

Novartis

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Novartis International AG is a Swiss multinational pharmaceutical company based in Basel, Switzerland, ranking number one in sales (57.9 billion US\$) among the world-wide industry in 2013.^[2]

Novartis manufactures such drugs as clozapine (Clozaril), diclofenac (Voltaren), carbamazepine (Tegretol), valsartan (Diovan) and imatinib mesylate (Gleevec/Glivec). Additional agents include cyclosporin (Neoral/Sandimmun), letrozole (Femara), methylphenidate (Ritalin), terbinafine (Lamisil), and others.

In 1996, Ciba-Geigy merged with Sandoz, and the pharmaceutical and agrochemical divisions of both companies formed Novartis as an independent entity. Other Ciba-Geigy and Sandoz businesses were sold, or like Ciba Specialty Chemicals, spun off as independent companies. The Sandoz brand disappeared for 3 years, but was revived in 2003 when Novartis consolidated its generic drugs businesses into a single subsidiary and named it Sandoz. Novartis divested its agrochemical and genetically modified crops business in 2000 with the spinout of Syngenta in partnership with AstraZeneca, which also divested its agrochemical business.

Novartis is a full member of the European Federation of Pharmaceutical Industries and Associations (EFPIA)^[3] the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA),^[4] and the Pharmaceutical Research and Manufacturers of America (PhRMA).^[5]

Contents

- 1 Corporate structure
 - 1.1 Novartis Global Business Solution Centre
- 2 Place in its market segments
- 3 History
 - 3.1 Ciba-Geigy
 - 3.2 Sandoz (before formation of Novartis)
 - 3.3 Post-merger
 - 3.3.1 2015
- 4 Research
- 5 Basel headquarters campus redesign
- 6 Products
 - 6.1 Pharmaceuticals
 - 6.2 Consumer health
 - 6.3 Animal health
 - 6.3.1 Pet Care
 - 6.3.2 Livestock

Novartis International AG



Type	Public company AG
Traded as	SIX: NOVN (http://www.six-swiss-exchange.com/search/quotes_en.html?security=NOVN), NYSE: NVS (https://www.nyse.com/quote/XNYS:NVS) BSE: 500672 (http://www.bseindia.com/stock-share-price/x/y/500672/)
Industry	Pharmaceuticals
Founded	1996 (from merger)
Headquarters	Basel, Switzerland
Key people	Joerg Reinhardt (Chairman), Joseph Jimenez (CEO)
Products	Pharmaceuticals, generic drugs, over-the-counter drugs, vaccines, diagnostics, contact lenses, animal health (list...)
Revenue	▲ US\$57.9 billion (2013) ^[1]
Operating income	▼ US \$10.980 billion (2013) ^[1]
Net income	▼ US \$12.533 billion (2013) ^[1]
Total assets	▲ US \$126.254 billion (2013) ^[1]
Total equity	▲ US \$74.472 billion (2013) ^[1]
Number of employees	▲ 135,696 (FTE, end 2013) ^[1]
Subsidiaries	Ciba Vision, Sandoz, Alcon, Chiron Corporation
Website	www.novartis.com (http://www.novartis.com/)

- 6.3.3 Bioprotection (insect and rodent control)
- 7 Controversies and criticism
 - 7.1 Challenge to India's patent laws
 - 7.2 Sexual discrimination class action from 5,600 current and former employees
 - 7.3 Off-label marketing and other marketing violations
 - 7.4 Fighting off-label prescribing of competitor's drug
 - 7.5 Valsartan data scandal in Japan
- 8 See also
- 9 Notes and references
- 10 External links

Corporate structure

Novartis AG is a publicly-traded Swiss holding company that operates through the Novartis Group. Novartis AG owns, directly or indirectly, all companies worldwide that operate as subsidiaries of the Novartis Group.^{[6]:117}

The businesses of Novartis are divided into six operating divisions: Pharmaceuticals, Alcon (eye care), Vaccines and Diagnostics, Sandoz (generics), Consumer (divided into two divisions: Over-the-Counter and Animal Health), and Corporate.^{[6]:150} Novartis operates directly and through dozens of subsidiaries in countries around the world, each of which fall under one of the divisions, and that Novartis categorizes as fulfilling one or more of the following functions: "Holding/Finance: the entity is a holding company and/or performs finance functions for the Group; Sales: the entity performs sales and marketing activities for the Group; Production: the entity performs manufacturing and/or production activities for the Group; and Research: the entity performs research and development activities for the Group."^{[6]:251–253}

Novartis AG also holds 33.3% of the shares of Roche however, it does not exercise control over Roche. Novartis also owned 24.9% of Idenix Pharmaceuticals prior to its sale to Merck & Co, Inc.^{[6]:117} Novartis also has two significant license agreements with Genentech, a Roche subsidiary. One agreement is for Lucentis; the other is for Xolair, both of which Novartis markets outside the US.^{[6]:239}

Novartis Global Business Solution Centre

Novartis has established a multi-functional centre at Hyderabad, India in order to offshore several of its R&D, clinical development, medical writing and administrative functions.^[7] This centre spans more than 870,000 square feet and is enough to house 8000 people.^[8]

Place in its market segments

Overall, Novartis was the world's second largest pharmaceutical company in 2011.^[9] An IMS Health report ranked Novartis as the biggest pharma company in 2012.^[10]

Alcon: Alcon was already the world's largest and most profitable eye care company when Novartis bought it, with 2009 annual sales of \$6.5 billion and net income of \$2 billion. At that time, Novartis stated that it believed the two companies could generate approximately \$200 million of potential annual pre-tax cost synergies.^[11]

Sandoz: As of 2013, Sandoz was the world's second largest generic drug company, contributing US\$1.09 billion to Novartis' operating profit on US\$8.70 billion in revenue in 2012.^[12] Sandoz' biosimilars leads its field, getting the first biosimilar approvals in the EU.^{[13][14]}

Vaccines and Diagnostics: As of 2013 Novartis was considering selling this division off. While "sales in the unit were up 14% for the first half of 2013, it reported an operating loss of \$240 million in the first half of 2013 after a \$250 million loss for all 2012.... Vaccine revenue was \$1.4 billion in 2012 and has been forecast to more than double to \$3.14 billion by 2018."^[15]

Consumer: Novartis is not a leader in the over the counter or animal health segments; its leading OTC brands are Excedrin and Theraflu, but sales have been slowed by problems at its key US manufacturing plant.^[16]

In 2012, Novartis ranked 7th on the Access to Medicine Index,^{[17]:88} which "ranks companies on how readily they make their products available to the world's poor."^[18] In 2010, Novartis was in the top three pharma companies (as it was in 2008).^[18]

History

Novartis was created in 1996 from the merger of **Ciba-Geigy** and **Sandoz Laboratories**, both Swiss companies with long histories. Ciba-Geigy was formed in 1970 by the merger of **J. R. Geigy Ltd** (founded in Basel in 1758) and **CIBA** (founded in Basel in 1859). Combining the histories of the merger partners, the company's effective history spans 250 years.^[19]

Ciba-Geigy

In 1859, Alexander Clavel (1805–1873) took up the production of fuchsine in his factory for silk-dyeing works in Basel. In 1864, a new site for the production of synthetic dyes was constructed, and in 1873, Clavel sold his dye factory to the new company Bindschedler and Busch. In 1884, Bindschedler and Busch was transformed into a joint-stock company with the name "Gesellschaft für Chemische Industrie Basel" (Company for Chemical Industry Basel). The acronym, CIBA, was adopted as the company's name in 1945.

Johann Rudolf Geigy-Gemuseus (1733–1793) began trading in 1758 in "materials, chemicals, dyes and drugs of all kinds"^{[20][21]} in Basel, Switzerland. Johann Rudolf Geigy-Merian (1830–1917) and Johann Muller-Pack acquired a site in Basel in 1857, where they built a dyewood mill and a dye extraction plant. Two years later, they began the production of synthetic fuchsine. In 1901, they formed the public limited company Geigy and the name of the company was changed to J. R. Geigy Ltd in 1914.

In 1925, J. R. Geigy Ltd. began producing textile auxiliaries,^[22] an activity which Ciba took up in 1928.

In 1939, Geigy chemist Paul Hermann Müller discovered that DDT was effective against malaria-bearing insects. He received the 1948 Nobel Prize in Medicine for this work.

CIBA and Geigy merged in 1971 to form Ciba-Geigy Ltd. /ˌsiːbə ˈɡaɪɡi/. In the United States, the Geigy staff relocated to join the CIBA staff at its American headquarters for research in Ardsley, New York.

In 1980, Ciba-Geigy set up the company, Ciba Vision, to enter the contact lens market.^[23]

In 1992 Ciba-Geigy agreed to pay New Jersey \$62 million for illegal waste dumping.^[24]



Novartis AG headquarters in Basel

In 1996 Ciba-Geigy merged with Sandoz, with the pharmaceutical and agrochemical divisions of both staying together to form Novartis. Other Ciba-Geigy and Sandoz businesses were spun off as independent companies.^{[25][26]} Notably, Ciba Specialty Chemicals was spun out as an independent company,^{[26][27]} and "Sandoz's Master Builders Technologies, a producer of chemicals for the construction industry, (was sold off) to SKW Trostberg A.G., a subsidiary of the German energy company Viag, and its North American corn herbicide business (was sold off) to the German chemical maker BASF A.G."^[27]

Sandoz (before formation of Novartis)

Before the 1996 merger with Ciba-Geigy to form Novartis, Sandoz Pharmaceuticals (Sandoz AG) was a pharmaceutical company headquartered in Basel, Switzerland (as was Ciba-Geigy), and was best known for developing drugs such as Sandimmune for organ transplantation, the antipsychotic Clozaril, Mellaril Tablets and Serentil Tablets for treating psychiatric disorders, and Cafergot Tablets and Torecan Suppositories for treating migraine headaches.

The *Chemiefirma Kern und Sandoz* ("Kern and Sandoz Chemistry Firm") was founded in 1886 by Alfred Kern (1850–1893) and Edouard Sandoz (1853–1928). The first dyes manufactured by them were alizarinblue and auramine. After Kern's death, the partnership became the corporation *Chemische Fabrik vormals Sandoz* in 1895. The company began producing the fever-reducing drug antipyrin in the same year. In 1899, the company began producing the sugar substitute, saccharin. Further pharmaceutical research began in 1917 under Arthur Stoll (1887–1971), who is the founder of Sandoz's pharmaceutical department in 1917.^[28] In 1918, Arthur Stoll isolated ergotamine from ergot; the substance was eventually used to treat migraine and headaches and was introduced under the trade name Gynergen in 1921.

Between the World Wars, Gynergen (1921) and Calcium-Sandoz (1929) were brought to market. Sandoz also produced chemicals for textiles, paper, and leather, beginning in 1929. In 1939, the company began producing agricultural chemicals.

The psychedelic effects of lysergic acid diethylamide (LSD) were discovered at the Sandoz laboratories in 1943 by Arthur Stoll and Albert Hofmann.^{[29][30]} Sandoz began clinical trials and marketed the substance, from 1947 through the mid-1960s, under the name *Delysid* as a psychiatric drug, thought useful for treating a wide variety of mental ailments, ranging from alcoholism to sexual deviancy. Sandoz suggested in its marketing literature that psychiatrists take LSD themselves,^[31] to gain a better subjective understanding of the schizophrenic experience, and many did exactly that and so did other scientific researchers. The Sandoz product received mass publicity as early as 1954, in a Time Magazine feature.^[32] Research on LSD peaked in the 1950s and early 1960s. Sandoz withdrew the drug from the market in the mid-1960s. The drug became a cultural novelty of the 1960s after psychologist Timothy Leary at Harvard University began to promulgate its use for recreational and spiritual experiences among the general public.

Sandoz opened its first foreign offices in 1964.

In 1967, Sandoz merged with Wander AG (known for Ovomaltine and Isostar). Sandoz acquired the companies Delmark, Wasabröd (a Swedish manufacturer of crisp bread), and Gerber Products Company (a baby food company).

On 1 November 1986, a fire broke out in a production plant storage room, which led to Sandoz chemical spill and a large amount of pesticide being released into the upper Rhine river. This exposure killed many fish and other aquatic life.

In 1995, Sandoz spun off its specialty chemicals business to form Clariant. Subsequently, in 1997, Clariant merged with the specialty chemicals business that was spun off from Hoechst AG in Germany.^[33]

In 1996 Sandoz merged with Ciba-Geigy, with the pharmaceutical and agrochemical divisions of both staying together to form Novartis.

Post-merger

In 1998, the company made headlines with its biotechnology licensing agreement with the University of California at Berkeley Department of Plant and Microbial Biology. Critics of the agreement expressed concern over prospects that the agreement would diminish academic objectivity, or lead to the commercialization of genetically modified plants. The agreement expired in 2003.

In 2000 Novartis and AstraZeneca combined their agrobusiness divisions to create a new company, Syngenta.^{[34][35]}

In 2003, Novartis organized all its generics businesses into one division, and merged some of its subsidiaries into one company, reusing the predecessor brand name of Sandoz.^[36]

In 2005, Novartis expanded its subsidiary Sandoz significantly though the US\$8.29 billion acquisition of Hexal, one of Germany's leading generic drug companies, and Eon Labs, a fast-growing United States generic pharmaceutical company.^[37]

In 2006, Novartis acquired the California-based Chiron Corporation. Chiron formerly was divided into three units: Chiron Vaccines, Chiron Blood Testing, and Chiron BioPharmaceuticals. The biopharmaceutical unit was integrated into Novartis Pharmaceuticals, while the vaccines and blood testing units were made into a new Novartis Vaccines and Diagnostics division.^[38]

Also in 2006, Sandoz became the first company to have a biosimilar drug approved in Europe with its recombinant human growth hormone drug.^[39]

In 2007, Novartis sold the Gerber Products Company to Nestlé as part of its continuing effort to shed old Sandoz and Ciba-Geigy businesses and focus on healthcare.^[40]

In 2009, Novartis reached an agreement to acquire an 85% stake in the Chinese vaccines company Zhejiang Tianyuan Bio-Pharmaceutical Co., Ltd. as part of a strategic initiative to build a vaccines industry leader in this country and expand the Group's limited presence in this fast-growing market segment. This proposed acquisition will require government and regulatory approvals in China.^[41]

In 2010, Novartis offered to pay US \$39.3 billion to fully acquire Alcon, the world's largest eye-care company, including a majority stake held by Nestlé. Novartis had bought 25% of Alcon in 2008.^[42] Novartis created a new division and called it Alcon, under which it placed its CIBA VISION subsidiary and Novartis Ophthalmics, which became the second-largest division of Novartis.^[43]

In 2011, Novartis acquired the medical laboratory diagnostics company Genoptix to "serve as a strong foundation for our (Novartis') individualized treatment programs".^[44]

In 2012, the Company cut ~2000 positions in the United States, most in sales, in response to anticipated revenue downturns from the hypertension drug Diovan, which was losing patent protection, and the realization that the anticipated successor to Diovan, Rasilez, was failing in clinical trials.^[45] The 2012 personnel reductions follow ~2000 cut positions in Switzerland and the United States in 2011, ~1400 cut positions in the United States in 2010, and a reduction of "thousands" and several site closures in previous years.^[46]

Also in 2012, Novartis became the biggest manufacturer of generic skin care medicine, after agreeing to buy Fougera Pharmaceuticals for \$1.525 billion in cash.^[47]

In 2013, the Indian Supreme Court issued a decision rejecting Novartis' patent application in India on the final form of Gleevec, Novartis's cancer drug; the case caused great controversy.^[48]



Suffern, New York: one of the **Novartis** pharmaceutical production facilities in the United States

In 2013, Novartis was sued again by the US government, this time for allegedly bribing doctors for a decade so that their patients are steered towards the company's drugs.^[49]

In January 2014, Novartis announced plans to cut 500 jobs from its pharmaceuticals division.^[50]

In February 2014, Novartis announced that it has acquired CoStim Pharmaceuticals.^[51]

In May 2014, Novartis bought the ex-US rights to Ophthotech's Fovista (an anti-PDGF aptamer, also being investigated for use in combination with anti-VEGF treatments) for up to \$1 billion. Novartis will acquire exclusive rights to market the eye drug outside of America whilst retaining US marketing rights. The company agreed to pay Ophthotech \$200 million upfront, and \$130 million in milestone payments relating to Phase III trials. Ophthotech is also eligible to receive up to \$300 million dependent upon future marketing approval milestones outside of America and up to \$400 million relating to sales milestones.^[52] In September 2014, Ophthotech received its first \$50 million phase III trial milestone payment from Novartis.^[53]

In April 2014, Novartis announced that it would acquire GlaxoSmithKline's cancer drug business for \$16 billion as well as selling its vaccines business to GlaxoSmithKline for \$7.1 billion.^[54]

In August 2014 *Genetic Engineering & Biotechnology News* reported that Novartis had acquired a 15% stake in Gamida Cell for \$35 million, with the option to purchase the whole company for approximately \$165 million.^[55]

In October 2014, Novartis announced its intention to sell its influenza vaccine business (inclusive of its development pipeline), subject to regulatory approval, to CSL for \$275 million.^[56]

2015

In March 2015, the company announced BioPharma had completed its acquisition of two Phase III cancer-drug candidates; the MEK inhibitor binimetinib (MEK 162) and the BRAF inhibitor encorafenib (LGX818), for \$85 million.^[57] Further, the company sold its RNAi portfolio to Arrowhead Research for \$10 million and \$25 million in stock.^[58]

Research

The company's global research operations, called "Novartis Institutes for BioMedical Research (NIBR)" have their global headquarters in Cambridge, Massachusetts, United States.^{[59][60]} Two research institutes reside within NIBR that focus on diseases in the developing world: Novartis Institute for Tropical Diseases, which works on tuberculosis, dengue, and malaria and Novartis Vaccines Institute for Global Health, which works on salmonella typhi (typhoid fever) and shigella.^[61]

Novartis is also involved in publicly funded collaborative research projects, with other industrial and academic partners. One example in the area of non-clinical safety assessment is the InnoMed PredTox project.^{[62][63]} The company is expanding its activities in joint research projects within the framework of the Innovative Medicines Initiative of EFPIA and the European Commission.^[64]

Basel headquarters campus redesign

An ongoing Basel Campus Project has the aim to transform Novartis headquarters in Basel "from an industrial complex to a place of innovation, knowledge, and encounter".^[65] The pharmaceutical giant decided to transform the existing Sandoz office buildings and chemical factories of its headquarters in 2001.

In 1999 PWP Landscape Architecture won the competition for a landscape master plan that would transform a 51-acre site beside the Rhine River from a paved industrial landscape crisscrossed with train tracks into a modern—and largely pedestrian—research and administrative campus filled with outdoor art, trees, greens, and parks. The plan also dealt with an extensive network of existing underground infrastructure.^[66]

The buildings gradually were demolished and replaced with works by architects and artists of international stature. Frank Gehry, Rafael Moneo, and from SANAA, Kazuyo Sejima and Ryue Nishizawa were among the architects and Jenny Holzer and Richard Serra among the artists. Marked diversity of forms now dominates the campus. Novel features and technologies were introduced by Gehry to conform to the building standards of the Swiss government that prohibit air-conditioning, while still selecting a contemporary style of massive use of glass exteriors. One adaptation by the architect includes the integration of a building vent, teepee-style, through the roof, which creates a chimney effect that draws cool air in at the lower levels and vents warmer air.

Products

Pharmaceuticals

Name	Indication(s) or drug type/class	Sales US\$millions	Sales year	% Change	Notes
Aclasta / Reclast (zoledronic acid)	Osteoporosis	590	2012 ^[67]	-4%	
Adelphane-Esidrex (reserpine/dihydralazine/hydrochlorothiazide)	Hypertension				
Afinitor/Sertican/Zortress (everolimus)	Prevention of transplant rejection, various cancers	797	2012 ^[67]	80%	
Amturnide (aliskiren/amlodipine/hydrochlorothiazide)	Hypertension				
Anafranil (clomipramine)	Major depressive disorder, obsessive-compulsive disorder				
Arcapta Neohaler/Onbrez Breezhaler (indacaterol)	COPD				
Brinaldix (clopamide)	Hypertension				
Clozaril/Leponex (clozapine)	Treatment-resistant schizophrenia				
Coartem/Riamet (artemether/lumefantrine)	Malaria (uncomplicated)				
Comtan (entacapone)	Parkinson's disease	530	2012 ^[67]	-14%	
Diovan (valsartan)	Hypertension	4,417	2012 ^[67]	-22%	
Eucreas/Galvus Met (vildagliptin/metformin)	Diabetes mellitus type 2				
Exelon Patch (rivastigmine)	Alzheimer's disease	1,050	2012 ^[67]	-2%	
Exforge (amlodipine/valsartan)	Hypertension	1,352	2012 ^[67]	12%	
Exjade (deferasirox)	Chronic iron overload	870	2012 ^[67]	2%	
Famvir (famciclovir)	Herpes zoster and other <i>Herpesvirus</i> infection				

Fanapt (iloperidone)	Schizophrenia				
Femara (letrozole)	Breast cancer	438	2012 ^[67]	-52%	
Focalin (dexmethylphenidate)	ADHD				First US generics of Focalin became available in 2007 ^[68] Focalin XR became available in 2012. ^[69]
Foradil/Foradile (formoterol)	Asthma, COPD				
Galvus (vildagliptin)	Diabetes mellitus type 2	910	2012 ^[67]	39%	
Gilenya (fingolimod)	Multiple sclerosis	1,195	2012 ^[67]	142%	
Gleevec/Glivec (imatinib)	Oncology, Chronic myelogenous leukemia	4,675	2012 ^[67]	0%	
Hygroton (chlortalidone)	Hypertension				
Ilaris (canakinumab)	Cryopyrin-associated periodic syndrome				
Jakavi/Jakafi (ruxolitinib)	Myelofibrosis (of intermediate to high risk)				
Lamisil (terbinafine)	Fungal infections				
Lescol (fluvastatin)	Hypercholesterolemia	665	2007 ^[70]	-8%	
Lioresal (baclofen)	Spasticity				
Lotrel (amlodipine/benazepril)	Hypertension	748	2007 ^[70]	-34%	
Lucentis (ranibizumab)	Age-related macular degeneration	2,398	2012 ^[67]	17%	
Ludiomil (maprotiline)	Major depressive disorder				
Mellaril (thioridazine)	Schizophrenia				
Myfortic (mycophenolic acid)	Prevention of transplant rejection	579	2012 ^[67]	12%	
Navoban (tropisetron)	Chemotherapy-induced nausea and vomiting				
Ritalin (methylphenidate)	ADHD	554	2012 ^[67]	1%	
Sandimmune/Neoral (cyclosporin)	Prevention of transplant rejection	821	2012 ^[67]	-9%	
Sandostatin (octreotide)	Acromegaly	1,512	2012 ^[67]	5%	
Signifor (Pasireotide)	Cushing's				

	disease ^{[71][72]}				
Simulect (basiliximab)	Prevention of transplant rejection				
Sirdalud (tizanidine)	Spasticity				
Spersallerg (antazoline/tetrahydrozoline)	Allergic conjunctivitis				
Stalevo (carbidopa/levodopa/entacapone)	Parkinson's disease				
Tasigna (nilotinib)	Chronic myelogenous leukemia (first-line treatment ^[73])	998	2012 ^[67]	39%	NICE formulary approval, January 2012 ^[73]
Tegretol (carbamazepine)	Epilepsy, bipolar disorder	413	2007 ^[70]	6%	
Tekamlo (aliskiren/amlodipine)	Hypertension				
Tekturna/Rasilez (aliskiren)	Hypertension				
Termalgin (paracetamol)	Fever, mild pain				
Tobi (tobramycin)	Prevention of <i>Pseudomonas aeruginosa</i> infection in cystic fibrosis	350 (US only)	2012 ^[74]		Teva introduced generic in the US in 2013 ^[74]
Tofranil (imipramine)	Major depressive disorder, enuresis				
Trileptal (oxcarbazepine)	Epilepsy, bipolar disorder	690 (US only)	2007 ^[75]		Teva introduced generic in 2008 ^[75]
Tyzeca/Sebivo (telbivudine)	Hepatitis B				
Visudyne (verteporfin)	Age-related macular degeneration (wet form)				
Voltaren (diclofenac)	Acute pain, inflammatory disorders (such as rheumatoid arthritis)	759 (excl. OTC)	2012 ^[67]	-4%	
Zometa (zoledronic acid)	Prevention of bone fractures in cancer patients	1,288	2012 ^[67]	-13%	
Xolair (omalizumab)	Asthma (moderate to severe)	504	2012 ^[67]	4%	
Zaditen (ketotifen)	Asthma, allergic conjunctivitis				

Consumer health

- Benefiber
- Bialcol Alcohol

- Buckley's cold and cough formula
- Bufferin
- ChestEze
- Comtrex cold and cough
- Denavir/Vectavir
- Desenex
- Doan's pain relief
- Ex-Lax
- Excedrin
- Fenistil
- Gas-X
- Habitrol
- Keri skin care
- Lamisil foot care
- Lipactin herpes symptomatic treatment
- Maalox
- Nicotinell
- No-doz
- Quinvaxem (Pentavalent vaccine)
- Otrivine
- Prevacid 24HR
- Savlon
- Tavist
- Theraflu
- Triaminic
- Vagistat
- Tixylix
- Voltaren

In January 2009, the United States Department of Health and Human Services awarded Novartis a \$486 million contract for construction of the first U.S. plant to produce cell-based influenza vaccine, to be located in Holly Springs, North Carolina. The stated goal of this program is the capability of producing 150,000,000 doses of pandemic vaccine within six months of declaring a flu pandemic.^[76]

Animal health

Pet Care

- Interceptor (Milbemycin oxime), oral worm control product
- Sentinel Flavor Tabs (Milbemycin oxime, Lufenuron), oral flea control product
- Deramaxx (Deracoxib), oral treatment for pain and inflammation from osteoarthritis in dogs
- Capstar (Nitenpyram), oral tablet for flea control
- Milbemax (Milbemycin oxime, Praziquantel), oral worm treatment
- Program (Lufenuron), oral tablet for flea control

Livestock

- Acataalk Duostar (Fluazuron, Ivermectin), tick control for cattle
- CLiK (Dicyclanil), blowfly control for sheep
- Denagard (Tiamulin)
- Fasinex (Triclabendazole)
- ViraShield

Bioprotection (insect and rodent control)

- Actara (Thiamenthoxam)
- Atrazine (Atrazine)
- Larvadex (Cyromazine)
- Neporex (Cyromazine)
- Oxyfly (Lambda-cyhalothrin))
- Virusnip (Potassium monopersulfate)

Controversies and criticism

Challenge to India's patent laws

Novartis fought a seven-year, controversial battle to patent Gleevec in India, and took the case all the way to the Indian Supreme Court, where the patent application was finally rejected. The patent application at the center of the case was filed by Novartis in India in 1998, after India had agreed to enter the World Trade Organization and to abide by worldwide intellectual property standards under the TRIPS agreement. As part of this agreement, India made changes to its patent law; the biggest of which was that prior to these changes, patents on products were not allowed, while afterwards they were, albeit with restrictions. These changes came into effect in 2005, so Novartis' patent application waited in a "mailbox" with others until then, under procedures that India instituted to manage the transition. India also passed certain amendments to its patent law in 2005, just before the laws came into effect, which played a key role in the rejection of the patent application.^[48]

The patent application^{[77][78]} claimed the final form of Gleevec (the beta crystalline form of imatinib mesylate).^{[79]:3} In 1993, during the time India did not allow patents on products, Novartis had patented imatinib, with salts vaguely specified, in many countries but could not patent it in India.^{[80][81]} The key differences between the two patent applications, were that 1998 patent application specified the counterion (Gleevec is a specific salt - imatinib mesylate) while the 1993 patent application did not claim any specific salts nor did it mention mesylate, and the 1998 patent application specified the solid form of Gleevec - the way the individual molecules are packed together into a solid when the drug itself is manufactured (this is separate from processes by which the drug itself is formulated into pills or capsules) - while the 1993 patent application did not. The solid form of imatinib mesylate in Gleevec is beta crystalline.^[82]

As provided under the TRIPS agreement, Novartis applied for Exclusive Marketing Rights (EMR) for Gleevec from the Indian Patent Office and the EMR was granted in November 2003.^[83] Novartis made use of the EMR to obtain orders against some generic manufacturers who had already launched Gleevec in India.^[84] Novartis set the price of Gleevec at USD 2666 per patient per month; generic companies were selling their versions at USD 177 to 266 per patient per month.^[85] Novartis also initiated a program to assist patients who could not afford its version of the drug, concurrent with its product launch.^[86]

When examination of Novartis' patent application began in 2005, it came under immediate attack from oppositions initiated by generic companies that were already selling Gleevec in India and by advocacy groups. The application was rejected by the patent office and by an appeal board. The key basis for the rejection was the part of Indian patent law that was created by amendment in 2005, describing the patentability of new uses for known drugs and modifications of known drugs. That section, Paragraph 3d, specified that such inventions are patentable only if "they differ significantly in properties with regard to efficacy."^{[84][87]} At one point, Novartis went to court to try to invalidate Paragraph 3d; it argued that the provision was unconstitutionally vague and that it violated TRIPS. Novartis lost that case and did not appeal.^[88] Novartis did appeal the rejection by the patent office to India's Supreme Court, which took the case.

The Supreme Court case hinged on the interpretation of Paragraph 3d. The Supreme Court decided that the substance that Novartis sought to patent was indeed a modification of a known drug (the raw form of imatinib, which was publicly disclosed in the 1993 patent application and in scientific articles), that Novartis did not present evidence of a difference

in therapeutic efficacy between the final form of Gleevec and the raw form of imatinib, and that therefore the patent application was properly rejected by the patent office and lower courts.^[89]

Although the court ruled narrowly,^[90] and took care to note that the subject application was filed during a time of transition in Indian patent law,^[91] the decision generated widespread global news coverage and reignited debates on balancing public good with monopolistic pricing, innovation with affordability etc.^{[92][93][94]}

Had Novartis won and gotten its patent issued, it could not have prevented generics companies in India from continuing to sell generic Gleevec, but it could have obligated them to pay a reasonable royalty under a grandfather clause included in India's patent law.^{[95][96]}

In reaction to the decision, Ranjit Shahani, vice-chairman and managing director of Novartis India Ltd was quoted as saying "This ruling is a setback for patients that will hinder medical progress for diseases without effective treatment options."^[97] He also said that companies like Novartis would invest less money in research in India as a result of the ruling.^[48] Novartis also emphasized that it continues to be committed to access to its drugs; according to Novartis, by 2013, "95% of patients in India—roughly 16,000 people—receive Glivec free of charge... and it has provided more than \$1.7 billion worth of Glivec to Indian patients in its support program since it was started...."^[86]

Sexual discrimination class action from 5,600 current and former employees

On May 17, 2010, a jury in the United States District Court for the Southern District of New York awarded \$3,367,250 in compensatory damages against Novartis, finding that the company had committed sexual discrimination against twelve female sales representatives and entry-level managers since 2002, in matters of pay, promotion, and treatment after learning that the employees were pregnant. Two months later the company settled with the remaining plaintiffs for \$152.5 million plus attorney fees.^[98]

Off-label marketing and other marketing violations

In September 2008, the U.S. Food and Drug Administration (FDA) sent a notice to Novartis Pharmaceuticals regarding its advertising of Focalin XR, an ADHD drug, in which the company overstated its efficacy while marketing to the public and medical professionals.^[99]

In 2005 federal prosecutors opened an investigation into Novartis' marketing of several drugs: Trileptal, an antiseizure drug; three drugs for heart conditions - Diovan (the company's top-selling product), Exforge, and Tekturna; Sandostatin, a drug to treat a growth hormone disorder; and Zelnorm, a drug for irritable bowel syndrome.^[100] In September, 2010, Novartis agreed to pay US\$422.5 million in criminal and civil claims and to enter into a Corporate Integrity Agreement with the US Office of the Inspector General.^[101] According to the New York Times "Federal prosecutors accused Novartis of paying illegal kickbacks to health care professionals through speaker programs, advisory boards, entertainment, travel and meals. But aside from pleading guilty to one misdemeanor charge of mislabeling in an agreement that Novartis announced in February, the company denied wrongdoing."^[100] In the same New York Times article, Frank Lichtenberg, a Columbia professor who receives pharmaceutical financing for research on innovation in the industry, said off-label prescribing was encouraged by the American Medical Association and paid for by insurers, but off-label marketing was clearly illegal. "So it's not surprising that they would settle because they don't have a legal leg to stand on."

In April 2013, federal prosecutors filed two lawsuits against Novartis under the False Claims Act for off-label marketing and kickbacks; in both suits, prosecutors are seeking treble damages.^{[102][103]} The first suit "accused Novartis of inducing pharmacies to switch thousands of kidney transplant patients to its immunosuppressant drug Myfortic in exchange for kickbacks disguised as rebates and discounts".^[102] In the second, the Justice Department joined a *qui tam*,

or whistleblower, lawsuit brought by a former sales rep over off-label marketing of three drugs: Lotrel and Valtorna (both hypertension drugs), and the diabetes drug, Starlix.^[103] Twenty-seven states, the District of Columbia and Chicago and New York also joined.^[102]

Fighting off-label prescribing of competitor's drug

Outside the US, Novartis markets the drug ranibizumab (trade name Lucentis), which is a monoclonal antibody fragment derived from the same parent mouse antibody as bevacizumab (Avastin). Both Avastin and Lucentis were created by Genentech which is owned by Roche; Roche markets Avastin worldwide, and also markets Lucentis in the US. Lucentis has been approved worldwide as a treatment for wet macular degeneration and other retinal disorders; Avastin is used to treat certain cancers. Because the price of Lucentis is much higher than Avastin, many ophthalmologists began having compounding pharmacies formulate Avastin for administration to the eye, and began treating their patients with Avastin.^[104] In 2011, four trusts of the National Health Service in the UK issued policies approving use and payment for administering Avastin for macular degeneration, in order to save money, even though Avastin had not been approved for that indication.^[105] In April 2012, after failing to persuade the trusts that it was uncertain whether Avastin was as safe and effective as Lucentis, and in order to retain the market for Lucentis, Novartis announced it would sue the trusts.^{[105][106]} However, in July Novartis offered significant discounts (kept confidential) to the trusts, and the trusts agreed to change their policy,^[107] and in November, Novartis dropped the litigation.^[108]

Valsartan data scandal in Japan

In the summer of 2013, two Japanese universities retracted several publications of clinical trials that purported to show that Valsartan (branded as Diovan) had cardiovascular benefits, when it was found that statistical analysis had been manipulated, and that a Novartis employee had participated in the statistical analysis but had not disclosed his relationship with Novartis but only his affiliation with Osaka City University, where he was a lecturer.^[109]^[110] The scandal led to several Japanese hospitals to stop using the drug and media outlets to run reports on the scandal and issues with the pharmaceutical industry in Japan.^[109] In January 2014 Japan's Health Ministry filed a criminal complaint with the Tokyo public prosecutor's office against Novartis and an unspecified number of employees, for allegedly misleading consumers through advertisements that used the research to support the benefits of Diovan.^[111] On 1 July 2014 the prosecutor's office announced it was formally charging the company and one of its employees.^[112]

See also

- List of pharmaceutical companies
- Pharmaceutical industry in Switzerland

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