US008293273B2

(12) **United States Patent**
Villa et al.

(10) **Patent No.: US 8,293,273 B2**
(45) **Date of Patent: *Oct. 23, 2012**

(54) **CONTROLLED RELEASE AND TASTE MASKING ORAL PHARMACEUTICAL COMPOSITION**

(75) Inventors: **Roberto Villa**, Lecco (IT); **Massimo Pedrani**, Gignese (IT); **Mauro Ajani**, Milan (IT); **Lorenzo Fossati**, Milan (IT)

(73) Assignee: **Cosmo Technologies Limited**, Dublin (IE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/462,409**

(22) Filed: **May 2, 2012**

(65) **Prior Publication Data**

US 2012/0213850 A1 Aug. 23, 2012

Related U.S. Application Data

(63) Continuation of application No. 13/249,839, filed on Sep. 30, 2011, which is a continuation of application No. 12/210,969, filed on Sep. 15, 2008, now Pat. No. 8,029,823, which is a continuation-in-part of application No. 10/009,532, filed as application No. PCT/EP00/05356 on Jun. 9, 2000, now Pat. No. 7,431,943.

(30) **Foreign Application Priority Data**

Jun. 14, 1999 (IT) MI99A001317
Mar. 3, 2000 (IT) MI00A000422

(51) **Int. Cl.**
A61K 9/20 (2006.01)
A61K 9/28 (2006.01)
A61K 9/30 (2006.01)

(52) **U.S. Cl.** **424/464**; 424/474; 424/475

(58) **Field of Classification Search** ..... None
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,608,248	A	8/1986	Knecht et al.	
5,320,848	A	6/1994	Geyer	
5,342,625	A	8/1994	Hauer	
5,534,501	A	7/1996	Samain	
5,597,844	A	1/1997	Chauhan	
5,643,602	A	7/1997	Ulmius	
5,811,388	A	9/1998	Friend et al.	
5,840,332	A	11/1998	Lerner et al.	
5,908,833	A *	6/1999	Brattsand et al.	514/26
5,965,167	A	10/1999	Sanghvi	
6,140,308	A	10/2000	Brattsand	
6,190,692	B1	2/2001	Busetti	
6,258,377	B1	7/2001	New	
6,368,635	B1	4/2002	Akiyama	
7,410,652	B2	8/2008	Villa et al.	
7,431,943	B1 *	10/2008	Villa et al.	424/468
8,029,823	B2 *	10/2011	Villa et al.	424/464
2012/0021052	A1	1/2012	Villa et al.	
2012/0021053	A1	1/2012	Villa et al.	

FOREIGN PATENT DOCUMENTS

CA	2119253		11/1998
DE	41 31 562	A1	3/1993
EP	0 375 063	B1	6/1990
EP	0 453 001	A1	10/1991
EP	0482576		4/1992
EP	0 514 008		11/1992
EP	0 514 008	A1	11/1992
EP	0514008		11/1992
GB	935639		9/1963
JP	63048226		2/1988
JP	4159217		6/1992
JP	5132416		5/1993
JP	6510772		12/1994
JP	6511478		12/1994
JP	8503482		4/1996
JP	2000510488		8/2000
JP	2000515130		11/2000
WO	93/00889	A1	1/1993
WO	96/13273		5/1996
WO	9800169		1/1998
WO	WO 99/11245		3/1999
WO	WO 99/17752		4/1999

OTHER PUBLICATIONS

Jantzen, G.M. et al., "Sustained- and Controlled-Release Drug Delivery Systems," Modern Pharmaceutics, 3rd Edition, Revised and Expanded, pp. 575-609, © 1996 by Marcel Dekker, Inc., 37 pages.
Steward, P., "Review of Pharmaceutical Controlled Release Methods and Devices", 1995, pp. 1-9.
Jantzen, et al., "Sustained/Controlled-Release Drug Delivery", Modern Pharmaceutics, 3rd Edition, pp. 582-589.
Physical Pharmacy, Chapter 19: Drug Product Design, Oct. 1993, pp. 515-519.
Moro, et al., "Drug Delivery Systems: Diffusion Controlled Systems", II Prodotto Chimico & Aerosol Selezione (The Chemical & Aerosol Selection), Apr. 1985, pp. 16-24.
Brunner, M. et al., "Gastrointestinal Transit, Release and Plasma Pharmacokinetics of a New Oral Budesonide Formulation," British Journal of Clinical Pharmacology, DOI:10.1111/j.1365-2125.2005.02517.x, pp. 1-8, copyright 2005 Blackwell Publishing Ltd., 8 pages.
Brunner, M. et al., "Gastrointestinal Transit and 5-ASA Release From a New Mesalazine Extended-Release Formulation," Alimentary Pharmacology and Therapeutics, vol. 17, pp. 395-402, copyright 2003 Blackwell Publishing Ltd., 8 pages.

(Continued)

Primary Examiner — Susan Tran

(74) *Attorney, Agent, or Firm* — Rothwell, Figg, Ernst & Manbeck p.c.

(57) **ABSTRACT**

Controlled release and taste masking compositions containing one or more active principles inglobated in a three-component matrix structure, i.e. a structure formed by successive amphiphilic, lipophilic or inert matrices and finally inglobated or dispersed in hydrophilic matrices. The use of a plurality of systems for the control of the dissolution of the active ingredient modulates the dissolution rate of the active ingredient in aqueous and/or biological fluids, thereby controlling the release kinetics in the gastrointestinal tract.

OTHER PUBLICATIONS

Angelucci et al., "Budesonide for Inflammatory Bowel Disease Treatment," Current Medicinal Chemistry, 2008, vol. 15, No. 14, pp. 2-9.

D'Haens, G.R. et al., "Budesonide MMX™ Is Active and Safe in Patients With Active Left-Sided Ulcerative Colitis," Br J Clinic Pharmacol., 2005, vol. 61, 3 pages.

Sandborn, W.J., "Budesonide MMX® 9 mg: Analysis of Pooled Data From Two Phase 3 Studies," poster, 1 page.

Maejima, T., "Application of Tumbling Melt Granulation Method to Prepare Controlled-Release Beads by Coating with Mixture of Functional Non-Meltable and Meltable Materials," Chem. Pharm. Bull., 1998, vol. 46, No. 3, pp. 531-533, © 1998 Pharmaceutical Society of Japan.

Sandborn, W.J. et al., "Budesonide MXX® 9 mg For the Induction of Remission of Mild-to-Moderate Ulcerative Colitis (UC): Data From a Multicenter, Randomized, Double-Blind Placebo-Controlled Study in North America and India," Presentation at DDW 2011, Poster, 1 page.

D'Haens, G.R., et al., "Clinical Trial: Preliminary Efficacy and Safety Study of a New Budesonide-MMX® 9 mg Extended-Release Tablets in Patients With Active Left-Sided Ulcerative Colitis," Journal of Crohn's and Colitis, 2010, vol. 4, pp. 153-160, © copyright 2009 European Crohn's and Colitis Organisation.

Flanders, P. et al., The Control of Drug Release From Conventional Melt Granulation Matrices, Drug Development and Industrial Pharmacy, 1987, vol. 13, No. 6, pp. 1001-1022, © 1987 Marcel Dekker, Inc.

Ferraboschi, P. et al., "Estimation and Characterisation of Budesonide Tablets Impurities," Journal of Pharmaceutical and Biomedical Analysis, 2008, vol. 47, pp. 636-640, © 2008 Elsevier B.V.

Fiorino, G. et al., "New Drug Delivery Systems in Inflammatory Bowel Disease: MMX™ and Tailored Delivery to the Gut," Current Medicinal Chemistry, 2010, vol. 17, pp. 1851-1857, © 2010 Bentham Science Publlishers Ltd.

Koutroubakis, I., "Recent Advances in the Management of Distal Ulcerative Colitis," World Journal of Gastrointestinal Pharmacology and Therapeutics, 2010, vol. 1, No. 2, pp. 43-50, © 2010 Baishideng.

* cited by examiner

CONTROLLED RELEASE AND TASTE MASKING ORAL PHARMACEUTICAL COMPOSITION

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of application Ser. No. 13/249,839 filed on Sep. 30, 2011; which is a continuation of application Ser. No. 12/210,969 filed on Sep. 15, 2008, now U.S. Pat. No. 8,029,823; which is a continuation-in-part of application Ser. No. 10/009,532 filed on Dec. 12, 2001, now U.S. Pat. No. 7,431,943; which is the 35 U.S.C. 371 national stage of International application PCT/EP00/05356 filed on Jun. 9, 2000; which claimed priority to Italian applications MI2000A000422 and MI99A001317 filed Mar. 3, 2000 and Jun. 14, 1999, respectively. The entire contents of each of the above-identified applications are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

The present invention relates to controlled release and taste masking compositions containing budesonide as active ingredient incorporated in a three-component matrix structure, i.e. a structure formed by successive amphiphilic, lipophilic or inert matrices and finally incorporated or dispersed in hydrophilic matrices. The use of a plurality of systems mechanism for the control of the dissolution of the active ingredient modulates the dissolution rate of the active ingredient in aqueous and/or biological fluids, thereby controlling the release kinetics in the gastrointestinal tract, and it also allows the oral administration of active principles having unfavourable taste characteristics or irritating action on the mucosae of the administration site, particularly in the buccal or gastric area.

The compositions of the invention are suitable to the oral administration or the efficaciously deliver the active ingredient acting topically at some areas of the gastrointestinal tract.

The preparation of a sustained, controlled, delayed, extended or anyhow modified release form can be carried out according to different techniques:

1. The use of inert matrices, in which the main component of the matrix structure opposes some resistance to the penetration of the solvent due to the poor affinity towards aqueous fluids; such property being known as lipophilia.
2. The use of hydrophilic matrices, in which the main component of the matrix structure opposes high resistance to the progress of the solvent, in that the presence of strongly hydrophilic groups in its chains, mainly branched, remarkably increases viscosity inside the hydrated layer.
3. The use of bioerodible matrices, which are capable of being degraded by the anzimes of some biological compartment.

All the procedures listed above suffer, however, from drawbacks and imperfections.

Inert matrices, for example, generally entail non-linear, but exponential, release of the active ingredient.

Hydrophilic matrices: have a linear behaviour until a certain fraction of active ingredient has been released, then significantly deviate from linear release.

Bioerodible matrices are ideal to carry out the so-called "sire-release", but they involve the problem of finding the suitable enzyme or reactive to degradation. Furthermore, they frequently release in situ metabolites that are not wholly toxicologically inert.

1022, (1987) discloses a process making use of varying amounts of colloidal silica as a porization element for a lipophilic inert matrix in which the active ingredient is incorporated

The same notion of canalization of an inert matrix is described in U.S. Pat. No. 4,608,248 in which a small amount of a hydrophilic polymer is mixed with the substances forming an inert matrix, in a non sequential compenetration of different matrix materials. EP 375,063 discloses a technique for the preparation of multiparticulate granules for the controlled-release of the active ingredient which comprises co-dissolution of polymers or suitable substances to form a inert matrix with the active ingredient and the subsequent deposition of said solution on an inert carrier which acts as the core of the device. Alternatively, the inert carrier is kneaded with the solution containing the inert polymer and the active ingredient, then the organic solvent used for the their dissolution is evaporated off to obtain a solid residue. The resulting structure is a "reservoir", i.e. is not macroscopically homogeneous along all the symmetry axis of the final form. The same "reservoir" structure is also described in Chem. Pharm. Bull. 46 (3), 531-533, (1998) which improves the application through an annealing technique of the inert polymer layer which is deposited on the surface of the pellets.

To the "reservoir" structure also belong the products obtained according to the technique described in WO 93/00889 which discloses a process for the preparation of pellets in hydrophilic matrix which comprises: —dissolution of the active ingredient with gastro resistant hydrophilic polymers in organic solvents; —drying of said suspension; —subsequent kneading and formulation of the pellets in a hydrophilic or lipophilic matrix without distinction of effectiveness between the two types of application. EP 0 453 001 discloses a multiparticulate with "reservoir" structure inserted in a hydrophilic matrix. The basic multiparticulate utilizes two coating membranes to decrease the release rate of the active ingredient, a pH-dependent membrane with the purpose of gastric protection and a pH-independent methacrylic membrane with the purpose of slowing down the penetration of the aqueous fluid. WO 95/16451 discloses a composition only formed by a hydrophilic matrix coated with a gastro-resistant film for controlling the dissolution rate of the active ingredient. When preparing sustained-, controlled-release dosage forms of a medicament topically active in the gastrointestinal tract, it is important to ensure a controlled release from the first phases following administration, i.e. when the inert matrices have the maximum release rate inside the logarithmic phase, namely the higher deviation from linear release. Said object has been attained according to the present invention, through the combination of an amphiphilic matrix inside an inert matrix, the latter formulated with a lipophilic polymer in a superficial hydrophilic matrix. The compositions of the invention are characterized by the absence of a first phase in which the medicament superficially present on the matrix is quickly solubilized, and by the fact the amphiphilic layer compensate the lack of affinity of the aqueous solvent with the lipophilic compounds forming the inner inert matrix.

DISCLOSURE OF THE INVENTION

The invention provides controlled release and taste masking oral pharmaceutical compositions containing as active ingredient budesonide comprising:

a) a matrix consisting of lipophilic compounds with melting point lower than 90° C. and optionally by amphiphilic

b) an amphiphilic matrix;
c) an outer hydrophilic matrix in which the lipophilic matrix and the amphiphilic matrix are dispersed;
d) optionally other excipients.

A particular aspect of the invention consists of controlled release oral compositions containing as active ingredient budesonide comprising:

a) a matrix consisting of amphiphilic compounds and lipophilic compounds with melting point below 90° C. in which the active ingredient is at least partially incorporated;
b) an outer hydrophilic matrix in which the lipophilic/amphiphilic matrix is dispersed, preferably by mixing;
c) optionally other excipients.

A further aspect of the invention provides taste masking oral pharmaceutical compositions budesonide containing comprising:

an inert or lipophilic matrix consisting of C6-C20 alcohols or C8-C20 fatty acids or esters of fatty acids with glycerol or sorbitol or other polyalcohols with carbon atom chain not higher than six:
an amphiphilic matrix consisting of polar lipids of type I or II or glycols partially etherified with C1-C4 alkyl chains;
an outer hydrophilic matrix containing the above matrices, mainly formed by saccharide, dextrin, polyalcohol or cellulose compounds or by hydrogels or their mixtures;
optional excipients to give stability to the pharmaceutical formulation.

DETAILED DISCLOSURE OF THE INVENTION

The compositions of the invention can be prepared by a method comprising the following steps:

a) the active ingredient, represented by budesonide, is first inglobated by simple kneading or mixing in a matrix or coating consisting of compounds having amphiphilic properties, which will be further specified below. The active ingredient can be mixed with the amphiphilic compounds without the aid of solvents or with small amounts of water-alcoholic solvents.
b) the matrix obtained as specified under a) is incorporated in a low melting lipophilic excipient or mixture of excipients, if necessary while heating to soften and/or melt the excipient itself, which thereby incorporates the active ingredient by simple dispersion forming an inert matrix which can be reduced in size to obtain inert matrix granules containing the active ingredient particles.
c) the inert matrix granules are subsequently mixed together with one or more hydrophilic water-swellable excipients. The mixture is then subjected to compression or tabletting. This way, when the tablet is contacted with biological fluids, a high viscosity swollen layer is formed, which coordinates the solvent molecules and acts as a barrier to penetration of the aqueous fluid itself inside the new structure. Said barrier antagonizes the starting "burst effect" caused by the dissolution of the medicament inglobated inside the inert matrix, which is in its turn inside the hydrophilic matrix. The amphiphilic compounds which can be used according to the invention comprise polar lipids of type I or II (lecithin, phosphatidylcholine, phosphatidylethanolainine), ceramides, glycol alkyl ethers such as diethylene glycol monomethyl ether (Transcutol®). The lipophilic matrix consists of substances selected from unsaturated or hydrogenated alcohols or fatty acids, salts, esters or amides thereof, fatty acids mono-, di- or triglycering melting point within the range of 40 to 90° C., preferably from 60 to 70 C. If desired, a fatty acid calcium salt may be incorporated in the lipophilic matrix which is subsequently dispersed in a hydrophilic matrix prepared with alginic acid, thus remarkably increasing the hydrophilic matrix viscosity following penetration of the solvent front until contact with the lipophilic matrix granules dispersed inside. An amphiphilic matrix with high content in active ingredient, typically from 5 to 95% w/w, in particular from 20 to 70%, is first prepared by dispersing the active ingredient in a mixture of amphiphilic compounds, such as lecithin, other type II polar lipids, surfactants, or in diethylene glycol monoethyl ether; the resulting amphiphilic matrix is then mixed or kneaded, usually while hot, with lipophilic compounds suitable to form an inert matrix, such as saturated or unsaturated fatty acids, such as palmitic, stearic, myristic, lauric, laurylic, or oleic acids or mixtures thereof with other fatty acids with shorter chain, or salts or alcohols or derivatives of the cited fatty acids, such as mono-, di-, or triglyceride or esters with polyethylene glycols, alone or in combination with waxes, ceramides, cholesterol derivatives or other apolar lipids in various ratios so that the melting or softening points of the lipophilic compounds mixtures is within the range of 40 to 90 C, preferably from 60 to 70 C. Alternatively, the order of formation of the inert and amphiphilic matrices can be reversed, incorporating the inert matrix inside the amphiphilic compounds. The resulting inert lipophilic matrix is reduced into granules by an extrusion and/or granulation process, or any other known processes which retain the homogeneous dispersion and matrix structure of the starting mixture. The hydrophilic matrix consists of excipients known as hydrogels, i.e. substances which when passing from the dry state to the hydrated one, undergo the so-called "molecular relaxation", namely a remarkable increase in mass and weight following the coordination of a large number of water molecules by the polar groups present in the polymeric chains of the excipients themselves. Examples of hydrogels which can be used according to the invention are compounds selected from acrylic or methacrylic acid polymers or copolymers, alkylvinyl polymers, hydroxyalkyl celluloses, carboxyalkyl celluloses, polysaccharides, dextrins, pectins, starches and derivatives, natural or synthetic gums, alginic acid. In case of taste-masking formulations, the use of polyalcohols such as xylitol, maltitol and mannitol as hydrophilic compounds can also be advantageous. The lipophilic matrix granules containing the active ingredient are mixed with the hydrophilic compounds cited above in a weight ratio typically ranging from 100:0.5 to 100:50 (lipophilic matrix: hydrophilic matrix). Part of the active ingredient can optionally be mixed with hydrophilic substances to provide compositions in which the active ingredient is dispersed both in the lipophilic and the hydrophilic matrix, said compositions being preferably in the form of tablets, capsules and/or minitablets. The compression of the mixture of lipophilic and/or amphiphilic matrix, hydrogel-forming compound and, optionally, active ingredient not inglobated in the lipophilic matrix, yields a macroscopically homogeneous structure in all its volume, namely a matrix containing a dispersion of the lipophilic granules in a hydrophilic matrix. A similar result can also be obtained by coating the lipophilic matrix granules with a hydrophilic polymer coating. The tablets obtainable according to the invention are subjected to known coating processes with a gastro-

lose derivatives, such as cellulose acetophthalate. The composition of the invention can further contain conventional excipients, for example bioadhesive excipients such as chitosans, polyacrylamides, natural or synthetic gums, acrylic acid polymers.

The compositions of the invention are preferably in the form of tablets, capsules or minitablets. In terms of dissolution characteristics, contact with water or aqueous fluids causes the immediate penetration of water inside the more superficial layer of the matrix which, thanks to the presence of the aqueous solvent, swells due to the distension of the polymeric chains of the hydrogels, giving rise to a high viscosity hydrated front which prevents the further penetration of the solvent itself linearly slowing down the dissolution process to a well determined point which can be located at about half the thickness, until the further penetration of water would cause the disintegration of the hydrophilic layer and therefore the release of the content which, consisting of inert matrix granules, however induces the diffusion mechanism typical of these structures and therefore further slows down the dissolution profile of the active ingredient. The presence of the amphiphilic matrix inside the lipophilic matrix inert allows to prevent any unevenness of the release profile of the active ingredient. The surfactants present in the amphiphilic portion promote wettability of the porous canaliculuses which cross the inert matrix preventing or reducing resistance to penetration of the solvent inside the inert matrix. To obtain taste masking tablets, the components of the hydrophilic matrix are carefully selected to minimize the active substance release time through penetration accelerated by the canalization induced by the hydrophilic compound.

EXPERIMENTAL PART

To test the effective ability of the formulations of the invention to modify the release rate and extent of the active ingredient from the dosage form suitable for the drug administration, before any pharmacokinetic study on patients or volunteers, the dissolution test is taken as monitoring and discriminating tool. Dissolution Test Method.

Tablets according to the present invention undergo to dissolution test to verify the formulation capacity in modulating and controlling the rate by which the active ingredient is leaked by the device or dosage form in the environmental medium, generally a buffered solution simulating gastric or intestinal juices.

The dissolution test is performed by introducing individual tablets in a glace vessel containing from 500 to 1000 ml of a buffered solution set to different pH conditions (pH 1, 6.4 and 7.2 are the pH condition generally used in this test applications), so that the whole digestive tract pH conditions, from stomach to large intestine, should be reproduced. To simulate the human body conditions, the test is carried out at a temperature of 37° C.+−<=2° C. and at predetermined time periods samples of the dissolution medium are withdrawn to detect the percentage of active ingredient dissolved over time.

The tablets according to the present invention, when designed to be used to treat inflammatory bowel disease, in principle have to show a good resistance, thanks to the polymeric film resistant to the low pH conditions (intended as <5 to simulate the gastric environment) applied to cover the tablet surface, resistance which last at least for two hours; to target the large intestinal sectors, also the pH condition of 6.4 shown unsuitability to determine a drug leakage from the administration device for a short exposition time and only during a timeframe from 6 to 12 hours; the dissolution percentage obtained with this tablet formulation were below 15% at first hour sampling, below 25% at second hour sampling, then values were in the range 25% to 55% at fourth hour and a dissolution greater than 80% was achieved at 8^{th} hour sampling.

Example 1

2.7 kg of budesonide, 3.0 kg of lecithin (amphiphilic matrix forming material) and 3.0 kg of stearic acid (lipophilic matrix forming material) are mixing after sieving till an homogeneous mixture is obtained; then add 39.0 kg of inert, functional excipients and 9.0 kg of low viscosity hydroxypropylcellulose (binder) and mix for 10 minutes before adding purified water and kneading to a suitable consistence. Then pass the granulate through a rotating granulator equipped with the suitable screen and transfer the granulate to the fluid bed drier to lower the residual moisture content under 3%.

After a new sieving on the dry, the granulate is added of 9.0 kg of hydroxypropylcellulose (hydrophilic matrix forming material) and the suitable amount of functional excipients (in particular, microcrystalline cellulose, lactose and silicon dioxide) and, after 15 minutes of mixing, magnesium stearate in a suitable quantity to act as lubricant is added.

After a final blending, tablets of around 300 mg of unitary weight are generated.

The core are then subjected to be coated with a suspension obtained introducing into a stainless steel container 5.8 kg of Eudragit™ (methacrylate copolymers), 0.6 kg of triethylcitrate and 3.0 kg of dyes and talc, using alcohol as solvent.

The mean dissolution percentage (as average of six or more tablets) obtained with this tablet formulation were around 10-20% at second hour sampling, in the range 25% to 65% at fourth hour and a dissolution greater than 80% was achieved at 8^{th} hour sampling.

Example 2

Component	mg/tablet
Tablet	
Budesonide	9.0
Stearic Acid	10.0
Lecithin	10.0
Microcristalline cellulose	156.0
Hydroxypropylcellulose	60.0
Lactose monohydrate	50.0
Silicon dioxide	2.0
Magnesium stearate	3.0
Coating materials	
Eudragit L100	14.0
Eudragit S100	12.0
Talc	7.9
Titanium dioxiede	4.5
Triethylcitrate	1.6
Alcohol	q.s.

According to the present invention, coated tablets individually weighing about 220 mg are obtained.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.