

Global Patenting and Branding Strategy

**Presentation by
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organized by the World Intellectual Property Organization
in cooperation with the Hungarian Intellectual Property Office
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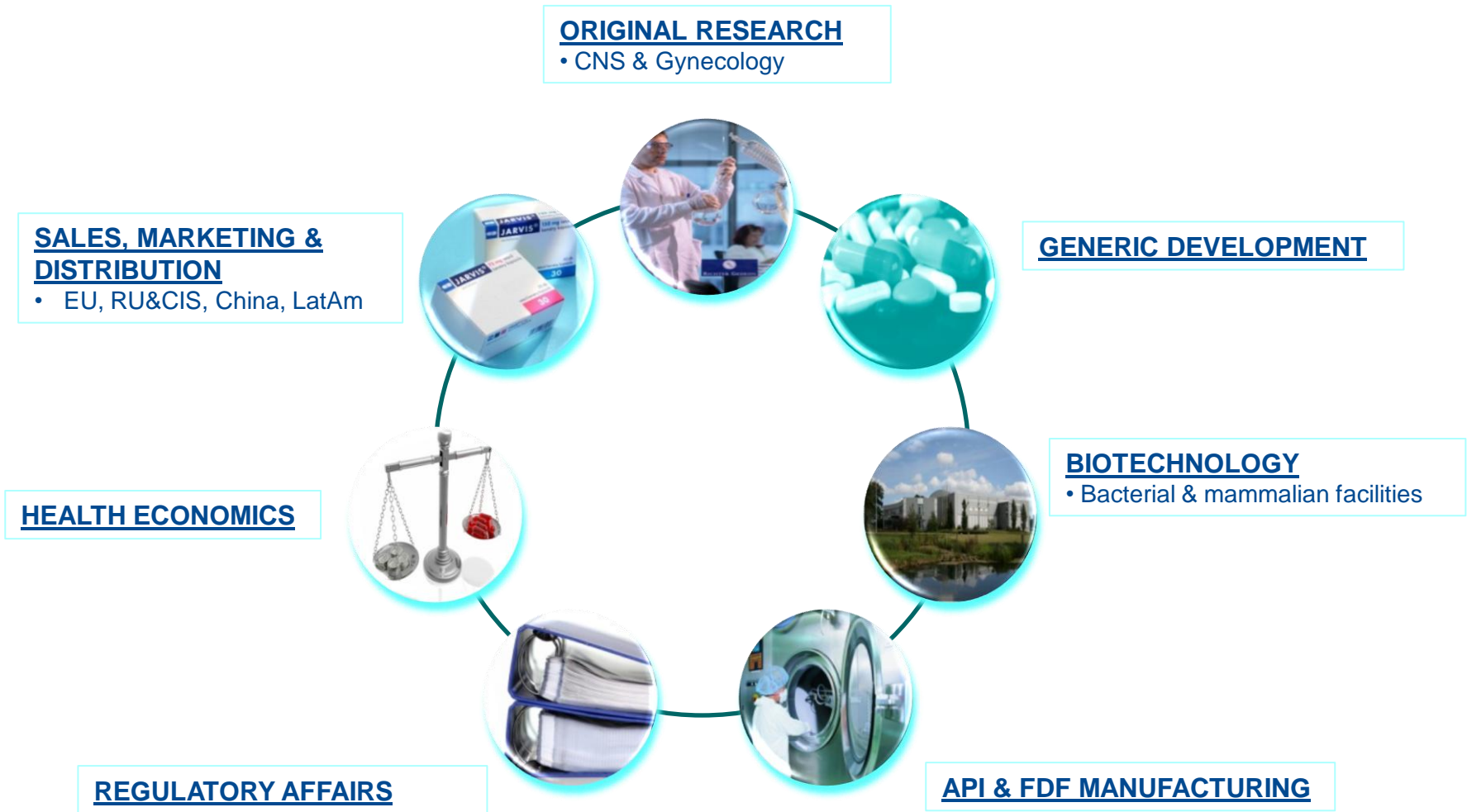
Corporate overview

- Innovation-driven specialty pharmaceutical company
- Vertically integrated (engaged in pharmaceutical manufacturing, research and development, sales and marketing)
- Headquarters: Budapest, Hungary
- Company founded in 1901
- Publicly listed since 1994
- Total sales: 1,179 M EUR (+3%) in 2015
- Number of employees: 11 650
- International locations: 31
- R&D spending: 10-12%
- Regional leader in R&D with more than 1000 researchers



„Delivering quality therapy through generations”

Areas of expertise



International presence



PRODUCTS SOLD IN OVER 100 COUNTRIES VIA OWN ORGANIZATIONS AND PARTNERS

Subsidiaries, joint venture companies, representative offices, etc.

Leading pharmaceutical group in the region

Pharmaceutical companies



Parent company: Gedeon Richter
Founded: 1901



Russia: Gedeon Richter RUS
Greenfield investment (1996)



Romania: Gedeon Richter Romania
Acquisition (1998)



Poland: GR Polska
Acquisition (2002-2008)



India: Richter Themis
Joint venture (2004)



Germany: Richter-Helm Biologic
Joint venture (2007)



Switzerland: PregLem
Acquisition (2010)



China: Gedeon Richter Rxmidas
Joint venture (2010/2013)



Brasil: Gedeon Richter do Brasil
Joint venture (2013)



Mexico: Gedeon Richter Mexico, S.A.P.I. de C.V.
Joint venture (2013)



Curaçao: Mediplus
Joint venture (2014)

Wholesale and retail

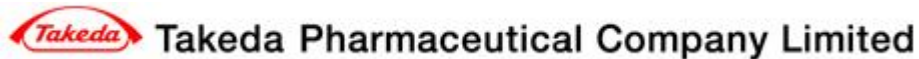
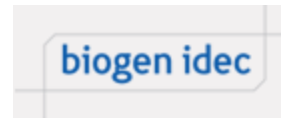
Pharmafarm: wholesale (Romania)

Gedeon Richter Farmacia: retail (Romania, 120 pharmacies)

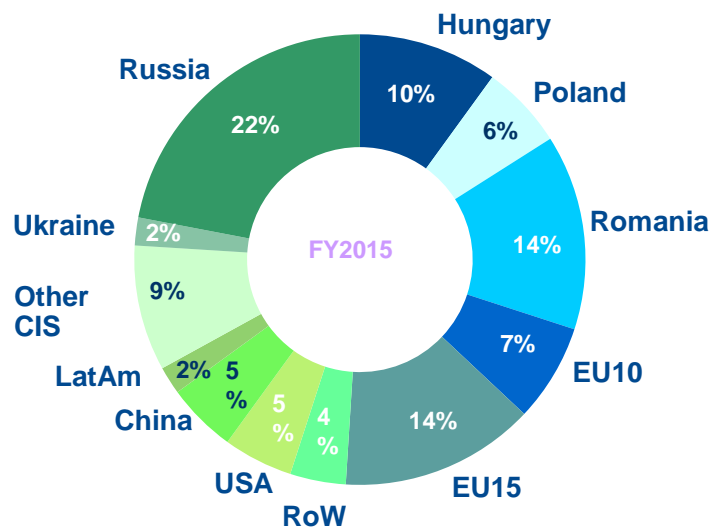
+ further minority interests in wholesale and pharmacies

Recent acquisition: Finox Biotech (Finox AG) CH

Partnerships

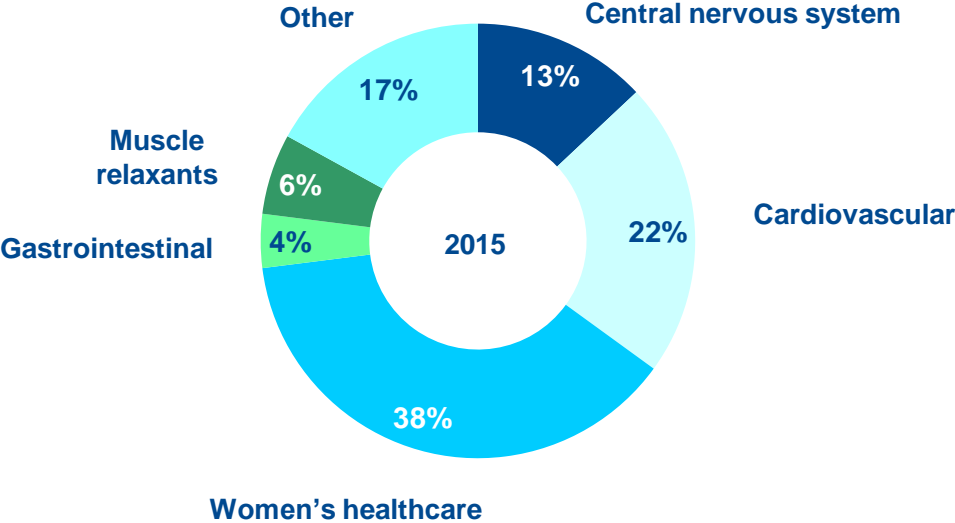


Geographical composition of Group sales



Total:
HUF 365.2bn
EUR 1.179m

Pharmaceutical sales by therapeutic areas

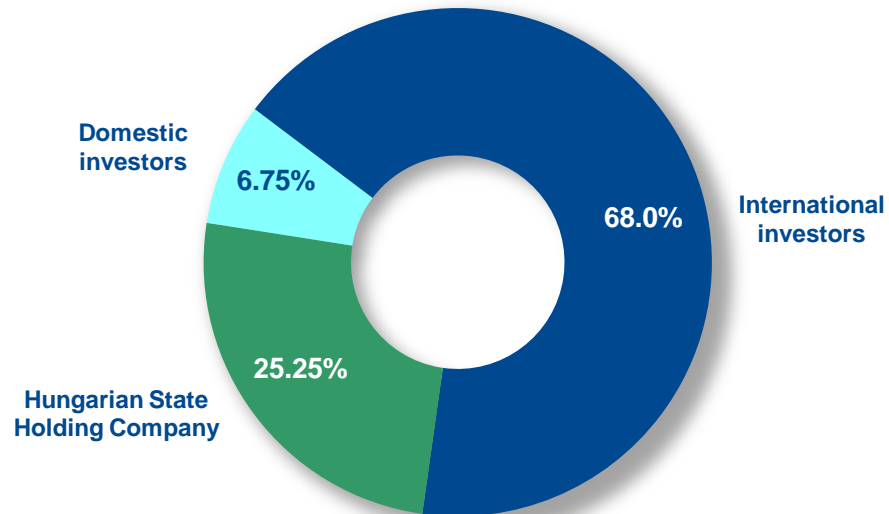


Total: EUR 997.5m

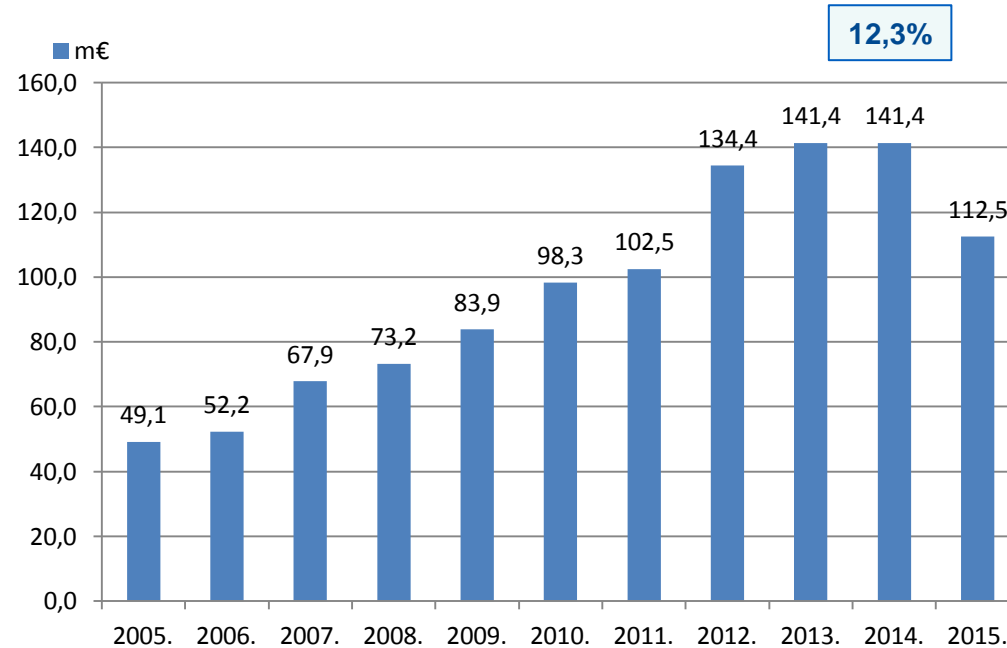


Ownership structure

December 2015



Richter R&D (m€)



R&D expenses in 2015: 112,5 mEUR (9,5 % of consolidated sales)

Richter within the pharmaceutical industry

- challenges:
 - demographic changes – limited willingness to cover healthcare costs by payers
 - increasing generic competition – pricing pressure
- possible responses:
 - going global – economies of scale
 - going special – high added value
- Richter's approach: specialty pharma – high added value
 - female healthcare
 - original research
 - biosimilars
 - new geographies... (WEU, LatAm, China)

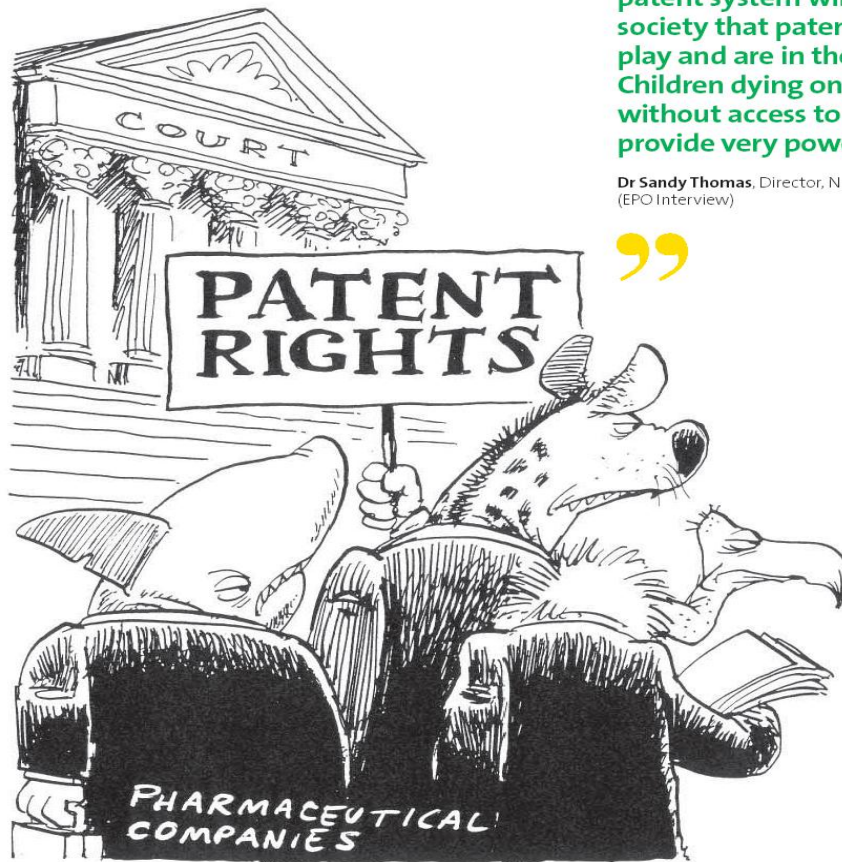
IP in the pharma sector - specialities

- **patent- and trademark-intensive industry:**
 - 35% of patents valid in Hungary are held by the pharmaceutical industry (the highest share of all the technical fields)
 - the third most frequently indicated class of G&S is Class 5 (pharmaceutical and sanitary preparations)
- **„battles” over regulatory issues and IP jurisprudence: originator companies *versus* generic/biosimilar producers (patent strategies to prevent or delay generic entry such as forming patent “thickets” or filing divisionals or applications for “secondary” patents)**
- **patents are maintained the longest in the pharma sector (usually for the full term) + additional protection following the expiry of the basic patent (e.g. SPCs in EU MSs, patent term extension in the USA)**

IP in the pharma sector – specialities (continued)

- strong competition law surveillance of patent settlements and other agreements in the sector
- public interest considerations (access to medicines, public health care expenditure), see e.g. Doha-type compulsory licensing for export
- selection of trademarks: having regard to WHO's INNs and meeting marketing authorisation requirements concerning the name of the medicinal product
- other specialities: patentability of second and further medical uses, *Bolar* provision on pre-patent expiry development, interplay with data and marketing exclusivity, special rules on the patentability and protection of biotechnological inventions

IP in the pharma sector – specialities (continued)



The greatest challenge for the patent system will be convincing society that patents have a role to play and are in the public interest. Children dying on the streets without access to medicines provide very powerful symbols

Dr Sandy Thomas, Director, Nuffield Council on Bioethics (EPO Interview)

”



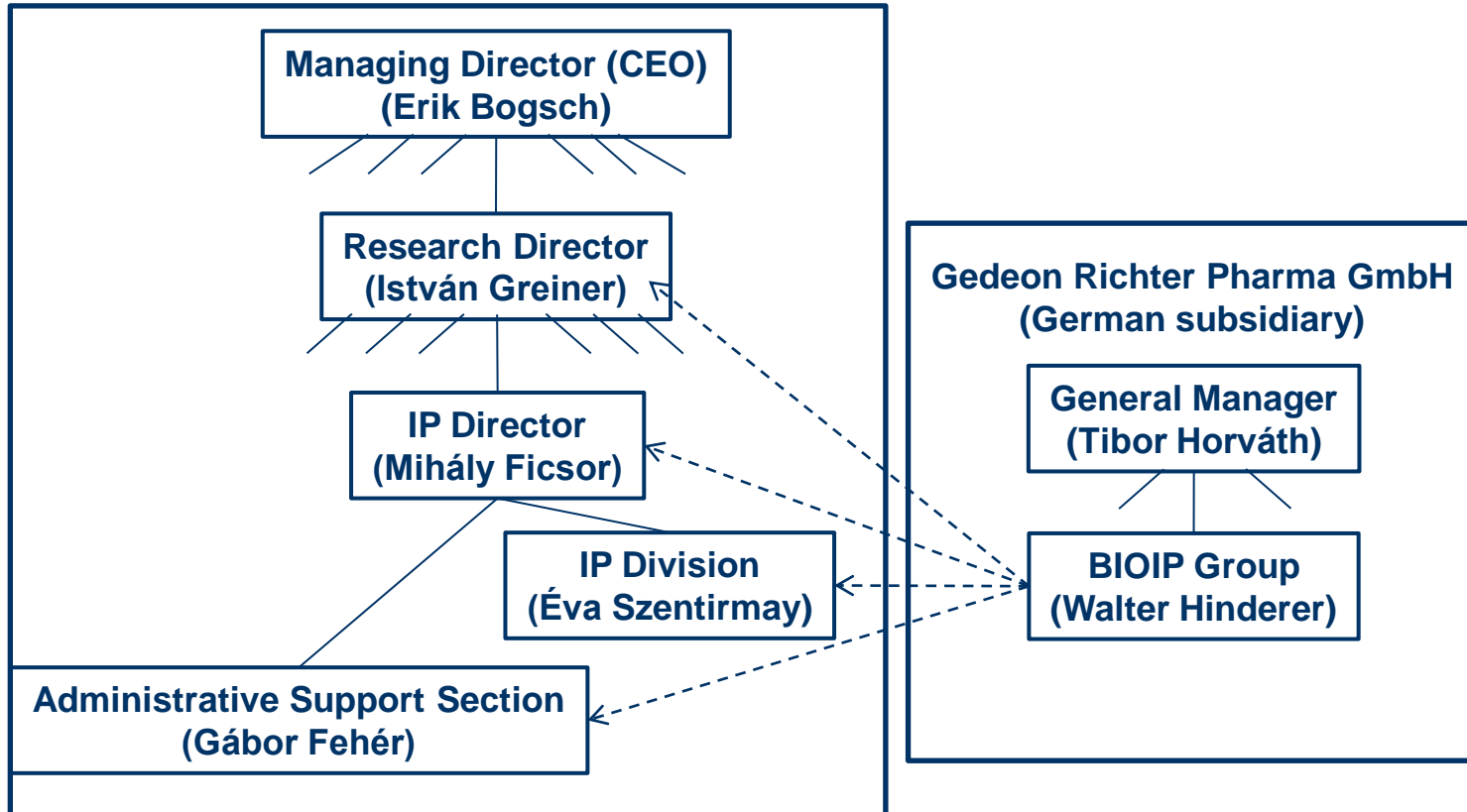
Milestones in Richter's IP environment

- 1890: first Hungarian Trademark Act
- 1895/1896: first Hungarian Patent Act, establishment of the Hungarian Patent Office (no product patents for pharmaceuticals only for processes for their manufacturing)
- 1909: Hungary's accession to the Madrid Agreement Concerning the International Registration of Trademarks
- 1980: Hungary's accession to the Patent Cooperation Treaty (PCT)
- 1994: introduction of product patents for pharmaceuticals coupled with transitional arrangements (pipeline patents) following the intergovernmental agreement concluded with the USA in 1993;
- adoption of the current Patent Act (Act XXXIII of 1995 on the Protection of Inventions by Patents) in line with European norms
- 1997: adoption of the current Trademark Act (Act XI of 1997 on the Protection of Trademarks and Geographical Indications) following, to the extent possible, the EC Trade Mark Directive
- 2003: Hungary's accession to the European Patent Convention/Organisation
- 2004: accession to the European Union – acceptance of the IP *acquis communautaire*, transitional arrangements for SPCs and parallel trade (specific mechanism), extension of the CTM system to Hungary (with transitional arrangements)
- 2011: Hungary's accession to the Agreement on the application of Article 65 EPC (London Agreement)
- 2017: Hungary joins the EU's UPP/UPC system (?)

IP at Richter: main types of activity

- **in line with the company's strategic goals: protection of the results of original research, biotechnological and generic development, and other intellectual creations or assets + strengthening the firm's market position and competitiveness through:**
 - obtaining and maintaining IP protection;
 - enforcing IP rights, preventing or stopping their infringement
 - monitoring the IP status of competing products
 - challenging others' IP rights to ensure freedom to operate (filing oppositions or revocation/cancellation requests)
- **IP support for R&D, manufacturing, trade, marketing and other partnerships, preparation of patent- and trademark-related transactions (license or transfer/assignment agreements)**
- **stimulating creativity and safeguarding the company's intellectual assets through administering the internal system of employees' inventions**
- **adding valuable information to the company's knowledge-base through patent search in order to avoid parallel research and development (or „re-inventing”)**

IP at Richter: organizational chart



Product portfolio & related IP tasks I.

Pharmaceutical R&D covers three strategic areas:

- **research and development of new chemical entities (NCEs)**
- **development of generic products**
- **recombinant biotechnological activities**

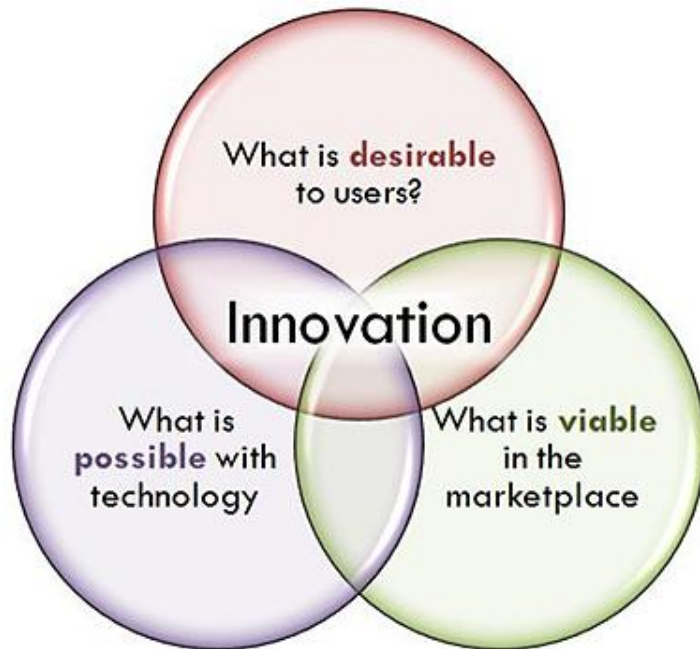
Proprietary research activities are focused on compounds for the diseases of the central nervous system (CNS) (schizophrenia, bipolar mania, cognition, etc.).

The current portfolio includes 21 ongoing projects at different stages of product development.

Product portfolio & related IP tasks II.

Original research projects

- assignment a patent attorney to the project
- novelty exam – „in house” search report
- competitor evaluation
- development of IP strategy
- monitoring for regular project reports
- preparing & maintaining applications
- initiating PCT & national/regional phases



APIs

intermediates

indications

combinations

processes

*salts,
polymorphs*

compositions

Product portfolio & related IP tasks III.

Generic development projects

- SM/PD propose a generic development project
- assignment of a patent attorney to the project
 - basic report preparation
 - patent situation of API, composition, indication
 - during the development
 - patent evaluation of suppliers
 - continuous communication & update
 - preparation of patent application
(new manufacturing process/morphologic modification/composition/use)
 - filing cancellation/revocation requests, opposition if necessary
 - registration support (declaration of non-infringement)
 - after launch litigation



IP at Richter: filing strategies

- **patents**: national application filed with HIPO, international application under the PCT within (at the end of) the priority year designating the EPO (Euro-PCT route) (Chapter II – seldom, SIS, PPH-PCT combination – almost never, amendments usually in the national/regional phase only), validation of European patents also in Hungary (lapse of national ones)
- **advantages of the PCT:**
 - postponement of the major costs associated with global patenting;
 - strong basis for patenting decisions through high-quality, reliable search reports and patentability opinions
 - harmonized formal requirements, protection from certain inadvertent errors
 - possibility to file *one* application – the international application – in *one* place, in *one* language and to pay *one* initial set of fees, while this international application has the effect of a national or regional application, which, without the PCT, one would have to file separately for each country or region.
 - extremely wide geographical coverage (151 Contracting States)

IP at Richter: filing strategies

- **trademarks**: national application filed with HIPO, international application under the Madrid system, national applications in jurisdictions outside the Madrid system, EU TMs – not too frequently due to higher risk of opposition
- **advantages of the Madrid system**:
 - centralized filing and management procedure: *one* international application, in *one* language, with *one* set of fees, to obtain international registration in multiple territories,
 - possibility to expand protection into new markets;
 - cost-efficiency (saving time and money): no need to pay for translations into multiple languages or to spend extra time working through the administrative procedures of multiples offices
 - broad geographic coverage (more than 80% of world trade)
- **patents & trademarks**: scope of targeted countries – depends on the company's market, trade or other interest

Richter: market leader in Hungary in the field of IP, too

- Among Hungarian companies, Gedeon Richter owns the highest number of patents valid in Hungary (68 patents granted by HIPO and 44 European patents validated in Hungary).
- Of all right-holders, Richter has the highest number of trademarks in Hungary (1070), and last year it was the top filer with 115 national TM applications.

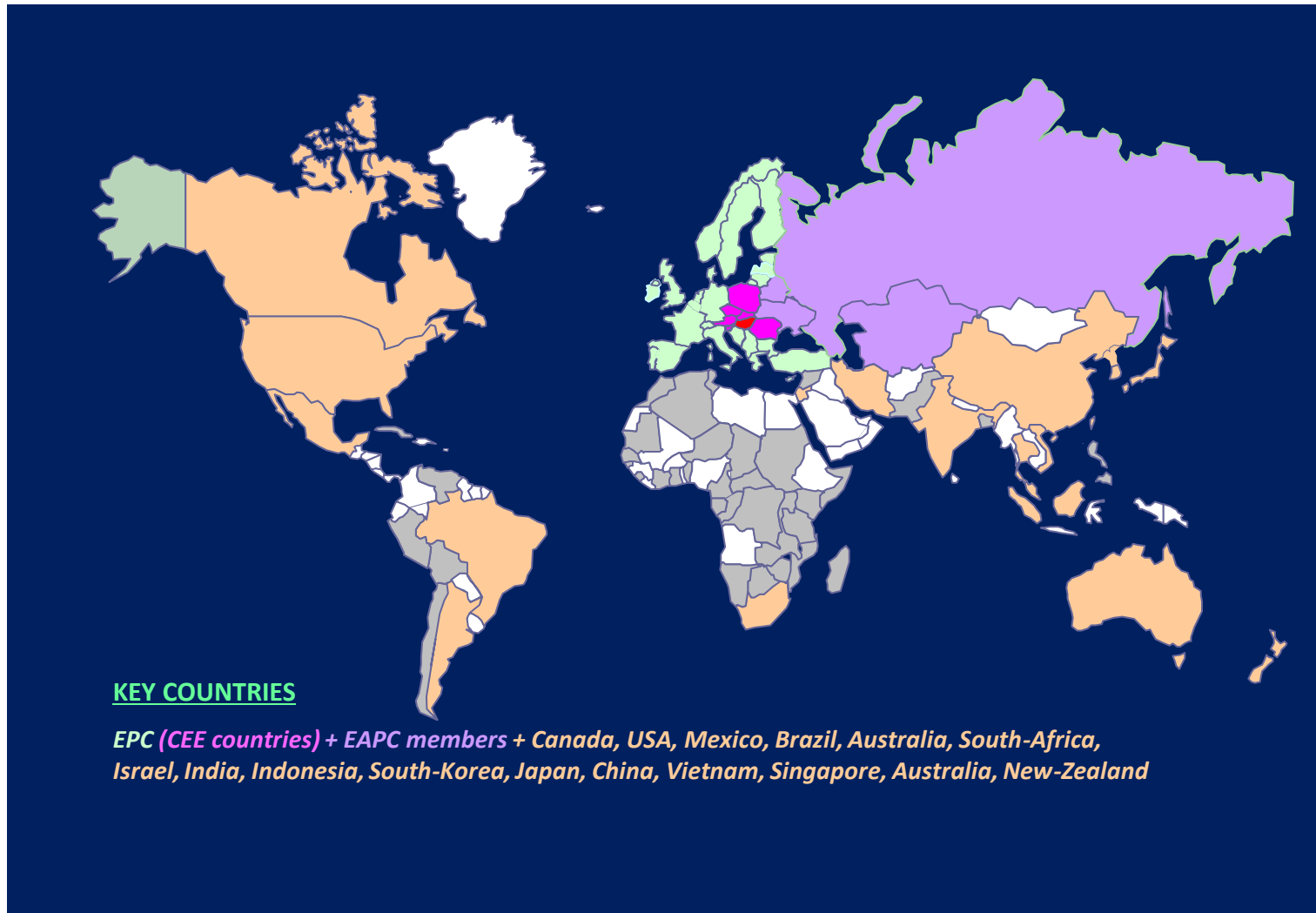
Richter: multinational company – multinational IP activity

Richter has 20 947 trademarks registered in 142 countries concerning 1408 signs.

Richter owns 2134 patents in 138 countries concerning 154 patent families.

In IP matters, Richter operates a global network of 123 patent law and patent attorney firms.

Countries of key IP interest



Trademarks with the broadest geographical coverage

Trademark	Number of countries
Postinor	107
Belara	103
Escapelle	98
Curiosin	88
Rigevidon	87
Rekognis	83
Cavinton	81
RG Gedeon Richter (ábrás)	78
Tri-Regol	70
Jadiza	67

Top applicants in the Madrid system (2015)

Annex 6: Top Madrid applicants

Rank	Applicant's name	Origin	Number of Madrid applications, 2015	Change on 2014
1	Novartis	Switzerland	197	-84
2	Lidl	Germany	152	24
3	L'Oréal	France	130	36
4	Philips Electronics	Netherlands	126	41
5	Richter Gedeon Nyrt	Hungary	124	104
6	Boehringer Ingelheim	Germany	90	-2
7	Apple	United States of America	85	35
8	Daimler	Germany	83	22
9	Biofarma	France	81	41
10	Glaxo Group Limited	United Kingdom	68	-166
11	Janssen Pharmaceutica	Belgium	60	35
12	Henkel	Germany	56	-34
13	Egis Gyógyszergyár	Hungary	55	-77
14	World Medicine	Turkey	54	-22
15	ETI Gida	Turkey	52	41
15	Philip Morris	Switzerland	52	-10
17	Universal Entertainment Corporation	Japan	51	-3
18	Nestlé	Switzerland	48	-64
19	August Storck	Germany	47	21
20	Kronoplus Technical	Switzerland	46	37
20	Microsoft	United States of America	46	15
22	Krka	Slovenia	44	3
23	Abercrombie & Fitch Europe	Switzerland	43	19
23	Gilead Sciences	Ireland	43	6
25	Samsung Electronics	Republic of Korea	41	16
26	BMW	Germany	37	-9
26	Syngenta Participations	Switzerland	37	-9
28	Deutsche Telekom	Germany	36	23
29	Siemens	Germany	35	-3
29	Volkswagen	Germany	35	9
31	BSH Hausgeräte	Germany	33	0
31	UST Global (Singapore)	Singapore	33	32
33	Bayer	Germany	31	-9
33	Kaufland	Germany	31	-2
33	RiGO Trading	Luxembourg	31	31
33	Valeant	Poland	31	-8
37	Migros	Switzerland	30	7
38	Continental Reifen Deutschland	Germany	29	12
39	Actavis Group	Iceland	28	-39
39	Make-Up Art Cosmetics	United States of America	28	25
39	Merck	Germany	28	7
39	Societe Parisienne de Parfums et Cosmetiques	France	28	27
43	MWR Holdings	United States of America	27	27
43	Sun Pharmaceutical Industries	India	27	27
43	Supraten	Republic of Moldova	27	26
43	ZEG	Germany	27	9
47	Cbsa Investments	Australia	26	26
47	Diffulice	Switzerland	26	24
47	Hermes International	France	26	8
47	Japan Tobacco	Japan	26	-7

Source: WIPO

European specialty pharmaceutical company

Over **100 years** of industry **experience**

Stable financial and investor background

Independent

Recognized expertise in **CNS & gynecology**

Niche market player

Innovation & quality is our **passion**

Extensive distribution & marketing network



Mr. Gedeon Richter

Gedeon Richter Plc., Budapest, Hungary



GEDEON RICHTER

Thank you for your kind attention!

