

Intellectual Property Quality Enforcement Analysis AstraZeneca plc

April 17, 2018

Since the commencement of China's accession process into the World Trade Organization in the late 1990s, several U.S. companies have encouraged the government of the United States to recite sweeping allegations of the "theft" of intellectual property by the Chinese. Having spent considerable time in China since 1999, we have personally witnessed several instances of misappropriated products on **copyrighted** and **trademarked** goods and services. And while there are well-documented instances in which Chinese individuals, firms, and agencies of government have accessed corporate secrets, the allegation of general IP theft and misappropriation is reckless.

Since the 1980s, many U.S. and European firms have sold intellectual property to the Chinese as part of commercial sales. While they failed to disclose these sales with any precision in shareholder filings, the allegation that IP was stolen, appropriated or transferred under duress is false. If a firm makes an economic decision in which it exchanges technology for revenue, that's its own decision. If China makes such sale conditions a requisite component of approved transactions, the foreign firm and its shareholders need to weigh the short-term economic value of the transaction against the long-term consequence of releasing certain rights.

Of greater concern is the wholly falsifiable "presumption of validity" which has shrouded gross abuses of the patent systems in the U.S., Europe and Japan. Upon review, most issued patents are held invalid in part or in whole whether that review happens within the Patent Trial Appeals Board (PTAB) or in the U.S. Court of Appeals for the Federal Circuit (CAFC). Consistent with M·CAM CEO Dr. David E. Martin's testimony to the United States House Judiciary Committee in 2001¹, two thirds of patents' claims subjected to a second review are modified or rejected². It is therefore wholly illogical to presume that China is "stealing" what in the majority of cases should never have been granted **by the United States' own rules.**

In the interest of a more complete conversation about U.S. innovation, M·CAM has conducted a commercial fitness review of the patents held by AstraZeneca. The information provided represents patents which were available for review at the time the patent rights were granted to AstraZeneca but, for a variety of reasons, were not explicitly included in the United States Patent and Trademark Office's review of patentability. As patentable distinction was not considered for each of the "precedent" innovations, China or any other competitor or country may elect to develop commercial products or services based on the information contained in these precedent disclosures.

¹ http://commdocs.house.gov/committees/judiciary/hju72305.000/hju72305 0f.htm

² https://www.morganlewis.com/~/media/files/publication/presentation/speech/smyth_uspatentinvalidity_sept12

Analysis

§1: Selected AstraZeneca patents and selected commercial alternatives

US8455617 – Melanocortin receptor-specific peptides

Commercial Alternative Documents

Patent Number	Patent Title
US6534503	Melanocortin receptor-3 ligands to treat sexual dysfunction
US6284735	HP-3228 and related peptides to treat sexual dysfunction
WO2006014552	CYCLIC PEPTIDES FOR TREATMENT OF CACHEXIA

US7268230 – Quinazoline compounds

Commercial Alternative Documents

Patent Number	Patent Title
US5821246	Aniline derivatives
US5616582	Quinazoline derivatives as anti-proliferative agents
US5580870	Quinazoline derivatives
WO9615118A1	ANILINE DERIVATIVES
WO9615118	ANILINE DERIVATIVES
WO9609294A1	SUBSTITUTED HETEROAROMATIC COMPOUNDS AND THEIR USE IN MEDICINE
WO9609294	SUBSTITUTED HETEROAROMATIC COMPOUNDS AND THEIR USE IN MEDICINE

US6858618 – Use of rosuvastatin (zd-4522) in the treatment of heterozygous familial hypercholesterolemia

Commercial Alternative Documents

Patent Number	Patent Title
WO200045819A1	USE OF CHOLESTEROL-LOWERING AGENT
WO200045819	USE OF CHOLESTEROL-LOWERING AGENT
WO200045818A1	USE OF 3-HYDROXY-3-METHYLGLUTARYL COENZYM A REDUCTASE INHIBITORS FOR THE MANUFACTURE OF A MEDICAMENT FOR THE TREATMENT OF DIABETIC NEUROPATHY
WO200045818	USE OF 3-HYDROXY-3-METHYLGLUTARYL COENZYM A REDUCTASE INHIBITORS FOR THE MANUFACTURE OF A MEDICAMENT FOR THE TREATMENT OF DIABETIC NEUROPATHY
WO200042024A1	CRYSTALLINE BIS[(E)-7-[4-(4-FLUOROPHENYL)-6-ISOPROPYL-2-[METHYL (METHYLSULFONYL) AMINO] PYRIMIDIN-5-YL](3R,5S)-3, 5-DIHYDROXYHEPT-6-ENOIC ACID]CALCIUM SALT

$\S 2: Selected\ AstraZeneca\ patents$

Patent Number	Patent Title
US8492560 (Quinazoline derivatives as angiogenesis inhibitors
US8445647 I	Modified exendins and exendin agonists
US7819075 I	Inhaler device counter
US7803954 I	Mandelic acid derivatives and their use as thrombin inhibitors
US7795283	Oxadiazole derivative as DGAT inhibitors
US7790927 I	Processes for the preparation of optically active intermediates
US7772403	Process to prepare sulfonyl chloride derivatives
US7759328	Composition for inhalation
US7754750 I	Metalloproteinase inhibitors
US7754735	Substituted indoles
US7749997 I	Pyrimido [4,5-B] -Oxazines for use as DGAT inhibitors
US7745475 I	Heteroaryl benzamide derivatives as GLK activators
US7737135	Biphenyloxyacetic acid derivatives for the treatment of respiratory disease
US7732171 I	Process for the preparation of dihydroxy esters and derivatives thereof
US7718812 I	Process for the preparation of 2-(6-substituted-1,3-dioxane-4-yl) acetic acid derivates
US7709521 S	Substituted indole derivatives for pharmaceutical compositions for treating respiratory diseases
US7696214 (Quinazoline derivatives for the treatment of tumours
US7687535	Substituted 3-sulfur indoles
US7648992 I	Hydantoin derivatives for the treatment of obstructive airway diseases
US7645751 I	Mandelic acid derivatives and their use as thrombin inhibitors
US7642259 I	Heteroaryl benzamide derivatives for use as GLK activators in the treatment of diabetes
US7632840	Quinazoline compounds for the treatment of hyperproliferative disorders
US7625934	Metalloproteinase inhibitors
US7618993	Compounds
US7615045 I	Hydrophilic urinary catheter having a water-containing sachet
US7587988 I	Inhaler device counter
US7569577 (Quinazoline derivatives as tyrosine kinase inhibitors
US7524955	Process for the preparation of pyrimidine compounds
US7517989 I	Piperidine derivatives useful as modulators of chemokine receptor activity
US7511140 I	Process for preparing the calcium salt of rosuvastatin
US7495013	Chemical compounds
US7488497	Oral pharmaceutical dosage forms comprising a proton pump inhibitor and a NSAID
US7442811 I	Process for the preparation of dioxane acetic acid esters
US7427631	Metalloproteinase inhibitors
US7425560	Thioxanthine derivatives as myeloperoxidase inhibitors
US7416865	Process for the preparation of dihydroxy esters and derivatives thereof
US7411070	Form of S-omeprazole
US7402585	Substituted quinazoline derivatives as inhibitors of aurora kinases
US7390908	Compounds effecting glucokinase
US7358376	Substituted Thiophene compounds
US7332483	Amide derivatives
US7304156	Preparation of aminopyrimidine compounds

US7268230	Quinazoline compounds
US7264470	Implant having circumferentially oriented roughness
US7262201	Quinazoline derivatives
US7253173	4(Phenyl-piperazinyl-methyl) benzamide derivatives and their use for the treatment of pain of gastrointestinal disorders
US7241764	4(phenyl-piperazinyl-methyl) benzamide derivatives and their use for the treatment of pain or gastrointestinal disorders
US7238811	Chemical compounds
US7238684	Benzothiadiazepine derivatives, processes for their preparation and pharmaceutical compositions containing them
US7229994	4(phenyl-piperazinyl-methyl) benzamide derivatives and their use for the treatment of pain anxiety or gastrointestinal disorders
US7228860	Inhaler with vibrational powder dislodgement
US7227038	Adamantane derivatives, processes for their preparation and pharmaceutical composition containing them
US7226943	Benzothiepine ileal bile acid transport inhibitors
US7220247	Automatically operable safety shield system for syringes
US7202236	Modified release pharmaceutical formulation
US7192946	Benzothiazepine derivatives
US7192945	Benzothiazepine derivatives
US7173038	Quinazoline derivatives as VEGF inhibitors
US7157255	Process for the preparation of dihydroxy esters and derivatives thereof
US7153964	Pyrimidine compounds
US7143764	Inhalation device
US7141583	Oxazolidinone derivatives with antibiotic activity
US7132457	Adamantane derivatives
US7132416	Benzothiazepine and benzothiazepine derivatives with ileal bile acid transport (IBAT) inhibotory activity for the treatment hyperlipidaemia
US7129352	Crystalline salts of 7-′4-(4-fluorophenyl) -6-isopropyl-2-′methyl (methylsulfonyl) amino!pyrimidin-5-yl!- (3R, 5S) -3, 5-dihydroxyhept-6-enoic acid
US7129233	Mandelic acid derivatives and their use as thrombin inhibitors
US7125896	Thiophene carboxamide compounds as inhibitors of enzyme IKK-2
US7125864	Benzothiazepine derivatives for the treatment of hyperlipidemia
US7118552	Automatically operable safety shield system for syringes
US7115615	Quinazoline derivatives
US7087048	Hydrophilic urinary catheter having a water-containing sachet
US7074800	Quinazoline derivatives as angiogenesis inhibitors
US7067663	Triazolo pyrimidine compounds
US7067522	2,4,DI (hetero-) arylamino (-oxy)-5-substituted pyrimidines as antineoplastic agents
US7056907	Mandelic acid derivatives and their use as thrombin inhibitors
US7047967	Inhaler
US7008945	Amide derivatives
US6977259	Quinoline derivatives and their use as aurora 2 kinase inhibitors
US6958343	Thiazolopyrimidines and their use as modulators of chemokine receptor activity
US6951874	Compounds
US6946478	Compounds
US6939872	2-anilino-pyrimidine derivatives as cyclin dependent kinase inhibitors
US6927222	Compounds
US6906058	1,5-Benzothiazepines and their use as hypolipidaemics
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US6875872	Compounds
US6875446	Method for prophylaxis and/or treatment of thromboembolism
US6858618	Use of rosuvastatin (zd-4522) in the treatment of heterozygous familial hypercholesterolemia
US6841554	Crystalline salts of 7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl]-(3r,5s)-3,5-dihydroxyhept-6-enoic acid
US6838464	2,4-Di(hetero-)arylamino(-oxy)-5-substituted pyrimidines as antineaoplastic agents
US6827947	Film coating
US6805116	Inhalation device
US6784174	Pyridine and pyrimidine derivatives and their use as inhibitors of cytokine mediated disease
US6743939	Phenylheteroalkylamine derivatives
US6736805	Hydrophilic urinary catheter having a water-containing sachet
US6722363	Device for emptying cavities containing powder by means of suction
US6716831	2,4-diamino-pyrimidine deprivatives having anti-cell proliferative activity
US6713483	[1,2,3]-triazolo[4,5-d] pyrimidine compounds
US6710052	Pyrimidine compounds
US6673819	Compounds useful as antibacterial agents
US6670368	Pyrimidine compounds with pharmaceutical activity
US6660279	Stability for injection solutions
US6655380	Inhalation device
US6623759	Stable drug form for oral administration with benzimidazole derivatives as active ingredient and process for the preparation thereof
US6613354	Oral pharmaceutical dosage forms comprising a proton pump inhibitor and a NSAID
US6610323	Oral pharmaceutical pulsed release dosage form
US6589959	Crystalline bis[(e)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl](3R,5S)-3,5-dihydroxyhept-6-enoic acid]calcium salt
US6579884	Compounds
US6461642	Crystallization using supercritical or subcritical fluids
US6436902	Therapeutic preparations for inhalation
US6433186	Amidino derivatives and their use as thormbin inhibitors
US6428810	Pharmaceutical formulation comprising omeprazole
US6415784	Inhaler
US6401712	Inhaler
US6392036	Dry heat sterilization of a glucocorticosteroid
US6369085	Form of S-omeprazole
US6365184	Oral pharmaceutical dosage forms comprising a proton pump inhibitor and a NSAID
US6291458	Morpholinobenzamide salts
US6262028	Prodrugs of thrombin inhibitors
US6251910	1,2,3-triazolo[4,5-d]pyrimidines as P2T receptor antagonists
US6207188	Omeprazole sodium salt
US6162816	Crystalline form of the S-enantiomer of omeprazole
US6090827	Pharmaceutical formulation of omeprazole
WO2004056808C1	NOUVEAUX DERIVES DE PIPERIDINE EN TANT QUE MODULATEURS DU RECEPTEUR CCR5 DE LA CHIMIOKINE
WO2004041802C1	DERIVES DE 4PHENYLPIPERAZINYLMETHYL BENZAMIDE ET UTILISATION DE CEUXCI POUR LE TRAITEMENT DE LA DOULEUR ET DES TROUBLES GASTROINTESTINAUX

For a more detailed examination of the patents mentioned in this report, please contact us at: patentlyobvious@m-cam.com.

M·CAM's Patent Glossary

Aligned Sector: The business sector in which the product(s) resulting from the patent(s) is currently or intended to be sold.

Applicant: The person or corporation that applies for a patent with the intent to use, manufacture or license the technology

of the invention; under U.S. law, except in special situations, the applicant(s) must be the inventor(s).

Application: Complete papers submitted to the U. S. Patent and Trademark Office seeking a patent including oath,

specification, claims, and drawings. This usually does not signify a Provisional Patent Application, but only a

regular patent application.

Art: The established practice and public knowledge within a given field of technology. This also identifies a process or

method used to produce a useful result. A term used in consideration of the problem of patentable novelty encompassing all that is known prior to the filing date of the application in the particular field of the invention.

Assignee: The person(s) or corporate body to whom the law grants or vests a patent right. This refers to the person or

corporate entity that is identified as the receiver of an assignment.

Business Method

Patent: A patent that controls the way a business process is undertaken. The issuance of these patents by the United

States Patent and Trademark Office (USPTO) is new and controversial, since many allege that it is unfair to allow

a patent on a way of doing business.

<u>Citation</u>: This may include patents or journal articles that the applicant or examiner deems relevant to a current

application. A reference to legal authorities or a prior art documentation are examples of a citation.

<u>Claim</u>: The language in a patent application that defines the legal scope of the patent. Most patents have numerous

claims. This is typically the single most important section in the application.

<u>Concurrent Art</u>: Concurrent art occurs when related patent applications are being examined by the USPTO at the same time. It is

difficult for any company or inventor to know, at the time they file for a patent, whether a "related" patent

application exists.

Filing Date: The date when a properly prepared application reaches the patent office in complete form.

Innovation Cycle: A description of the commercialization timeframe for the intellectual property.

Innovation Space: M·CAM's representation of the innovation(s) that occur before, during, and after the pending period of the

subject patent. The innovation space is the first place to look for patents that are closely related to the subject patent and that may impact the defensibility of the subject patent or create opportunities for patent licensing.

Issue Date: Not to be confused with the filing date, which is the date the patent application was physically received by the

U.S. Patent and Trademark Office. This is the date on which the patent actually issues.

Non-Aligned

<u>Sector</u>: Any sector in which the patent can be used or sold, other than the sector for which the patent or resultant

product was invented or intended.

Pod: A group of patents owned by a company that should be treated as a single unit of innovation (e.g., a certain

group of patents that comprise a single product or multiple related products).

Prior Art: Any relevant patent that was issued before the patent being analyzed. If this previous patent was specifically

mentioned in the new patent's application, the previous patent is referred to as "cited prior art". If it was NOT

mentioned, then that previous patent is referred to as "uncited prior art".

<u>Subsequent Art</u>: Any patent that has a filing date with the USPTO that is after the issuance date of the subject patent. This

subsequent art patent may or may not have cited (see "Citation" above) the subject patent. As subsequent art represents more recent innovation than the subject patent, it has great potential to shrink the market

opportunity for the subject patent.

A Brief Primer on the Patent System

In recent years, the importance of patents and intellectual property rights as an important variable in the marketplace has come to the forefront of the public consciousness as world leaders declare their country's lead in the innovation race. Damaging intellectual property litigation is becoming increasingly common across all industries. This is exacerbated when patent rights are granted for non-novel ideas. A vast amount of precedent innovation is unconsidered by patent-granting authorities in the creation of new IP rights. Patent granting authorities including the United States Patent and Trademark Office (USPTO), European Patent Office (EPO), Japanese Patent Office (JPO), Chinese State Intellectual Property Office (SIPO), Korean Intellectual Property Office (KIPO) and many others are constrained by the use of patent classification systems which are routinely circumvented by patent applicants.

There is a two-way social contract underlying the patent system. In the United States, patent terms are generally limited to 20 years from the date of application. By statutory intention, once a patent has expired, the patent holder loses the right to exclude others from fully utilizing any innovation described in the patent. A large number of patents enter the public domain when they are "abandoned" – when owners discontinue paying patent maintenance fees. Patents also only provide an exclusionary right in the country for which the patent is filed. As demonstrated by the Global Innovation Commons³ (G.I.C.), using intellectual property available in the public domain eliminates the need to pay licensing fees on those innovations in countries where the patent was never registered, or worldwide, if abandoned.

Patently Obvious® is a weekly report focusing on select groups of patents in order to increase transparency in markets, addressing information asymmetries, and providing a more level playing field for all parties.

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³ http://www.globalinnovationcommons.org/