and Prostate Cancer. Each of these three individual parts is evaluated according to standardized criteria in a five pillar pipeline drug assessment methodology to compare drug development strategies in oncology. This makes it easy to find and compare analysis not only within one single cancer focus area but also between different areas.

Synonsis

Colorectal Cancer based on the publication: 'A Decision Support Tool for Optimizing The Colorectal Cancer Pipeline: From Research and Development to Market'

The colorectal cancer report part comprises defined and up to date development strategies for 347 colorectal cancer drugs within the portfolio of 182 investigators, from Ceased to Marketed. This part extensively analyses their 210 identified drug targets, organized into 205 drug target strategies, and assesses them in eight different compound strategies in colorectal cancer.

Melanoma based on the publication: 'Melanoma Drug Development Analysis: From First-in-Class to Best-in-Class?'

The melanoma drug report part comprises defined and up to date development strategies for 282 drugs within the portfolio of 164 companies world-wide, from Ceased to Marketed. The report extensively analyses their 226 identified drug targets, organized into 187 drug target strategies, and assesses them in melanoma.

Prostate Cancer based on the publication: 'Competitive Handbook towards Personalized Medicine in Prostate Cancer'

The prostate cancer drug report part comprises defined and up to date development strategies for 394 drugs within the portfolio of 222 companies world-wide, from Ceased to Marketed. The report extensively analyses their 227 identified drug targets, organized into 216 drug target strategies, and assesses them in breast cancer drug development.

Innovative Company: NA Innovative Product: NA

# **CONCLUSION:**

The labeling process described in this report helped our project improve the optimization of the BERT algorithm for detecting innovation. This report also serves as a guide for any future human labeling of articles to increase the accuracy of automated methods for detecting business product innovation in articles.

## **REFERENCES**

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- Oslo Manual (2018). *Guidelines for Collecting, Reporting, and Using Data on Innovation* (4<sup>th</sup> ed.). OECD Publishing, Paris.

#### About the University of Virginia's Social and Decision Analytics Division

The Social and Decision Analytics Division (SDAD) is a leading Division in the Biocomplexity Institute at the University of Virginia. The Biocomplexity Institute is at the forefront of a scientific evolution, applying a deeply contextual approach to answering some of the most pressing challenges to human health and well-being within our changing environment. SDAD was created in the fall of 2013 to extend the Biocomplexity Institute's capabilities in social informatics, policy analytics, and program evaluation. The researchers at SDAD form a multidisciplinary team, with expertise in statistics, policy and program evaluation, economics, political science, psychology, computational social science, and data governance and information architecture. SDAD's mission is to embrace today's data revolution, developing evidence-based research and quantitative methods to inform policy decision-making and evaluation.